



UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of)	
)	PUBLIC
THE NORTH CAROLINA [STATE] BOARD)	
OF DENTAL EXAMINERS,)	DOCKET NO. 9343
)	
Respondent.)	

**RESPONDENT'S REPLIES TO COMPLAINT COUNSEL'S
PROPOSED FINDINGS OF FACT**

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GENERAL OBJECTIONS

Pursuant to the Administrative Law Judge's Order on Post-Trial Briefs, Respondent provides below its Reply Findings of Fact numbered to correspond to the findings proposed by Complaint Counsel that Respondent is refuting and using the same outline headings that Complaint Counsel used in its Proposed Findings of Fact. Where applicable, Respondent has indicated that it has no specific response or it does not disagree. Further, Respondent has limited itself to directly contradicting Complaint Counsel's Proposed Findings and, pursuant to that end, has noted a number of objections to the statements made by Complaint Counsel, including blatant and egregious misstatements of the record. The objectionable statements appear to follow a general pattern that is described as follows:

- **Duplicative Statements:** Complaint Counsel provides numerous statements that are either reiterated paraphrases of previous proposed findings or, more often, word-for-word or nearly word-for-word duplicate statements of previous proposed findings. Respondent objects on the basis that it is improper and burdensome for it to continually respond to the same statement over and over again, especially given the reality that these duplicates appear in a significant number of statements, in fact well over a hundred by Respondent's count. This has imposed needless expense on Respondent.

- **Unsupported Statements:** Complaint Counsel provides numerous statements that are not supported with any record evidence at all (for instance, the first 30 proposed findings). This clearly violates the ALJ's Order on Post-trial Briefs and

Rule 3.46. Further, this in essence amounts to Complaint Counsel testifying on the record without any evidence in support.

- **Statements of law, not fact:** Complaint Counsel includes in its Proposed Findings numerous statements of law that are not properly included in its Proposed Findings of Fact and should be included instead in its Conclusions of Law.
- **Statements of argument, not fact:** Complaint Counsel includes in its Proposed Findings numerous statements of argument that are not properly included in its Proposed Findings of Fact and should be included instead in Complaint Counsel's Post-Trial Brief.
- **Opinion Statements by Complaint Counsel:** Complaint Counsel asserts numerous opinion statements that are clearly not reflected in the cited record evidence or for which no support is provided at all. This in essence amounts to Complaint Counsel testifying on the record without any evidence in support.
- **Non-designated Deposition Testimony:** Complaint Counsel includes statements that cite to deposition testimony that was not designated in their Deposition Designations.
- **Clear Misrepresentations of the Record:** Worst of all, and most frequently, there are numerous instances where Complaint Counsel has mischaracterized or affirmatively misrepresented record evidence. This has forced Respondent to point out each and every instance that it could find in the limited time provided for replying to Complaint Counsel's more than 200 pages of well over 1300

proposed facts. In many instances, Respondent has resorted to providing the entire sections of the transcript illustrating the actual testimony of witnesses to demonstrate where Complaint Counsel has clearly and improperly misstated the record or misrepresented a witness's testimony. In the vast majority of instances of this that Respondent has noted, such misstatements or misrepresentations, if accepted, would alter the clear meaning of portions of the record in a way that favors Complaint Counsel's theory of the case. Following this same pattern, Complaint Counsel has:

- Edited a direct quotation so as to change the true meaning of the quotation.
- Cited portions of a witness' trial or deposition testimony that clearly do not address the statement for which the witness' testimony is cited.
- Cited exhibits in the record that clearly do not address the statement for which the exhibit is cited.
- Cited to portions of a witness' statement that actually **contradicts** the statement for which it is cited in support.
- Cited to portions of a witness' answer that quotes only part of the witness' answer in the statement or in the parenthetical explanation but excises the rest of the sentence or answer which clearly qualifies or substantially modifies the meaning of the quotation.
- Cited a Joint Stipulation of fact but providing language that contains an assumption and was not agreed upon by the parties.

Respondent also objects to Complaint Counsel's failure to make any attempt to comply with the ALJ's Protective Order in this matter with respect to information designated as confidential by Respondent pursuant to FTC Rules and North Carolina state law and contained in Complaint Counsel's Proposed Findings of Fact. This objection is described in greater detail in Respondent's Expedited Motion to Prevent Public Posting of Complaint Counsel's Post-Trial Brief and Proposed Findings of Fact and Conclusions of Law Containing Confidential Information on the Federal Trade Commission's Website, as filed on April 29, 2011. Thus, in order to comply with the deadline imposed by Judge Chappell's Order Granting Respondent's Second Motion for Extension of Time and Rescheduling Closing Argument (April 25, 2011) and in reliance upon the Secretary's notification of May 2, 2011, that no other filings by either party will be posted on the public Commission website until further notice, Respondent maintains its objection as to the confidential nature of certain proposed findings of fact contained in these Replies to Complaint Counsel's Proposed Findings of Fact.

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I. Introduction and Theory of the Case

1. The North Carolina State Board of Dental Examiners (the "Board") is a combination of dentists that is excluding competition from non-dentists in the provision of teeth whitening services.

Response to Finding No. 1:

Although Complaint Counsel presents this so-called fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 ("All proposed findings of fact shall be supported by specific references to the evidentiary record."). Complaint Counsel has provided no evidentiary support for its statement that the Board is a "combination of dentists", and there is no basis in the record for this finding.

Further, the Board is a creature of statute. There is no evidence that the dentist members of the board contracted, combined or conspired, much less "colluded" to exclude competition. There is no evidence that they ever voted in a way to exclude competition. There is no evidence that they consciously did anything other than enforce a state statute which forbade non-licensees from offering or rendering the service of removal of stains from teeth. The Board dentists did not adopt that statute, and, indeed, did not lobby for passage of the law. But, as required by state statute, they were public officials sworn to enforce the DPA. There is no evidence that as a group or even individually they evaluated any of the illegal teeth-whitening service providers as competitors, or took any step to exclude competitors. The actions they took were analogous to their routine licensing decisions by which, each day, they might discipline, suspend or decline

licensure to an unqualified or dishonest applicant. The good faith enforcement of an unambiguous state statute is not a combination to restrain trade.

2. The Board's six dentists members are elected by licensed North Carolina dentists.

Response to Finding No. 2:

Although Complaint Counsel presents this fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 ("All proposed findings of fact shall be supported by specific references to the evidentiary record."). Otherwise, Respondent has no specific response.

3. The six Board dentist members control the Board.

Response to Finding No. 3:

Although Complaint Counsel presents this so-called fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 ("All proposed findings of fact shall be supported by specific references to the evidentiary record.").

Further, Respondent disputes Complaint Counsel's statement of the six dentist Board members as "control[ling]" the Board. The responsibilities of the various Board members are far more complicated than this statement purports to suggest. *See* CX19 at 1, 5 (detailing which types of matters the three different types of members of the Board may vote on). Complaint Counsel has provided no evidentiary support for its statement that the dental Board members "control" the Board.

4. The Board has the power to exclude.

Response to Finding No. 4:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement that the Board “has the power to exclude.” Further, the term “exclude” is not defined and thus the proposed finding is incomplete as stated.

5. There are Board members and dentists that offer teeth whitening services in North Carolina.

Response to Finding No. 5:

Although Complaint Counsel presents this fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Otherwise, Respondent has no specific response.

6. Non-dentist teeth whitening service providers in North Carolina compete for sales of teeth whitening services with licensed North Carolina dentists.

Response to Finding No. 6:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its

statement that “[n]on-dentist teeth whitening service providers in North Carolina compete for sales of teeth whitening services with licensed North Carolina dentists.”

7. Non-dentist teeth whitening service providers in North Carolina offer teeth whitening services to the public primarily in beauty salons, spas, warehouse clubs, and malls.

Response to Finding No. 7:

Although Complaint Counsel presents this fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Otherwise, Respondent has no specific response.

8. The Board’s dentist members and its dentist constituents have a financial interest in prohibiting teeth whitening by non-dentists.

Response to Finding No. 8:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement that “[t]he Board’s dentist members and its dentist constituents have a financial interest in prohibiting teeth whitening by non-dentists.” Further, the term “financial interest” is not defined, making this statement meaningless for lack of specificity.

9. “[T]he Board is controlled by participants in the market.” Opinion of the Commission, *In re Board of Dental Examiners*, No. 9343, at 13 (February 3, 2011) (“State Action Opinion”) at 14.

Response to Finding No. 9:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Further, this is a statement of opinion, not a finding of fact.

10. The Board has acted vigorously to prohibit non-dentist teeth whitening in North Carolina.

Response to Finding No. 10:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement that “[t]he Board has acted vigorously to prohibit non-dentist teeth whitening in North Carolina.”

11. Without statutory authority, the Board has repeatedly engaged in a variety of actions to deter the entry of non-dentist teeth whitening service providers and taken actions to ensure that existing non-dentist teeth whiteners exit the market.

Response to Finding No. 11:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the

evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement. Further, this statement is a conclusion of law, not a fact.

Further, the record evidence clearly contradicts this statement. *See* Respondent’s Proposed Findings of Fact Nos. 272-277 (describing the evidence supporting the Board’s enforcement authority with respect to cease and desist letters).

12. Specifically, the Board has issued more than 40 “Cease and Desist Orders” to non-dentist competitors providing teeth whitening services.

Response to Finding No. 12:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”).

Further, Respondent disputes that non-dentist recipients of cease and desist letters are “competitors” of the Board. Complaint Counsel has provided no evidentiary support for its statement.

13. The Commission has held that it is undisputed that the letters were intended as and received as orders from the Board.

Response to Finding No. 13:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the

evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement.

Further, the record evidence clearly contradicts this statement. Recipients of cease and desist letters had the ability to challenge the letters in court. *See* Respondent’s Proposed Findings of Fact Nos. 293-300. Non-dental teeth whiteners admitted they were aware that they could challenge these letters but chose not to. *See* Respondent’s Proposed Findings of Fact Nos. 301-306. One teeth whitener testified at trial that she wrote a letter back to the Board explaining that in her opinion she was not engaged in the practice of dentistry. *See* Respondent’s Proposed Findings of Fact Nos. 725-727.

14. These orders were issued without statutory authority, and in many cases, without any factual investigation.

Response to Finding No. 14:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement. The statement also is a conclusion of law, not a fact.

Further, the record evidence clearly contradicts this statement. The Board issued cease and desist letters in accordance with its statutory authority. *See* Respondent’s Proposed Findings of Fact Nos. 272-277 (describing the evidence supporting the Board’s enforcement authority with respect to cease and desist letters). Also, all teeth whitening cases were investigated and decided by the Board on a case-by-case basis. *See*

Respondent's Proposed Findings of Fact No. 100; *see also* Nos. 101-237 (providing details of investigation of particular teeth whitening cases in the record).

15. Non-dentists that have been ordered to "Cease and Desist" have exited the market as a result.

Response to Finding No. 15:

Although Complaint Counsel presents this so-called fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 ("All proposed findings of fact shall be supported by specific references to the evidentiary record.").

Complaint Counsel has provided no evidentiary support for its statement that non-dentists have exited the market as a result of receiving cease and desist letters for the unauthorized practice of dentistry. In fact, one non-dentist teeth whitener testified that teeth whitening sales had dropped off significantly since 2009 due to the economy. *See* Respondent's Proposed Findings of Fact No. 626.

16. The Board has also sent letters to lessors of mall retail space stating that non-dentist teeth whitening is the practice of dentistry and unlawful in North Carolina. These letters have asked for the assistance of the mall operators in not leasing to non-dentist teeth whiteners.

Response to Finding No. 16:

Although Complaint Counsel presents this so-called fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2

(“All proposed findings of fact shall be supported by specific references to the evidentiary record.”).

Further, there is no basis in the record for this fact, and in fact the record evidence directly contradicts the second sentence of this statement – the letters did not ask the mall operators not to lease space to teeth whitening businesses operated by non-dentists. *See* Respondent’s Proposed Findings of Fact No. 307.

17. These actions have resulted in mall property lessors terminating leases and refusing to lease space to non-dentist teeth whitening service providers in malls across North Carolina.

Response to Finding No. 17:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”).

Further, there is no basis in the record for this fact, and in fact the record evidence directly contradicts this statement. John Gibson testified that his company’s leases required that all tenants be in compliance with local laws, and that he would not decline a tenant that wanted to lease a kiosk at his mall to provide over-the-counter teeth whitening products. *See* Respondent’s Proposed Findings of Fact Nos. 321, 319.

18. The Board’s conduct has caused non-dentist teeth whitening service providers to exit the market and has deterred the entry of non-dentist teeth whitening service providers in North Carolina malls.

Response to Finding No. 18:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to

provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for this statement.

19. The Board has also convinced the North Carolina Board of Cosmetics Arts to warn cosmetologists that “only a licensed dentist or dental hygienist acting under the supervision of a licensed dentist” may provide these services and that the “unlicensed practice of dentistry in our state is a misdemeanor.”

Response to Finding No. 19:

Although Complaint Counsel presents this fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Otherwise, Respondent has no specific response.

20. The Dental Board’s conduct caused exit by cosmetologists from the teeth whitening market, deterred cosmetologists from purchasing teeth whitening products, and deterred entry of cosmetologists into the market for teeth whitening services.

Response to Finding No. 20:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for this statement, and there is no basis in the record for this finding.

21. The Board’s conduct to excluded a new and low cost class of competitors is an inherently suspect restraint of trade.

Response to Finding No. 21:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for this statement. Also, this statement is a conclusion of law, not a statement of fact.

22. The Board’s exclusionary conduct has had anticompetitive effects including causing low cost competitors to exit the market for teeth whitening services and has deterred the entry of low cost competitors to enter the market for the provision of teeth whitening services in North Carolina.

Response to Finding No. 22:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for this statement.

23. The exclusion of non-dentist teeth whitening is harmful to consumers because it denies consumers options they prefer, and likely increases the prices of the remaining options.

Response to Finding No. 23:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the

evidentiary record.”). Complaint Counsel has provided no evidentiary support for this statement.

Further, evidence presented by Complaint Counsel at trial indicated that of the 55 percent of the general population engaged in teeth whitening, 14 percent used professional dentist teeth whitening and 86 percent used over-the-counter products. (CX489 at 22). The survey also indicated that 71 percent of the dental patients who used custom-made trays from dentists were either satisfied or very satisfied with the results, whereas only 34 percent of those using over-the-counter products were satisfied or very satisfied with the results. (CX489 at 30).

24. The exclusion of non-dentist teeth whitening is harmful to consumers because it denies consumers options they prefer, increases the prices of the remaining options, and removes innovative products from the market.

Response to Finding No. 24:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”).

To the extent that this finding resembles the previous one, see Respondent’s response to No. 23. Further, there is no basis in the record for Complaint Counsel’s claim that “[t]he exclusion of non-dentist teeth whitening is harmful to consumers because it . . . removes innovative products from the market.” Dr. Baumer testified to his finding that there is nothing innovative about non-dentist teeth whitening. *See* Respondent’s Proposed Findings of Fact No. 564.

25. Consumer injury will continue and grow unless the Board’s exclusionary conduct is enjoined.

Response to Finding No. 25:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement, and there is no basis in the record for this finding. This proposed finding is also prospective and cannot be established with a mere assertion unsupported by any record evidence.

26. There is no cognizable efficiency justification offsetting the consumer harm.

Response to Finding No. 26:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement.

Further, the record evidence directly contradicts this statement. Dr. Baumer testified that there is value in the Board’s enforcement of the Dental Practice Act to exclude untrained non-licensees. (Baumer, Tr. 1708) (“If one in ten customers of a non-dentist teeth whitener ten years from now suffered from oral cancer because of the ignorance of these people, surely that bullet is inaccurate. When you measure costs and benefits, you can

measure value of life and the value of injury and you can set that against consumer surplus or consumer welfare, and those trade-offs are made on a regular basis.”).

27. Complete exclusion is not justified by any economic argument set forth by the Board.

Response to Finding No. 27:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Complaint Counsel has provided no evidentiary support for its statement, nor has it defined what “complete exclusion” means.

Further, as explained above in Respondent’s Response to Finding No. 26, Dr. Baumer testified that there is value in the Board’s enforcement of the Dental Practice Act to exclude untrained non-licensees. (Baumer, Tr. 1708).

28. Respondent’s claims of health, safety, and other consumer protection problems associated with kiosk/spa teeth whitening providers have little evidentiary support.

Response to Finding No. 28:

Although Complaint Counsel presents this so-called fact in a section styled “Introduction and Theory of the Case”, that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 (“All proposed findings of fact shall be supported by specific references to the evidentiary record.”). Ironically, Complaint Counsel itself provides no evidentiary

support for its statement that there is little evidentiary support of health and safety issues with respect to kiosk/spa teeth whitening.

In fact, the Board provided numerous examples of such health and safety issues, including the testimony of an expert in the fields of practical and clinical esthetic and restorative dentistry, the testimony of, Mr. Runsick, an actual consumer, the testimony of a dentist that evaluated Mr. Runsick's injury that was caused by teeth whitening, the testimony of licensed dentists regarding the health and safety issues involved with kiosk/spa teeth whitening, and the documentary evidence of other consumers injured by kiosk/spa teeth whitening. *See* Respondent's Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531. Additionally, Complaint Counsel's expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466).

29. To the extent there could be any legitimate, cognizable efficiency concerns, less restrictive alternatives are available.

Response to Finding No. 29:

Although Complaint Counsel presents this so-called fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. *See* Order on Post-Trial Briefs at 2 ("All proposed findings of fact shall be supported by specific references to the evidentiary record."). Complaint Counsel has provided no evidentiary support for its statement.

30. The Commission has held in this case that the state action doctrine does not protect the Board's conduct, and no other defense identified by the Board has merit.

Response to Finding No. 30:

Although Complaint Counsel presents this so-called fact in a section styled "Introduction and Theory of the Case", that does not absolve Complaint Counsel of its responsibility to provide evidentiary support for asserting this fact. See Order on Post-Trial Briefs at 2 ("All proposed findings of fact shall be supported by specific references to the evidentiary record."). Complaint Counsel has provided no evidentiary support for its statement. Also, this statement is a conclusion of law, not a statement of fact.

II. The North Carolina State Board of Dental Examiners

31. The North Carolina State Board of Dental Examiners (the "Board") is an agency of the State of North Carolina, and is charged with regulating the practice of dentistry in the interest of the public health, safety, and welfare of the citizens of North Carolina. The Board is organized, exists, and transacts business under and by virtue of the laws of the State of North Carolina, with its principal office and place of business located at 507 Airport Blvd., Suite 105, Morrisville, NC 27560 (Joint Stipulations of Law and Fact ¶ 1).

Response to Finding No. 31:

Respondent has no specific response.

32. "[T]he Board is controlled by participants in the market." Opinion of the Commission, *In re North Carolina Board of Dental Examiners*, No. 9343, at 13 (February 3, 2011) ("State Action Opinion") at 14.

Response to Finding No. 32:

Respondent disputes this proposed finding of fact as an opinion not fact.

A. Composition and Election/Selection of Board Members

1. Composition of Board

33. The Board consists of eight members: six licensed dentists, one licensed dental hygienist, and one consumer member. The consumer member is neither a dentist nor a dental hygienist. (CX0019 at 001, Dental Practice Act § 90-22(b); Opinion of the Commission, *In re North Carolina Board of Dental Examiners*, No. 9343, at 13 (February 3, 2011) Opinion of Commission, State Action Opinion at 4; Joint Stipulations of Law and Fact ¶ 2; (White, Tr. 2194).

Response to Finding No. 33:

Respondent has no specific response.

34. Each dentist member is elected to the Board by the licensed dentists of North Carolina pursuant to N.C. Gen. Stat. 90-22(b),(c). (Joint Stipulations of Law and Fact ¶ 6; White, Tr. 2242).

Response to Finding No. 34:

Respondent has no specific response.

35. The dental hygienist member of the Board is elected to the Board by the licensed dental hygienists of North Carolina. (CX0019-001, Dental Practice Act § 90-22(b); (White, Tr. 2242-2243).

Response to Finding No. 35:

Respondent has no specific response.

36. Of the eight Board members, only the consumer representative is selected by North Carolina public officials (Joint Stipulations of Law and Fact ¶ 3). The consumer member is appointed by the governor. (White, Tr. 2243).

Response to Finding No. 36:

Respondent has no specific response.

37. The Consumer member was added to the Board to ensure dentist Board members protect the public interest even when it is against the interest of dentists. (CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0028 at 005; CX0559-008 (Efird, Dep. at 23).

Response to Finding No. 37:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record. The exhibits cited by Complaint Counsel in support of this proposed finding of fact actually offer the following rationale for the addition of the consumer board member:

“It is important that members of the profession understand that Board members must be careful to act in the public interest even when that action may be unpopular [emphasis added] with the membership of the profession. Consumer Board member roles were created to see that this is the case.” (CX28 at 5; CX219 at 5; CX242 at 5 ; CX449 at 5).

Further, Ms. Efird simply testified that her role was to “look out for the welfare of the consumer.” (CX559 (Efird, Dep. at 23)).

2. The Election of Dentist and Hygienist Board Members

38. The election of dentist and hygienist Board members is governed by N.C. Gen. Stat. § 90-22(c)(3). (Joint Stipulations of Law and Fact ¶ 5).

Response to Finding No. 38:

Respondent has no specific response.

39. The election of dentist and hygienist Board members is “conducted by the Board of Dental Examiners which is hereby constituted a Board of Dental Elections.” (CX0019 at 002, Dental Practice Act § 22(c)(3).

Response to Finding No. 39:

Respondent has no specific response.

40. Each dentist elected to the Board must be licensed and actively engaged in the practice of dentistry while serving on the Board. (CX0019 at 001, Dental Practice Act § 90-22(b)).

Response to Finding No. 40:

Respondent has not specific response.

41. Only licensed dentists from North Carolina are eligible voters in Board elections of dentists. (Joint Stipulations of Law and Fact ¶ 4).

Response to Finding No. 41:

Respondent has no specific response.

42. The Board is accountable to North Carolina’s licensed dentists because the six dentist members of the Board are elected directly by their professional colleagues, the other licensed dentists in North Carolina. Opinion of Commission [State Action Opinion] at 13; (CX0019 at 001, Dental Practice Act § 90-22(b)).

Response to Finding No. 42:

Respondent disputes this proposed finding of fact as it states an opinion – not fact.

3. The Board Members Are Practicing Dentists

43. Board members must be actively practicing dentistry in order to serve on the Board. (CX0574 at 007 (White, IHT at 25)). Since June 2002, all dentists serving on the Board have been full-time practicing dentists. (CX0563 at 003-004, 010 (Goode, IHT at

9-10, 34). Board members Allen, Burnham, Brown, Feingold, Hardesty, Holland, Morgan, Owens, and Wester all testified they were actively practicing when they served on the Board. (CX0554 at 006 (Allen, Dep. at 17); CX0555 at 004 (Brown, Dep. at 8); CX0556 at 004 (Burnham, Dep. 9);(CX0560 at 004 (Feingold, Dep. at 9); Hardesty, Tr. 2760-2761; CX0567 at 006 (Holland, Dep. at 14); CX0569 at 004 (Morgan, Dep. at 9); (Owens, Tr. 1435); CX0572 at 004 (Wester, Dep. at 7)).

Response to Finding No. 43:

Respondent has no specific response.

44. During their tenure, Board members continue to provide for-profit dental services, including teeth whitening. (CX0560 at 48 (Feingold, Dep. at 183-184); CX0567 at 017 (Holland, Dep. at 58); CX0572 at 009 (Wester, Dep. 26-28); CX0554 at 007 (Allen, Dep. at 18); State Action Opinion at 4).

Response to Finding No. 44:

Respondent has no specific response.

45. Board members have admitted that they may compete with other dentists, and that they would recuse themselves if a dentist they competed with came before the Board. (CX0554 at 020 (Allen, Dep. at 70-72); CX0555 at 028 (Brown, Dep. at 104); CX0567 at 011 (Holland, Dep. at 36-37); CX0572 at 030-031 (Wester, Dep. at 113-114)).

Response to Finding No. 45:

Respondent disputes this proposed finding as to the assumption contained therein that Board members who are dentists are in competition with non-dentist supervised teeth whiteners.

**4. The Board Compared to Other Professional Licensing Boards
in North Carolina and Other States**

46. The Board differs from other professional licensing boards in North Carolina because seven of its eight members are elected by the professionals it regulates. (CX0862 at 027-028).

Response to Finding No. 46:

Respondent disputes this proposed finding of fact in that it contains an assumption that the composition of the Board would predispose the Board to fulfill its statutory duty to protect the health, safety and welfare of North Carolina citizens in a manner that is different from all other North Carolina professional licensing boards.

47. By contrast, regulated persons directly select far fewer, and sometimes no, members of the vast majority of other North Carolina licensing boards.

a. Many boards contain members appointed by the Governor, other governmental bodies, or other organizations without input from the licensees of the board. (CX0862 at 003 (Acupuncture Licensing Board); CX0862 at 004 (Agency for Public Telecommunications); CX0862 at 004-005 (Alarm Systems Licensing Board); CX0862 at 005 (Appraisal Board); CX0862 at 006 (Board for Licensing of Geologists); CX0862 at 006-007 (Board for Licensing of Soil Scientists); CX0862 at 007 (Board of Architecture); CX0862 at 007-008 (Board of Athletic Trainer Examiners); CX0862 at 008 (Board of Certified Public Accountant Examiners); CX0862 at 008 (Board of Cosmetic Art Examiners); CX0862 at 008- 009 (Board of Dietetics/Nutrition); CX0862 at 009 (Board of Electrolysis Examiners); CX0862 at 009 (Board of Speech and Language Pathologists); CX0862 at 011-012 (Board of Landscape Architects); CX0862 at 012 (Board of Licensed Professional Counselors); CX0862 at 012 (Board of Massage and Bodywork Therapy); CX0862 at 016-017 (Code Officials Qualification Board); CX0862 at 017-018 (Home Inspector Licensure Board); CX0862 at 018-019 (Interpreter and Transliterator Licensing Board); CX0862 at 020-21 (Locksmith Licensing Board); CX0862 at 021-022 (Marriage and Family Therapy Licensure Board); CX0862 at 022-023 (Wastewater Contractors and Inspectors Certification Board); CX0862 at 023-024 (Private Protective Services Board); CX0862 at 024-025 (Recreational Therapy Licensure Board); CX0862 at 025 (Real Estate Commission); CX0862 at 025 (Respiratory Care Board); CX0862 at 025-026 (Small Business Contractor Authority); CX0862 at 026 (Social Work Certification and Licensure Board); CX0862 at 027 (Board of Barber Examiners); CX0862 at 027 (Board of Chiropractic Examiners); CX0862 at 031-032 (Board of Environmental Health Specialist Examiners); CX0862 at 033 (Board of Fee-Based Pastoral Counselors); CX0862 at 033 to 034 (Board of Examiners of Plumbing, Heating, and Fire Sprinkler); CX0862 at 034 (State Board of Opticians); CX0862 at 034-035 (Board of Refrigeration Examiners); CX0862 at 035 (Board of Registrations for Foresters); CX0862 at 036 (Board for General Contractors); CX0862 at 037 (Veterinary Medical Board).

b. Other boards contain either (1) some members selected by the Governor or other governmental body from a "slate" of candidates suggested by the regulated

industry, as well as other members appointed by the Governor or other government body without input by the licensees of the board, or (2) a minority of members directly selected by the licensees of the board. (CX0862 at 005 (Auctioneers Commission); CX0862 at 010 (Board of Examiners in Optometry); CX0862 at 010-011 (Board of Funeral Service); CX0862 at 013-014 (Board of Occupational Therapy); CX0862 at 015 (Board of Physical Therapy Examiners); CX0862 at 015-016 (Board of Podiatry Examiners); CX0862 at 019-020 (Irrigation Contractors' Licensing Board); CX0862 at 020 (Landscape Contractors' Registration Board); CX0862 at 022 (Medical Board); CX0862 at 024 (Psychology Board); CX0862 at 031-032 (Board of Examiners for Engineers and Surveyors); CX0862 at 032-033 (Board of Examiners of Electrical Contractors); CX0862 at 035-036 (Board of Hearing Aid Dealers and Fitters).

c. Only a few North Carolina boards are similar to the Board in that a majority of their members are directly selected by the regulated industry. (CX0862 at 011 (Board of Law Examiners); CX0862 at 013 (Board of Nursing); CX0862 at 014-015 (Board of Pharmacy); CX0862 at 026-027 (State Bar Council); CX0862 at 036-037 (Substance Abuse Professional Practice Board)).

Response to Finding No. 47 (a, b & c):

Respondent disputes this proposed finding of fact to the extent that it contains an assumption that the composition of the Board would predispose the Board to fulfill its statutory duty to protect the health, safety and welfare of North Carolina citizens in a manner that is different from all other North Carolina professional licensing boards.

48. Unlike professional licensing boards in some other states (CX0488 at 049), the Board is not part of another North Carolina department. (CX0019 at 001, Dental Practice Act § 90-22(b); (Board is "the agency of the State for the regulation of the practice of dentistry in this State"; (White, Tr. 2255) (other states have "umbrella agencies" over licensing boards); CX0572 at 031 (Wester, Dep. at 115-116 (no other agency regulates dentistry)). For example, the California Dental Board is subsumed within California's Department of Consumer Affairs and Wisconsin's Board of Dentistry is related to Wisconsin's Department of Regulation. (CX0488 at 048-049).

Response to Finding No. 48:

Respondent disputes this proposed finding of fact to the extent that it contains an assumption that the composition of the Board would predispose the Board to fulfill its statutory duty to protect the health, safety and welfare of North Carolina citizens in a

manner that is different from professional licensing boards in other states. Respondent also disputes this proposed finding of fact based on the undefined term, “not part of another North Carolina department.”

5. Dentists Campaign for Positions on the Board

49. The Board considers licensed North Carolina dentists to be constituents. (CX0581 (Bakewell, Dep. at 20-21; White, Tr. 2276).

Response to Finding No. 49:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Ms. Bakewells’ testimony was in the context of general discussions by Board members with other dentists as part of their duties to “serve the public,” of which other dentists would be considered a member. (CX581 (Bakewell, Dep. at 21). Mr. White’s testimony was made in the context of a question from Complaint Counsel about being responsive to complainants or others who brought an issue to the Board’s attention. (White, Tr. at 2276). Actually, “constituent” was the word used by Complaint Counsel during Mr. White’s questioning to describe congressmen or citizens who contacted the FTC. (White, T. at 2276).

50. Board members engage in campaigning when they run for a position on the Board. (CX0574 at 008 (White, IHT at 28-29); Hardesty, Tr. 2796-2798).

Response to Finding No. 50:

Respondent disputes this proposed finding of fact to the extent that it uses the undefined term “campaigning.” It also mischaracterizes the record. Mr. White’s testimony was that candidates “will send out a letter asking for support”; to the extent that that’s a campaign, they do campaign.” (CX574 (White, IHT at 28-29). Dr. Hardesty also testified that he did not engage in campaigning other than sending out one letter. (Hardesty, Tr. at 2796).

51. If an election is contested, candidates may distribute letters and make speeches that discuss the reasons they want to serve on the Board, including their positions on issues that may come before the Board. (Joint Stipulations of Law and Fact ¶ 9). An election is “contested” when there are more candidates running for election than there are available Board positions. (Joint Stipulations of Law and Fact ¶ 8).

Response to Finding No. 51:

Respondent has no specific response.

52. Dr. Hardesty testified that he campaigned “like any other politician” when he ran in a contested election by telling constituents that he was running and shaking hands. (Hardesty, Tr. 2796-2798). Dr. Hardesty engaged in campaigning efforts that included sending a letter to all the licensed dentists in the state and asking for their vote, and meeting and talking with dentists at local dental society meetings. (CX0566 at 009 (Hardesty, IHT at 32-33)).

Response to Finding No. 52:

Respondent disputes this proposed finding of fact as an incomplete statement of the record and as containing an assumption and as containing the undefined term

“campaigning.” The record shows that Complaint Counsel was the first to utter the words “like any other politician” as a question directed to Dr. Hardesty, to which he responded by repeating Complaint Counsel’s words. (CX566 (Hardesty, IHT at 33)).

Dr. Hardesty also testified that “I don’t really consider that like any other politician because I didn’t make any promises, I just said I’m running for office.” (Hardesty, Tr. at 2797, emphasis added).

53. Dr. Feingold sent a letter to all the licensed dentist in North Carolina expressing his desire to be elected to the Board. (CX0560 at 011 (Feingold, Dep. at 34)). In addition, Board member Dr. Morgan introduced him to influential dentist from different areas of North Carolina at the three-day annual convention of the North Carolina Dental Society. There, Dr. Feingold solicited support for his Board candidacy. (CX0560 at 11 (Feingold, Dep. at 35)).

Response to Finding No. 53:

Respondent disputes this proposed finding of fact as containing an assumption. Dr. Feingold testified in this same line of questioning that he did not discuss financial or economic issues facing the profession when he asked other dentists for their support. (RX56 (Feingold, Dep. at 36)).

54. Dr. Burnham sent letters to all of the licensed dentists in North Carolina each time that he ran for a Board position telling them that he would appreciate their vote. (CX0556 at 017-018 (Burnham, Dep. at 61-62)).

Response to Finding No. 54:

Respondent has no specific response.

55. Dr. Brown sent a letter to dentists in North Carolina stating that he was interested in continuing the Board's practice of self-regulation when he ran in his first contested election. (CX0555 at 037 (Brown, Dep. at 140-141)).

Response to Finding No. 55:

Respondent disputes this proposed finding of fact as an incomplete characterization the record. Dr. Brown also testified that he "just tried to make people know who I was" by providing a curriculum vitae. (CX555 (Brown, Dep. at 140)).

56. Dr. Allen's colleagues thought he would be a good Board member because of his reputation as a clinician as well as his stated positions on standard of care issues, issues related to dental hygienists, and a controversy over dental implants. (CX0554 at 004-005 (Allen, Dep. at 9-10)). Dr. Allen sent letters to North Carolina dentists during his campaigns for a Board position. The letters explained why he should be elected and his qualifications. In one campaign, Dr. Allen set forth his stance against the unsupervised practice of dentistry by dental hygienists. (CX0554 at 017(Allen, Dep. at 58-59)).

Response to Finding No. 56:

Respondent disputes this proposed finding of fact as mischaracterizing Dr. Allen testimony in regard to the dental hygienist issue. In the testimony cited in support of this proposed finding of fact, Dr. Allen refers to the issue, but he does not give any indication of his position. (CX554 (Allen, Dep. at 9-10, 58-59)).

6. Board Member Terms and Board Members Serving Two or More Terms

57. The licensed dentists of North Carolina elect dentist members to the Board for a three year term. (CX0019 at 001, Dental Practice Act § 90-22(b); State Action Opinion at 4). Dentists elected to the Board usually begin their terms in August of the year of their election and end their terms three years later at the end of July. (CX0565 at 007 (Hardesty, Dep. at 20-21); White, Tr. 2202).

Response to Finding No. 57:

Respondent has no specific response.

58. The dentist members of the Board are elected for three-year terms and can run for reelection, but no person shall be nominated, elected, or appointed to serve more than two consecutive terms on said Board. (CX0019 at 001, Dental Practice Act § 90-22(b); Joint Stipulations of Law and Fact ¶ 7).

Response to Finding No. 58:

Respondent has no specific response.

59. Some of the dentist members of the Board have served two or more terms. Drs. Allen, Brown, Burnham, Hardesty, and Owens have served two terms on the Board. (CX0554 at 004 (Allen, Dep. at 7; CX0555 at 004 (Brown, Dep. at 9); CX0556 at 007 (Burnham, Dep. at 20), (CX0565 at 007 (Hardesty, Dep. at 20-21); CX0570 at 005 (Owens, Dep. At 11-12)). Drs. Morgan and Holland have served three or more terms on the Board. (CX0569 at 004-005 (Morgan, Dep. at 9-12); CX0567 at 005 (Holland, Dep. at 10-11)).

Response to Finding No. 59:

Respondent has no specific response.

7. The Members of the Board From 2004-2010

60. The Officers of the Board are elected by the Board members. The consumer member and the dental hygienist member are permitted to vote in the election for officers of the Board. (White, Tr. 2202).

Response to Finding No. 60:

Respondent has no specific response.

61. For the Board term year starting in August 2004, the Board consisted of Benjamin W. Brown (President), C. Wayne Holland (Immediate Past President), Stanley L. Allen

(Secretary-Treasurer), Neplus H. Hall (Dental Hygienist Member), Zannie Poplin Efirm (Consumer Member), Joseph S. Burnham, W. Stan Hardesty, and Brad C. Morgan. (CX0085 at 002, Annual Report to the Governor – 2005).

Response to Finding No. 61:

Respondent has no specific response.

62. For the Board term year starting in August 2005, the Board consisted of Stanley L. Allen (President), Benjamin W. Brown (Immediate Past President), Joseph S. Burnham, (Secretary-Treasurer), Neplus H. Hall (Dental Hygienist Member), Zannie Poplin Efirm (Consumer Member), Clifford O. Feingold, W. Stan Hardesty, and Ronald K. Owens. (CX0086 at 002, Annual Report to the Governor – 2006).

Response to Finding No. 62:

Respondent has no specific response.

63. For the Board term year starting in August 2006, the Board consisted of Joseph S. Burnham (President), Stanley L. Allen (Immediate Past President), W. Stan Hardesty (Secretary-Treasurer), Neplus H. Hall (Dental Hygienist Member), Zannie Poplin Efirm (Consumer Member), Clifford O. Feingold, C. Wayne Holland, and Ronald K. Owens. (CX0088 at 002, Annual Report to the Governor – 2007).

Response to Finding No. 63:

Respondent has no specific response.

64. For the Board term year starting in August 2007, the Board consisted of W. Stan Hardesty (President), Joseph S. Burnham (Immediate Past President), Ronald K. Owens (Secretary-Treasurer), Neplus H. Hall (Dental Hygienist Member), Zannie Poplin Efirm (Consumer Member), Clifford O. Feingold, C. Wayne Holland, and Brad C. Morgan. (CX0089 at 002, Annual Report to the Governor, 2008).

Response to Finding No. 64:

Respondent has no specific response.

65. For the Board term year starting in August 2008, the Board consisted of Ronald K. Owens (President), W. Stan Hardesty (Immediate Past President), C. Wayne Holland (Secretary-Treasurer), Jennifer A. Sheppard (Dental Hygienist Member), Zannie Poplin Efirm (Consumer Member), Joseph S. Burnham, Brad C. Morgan, and Millard W. Wester. (CX0091 at 002, Annual Report to the Governor – 2009).

Response to Finding No. 65:

Respondent has no specific response.

66. For the Board term year starting in August 2009 and ending in July 2010, the Board consisted of C. Wayne Holland (President), Ronald K. Owens (Immediate Past President), Brad C. Morgan (Secretary-Treasurer), Jennifer A. Sheppard (Dental Hygienist Member), James B. Hemby, Jr. (Consumer Member), W. Stan Hardesty, Kenneth M. Sadler, and Millard W. Wester. (CX0091 at 002-005, Annual Report to the Governor – 2009).

Response to Finding No. 66:

Respondent has no specific response.

B. The Board Is Funded by Licensees and Not the State of North Carolina

67. The Board does not receive appropriations from the North Carolina General Assembly. (White, Tr. 2192).

Response to Finding No. 67:

Respondent has not specific response.

68. The Board is solely funded by the dues or fees paid by licensed dentists and dental hygienists in North Carolina. (CX0577 at 009 (Oyster, Dep. at 26); CX0556 at 061 (Burnham, Dep. at 237)).

Response to Finding No. 68:

Respondent disputes this proposed finding of fact as a misrepresentation of the record. Respondent also objects to this proposed finding of fact as containing an assumption by the use of the term “dues;” there are no dues paid to the Board, and the Board is not authorized to collect such monies. (CX19 at 19-20; CX503 at 5). Further, Mr. White testified that most of the Board’s revenue comes from licensing and renewal fees paid by dentists and dental hygienists. (White, Tr. at 2192, emphasis added). The Board has reported income from other sources in its annual reports to the Governor. (CX503 at 5).

69. The operating budget for the Board comes from license fees paid by North Carolina dentists and hygienists. (Joint Stipulations of Law and Fact ¶ 11).

Response to Finding No. 69:

Respondent has no specific response.

70. In 2008, license renewal fees alone paid by licensed dentist and hygienists accounted for \$1,406,349 of the Board's reported revenue of \$1,957,859. (CX0503 at 005).

Response to Finding No. 70:

Respondent disputes this proposed finding of fact as containing an assumption due to the use of the term "alone."

71. In 2009, license renewal fees alone paid by licensed dentist and hygienists accounted for \$1,448,631 of the Board's reported revenue of \$2,001,692. (CX0503 at 005).

Response to Finding No. 71:

Respondent disputes this proposed finding of fact as containing an assumption due to the use of the term "alone."

72. The Board uses a portion of the fees paid by licensed North Carolina dentists and hygienists to pay the salaries and benefits of the Board's employees (CX0503 at 005).

Response to Finding No. 72:

Respondent has no specific response.

73. The Board can lobby the legislature with the assistance of the Dental Society. (CX0560 (Feingold, Dep. at 248-249); CX0056 at 005). The North Carolina Dental Society is a professional association of North Carolina Dentists that promotes, among other things, the pecuniary interests of North Carolina dentists. (CX0578 at 010 (Parker, Dep. 32); CX0577-006 (Oyster, Dep. at 15) (primary goals for the NCDS are maintaining adult and child Medicaid rates).

Response to Finding No. 73:

Respondent disputes this proposed finding of fact as a clear mischaracterization of the record. Mr. White testified that as a state agency, the Board could not lobby for passage of any statute. (White, Tr. at 2202). The testimony of Dr. Parker cited by Complaint

Counsel in support of this proposed finding does not reference the pecuniary interests of dentists. (CX578 (Parker, Dep. at 32)). To the contrary, Dr. Parker testifies that Society's goal is to "promote public health, public oral health, to maintain the scientific basis of the practice of dentistry and to advocate for issues that are important to both the public and our members and the dental profession as a whole." (CX578 (Parker, Dep. at 32)). Dr. Oyster's testimony was addressed to the priorities of the Society's legislative committee for the current year. (CX577 (Oyster, Dep. at 15)).

74. Over the last ten years, the Board has approached the North Carolina Dental Society to solicit its assistance to convince the legislature that the Board should be allowed to raise the fees it collects from licensed North Carolina dentists. (CX0578 at 038 (Parker, Dep. at 144-146); CX0555 at 063 (Brown, Dep. at 243-244)).

Response to Finding No. 74:

Respondent disputes this proposed finding of fact as a misrepresentation of the record. Dr. Parker's testimony reflects that the Board sought the assistance of the Dental Society because the fees that the Board was able to charge had reached their statutory cap. (CX578 (Parker, Dep. at 122-145)). Otherwise, if the statutory cap on fees has not been reached, the Board could change the fees by the rule-making process. (White, Tr. at 2201).

75. In approximately 2004-2005, the Board deemed it necessary to raise its fees. (CX0577 at 009 (Oyster, Dep. 26-27)). The Board had to justify its need for additional revenue collected from dentists to the North Carolina Dental Society. (Wester Tr. 1386; CX0555 at 063 (Brown, Dep. at 243-244)).

Response to Finding No. 75:

Respondent disputes this proposed finding of fact as containing an assumption that is not reflected in the record evidence that the Board would somehow need to prove to the Dental Society that a fee increase was justified. Dr. Brown's testimony as to justification

was presented as a hypothetical situation rather than a requirement. (CX555 (Brown, Dep. at 144)). The testimony of Dr. Wester as cited by Complaint Counsel reflects that an approach to the Society by the Board regarding the fee issue was a bid for their support. (Wester, Tr. at 1386).

76. Dr. Oyster of the North Carolina Dental Society testified on behalf of North Carolina's dentists, before the North Carolina House of Representatives and the North Carolina Senate, that the Board needed to raise its fees and that the state's dentists were willing to incur the fee increase. (CX0577 at 009 (Oyster, Dep. at 26-27)).

Response to Finding No. 76:

Respondent disputes this proposed finding of fact in that it is an incomplete statement of fact. Dr. Oyster testified that he appeared before the North Carolina House and Senate because the state's dentists did not want the Board to be without sufficient money to protect the public. (CX577 (Oyster, Dep. at 26-27)). Respondent also disputes this proposed finding of fact because it contains an assumption about the relationship between the Board and the Society.

C. The Authority and Duties of the Board

77. The Board is authorized and empowered by the Legislature of North Carolina to enforce the provisions of the Dental Practice Act. (Joint Stipulations of Law and Fact ¶ 12).

Response to Finding No. 77:

Respondent has no specific response.

**1. The Board's Authority over North Carolina Dentists -
Licensing And Disciplinary Proceedings**

78. The Board is the sole licensing authority for dentists in North Carolina. (CX0019 at 007, Dental Practice Act § 90-29(a)). The Board has the authority to issue licenses, renewals of licenses, and take disciplinary actions against dentists practicing in North Carolina. (CX0019 at 013, 015, 020, 021, Dental Practice Act §§ 90-30, 31, 34, 40, 40.1, 41).

Response to Finding No. 78:

Respondent has no specific response.

79. The dental hygienist and consumer member of the Board cannot participate or vote on Board matters concerning the issuance, renewal, or revocation of a dentist's license. The consumer member of the Board cannot participate or vote on Board matters concerning the issuance, renewal, or revocation of a dental hygienist's license. (CX0019 at 001, Dental Practice Act § 90-22(b)).

Response to Finding No. 79:

Respondent has not specific response.

80. Although the Dental Practice Act provides that the consumer member and dental hygienist member are only excluded from participating or voting on matters involving the "issuance, renewal or revocation of the license to practice dentistry," and, in the case of the consumer member, the license to practice dental hygiene), the dental hygienist and consumer members of the Board were excluded from participating in investigations of the unlicensed practice of dentistry, including investigations of non-dental teeth whitening. (CX0019 at 001, Dental Practice Act § 90-22(b)); (Hardesty, Tr. 2838) (the statute does not prohibit the consumer member or the hygienist member from serving as the case officer in a non-dentist teeth whitening investigation); (Wester, Tr. 1334-1335) (statutory prohibition of the consumer member and hygienist member does not include investigations of unlicensed practice of dentistry by non-dentist teeth whiteners); (Hardesty, Tr. 2838) (case officer assignments in teeth whitening investigations are reserved for dentists); CX0554 at 013 (Allen, Dep. at 44) (Dr. Allen never appointed the consumer member or the hygienist member to be on an investigative panel for an unauthorized practice of dentistry investigation); CX0559 at 008 (Efird, Dep. at 23) (consumer member of the Board did not participate in unauthorized practice of dentistry matters); CX0555 at 031 (Brown, Dep. at 114) (unauthorized practice of dentistry investigations were "not the specific duties of the consumer member"); CX0564 at 005 (Hall, Dep. at 12-13) (dental hygienist member did not participate in unlicensed practice of dentistry investigations).

Response to Finding No. 80:

Respondent disputes this proposed finding of fact as containing an assumption as to the exclusion of the dental hygiene member and consumer member of the Board from non-dentist supervised teeth-whitening investigations. N.C. Gen. Stat. § 90-29 is the applicable statute relative to the unauthorized practice of dentistry in North Carolina.

(CX19 at 7-8). The prohibition of the unauthorized practice of dentistry is accomplished

in N.C. Gen. Stat. § 90-29(b) by setting out a list of actions that constitute the practice of dentistry and declaring that if any person “does, undertakes or attempts to do, or claims the ability to do one of more of the following acts or things,” that constitutes the practice of dentistry. (CX19 at 7). As a practical matter, a case officer (the only position available to a Board member on an investigations panel) must have the ability to supervise and direct the course of the investigation based upon the statutory definition of the unauthorized practice of dentistry, as well as offer professional and technical assistance to the panel. (CX527 at 6, 67).

2. The Board Has No Authority over Non-licensees

81. The Board has no actual authority over non-dentists, and its only authorized recourse against non-dentists engaged in the practice of dentistry is to go through the courts. (CX0554 at 034 (Allen, Dep. at 129)); (CX0019 at 006, 007, 020-21, Dental Practice Act § 90-27, 29, 40, 40.1).

Response to Finding No. 81:

Respondent disputes this proposed finding of fact as containing an opinion and conclusion of law. Under the operation of N.C. Gen. Stat. §§ 90-40 (making the unauthorized practice of dentistry a misdemeanor) and 90-40.1 (enjoining unlawful acts), the Board has clearly been granted the authority to notify prospective defendants in advance of initiating a judicial proceeding.

82. The Dental Practice Act provides that it is unlawful for an individual to practice dentistry in North Carolina without a current license to practice dentistry issued by the Board. (CX0019 at 007, 020, Dental Practice Act § 90-29(a), 40, 40.1(a)).

Response to Finding No. 82:

Respondent has no specific response.

83. The Dental Practice Act sets forth practices that constitute the practice of dentistry. (CX0019 at 007-008, Dental Practice Act § 90-29(b)).

Response to Finding No. 83:

Respondent has no specific response.

84. Pursuant to N.C. Gen. Stat. § 90-40.1, violations of the Dental Practice Act can only be enjoined by the North Carolina superior court of any county in which the acts constituting the violation have been committed or in the county in which the defendant resides. (CX0019 at 020-21, Dental Practice Act § 90-40.1(c).

Response to Finding No. 84:

Respondent disputes this proposed finding of fact. Under the operation of N.C. Gen. Stat. §§ 90-40 (making the unauthorized practice of dentistry a misdemeanor) and 90-40.1 (enjoining unlawful acts), the Board has clearly been granted the authority to notify prospective defendants in advance of initiating a judicial proceeding.

85. The Dental Practice Act authorizes the Board to address suspected instances of the unlicensed practice of dentistry in either of two ways: the Board may petition a state court for an injunction, (CX0019 at 020-021, Dental Practice Act § 90-40.1), or it may request the district attorney to initiate a criminal prosecution. (CX0019 at 020, Dental Practice Act § 90-40; CX0581 at 021-022 (Bakewell, Dep. at 76-80)).

Response to Finding No. 85:

Respondent disputes this proposed finding of fact. Under the operation of N.C. Gen. Stat. §§ 90-40 (making the unauthorized practice of dentistry a misdemeanor) and 90-40.1 (enjoining unlawful acts), the Board has clearly been granted the authority to notify prospective defendants in advance of initiating a judicial proceeding. Respondent also disputes this proposed finding of fact as a mischaracterization and incomplete statement of Ms. Bakewell's testimony. In the testimony cited by Complaint Counsel in support of this proposed finding of fact, Ms. Bakewell is merely responding to questions about how the Board would go about requesting a criminal prosecution in the case of unauthorized practice and her experience with the same. (CX581 (Bakewell, Dep. at 76-80)). She does not indicate that those are the Board's only options. (CX581 (Bakewell, Dep. at 76-

80)). Ms. Bakewell has testified that the Board was authorized to issue an order to a non- licensee; however, she did not interpret the word order to mean a self-executing order “like that of a court.” (RX50 (Bakewell, Dep. at 215).

86. The Board’s authority to hold administrative hearings under the Dental Practice Act is limited to addressing conduct of its licensees or applicants for such a license. (CX0019 at 023, N.C. Gen. Stat. § 90-41.1(a)). The Board’s authority to hold administrative hearings under the Dental Practice Act does not include claims that a non- licensee is engaging in the unlicensed practice of dentistry. (CX0019 at 023, Dental Practice Act § 90-41.1(a)).

Response to Finding No. 86:

Respondent disputes this proposed finding of fact as containing an assumption that an administrative hearing of any sort is not available to non-licensees. The recipients of the cease and desist letters, as persons aggrieved in the teeth whitening cases, could have requested an administrative hearing proceeding under the Administrative Procedure Act, but did not do so. (White, Tr. 2232, N.C. Gen. Stat. § 150B-23(a)).

87. Dr. Owens testified that the Board had no authority to discipline non-licensees. (Owens, Tr. 1443, 1516).

Response to Finding No. 87:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and containing an assumption about the Board’s authority to issue cease and desist letters.

Dr. Owens further also testified, “[t]he Board has no authority for unlicensed individuals for discipline, so indeed, when we send out a cease and desist letter, it’s a request.”

(Owens, Tr. at 1515-1516).

88. The Board’s legal counsel, Ms. Bakewell, testified that the Board does not have the authority to enter self-enforcing orders to non-licensees to stop providing teeth whitening services. (CX0581 at 048 (Bakewell, Dep. at 182-183)).

Response to Finding No. 88:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. In the testimony cited by Complaint Counsel in support of this proposed finding of fact, Ms. Bakewell states that the Board does not have authority that is not in the Dental Practice Act. (CX581 (Bakewell, Dep. at 183)). Ms. Bakewell's testimony was not specifically directed at self-enforcing orders. (CX581 (Bakewell, Dep. at 182-183)).

89. With respect to teeth whitening investigations, Mr. White, the Board's Chief Operating Officer and a licensed attorney (White, Tr. 2188-2189), testified that the Board does not have the legal authority to order anyone to stop violating the Dental Practice Act. (White, Tr. 2284).

Response to Finding No. 89:

Respondent disputes this proposed finding of fact as an incomplete statement of fact. Mr. White further testified that the Board realizes that it cannot not issue an "effecting order," i.e., one that was complete and enforceable in itself without having to go to court. (White, Tr. at 2286). In his testimony, Mr. White drew an analogy to a property owner who could order a trespasser off the property, but had no legal means to enforce the order without turning to the police" to illustrate his point. (White, Tr. at 2286).

D. Complaints And Investigations of the Unauthorized Practice of Dentistry

1. Complaints, Case Assignments, Investigations

90. The Board conducts investigations of allegations that persons are engaged in the Unauthorized Practice of Dentistry ("UPD"). (CX0236 at 001-002; Owens, Tr. 1440-1441; 21 N.C.A.C. 16 U.0101; 21 N.C.A.C. 16 U.0102 (21 N.C.A.C. 16 *et seq.* contains the Board's Rules)). (Joint Stipulations of Law and Fact ¶ 19). The Board conducts investigations of licensees in connection with its authority to issue licenses, renewals of licenses, and take disciplinary actions against dentists practicing in North Carolina. (CX0019 at 013, 015, 020, 021, Dental Practice Act §§ 90-30, 31, 34, 40, 40.1, 41).

Response to Finding No. 90:

Respondent has no specific response.

91. The Board investigation and hearing process for licensee cases includes a receipt of complaint, investigation of complaint, and hearing regarding the investigation before the Board hearing panel. (CX0556 at 064 (Burnham, Dep. at 247)).

Response to Finding No. 91:

Respondent disputes this proposed finding of fact as an incomplete statement of fact. Dr. Burnham summarized the process in his testimony, but the Complaint Process as to licensees is described in greater detail in the Board's Investigations Manual. (CX527 at 1-70).

92. The Board's investigation process for non-licensee cases includes the receipt of complaint, an investigation, and a decision by case officer about how to proceed after the investigation. (CX0556 at 064 (Burnham, Dep. at 247-248)).

Response to Finding No. 92:

Respondent has no specific response.

a. Complaints Against Licensees and Non-licensees

93. The Board is a complaint driven institution. (Owens, Tr. 1641; Kwoka, Tr. 1212-1213; (CX0555 at 010-011 (Brown, Dep. At 33-35); (CX0556 at 064 (Burnham, Dep. at 247-248)).

Response to Finding No. 93:

Respondent has no specific response.

94. Complaint forms are the most common means of making a complaint to the Board, but they are less common for complaints pertaining to teeth whitening than for other complaints. (CX0563 at 007 (Goode, IHT at 23-25)).

Response to Finding No. 94:

Respondent disputes this proposed finding of fact as it contains an assumption. Further, it is a mischaracterization of Ms. Goode's testimony, which was that, in regard to teeth whitening complaints, the Board would less likely receive the standard complaint form.

(CX563 (Goode, IHT at 24). The “standard complaint form” was designed for complaints against licensees -- not the unauthorized practice of dentistry. (See, for example, RX5 at 2-5; RX21 at 4-6; RX25 at 22-24).

95. Consumer complaints to the Board regarding patient care must be made in writing on an official Board complaint form provided by the Board and authenticated as instructed on the complaint form. Telephone complaints regarding dental treatment are not accepted. (CX0527 at 008). The Board added the requirement that written complaints be notarized so the complainant would be signing a sworn statement and would hopefully provide truthful statements. (CX0561 at 031 (Friddle, Dep. at 117)).

Response to Finding No. 95:

Respondent disputes this proposed finding of fact as containing an assumption. The requirements as stated in the Board’s Investigations Manual would not apply to complaints made to the Board regarding non-dentist supervised teeth whitening because there is no patient involved and no dental treatment. (CX527 at 8).

96. The Board does not accept anonymous complaints for treatment-related issues concerning licensed dentists. In such cases, the Board requires a written statement. (CX0558 at 19 (Dempsey, IHT at 71-73); The secretary-treasurer of the Board will accept anonymous complaints in certain situations when the public safety is in danger, such as when there is a question about sterility and infection control or a complaint of an impaired dentist. (CX0556 at 009 (Burnham, Dep. at 26-27)).

Response to Finding No. 96:

Respondent disputes this proposed finding of fact as it contains an assumption. The evidence shows that the majority of complaints about teeth whitening were from an identifiable source. See .Complaint Counsel’s Proposed Findings of Fact #s 272, 273, 274 and 279, *infra*.

97. The Board requires that complaints regarding dentist misconduct be filed on official complaint forms rather than simply be memorialized in a letter to the Board. (CX0560 at 024-025 (Feingold, Dep. at 88-90)).

Response to Finding No. 97:

Respondent disputes this proposed finding of fact as containing an assumption. The requirements as stated in the Board's Investigations Manual would not apply to complaints made to the Board regarding non-dentist supervised teeth whitening because there is no patient involved and no dental treatment. (CX527 at 8).

98. Although the unlicensed practice of dentistry is not listed in the Board's Investigations Manual as an exception to the rule that requires all complaints be in written form. (CX0527 at 014), the Board will consider a complaint that a non-dentist teeth whitener is engaging in the unlicensed practice of dentistry even when the Board's normal complaint filing requirements are not met – the requirement for a notarized form may be waived. (CX0566 at 021 (Hardesty, IHT at 78-79)). A complaint to the Board consisting of an advertisement that shows a potential occurrence of the unlicensed practice of dentistry could lead to an investigation even if it was not submitted with a formal complaint form. (CX0560 at 050 (Feingold, Dep. at 192); CX0198 at 001-002).

Response to Finding No. 98:

Respondent disputes this proposed finding of fact as a misrepresentation of the record and as containing an assumption. The Board's Investigations Manual specifically states that “[c]onsumer complaints regarding patient care must be made in writing on an official Board complaint form provided by the Board office, or downloaded from the web site and authenticated per instructions on the complaint form.” (CX527 at 8, emphasis added). There is no requirement in the Board's Investigations Manual that complaints about the unauthorized practice of dentistry are required to be submitted on an official complaint form. (CX527 at 1-70). Complaint Counsel also misrepresents the portion of Dr. Hardesty's testimony that is cited in support of this proposed finding of fact. Dr. Hardesty testified that there were exceptions to the protocol of a notarized, written complaint, and one of those exceptions would be the unauthorized practice of dentistry.” (CX566 (Hardesty, IHT at 78-79)).

99. All complaints to the Board initially go to the Board's Deputy Operations Officer Terry Friddle (CX0562 at 011 (Friddle, IHT at 38-39)). Ms. Friddle assigns case numbers to the complaints and forwards the complaints to the Secretary-Treasurer. (White, Tr. 2219).

Response to Finding No. 99:

Respondent has no specific response.

100. The Board's Secretary-Treasurer receives all complaints filed with the Board and assigns them to a case officer. (White, Tr. 2202-2203); (Wester, Tr. 1280-1281).

Response to Finding No. 100:

Respondent has not specific response.

101. "Case review" is a screening process conducted by the Secretary-Treasurer to determine whether or not the Board has jurisdiction in a matter or if the information presented is not reasonably valid and reliable. (CX0527 at 006).

Response to Finding No. 101:

Respondent has no specific response.

102. The Secretary-Treasurer has wide discretion in assigning cases or investigations. (White, Tr. 2203). The Secretary-Treasurer may keep a case or assign the case to another Board member. The assigned Board member is referred to as the Case Officer for that investigation. (CX0562 at 011 (Friddle, IHT at 38-39); CX0556 at 007-008 (Burnham, Dep. at 21-22); Owens, Tr. 1440-1441).

Response to Finding No. 102:

Respondent has no specific response.

b. Investigations and the Investigative Panel

103. The Investigative Panel conducts investigations of alleged instances of the unlawful practice of dentistry. (Owens, Tr. 1440-1441; CX0527 at 006, 009-010, 015; CX0234 at 001-011).

Response to Finding No. 103:

Respondent has not specific response.

104. A Board Investigative Panel consists of the Case Officer, the Deputy Operations Officer or Board designee, and the Investigator assigned to the investigation. The Board's

legal counsel may participate in the panel meetings as needed. (CX0527 at 006; Owens, Tr. 1441; CX0554 at 012 (Allen, Dep. at 39)).

Response to Finding No. 104:

Respondent has no specific response.

105. The Case Officer is the Board member assigned by the Board President or Secretary-Treasurer whose duty it is to oversee an investigation. (CX0527 at 006). Deputy Operations Officer Friddle assigns an investigator (either Mr. Kurdys or Mr. Dempsey) and a case manager (either Ms. Friddle or Ms. Goode) to the case. (CX0562 at 011 (Friddle, IHT at 38-39)).

Response to Finding No. 105:

Respondent has no specific response.

106. Under the North Carolina Dental Practice Act, “[t]he dental hygienist [member] or the consumer member cannot participate or vote in any matters of the Board which involves (sic) the issuance, renewal or revocation of the license to practice dentistry in the State of North Carolina.” (CX0019 at 001, Dental Practice Act § 90-22). This restriction in the statute does not mention the unlicensed practice of dentistry, stain removal, or teeth whitening. (Wester, Tr. 1334-1335). There is no statutory provision that prohibits the consumer and hygienist Board members from being the case officer on an investigation involving non-dentists. (Hardesty, Tr. 2838).

Response to Finding No. 106:

Respondent disputes this proposed finding of fact as containing an assumption as to the exclusion of the dental hygiene member and consumer member of the Board from non-dentist supervised teeth-whitening investigations. N.C. Gen. Stat. § 90-29 is the applicable statute relative to the unauthorized practice of dentistry in North Carolina. (CX19 at 7-8). The prohibition of the unauthorized practice of dentistry is accomplished in N.C. Gen. Stat. § 90-29(b) by setting out a list of actions that constitute the practice of dentistry and declaring that if any person “does, undertakes or attempts to do, or claims the ability to do one of more of the following acts or things,” that constitutes the practice of dentistry. (CX19 at 7). As a practical matter, a case officer (the only position available to a Board member on an investigations panel) must have the ability to

supervise and direct the course of the investigation based upon the statutory definition of the unauthorized practice of dentistry, as well as offer professional and technical assistance to the panel. (CX527 at 6, 67).

107. Even though there is no prohibition against the consumer and hygienist Board member serving as the Case Officer on an investigation involving non-dentists, only dentists have served as Case Officers for teeth whitening investigations. (Hardesty, Tr. 2838); CX0563 at 009-010 (Goode, IHT at 33-34)).

Response to Finding No. 107:

Respondent disputes this proposed finding of fact as containing an assumption as to the exclusion of the dental hygiene member and consumer member of the Board from non-dentist supervised teeth-whitening investigations. N.C. Gen. Stat. § 90-29 is the applicable statute relative to the unauthorized practice of dentistry in North Carolina. (CX19 at 7-8). The prohibition of the unauthorized practice of dentistry is accomplished in N.C. Gen. Stat. § 90-29(b) by setting out a list of actions that constitute the practice of dentistry and declaring that if any person “does, undertakes or attempts to do, or claims the ability to do one of more of the following acts or things,” that constitutes the practice of dentistry. (CX19 at 7). As a practical matter, a case officer (the only position available to a Board member on an investigations panel) must have the ability to supervise and direct the course of the investigation based upon the statutory definition of the unauthorized practice of dentistry, as well as offer professional and technical assistance to the panel. (CX527 at 6, 67).

108. The non-dentist Board members do not participate in investigations relating to teeth whitening services performed by non-dentists or investigations of the unauthorized practice of dentistry. (CX0571 at 016 (Owens, IHT at 61); CX0566 at 008 (Hardesty, IHT at 27-28); CX0554 at 013 (Allen, Dep. at 44) (Dr. Allen never appointed either the hygienist member or the consumer representative on an investigative panel involving a UPD matter); CX0555 at 031-032 (Brown, Dep. at 117-118) (hygienist Board member cannot be assigned as a case officer on any investigations involving the unauthorized

practice of dentistry); CX0564 at 005 (Hall, Dep. at 12-13); CX0564 at 006 (Hall, Dep. 15-16) (Hall was not involved in any manner with the Board's investigations of teeth whitening)).

Response to Finding No. 108:

Respondent disputes this proposed finding of fact as containing an assumption as to the exclusion of the dental hygiene member and consumer member of the Board from non-dentist supervised teeth-whitening investigations. N.C. Gen. Stat. § 90-29 is the applicable statute relative to the unauthorized practice of dentistry in North Carolina. (CX19 at 7-8). The prohibition of the unauthorized practice of dentistry is accomplished in N.C. Gen. Stat. § 90-29(b) by setting out a list of actions that constitute the practice of dentistry and declaring that if any person "does, undertakes or attempts to do, or claims the ability to do one of more of the following acts or things," that constitutes the practice of dentistry. (CX19 at 7). As a practical matter, a case officer (the only position available to a Board member on an investigations panel) must have the ability to supervise and direct the course of the investigation based upon the statutory definition of the unauthorized practice of dentistry, as well as offer professional and technical assistance to the panel. (CX527 at 6, 67).

c. Case Officer Directs Investigation, Makes Recommendation, or Takes Enforcement Action

109. The Case Officer directs the investigation of a teeth whitening services performed by non-dentists and is assisted by other Board staff members. (Owens, Tr. 1441-1442); CX0571 at 014 (Owens, IHT at 50-51)).

Response to Finding No. 109:

Respondent has no specific response.

110. Board investigators perform undercover investigations in non-dentist teeth whitening cases posing as prospective clients at the direction of the Case Officer without identifying themselves as representatives of the Board. (CX0558 at 017 (Dempsey, IHT

at 64); (CX0038 at 004) (Hardesty directs Friddle to do a “sting” of a non-dentist teeth whitener where Board investigators pose as clients to have impressions made); CX0070 at 001; CX0367 at 001; CX0284 at 001; CX0201 at 001). Board investigator Dempsey visited several teeth whitening businesses where he did not identify himself as a representative or investigator for the Board. (CX0558 at 017 (Dempsey, IHT at 65)).

Response to Finding No. 110:

Respondent has no specific response.

111. Board investigators also perform investigations at the direction of the Case Officer where they identify themselves as Board employees and ask questions about the processes used by non-dentist teeth whiteners. (CX0367 at 001); CX0228 at 001-002; CX0247 at 001). Board investigators are also directed by case officers to take photographs of non-dentist teeth whiteners’ businesses such as kiosks in a mall. (CX0200 at 001; CX0201 at 001). Board investigator Dempsey often takes pictures and may write notes indicating whether non-dentist teeth whiteners had [dental] chairs set up, whether there were LED lights set up and if the providers were wearing lab coats. (CX0557 at 009 (Dempsey, Dep. at 28-29)).

Response to Finding No. 111:

Respondent disputes this proposed finding of fact. There is no evidence of case officers directing Board investigators to take photographs in the exhibits offered in support by Complaint Counsel. (CX2001 at 1; CX201 at 1).

112. The Case Officer is authorized by the Board to make enforcement decisions and take enforcement actions on its behalf. (CX0570 at 011 (Owens, Dep. at 37); CX0571 at 014, Owens, IHT at 50-51); (White, Tr. 2224).

Response to Finding No. 112:

Respondent has no specific response.

113. The case officer in a unlicensed practice of dentistry case makes the decision about whether to send a Cease and Desist Order to the target of the investigation. (CX0556 at 064 (Burnham, Dep. at 248)).

Response to Finding No. 113:

Respondent has no specific response.

114. The Case Officer can direct the Board attorney to take civil action or recommend criminal prosecution in an unlicensed practice of dentistry case. If that happens the Board would be informed at the next Board meeting. (White, Tr. 2224; CX0556 at 064 (Burnham, Dep. at 248)).

Response to Finding No. 114:

Respondent disputes proposed finding of fact in that it contains the assumption that these are the only options open to the case officer.

115. Decisions by Investigative panels or Case Officers to issue Cease and Desist Orders to non-dentists are made outside of public purview. (Response to RFA ¶ 44).

Response to Finding No. 115:

Respondent disputes this proposed finding of fact as containing an assumption.

Consistent with the Board's Investigations Manual, the case officer has the sole responsibility for proceeding in any investigation – those involving licensees as well as those of the unauthorized practice of dentistry. (CX527 at 6, 9-10, 67). The Response to the Request for Admissions cited by Complaint Counsel in support of this proposed finding admits that, if necessary, any discussions regarding enforcement actions of the unauthorized practice take place in closed session at Board meetings. (Respondent's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, ¶ 44).

116. Dr. Brown testified that the point in an investigative process that a Cease and Desist Order would be issued would probably be if there wasn't clear evidence that a case against the target of the investigation could be won. (CX0555 at 060 (Brown, Dep. at 231)).

Response to Finding No. 116:

Respondent disputes this proposed finding of fact as containing an assumption. Dr. Brown was asked whether he knew at what point during the investigative process other case officers issued cease and desist letters. (CX555 (Brown, Dep. at 231)). He then

offered his conjecture that it would probably be if there was not clear evidence.

(CXX555 (Brown, Dep. at 231)).

d. Requirement of Board Vote Before Closing An Investigation

117. The Case Officer can recommend to the Board that a case be closed, but the Board must approve the closing of any investigation including unlicensed practice of dentistry investigations. (CX0563 at 014-015 (Goode, IHT at 53-54); CX0556 at 064 (Burnham, Dep. at 248); CX0558 at 021 (Dempsey, IHT at 81)).

Response to Finding No. 117:

Respondent has no specific response.

118. The Board's Deputy Operations Officer periodically circulates a list of "Investigative Files Proposed to Be Closed" to "Members of the Board." The list is sent to all Board members that can vote on a matter, which includes all Board members that are dentists and the hygienist Board member if the case pertains to a hygienist. Board members permitted to vote are asked whether they approve of closing each investigation listed. (CX0660 at 001; CX0622 at 001; CX0660 at 001; CX0562 at 004-005 (Friddle, IHT at 13-14)). The applicable Board members would receive the proposed closing file by email and, in some instance, vote by e-mail. (CX0554 at 021 (Allen, Dep. at 74)).

Response to Finding No. 118:

Respondent has no specific response.

119. The closure of an open investigation must be approved by a vote of the Board. (CX0527 at 067). Only the six dentists on the Board are allowed to vote on license matters, except that the hygienist member can vote on license matters related to dental hygienists. (Wester, Tr. 1316-1317).

Response to Finding No. 119:

Respondent has no specific response.

120. Reports recommending that non-dentist teeth whitening investigations be closed as well as the basis for doing so are submitted to Board members outside of public Board meetings. Only the dentist members are copied on the closure reports. (CX0562 at 004-005 (Friddle, IHT at 13-14); CX0530 at 004; CX0659 at 001; CX0623 at 001).

Response to Finding No. 120:

Respondent disputes this proposed finding of fact. In the testimony of Ms. Friddle cited by Complaint Counsel in support of this proposed finding of fact, she testifies that the investigative staff also received copies of the closure reports and Mr. White as well. (CX562 (Friddle, IHT at 13-14)). Ms. Friddle's testimony did not mention anything about Board meetings in relation to the closure reports, nor did the other exhibits cited by Complaint Counsel. (CX562 (Friddle, IHT at 13-14); CX530; CX659; CX623).

2. Hearings

121. The Board does not conduct hearings for unlicensed practice of dentistry matters. (CX0554 at 013 (Allen, Dep. at 43); CX0574 at 011 (White, IHT at 39)). The Board is not authorized to conduct hearings related to the unauthorized practice of dentistry. (CX0555 at 025 (Brown, Dep. at 92)).

Response to Finding No. 121:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and as containing an assumption that an administrative hearing of any sort is not available to non-licensees. Recipients of cease and desist letters, as persons aggrieved in the teeth whitening cases, could have requested an administrative hearing proceeding under the Administrative Procedure Act, but did not do so. (White, Tr. 2232, N.C. Gen. Stat. § 150B-23(a)).

E. Board Meetings - Open and Closed Sessions

122. The Board generally meets once a month for three days. (White, Tr. 2194; CX0562 at 004 (Friddle, IHT at 12)).

Response to Finding No. 122:

Respondent has no specific response.

123. Board meetings are public and may be attended by the public, but members of the public rarely attend any Board meetings. (CX0581 at 030-031 (Bakewell, Dep. at 110-114); CX0556 at 013 (Burnham, Dep. at 42)).

Response to Finding No. 123:

Respondent has no specific response.

124. Upon the motion of a Board member, the Board will enter a "Closed Session" to conduct its meeting out of public eye. (CX0056 at 002, 005-007; CX0106 at 002, 004, 007, 009- 010; CX0109 at 001, 006-011; CX0107 at 002-006).

Response to Finding No. 124:

Respondent disputes this proposed finding of fact as containing an assumption. The Board's meetings are conducted pursuant to N.C. General Statute § 143-318, the Open Meetings Act, which governs whether state agencies must conduct their business in public view. (White, Tr. 2217-2218). The Act provides that certain activities are exempted from this requirement and may be discussed during sessions closed to the public, including receiving advice from legal counsel, offering an honorary degree, reviewing investigative matters, and review of proprietary testing material. (White, Tr. 2217-2218). The Board is not allowed to vote during closed sessions. (White, Tr. 2217-2218).

125. Generally, the Board enters a "Closed Session" to consult with Board Counsel; discuss investigations, including unlicensed practice of dentistry investigations; discuss personnel matters; discuss licensure matters; and to discuss hearing panel decisions. (CX0056 at 002, 005-007; CX0106 at 002, 004, 007, 009-010; CX109 at 001, 006-011; CX0107 at 002-006; CX0581 at 029 (Bakewell, Dep. at 109-110); CX0561 at 012 (Friddle, Dep. at 41)). The lone consumer member did not participate in any formal discussions about teeth whitening when the Board was in a closed session. (CX0559 at 004 (Efird, Dep. at 9)).

Response to Finding No. 125:

Respondent disputes this proposed finding of fact as creating an assumption and as an incomplete statement. Ms. Efird testified that she did not remember any formal

discussions of teeth whitening occurring in the boardroom. (CX559 (Efird, Dep. at 10)).

Ms. Efird testified that she did participate in some informal discussions. (CX559 (Efird, Dep. at 9)).

126. At a general meeting it was mentioned that the Board would be investigating complaints about teeth whitening, but any discussion did not proceed further in Hall's presence. (CX0564 at 006 (Hall, Dep. at 15-16)).

Response to Finding No. 126:

Respondent disputes this proposed finding of fact as a mischaracterization of Ms. Hall's testimony and as creating an assumption. Ms. Hall testified that at a general meeting, it was mentioned there were teeth whitening complaints and that the Board would be investigating them, but that's as far as the discussion went. (CX564 (Hall, Dep. at 16)).

127. When new members are elected to the Board, the Board sends them an informational letter. Among other things, the Board informs new members that the President of the Board is considered to be the "voice" of the Board and that other members are expected to follow his lead. (CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0028 at 005). They are also advised that Board decisions are unanimous and that the Board speaks with "one voice." (CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0028 at 005; CX0556 at 012 (Burnham, Dep. at 39); CX0569 at 030-031 (Morgan, Dep. at 113-115); CX0028 at 005).

Response to Finding No. 127:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. The exhibits cited by Complaint Counsel in support of the first sentence of this proposed finding of fact do not state that the Board members are to follow the Board President's lead; they state that Board members must refrain from voicing a personal opinion and permit the Board President to "speak for the Board." (CX449 at 5; CX219 at 5; CX242 at 5; CX28 at 5). The exhibits cited by Complaint Counsel in support of the second sentence do not reference unanimous Board decisions, nor do they mention that the Board speaks with "one voice." (CX449 at 5; CX219 at 5; CX242 at 5; CX28 at 5). Futher, Dr.

Burnham's testimony was the Board preferred to have the Board President speak in matters where the media was seeking information about a formal hearing. (CX556 (Burnham, Dep. at 39)). Dr. Morgan's testimony was that although Board members would hold and express different views at the time a matter was under discussion, by the time the matter was voted on by the Board, it generally was a unanimous vote. (CX569 (Morgan, Dep. at 115-116)).

128. New Board members are also cautioned that they "must act as one body and refrain from voicing personal opinion [and] avoid divulging how various members voted on a matter or voicing personal opinion when it differs from a Board decision. (CX0028 at 005; CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0556 at 012 (Burnham, Dep. at 39); CX0569 at 030-31 (Morgan, Dep. at 113-115)). They are further advised that junior members of the Board are expected to follow the lead of senior members of the Board. (CX0449 at 005; CX0219 at 005; CX0242 at 005).

Response to Finding No. 128:

Respondent disputes this proposed finding of fact as containing several assumptions and as mischaracterizing the record. Regarding the first sentence of this proposed finding of fact, Complaint Counsel has not closed the quotation so it is not possible for Respondent to formulate a precise response to this sentence. Further, Dr. Burnham's testimony was that the Board preferred to have the Board President speak in matters where the media was seeking information about a formal hearing. (CX556 (Burnham, Dep. at 39)). Dr. Morgan's testimony was that although Board members would hold and express different views at the time a matter was under discussion, by the time the matter was voted on by the Board, it generally was a unanimous vote. (CX569 (Morgan, Dep. at 115-116)). Regarding the last sentence of the proposed finding of fact, the new Board members are actually advised to "permit seasoned Board members and the Board Director to guide

you” – not advised that new members are expected to follow the lead of senior Board members. (CX449 at 5; CX219 at 5; CX242 at 5).

129. According to the letter sent to new Board members, “[T]he worst problem for the Board is when it is perceived that the public interest is not its main objective.” (CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0028 at 005).

Response to Finding No. 129:

Respondent disputes this proposed finding of fact as containing an assumption as to the intent of the Board. This particular statement was part of a section advising Board members to avoid divulging how various members voted on a matter or voicing a personal opinion when it differs from a Board decision. (CX449 at 5; CX219 at 5; CX242 at 5; CX28 at 5).

130. Discussion in the executive sessions of the Board are private and not shared with the public. (CX0028 at 005; CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0581 at 030 (Bakewell, Dep. at 110-113)). The Executive Committee of the Board consists of the president, the secretary-treasurer and the immediate past president, but the consumer member has never been on the executive committee. (CX0562 at 004 (Friddle, IHT at 13); CX0559 at 011 (Efrid, Dep. at 34-35)).

Response to Finding No. 130:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record and as containing an assumption not in the record. In the testimony used by Complaint Counsel in support of this proposed finding of fact, the terms “executive session” and “closed session” were used interchangeably by Complaint Counsel and Ms. Bakewell in a series of questions pertaining to meetings of the Board – not the Executive Committee. (CX581 (Bakewell, Dep. at 111)). Therefore, the reference in the second sentence of this proposed finding of fact to the “Executive Committee” is not relevant to the first sentence.

F. The North Carolina Dental Society And The Board

131. The North Carolina Dental Society (hereinafter "NCDS") is a professional association of North Carolina dentists. (CX0194 at 001). A partial purpose of the NCDS is to advocate for the economic interest of dental professions. (CX0578 at 11 (Parker, Dep. at 37); CX0577 at 006 (Oyster, Dep. at 15) (primary goals for the NCDS is to maintain adult and child Medicaid rates at levels with which dentists can participate).

Response to Finding No. 131:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

The testimony of Dr. Parker cited by Complaint Counsel in support of this proposed finding does not reference the economic interests of dentists. (CX578 (Parker, Dep. at 32)). To the contrary, Dr. Parker testifies that Society's goal is to "promote public health, public oral health, to maintain the scientific basis of the practice of dentistry and to advocate for issues that are important to both the public and our members and the dental profession as a whole." (CX578 (Parker, Dep. at 32)). Dr. Oyster's testimony was addressed to the priorities of the Society's legislative committee for the current year. (CX577 (Oyster, Dep. at 15).

132. All of the members of the Board are also members of the North Carolina Dental Society. (CX0556 at 044 (Burnham, Dep. at 169)).

Response to Finding No. 132:

Respondent has no specific response.

133. The Board's Executive Director, Mr. White, has been the official liaison between the Board and the NCDS. (White, Tr. 2256-2257). Dr. Litaker has served as the NCDS's official liaison for the Board for NCDS Legislative Committee. (CX0191 at 001).

Response to Finding No. 133:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

In response to Complaint Counsel's question as to whether he was the "liaison or point

person” for the Board’s interactions with the Dental Society, Mr. White answered, “yes.”

(White, Tr. at 2256-2257).

134. Board members also consider themselves “liaisons” between the Board and the licensees. (Hardesty, Tr. 2764-2765).

Response to Finding No. 134:

Respondent disputes this proposed finding of fact as a mischaracterization of Dr.

Hardesty’s testimony. Dr. Hardesty’s testimony was that board members were a liaison “as far as if they wanted” someone to go to generals meetings and bring greetings from the Board. (Hardesty, Tr. at 2764).

135. Drs. M. Alec Parker, William M. Litaker, and Gary D. Oyster of the North Carolina Dental Society gave testimony at depositions in this matter. (Parker on September 23, 2010; CX0578 at 003-102 (Parker, Dep. at 6-253); (Litaker on September 24, 2010; CX0576 at 003-031 (Litaker, Dep. at 6-131); (Oyster on September 24, 2010; CX0577 (Oyster, Dep. at 5-103)).

Response to Finding No. 135:

Respondent has no specific response.

136. The North Carolina is one third of a tripartite relationship among the American Dental Association (hereafter “ADA”), the NCDS, and any one of the many local dental societies of North Carolina. (CX0578 at 013 (Parker, Dep. at 42-43)).

Response to Finding No. 136:

Respondent is unable to provide a response to this proposed finding of fact as it is incomplete, and therefore, indecipherable.

137. Dr. Parker has been the Executive Director of the NCDS since January 2008. (CX0578-004-005 (Parker, Dep. at 9-10)). Dr. Oyster has served as the NCDS Chairman of the Legislative Committee since the mid-nineties. (CX0577 at 004-005 (Oyster, Dep. at 8-12)). Dr. Litaker was a trustee of the NCDS from 1999-2005. From 2006-2009, in successive one-year terms, he was secretary/treasurer, president-elect, president, and past president of the NCDS. (CX0576 at 004 (Litaker, Dep. at 7)).

Response to Finding No. 137:

Respondent has no specific response.

138. Twice annually, the Board and the members of the NCDS attend common gatherings. The two organizations and the North Carolina dental education institution convene for what is known as the tripartite meeting. And during the NCDS annual convention, the Board is provided a forum at which NCDS members can ask Board members questions. (CX0578 at 018 (Parker, Dep. at 62-63)).

Response to Finding No. 138:

Respondent has no specific response.

139. Board members appropriately give public statements to make the public aware of the Board's activities, including "[t]heir constituents," licensed dentists, by speaking at meetings of the North Carolina Dental Society. (CX0581 at 007 (Bakewell, Dep. at 20-21)).

Response to Finding No. 139:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

Ms. Bakewell's testimony was in the context of general discussions by Board members with other dentists as part of their duties to "serve the public," of which other dentists would be considered a member. (CX581 (Bakewell, Dep. at 21)).

III. Teeth Whitening - Popularity, Financial Interest, and Overview

A. Popularity

140. The American Academy of Cosmetic Dentistry ("AACD") reported in 2004 and the American Dental Association's ("ADA") Counsel for Scientific Affairs reported in 2009 that teeth whitening or bleaching has become one of the most popular esthetic dental treatments over the past two decades. (CX0397 at 001; CX0392 at 002).

Response to Finding No. 140:

Respondent has no particular response.

141. The AACD reported in 2004 that teeth whitening or bleaching is the number one requested cosmetic dentistry procedure, and has become a lucrative market for dentists. (CX0397 at 001).

Response to Finding No. 141:

Respondent disputes this proposed finding of fact. The exhibit cited by Complaint Counsel does not mention anything about whether teeth whitening is a lucrative market. (CX397 at 1).

142. A 2004 study by the AACD found that 99.7% of adult American respondents believed that a smile is an important social asset, and 74% believed an unattractive smile could hurt a person's chances for career success. (CX0385 at 003). A survey conducted by Discus Dental, a manufacturer of dentist teeth whitening products, revealed that 85% of dental patients want "whiter, brighter smiles." (CX0597 at 029).

Response to Finding No. 142:

Respondent disputes this proposed finding of fact as irrelevant and immaterial and to the extent the surveys were not specific to North Carolina, not relevant to the proceeding.

143. In 2007, the AACD reported that the number of dentist teeth whitening procedures had increased more than 300% in the previous five years (CX0397 at 001).

Response to Finding No. 143:

Respondent disputes this proposed finding of fact. This fact contains a presupposition subject to separate factual basis. It is not relevant to North Carolina. Further, the press release cited in support of this proposed finding of fact is dated June 22, 2006. (CX397 at 1). It also states that whitening treatments provided by dentists "have increased more than 300% since 1996" – a 300% increase over ten year period instead of five years. (CX397 at 1).

144. A 2008 national Gallup Poll reported that over 80% of dentists engage in the practice of teeth whitening. (CX0513 at 007).

Response to Finding No. 144:

Respondent notes that this was a national survey, and not a survey of North Carolina dentists. Nor does this particular finding of fact reference the amount of teeth whitening performed.

B. Teeth Whitening As A Source of Income For Board Members and North Carolina Dentists

145. In 2007 the AACD reported that a survey of approximately 5,500 dentists indicated that dentists performed an average of 70 teeth whitening procedures per dentist in 2006. Based upon these numbers, the average teeth whitening revenue per dentist was \$25,000 in 2006 (CX0383 at 002). Survey respondents reported performing 389,000 teeth whitening procedures resulting in revenue for a total revenue of \$138.8 million in 2006. (CX0383 at 002).

Response to Finding No. 145:

Respondent disputes this proposed statement of fact. This fact contains a presupposition subject to separate factual basis. It is not relevant to North Carolina or the general practice of dentistry because it relates to the subspecialty of cosmetic dentistry. Further, the survey results indicate that teeth whitening is still a small percentage of the practices of those who specialize as cosmetic dentists. (CX383 at 2). Although these cosmetic dentists did report performing an average of 70 teeth whitening procedures in 2006, which earned them \$25,000 in revenue, the bulk of their revenues came from other procedures. (CX383 at 2). The cosmetic dentists reported an average of 1,325 other procedures performed in 2006, for \$483,000. (CX383 at 2). Even among these cosmetic dentistry specialists, the percentage of their revenue generated from teeth whitening in the year 2006 was roughly 4.8%. (CX383 at 2).

146. A Procter & Gamble ("P&G") website article states that with proper marketing, a dental practice that treats 1,800 patients a year can earn an annual profit of \$35,100 by selling Crest Professional White Strips to patients. The article notes that by scheduling a followup final cosmetic exam where dentists point out other improvements through esthetic procedures that your "esthetic practice could explode overnight." (CX0381 at 002).

Response to Finding No. 146:

Respondent has no specific response.

147. A Gallup poll also found that dentists not providing teeth whitening might do so if there were product improvements or lower costs. (CX0513 at 029). To offer teeth whitening, all a “general” dentist needs to do is to start advertising cosmetic dentistry services. (Wester, Tr. 1341-1343; CX0571 at 005, 011 (Owens, IHT at 14, 40); CX0556 at 005, 038 (Burnham, Dep. at 10, 145); CX0578 at 005 (Parker, Dep. at 10-11); CX0567 at 006 (Holland, Dep. at 14)).

Response to Finding No. 147:

Respondent disputes this proposed finding of fact. The Gallup poll cited by Complaint Counsel was based on interviews of only 50 dentists. Further, Complaint Counsel has mischaracterized the testimony of Board members. The testimony was that there only one dental license in North Carolina – a general dentist. (Wester, Tr. at 1341-1342) Also, the American Dental Association does not recognize cosmetic dentistry as a specialty area. (CX571 (Hardesty, IHT at 40)).

148. Many of the Board members offer and perform teeth whitening services in their private practice. (State Action Opinion at 14; CX0467 at 001 (Dr. Owens); CX0554 at 006 (Allen, Dep. at 18); CX0556 at 038 (Burnham, Dep. at 145-146); CX0560 at 004-005 (Feingold, Dep. at 9-10); CX0564 at 011 (Hall, Dep. at 34); CX0565 at 005 (Hardesty, Dep. at 15); CX0567 at 017 (Holland, Dep. at 58); CX0569 at 009 (Morgan, Dep. at 27-28); CX0572 at 009 (Wester, Dep. at 26-27).

Response to Finding No. 148:

Respondent has no specific response.

149. Some dentist Board members provide teeth whitening services to patients and derive income from the provision of teeth whitening services. (CX0340 at 002 (Dr. Morgan); CX0378 at 005 (Dr. Hardesty); CX0467 at 001 (Dr. Owens); CX0554 at 007 (Allen, Dep. at 18); CX0556 at 038-039 (Burnham, Dep. at 145-149); CX0606 at 005 (Dr. Burnham); CX0614 at 001 (Dr. Wester)).

Response to Finding No. 149:

Respondent has no specific response.

150. Some dentists in North Carolina have averaged tens of thousands of dollars annually in revenue from the provision of teeth whitening procedures for the period from 2005 until August of 2010. (CX0599 at 003) (Charlotte, North Carolina dentist had revenue of \$117,490); (CX0605 at 003) (Chapel Hill, North Carolina dentist had revenue

of \$77,302); (CX0616 at 021) (Raleigh, North Carolina dentist had revenues of \$74,710); (CX0601 at 008) (Cary, North Carolina dentist had revenues of \$88,713); (CX0608 at 20 002) (Huntersville, North Carolina dentist had revenues of \$66,545); (CX0602 at 002) Another Huntersville, North Carolina dentist had revenues of \$149,806); (CX0600 at 003) (Greensboro, North Carolina dentist had revenues of \$197,970); (CX0603 at 003)(Wilmington, North Carolina dentist had revenues of \$118,298).

Response to Finding No. 150:

Respondent disputes this finding of fact as an incomplete statement of the record. It is also an opinion – not fact. The same documents cited by Complaint Counsel in support of this finding also show that the income derived from teeth whitening services by these dentists amounts to a relatively small fraction of the total revenues derived from their practices as a whole: (CX599 at 3) (Charlotte, North Carolina dentist – 6%); (CX616 at 21) (Raleigh, North Carolina dentist – less than 1%); (CX601 at 8) (Cary, North Carolina dentist – 2 1/2%); (CX0602 at 002) Another Huntersville, North Carolina dentist – 2%); (CX600 at 3) (Greensboro, North Carolina dentist – 10%); (CX603 at 3)(Wilmington, North Carolina dentist – less than 1%).

Respondent further notes that some of the dollar figures provided by Complaint Counsel in this proposed finding are mischaracterizations of the information provided in response to a *subpoena duces tecum* by these dentists. The revenues reported by the majority of these dentists actually represent the revenues of the entire practice – not the revenues of an individual dentist: Charlotte, NC dentist (CX599 at 1) (2 dentists); Raleigh, NC dentist F (CX616 at 25) (2 dentists); Huntersville, NC dentist (CX602 at 1) (2 dentists); Cary, NC dentist (CX600 at 1) (3 dentists); Wilmington, NC dentist (CX603 at 1) (2 dentists).

C. The Financial Interest of Board Members

151. The degree of substitution between dentist and non-dentist teeth whitening means that dentists have a financial interest in excluding non-dentists from the market. This is so because if dentists succeed in excluding non-dentists, an alternative that some fraction of

consumers prefer, the exclusion will shift demand in favor of the alternatives, including dentists themselves. (Kwoka, Tr. 1002).

Response to Finding No. 151:

Respondent disputes this proposed finding of fact because it is not a fact, it is hypothetical speculation by Dr. Kwoka.

152. Dr. Baumer agrees that it is “obvious” that dentists in North Carolina have a financial interest in excluding non-dentist teeth whitening. (RX0078 at 008; Baumer, Tr. 1856; CX0826 at 028 (Baumer, Dep. at 105)). Dr. Baumer agrees that Board members have a financial interest in prohibiting teeth whitening by non-dentists. (Baumer, Tr. 1875).

Response to Finding No. 152:

The use of quotations here is misleading because Dr. Baumer never used the word “obvious” in any of the cited portions of the documents cited by Complaint Counsel. In fact, the cite to his report is blatantly incorrect – Dr. Baumer never stated that dentists have a “financial interest” in excluding non-dental teeth whitening. He said that dentists have a “material interest [in] policing the profession.” (RX0078 at 008).

153. For example, Board member Dr. Hardesty’s dental practice is located less than two miles from the Crabtree Valley Mall where the Board took action against a non-dentist teeth whitener. (CX0565 at 024 (Hardesty, Dep. at 87); CX0068 at 001; CX0326). Dr. Hardesty reported that his dental practice in Raleigh, North Carolina recorded revenues from teeth whitening services of over \$41,000 for the period from 2005 through August 2010 (CX0378 at 012).

Response to Finding No. 153:

Although Dr. Hardesty did testify that his dental practice is located less than two miles from Crabtree Valley Mall where there was a non-dentist teeth whitener, there is no basis in the record for the assertion that this is an example of the preceding Proposed Finding.

154. Many of the Board members offer and perform teeth whitening services in their private practice and derive income from it. (State Action Opinion at 14; CX0560 at 048 (Feingold, Dep. at 183); CX0567 at 017 (Holland, Dep. at 58); CX0572 at 009 (Wester, Dep. at 26-28); CX0564 at 010-011 (Hall, Dep. at 33-34); CX0554 at 007 (Allen, Dep. at

18); CX0569 at 009 (Morgan, Dep. at 27-28); CX0467 at 001; CX0606 at 005; CX0614 at 001; CX0378 at 005).

Response to Finding No. 154:

Although it is true that some Board members offer and perform teeth whitening services, they have also testified that less than 2% of their revenues came from teeth whitening, and that such services were rarely requested. (Hardesty, Tr. 2777 (does not even do in-office teeth whitening anymore because no one asks for it); Owens, Tr. 1452 (“less than two percent”); Wester, Tr. 1289-1290 (“between a half and three-quarters of 1 percent”)).

155. Dr. Owens reported that his dental practice in Greensboro, North Carolina recorded revenues from teeth whitening services of over \$77,000 for the period from 2005 through August 2010. (CX0467 at 001). Dr. Owens testified that he earned revenue from teeth whitening during the period of time when he assigned teeth whitening cases to himself. (Owens, Tr. 1579). Dr. Owens is also the case officer on most of the teeth whitening cases. (White, Tr. 2224). Because Dr. Owens had “a number of teeth-whitening cases” the Board “just started assigning all the teeth-whitening cases to him” (CX0561 at 026-027 (Friddle, Dep. at 97-98)).

Response to Finding No. 155:

Respondent strongly objects to the inclusion of Dr. Owens’ revenue information in a publicly-filed document since he provided it to the Commission in response to a *subpoena duces tecum* (CX467), which specifically stated “[a]ll information submitted pursuant to this subpoena is subject to the confidentiality provisions of Section 21(f) of the Federal Trade Commission Act, 15 U.S.C. § 57b-2(f), and Rule 4.10 of the Federal Trade Commission.” The subpoena was also accompanied by the protective order issued by Judge Chappell in this matter. (For example, see CX616 at CQA-FTC-15 through CQA-FTC-18 (Complaint Counsel failed to number the individual pages of this exhibit)). Further, Respondent disputes this proposed finding of fact as a mischaracterization of the record. Dr. Owens testified that the revenues that he reported in response to the subpoena

were revenues that were earned by both himself and his partner; they were not solely his revenues. (Owens, Tr. at 1589-1590). Complaint Counsel has also mischaracterized Ms. Friddle's testimony by omission. Ms. Friddle testified that teeth whitening cases started to be assigned to Dr. Owens "in order to maintain consistency." (CX561 (Friddle, Dep. at 97-98)). Finally, Dr. Owens' dental practice is not located in Greensboro, North Carolina. (Owens, Tr. 1434).

156. The existence of a financial interest of dentists to exclude non-dentists is supported by the fact that teeth whitening is a frequently requested procedure in dentist offices. (CX0555 at 027 (Brown, Dep. at 100)). Dentists promote teeth whitening in their offices. (CX0565 at 027 (Hardesty, Dep. at 98); Hardesty, Tr. 2869).

Response to Finding No. 156:

First, this is a generalization based on one mere citation. In fact, most dentists testifying in connection with this case stated that teeth whitening accounted for less than 2% of their revenues, and that the procedure is very rarely requested. (Hardesty, Tr. 2777 (does not even do in-office teeth whitening anymore because no one asks for it); Owens, Tr. 1452 ("less than two percent"); Wester, Tr. 1289-1290 ("between a half and three-quarters of 1 percent"). Second, Dr. Brown actually stated that he was uncertain of the numbers regarding requests for tooth whitening. (CX0555 (Brown, Dep. at 100)).

Further, this statement is not an accurate reflection of the record evidence. The testifying dentists stated that they did not actively market their teeth whitening services. Although they would typically have brochures or posters visible in their office, they would only discuss the possibility of teeth whitening if asked about it by a patient or in relation to dental work such as crowns. (Wester, Tr. 1290; Owens, Tr. 1452-1453; Tilley, Tr. 1999-2000; Hardesty, Tr. 2777).

157. “[T]he existence of a financial interest of dentists in the exclusion of kiosk/spa operators does *not* require that dentists be the only substitutes for kiosk/spa operators It requires only that they compete with each other to a significant degree.” (CX0654 at 009).

Response to Finding No. 157:

This statement is one of opinion, not fact, and merely quotes Dr. Kwoka’s report.

Further, it contains an assumption that dentists compete with non-dentist teeth whiteners to a significant degree. There is no basis in the record for the validity of this assumption.

158. Board members have a significant, nontrivial financial interests in the business of their profession, including teeth whitening. (Kwoka, Tr. 1114; CX0826 at 029 (Baumer, Dep. at 106-107) (Board members “may well be influenced by the impact on the bottom line,” including the financial interest of dentists, in deciding whether to ban non-dentist teeth whitening)). They are in a position to enhance their incomes and those of their constituents. (Kwoka, Tr. 1115-1116).

Response to Finding No. 158:

The citation of Dr. Baumer’s deposition testimony for the first sentence blatantly misrepresents his testimony. Dr. Baumer only said that is “possible” that the financial interests of dentists could affect the Board’s judgment as to whether or not to ban teeth whitening. He then went on to point out that doing so would be a breach of their duty as sworn public servants, but allowed that for some degree of it is human nature. But he pointed out that Board members have gone to great lengths to avoid the appearance of impropriety by not assigning cases to case officers in the same geographic area, and also noted that for a member of the Board that derived less than 1 percent of their revenue from teeth whitening, their financial interest is far less significant than if they derived 25 percent of their revenue from it. (Baumer, Tr. 107-108). Nowhere in Dr. Baumer’s cited testimony does he define the Board members interest as a “nontrivial financial interest.”

D. Historical Overview of Teeth Whitening

159. Teeth may be whitened in several ways including: (1) bleaching using peroxidecontaining gels or serums that are applied to the teeth using a variety of delivery systems available from dentists, non-dentists, and OTC retailers; (2) physical stain removal; and (3) cosmetic dental restorations. (Giniger, Tr. 128-129; CX0653 at 009).

Response to Finding No. 159:

Respondent disputes this proposed finding of fact to the extent that it contains an assumption that all of the categories are legal in the state of North Carolina.

160. Teeth bleaching can be performed on vital and non-vital teeth. Vital teeth are essentially living teeth. (Giniger, Tr. 112-113). Non-vital teeth are essentially dead, where the nerves inside the teeth have ceased to function. (Giniger, Tr. 112-113, 287). The methods used to whiten vital and non-vital teeth differ. (*See generally* Giniger, Tr. 111-115).

Response to Finding No. 160:

Respondent has no specific response.

1. Teeth Whitening Prior to 1989

161. Before 1989, teeth bleaching was principally reserved for non-vital teeth or teeth that were likely soon to become non-vital. This is because the bleaching techniques at that time, such as applying concentrated hydrogen peroxide - called Superoxyl - on the affected tooth along with a heated instrument, were themselves likely to devitalize any vital tooth to which applied. (Giniger, Tr. 111-115, 373; CX0653 at 023).

Response to Finding No. 161:

Respondent has no specific response.

162. During the 1930s, when the North Carolina Legislature amended the North Carolina Dental Practices to limit the removal of stains to licensed dentists, stain removal on or in vital teeth would have typically required the use of sharp or highly abrasive dental instruments to scrape off or erode away stains from the teeth. (Giniger, Tr. 76, 111-112).

Response to Finding No. 162:

Dr. Haywood refuted this testimony, and testified that stain removal using teeth bleaching was done as far back as the 1800s. (Haywood, Tr. 2418). Dr. Haywood wrote an article on the history of stain removal entitled "The History and the Safety of Bleaching", which

traced teeth bleaching from its origins in the 1800s. (Haywood, Tr. 2437). Dr. Haywood testified that the term “dental stains” was used for bleaching research and bleaching publications since the 1800s. (Haywood, Tr. 2437). Such stains included stains from fluorosis and iron. (Haywood, Tr. 2437).

163. The inclusion of the stain removal provision coincides with the wide spread adoption of mechanical dental stain removal devices created for use in dental offices. The use of these instruments/techniques requires substantial knowledge and skill, without which patients can be greatly harmed. (CX0653 at 011).

Response to Finding No. 163:

As noted above in Respondent’s response to Proposed Finding No. 162, teeth bleaching was a known stain removal technique as far back as the 1800s.

164. For example, electrification of rotary polishing and scraping tools took place in the 1920s and 1930s. Prior to this, tools were operated by foot pedals, which limited the tools’ speed and torque. The advent of electric motors significantly increased the harm that could occur from these instruments. (Giniger, Tr. 131-132).

Response to Finding No. 164:

Respondent refers to its response to Proposed Finding No. 162.

165. In 1976, the available methods of stain removal involved pumice and flavored abrasive materials, as well as scaling of the teeth. A dentist would typically place the abrasive materials on a rotary instrument and polish off the external stain. (CX0554 at 011 (Allen, Dep. at 35-36)).

Response to Finding No. 165:

Respondent has no specific response.

166. Dentists remove stains, accretions, and deposits through the use of sharp, stainless-steel hand instruments that can damage a patient by lacerating flesh and perforating bone, and can pierce blood vessels and nerves within the mouth. Dentists use instruments that rotate cups at approximately 30,000 to 50,000 RPMs to remove stains with dentifrice. These cups can generate a very high heat that can damage the inside of teeth. (CX0566 at 011 (Hardesty, IHT at 40-41)).

Response to Finding No. 166:

Respondent disputes this proposed finding of fact as containing an assumption and as a mischaracterization of Dr. Hardesty's testimony. The proposed finding of fact contains the assumption that these are the only methods by which dentists remove stains, accretions, and deposits. Dr. Hardesty's testimony was that there could be "many different methods" by which stains, accretions, and deposits are removed. (CX566 (Hardesty, IHT at 40-41)).

2. Modern Teeth Whitening After 1989

167. Vital teeth bleaching was not popularized until after 1989, with the development of traybased systems to deliver and hold on the tooth low concentrations of peroxide at ambient temperatures. (Giniger, Tr. 111, 116; CX0653 at 023).

Response to Finding No. 167:

This statement contains a characterization by Dr. Giniger as to the popularity of vital teeth bleaching at a point prior to Dr. Giniger's involvement in the teeth whitening industry. Dr. Haywood published the first article on tray bleaching in 1989. (Haywood, Tr. 2389). He also testified that he has written an article on the history of teeth bleaching and that dentists have been bleaching both vital and non-vital teeth since the 1800s. (Haywood, Tr. 2437-2438).

168. In recent years, manufacturers have developed unique tray-less methods for OTC at-home bleaching. Crest Whitestrips from Proctor and Gamble (P&G) was first made available to consumers in 2001, and remains the top selling product. (CX0653 at 041).

Response to Finding No. 168:

Respondent has no specific response.

169. Stain removal is the physical removal of dental chromogens (stains on the surface or interior of the teeth). (Giniger, Tr. 132; CX0653 at 012, 015). Chromogens typically consist of carbon molecules that are linked by double bonds; the more double bonds, the deeper the color of the stain. (Giniger Tr. 152-153; CX0653 at 018).

Response to Finding No. 169:

Dr. Haywood testified that Dr. Giniger's theory of teeth whitening is not supported by scientific evidence and has no substantiation in scientific literature. (Haywood, Tr. 2445).

170. In contrast to stain removal, teeth bleaching does not remove stains, it temporarily lightens their color. However, the stains persists, and the color typically rebounds (reverts to original coloration). (Giniger Tr. 116-118, 132-133, 142; CX0653 at 006; Osborn, Tr. 699-700).

Response to Finding No. 170:

The bleaching mechanism both removes stains from teeth and changes the genetic color of the tooth, and so bleaching and teeth whitening are the same thing. (Haywood, Tr. 2404).

171. In the United States today, teeth bleaching products use carbamide peroxide or hydrogen peroxide as the bleaching agents. When carbamide peroxide is exposed to saliva, it breaks down to release hydrogen peroxide (with three parts carbamide peroxide yielding about one part hydrogen peroxide) and urea. A bleaching gel consisting of 10% carbamide peroxide, for example, would yield roughly 3% hydrogen peroxide and 7% urea. (Giniger Tr. 150-151, 246; Haywood, Tr. 2662; CX0653 at 018-019).

Response to Finding No. 171:

Respondent has no specific response.

172. Whatever the formulation, the mechanism of action is similar for all teeth bleaching products. Hydrogen peroxide generates free radicals of oxygen, which are high energy, unstable atoms, that will typically combine with the closest amenable molecule and alter its chemical structure. (Giniger, Tr. 150-152; CX0653 at 018-019).

Response to Finding No. 172:

Dr. Haywood testified that Dr. Giniger's theory of teeth whitening is not supported by scientific evidence and has no substantiation in scientific literature. (Haywood, Tr. 2445).

173. When placed near the surface of a tooth, free radical oxygen atoms break the carbon:carbon double bonds in chromogens, causing the chromogen to change from more colored to less colored. However, the stain particles remain and eventually revert to its original coloration. This is because the molecular structure of lighter-colored chromogen is less chemically stable than its original double-bonded structure. Because matter tends

to seeks its most stable state, the carbon double bonds eventually reform, the oxygen free radicals are released, and the molecule changes from less colored to more colored. (Giniger, Tr. 142-143, 151-154, 244-245; CX0653 at 006, 018-019).

Response to Finding No. 173:

Dr. Haywood testified that Dr. Giniger's theory of teeth whitening is not supported by scientific evidence and has no substantiation in scientific literature. (Haywood, Tr. 2445).

E. Teeth Whitening Market Participants

174. Currently, there are four broad categories of teeth whitening services available in North Carolina: (1) dentist in-office teeth whitening services; (2) dentist take-home teeth whitening products; (3) over-the-counter ("OTC") teeth whitening products; and (4) nondentist teeth whitening services in salons, retail stores, and mall kiosks. (CX0392 at 002; CX0053 at 004-005; Osborn, Tr. 650; Valentine, Tr. 515).

Response to Finding No. 174:

Respondent disputes this proposed finding of fact to the extent that it contains an assumption that all of the categories are legal in the state of North Carolina.

1. Dentist In-Office Teeth Whitening Services

175. Dentists offer and provide teeth whitening services in North Carolina. (CX0467 at 001; CX0578 at 007 (Parker Dep. at 12-14); CX0566 at 003 (Hardesty, IHT at 9); CX0576 at 005 (Litaker, Dep. at 11-12); CX0577 at 009 (Oyster, Dep. at 28); Wester, Tr. 1289; CX0554 at 007 (Allen, Dep. at 18-19); CX0641 at 001-067).

Response to Finding No. 175:

Respondent has no specific response.

176. Dentists in North Carolina offer both in-office teeth whitening services and take-home teeth whitening kits. (CX0571 at 006 (Owens, IHT at 20-21); CX0570 at 023 (Owens, Dep. at 84); CX0560 at 004-005, 048 (Feingold, Dep. at 9-10; 183); Hardesty, Tr. at 2775; CX0565 at 006 (Hardesty, Dep. at 15); CX0578 at 005 (Parker, Dep. at 11-12); CX0580 at 006-007 (Tilley, Dep. at 14-15, 19); CX0641 at 001-067).

Response to Finding No. 176:

Respondent has no specific response.

177. The teeth whitening products used by dentists for in-office teeth whitening generally have a higher concentration of the active ingredients hydrogen or carbamide peroxide than that typically available in non-dentist teeth whitening. (Joint Stipulations of Law and Fact ¶ 24). This is in part because manufacturers of teeth bleaching products, such as Discus Dental or Ultradent, will not sell their highest concentration bleach products to non-dentists. (Giniger, Tr. 334-335).

Response to Finding No. 177:

Respondent has no specific response.

178. During a lengthy preparatory time of up to 30 minutes, the patient's teeth are exposed using cheek retractors. Due to the high concentration of peroxide used in professional bleaching products (up to 38%), a protective barrier is applied so as to prevent the gums from burning. (Joint Stipulations of Law and Fact ¶ 24; Giniger, Tr. 168-169 (technique to apply professional bleaching product requires application of gingival barrier to protect the gums); Haywood Tr. 2692 (acknowledging that dentists can use 35 to 38 percent hydrogen peroxide)).

Response to Finding No. 178:

Respondent has no specific response.

179. The peroxide solution is thereafter painted directly on the teeth and a curing light is often placed in front of the teeth to activate the bleaching gel or expedite the whitening effect. (CX076 at 007 (Parker, Dep. at 21); CX0596 at 002). After 30 minutes, the gel is usually suctioned off the teeth using a dental vacuum. The gel is reapplied, the light (if used) is set again, and the treatment is repeated up to two more times for a total of 60-120 minutes of actual bleaching time. (Giniger, Tr. 164-172; CX0653 at 040).

Response to Finding No. 179:

Respondent has no specific response.

180. Dentist in-office teeth whitening costs \$300 or more. (CX0560 at 048 (Feingold Dep. at 183 (\$500)); CX0557 at 017 (Holland, Dep. at 58 (\$175 per arch); CX0053 at 001-002 (\$400); CX0108 at 008 (\$400-\$900); CX0096 at 004 (\$400-\$600); Hardesty, Tr. at 2805-2806 (\$675-\$750); CX0578 at 005 (Parker, Dep. at 12-13 (\$350)); CX0576 at 006 (Litaker, Dep. at 16 (\$380 per arch); CX0601 at 009 (\$550); CX0609 at 002 (regularly \$350); CX0611 at 004 (\$400); CX0616 at 034 (averaged \$537 for in-office bleaching)).

Response to Finding No. 180:

Respondent objects to this proposed finding of fact as being supported by testimony that is a misrepresentation of the record. Two of the dentists identified by Complaint Counsel as testifying that they charge a certain amount for in-office teeth whitening do not offer this service in their practices, and the charge cited in Complaint Counsel's proposed finding of fact is actually their fee for take-home teeth whitening. (RX63 (Holland, Dep. at 49-50); CX576 (Litaker, Dep. at 11-12)).

181. Dentist in-office teeth whitening provides results in one to three hours. (CX0601 at 026; CX0598 at 001; CX0641 at 040; CX0598 at 001 ("In-office whiteners usually take about 1-3 hours")).

Response to Finding No. 181:

Respondent has no specific response.

182. Zoom! and Bright Smile are two products used by dentists for in-office teeth whitening procedures. (Joint Stipulations of Law and Fact ¶ 25).

Response to Finding No. 182:

Respondent has no specific response.

2. Dentist Take-Home Teeth Whitening

183. Dentist take-home teeth whitening was popularized by a 1989 article by Drs. Heymann and Haywood which set forth the Nightguard Vital Bleaching technique: a tray-based system to deliver a low concentration of peroxide (typically 10% carbamide peroxide) to the tooth for an extended period of time, usually overnight. (Giniger Tr. 149-150, 156; CX0653 at 24).

Response to Finding No. 183:

Respondent has no specific response.

184. Take home kits provided by dentists include a custom-made whitening tray and whitening gel. (CX0580 at 006 (Tilley, Dep. at 14); CX0554 at 007 (Allen, Dep. at 18-19); (CX0566 at 003 (Hardesty, IHT at 9); CX0566 at 019 (Hardesty, IHT at 72); Wester, Tr. 1289).

Response to Finding No. 184:

Respondent has no specific response.

185. The consumer applies the whitening gel to his or her own teeth at home. (CX0571 at 006 (Owens, IHT at 20-21)).

Response to Finding No. 185:

Respondent has no specific response.

186. Take home kits provided by dentists can either be used as a follow-up to in-office treatment or as the sole teeth whitening service. (Joint Stipulations of Law and Fact 26).

Response to Finding No. 186:

Respondent has no specific response.

187. When used by themselves, take home kits provided by dentists may require the consumer to reapply the whitening solution multiple times to the teeth over multiple days. (Joint Stipulations of Law and Fact ¶ 27).

Response to Finding No. 187:

Respondent has no specific response.

188. Before a consumer can use a take home kit provided by a dentist, at least two visits to the dentist are required. Typically, in the first visit, the dentist examines the patient and takes an impression used to make a customized teeth whitening tray. Usually, in the second visit, the dentist delivers the tray and whitening solution, and provides instructions for whitening to the patient. (Joint Stipulations of Law and Fact ¶ 28).

Response to Finding No. 188:

Respondent disputes this proposed finding of fact as it does not conform to the wording of joint stipulation of law and fact ¶ 28 as agreed to by Respondent and Complaint Counsel, and adds the additional assumptive language “before a consumer can use a take home kit provided by a dentist.” (Joint Stipulations of Law and Fact ¶ 28).

189. Take-home kits typically cost hundreds of dollars, in part, because the dentist charges to fabricate the custom tray, provide instruction on its use, and supply the whitening product and kit. (CX0576 at 005-006 (Litaker, Dep. at 16-17 (\$380 per arch/\$760 for full mouth)); CX0577 at 009 (Oyster, Dep. at 29 (\$300)); CX0578 at 005 (Parker, Dep. at 12-13 (\$250)).

Response to Finding No. 189:

Respondent disputes this proposed finding of fact as containing an assumption and as a mischaracterization of the record. The dentist testimony cited in support of this proposed finding of fact by Complaint Counsel also includes a diagnostic examination by the dentist as an initial step to determine whether the patient does not have any contraindications to teeth whitening. (CX576 (Litaker, Dep. at 16-17 (price includes exam and radiographs); CX578 at 5 (Parker, Dep. at 13-14 (price included an exam))). Other Board members testified that the fees for take-home products for teeth whitening at their offices are less those cited by Complaint Counsel in this proposed finding of fact. (Hardesty, Tr. 2777 (\$130.00 per arch); RX49 (Allen, Dep. at 19-20 (\$97.50 total)); RX56 (Feingold, Dep. at 10 (\$199.00 for top and bottom)); RX60 (Hall, Dep. at 34 (\$200.00)); RX76 (Parker, Dep. at 13) (\$250.00)).

3. Over the Counter Teeth Whitening

Respondent objects to the inclusion of this market definition in Complaint Counsel's proposed findings of fact. Over-the-counter teeth whitening products were not included in Complaint Counsel's original definition of the market in the Complaint, that being the "provision of teeth whitening services in North Carolina," thereby excluding over-the-counter and take-home teeth whitening products. Compl. ¶ 7.

190. In recent years, manufacturers have developed unique tray-less methods for OTC at-home bleaching. Crest Whitestrips from Proctor and Gamble (P&G) was one of the first OTC teeth bleaching products on the market, and it remains the number one selling product today. When first made available to consumers in 2001, Whitestrips contained approximately 5% hydrogen peroxide. Now, the most popular Whitestrips contain appreciably more concentrated bleaching agents. Other manufacturers have also developed generic whitening strips as well, and the concentration of hydrogen peroxide in these strips has also increased significantly over the years. (CX0653 at 041).

Response to Finding No. 190:

Respondent disputes this proposed finding of fact as to the undefined term “appreciably more.”

191. OTC products typically use low concentrations of hydrogen peroxide or carbamide peroxide, applied daily for an extended period of time. OTC products are sold in a variety of locations including pharmacies, grocery stores, the internet, and even by dentists. (Giniger Tr. 205-206).

Response to Finding No. 191:

Respondent disputes this proposed finding of fact based on the undefined phrase “extended period of time.”

192. Available OTC products include gels, rinses, chewing gums, trays, and strips. In a 2006 report, NBC’s *Today* correspondent Janice Li[e]bennan reported that in 2005, the U.S. market for OTC products was \$41.4 billion. (Joint Stipulations of Law and Fact ¶ 22).

Response to Finding No. 192:

Respondent has no specific response.

193. OTC teeth whitening products include Crest Whitestrips. (CX0566-016 (Hardesty, IHT at 58-59); CX0555 at 019 (Brown Dep. at 67); CX0560 at 030 (Feingold, Dep. 111-112); CX0570 at 020 (Owens, Dep. 71-72)).

Response to Finding No. 193:

Respondent has no specific response.

194. In order to whiten teeth, OTC strips must be reapplied multiple times over multiple days. (Joint Stipulations of Law and Factulations of Fact ¶ 29).

Response to Finding No. 194:

Respondent has no specific response.

195. OTC strips and trays typically cost between \$15 and \$50, depending on brand, quantity, and concentration. (CX0382 at 001 (Crests 3D - \$43.97); CX0394 at 001 (White Strips Professional Effects - \$47.99, Crest 3d - \$47.79, Plus White 5 Minute Speed Whitening System - \$10.99, DenTek Complete White Professional Whitening - \$14.99)).

Response to Finding No. 195:

Respondent has no specific response.

4. Non-dentist Teeth Whitening Service Providers

196. Teeth whitening services have been offered and are offered by non-dentists in North Carolina. (Hughes, Tr. 934-936; Nelson, Tr. 733-734; Osborn, Tr. 668-670; Wyant Tr., 870-871; Valentine, Tr. 567). Teeth whitening is offered outside of dentists offices in kiosks, spas, retail stores, and salons. (Hughes, Tr. 934-936; Nelson, Tr. 733-734; Osborn, Tr. 668-670; Valentine, Tr. 519-520; Wyant Tr. 870-871).

Response to Finding No. 196:

Respondent disputes this proposed finding of fact as it contains the assumption that the teeth whitening services offered by non-dentists in North Carolina are legal.

197. Typically a non-dentist provider will follow a protocol provided by a teeth whitening manufacturer or distributor. While each protocol is slightly different, all require the operator to provide the customer with literature, and some require the customer to answer questions before the procedure begins. (CX0108 at 009; CX0049 at 056-067; Valentine, Tr. 545-546; Osborn, Tr. 653, 707; Nelson, Tr. 796-797).

Response to Finding No. 197:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

Respondent also objects to the undefined terms "typically" and "protocol." There are numerous instances of teeth whitening procedures where the above "protocols" were not followed during actual teeth whitening procedures. See, for example, RX11 at 5, 6 (no literature provided, no questions asked); RX15 at 9 (no literature provided); RX25 at 15 (no literature provided, no questions asked); Runsick, Tr. 2108-2109 (no literature provided, no questions asked)).

198. The provider generally will thereafter: (1) have the client sit in a chair; (2) don protective gloves; (3) place a bib around the client's neck; (4) take a tray from a sealed package, which is either pre-filled with peroxide solution or which the operator fills with the peroxide solution, and hand it to the customer, who places the tray into his or her mouth; (5) adjust the whitening light; and (6) start the timer. At the end of the procedure, the customer will remove the tray and hand it to the provider, who disposes of it.

(CX0108 at 010-012; CX0049 at 056-067; Osborn, Tr. 653, 655, 707-708; Nelson, Tr. 750, 757, 770, 796-797; Valentine, Tr. 533-534).

Response to Finding No. 198:

Respondent disputes this proposed finding of fact as a mischaracterization of the record and as containing an assumption. Non-dentists offering teeth whitening services in salons, retail stores, and mall kiosks do not universally follow the typical procedure as described in this proposed finding of fact. Specifically, those service providers do not universally: (1) place a bib around the client's neck; (2) don protective gloves; (3) take a tray from a sealed package, which is either pre-filled with peroxide solution or which the operator fills with the peroxide solution, and hand it to the customer, who places the tray into his or her mouth; (4) have the client sit in a "comfortable chair"; (5) adjust the whitening light; (6) start the timer; and (7) the customer will remove the tray and hand to the provider, who disposes it. (RX11 at 5, 6; RX15 at 9; RX27 at 1; RX25 at 15; RX22 at 18, 19; RX8 at 9; Runsick, Tr. 2108-2109).

199. Teeth whitening providers, manufacturers, and distributors testified at trial that the teeth when using the products they use or sell, that teeth could be whitened in less than one hour. (Nelson, Tr. 740) (whitening process took 20 minutes using WhiteScience); (Wyant, Tr. 868-869)(whitening process took 15 minutes after placement of whitening tray by customer with the SpaWhite system); (Osborn, Tr. 655).(whitening process took 15 minutes after placement of the BriteWhite whitening tray); (Valentine, Tr. 533)(once a customer had a tray inside his mouth, the session with the light would last 15 minutes with WhiteSmile).

Response to Finding No. 199:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and as containing an assumption that the results obtained by non-dentist teeth whitening were comparable to that provided by in-office dentist procedures. Industry witnesses testified that their customers would opt for additional sessions. Mr. Wyant testified that his

customers could opt for a two sessions, for a total of 30 minutes. (Wyant, Tr. at 878-869). Ms. Osborn testified that a whitening session lasted 20 minutes (not 15 minutes), and a customer could have three sessions in one hour. (Osborn, Tr. at 655-656). Ms. Osborn also recommended that customer come back the following week for another session. (Osborn, Tr. at 656). Mr. Valentine testified that some customers decided to do a “double application” of 15 minutes each. (Valentine, Tr. at 553-554).

200. Products used by non-dentists fall under many brand names, including WhiteSmile USA, Brite White, Beyond White Spa, Beyond Dental & Health, and SpaWhite. (Joint Stipulations of Law and Fact ¶ 21).

Response to Finding No. 200:

Respondent has no specific response.

F. Manufacturers and Suppliers of Teeth Whitening Products

201. Discus Dental is headquartered in Culver City, California (CX0535 at 001). Discus Dental only sells its products to licensed dentists and is the largest supplier of teeth whitening materials for dentists. (Giniger, Tr. 99, 334-335). Discus Dental sells the Zoom!, Zoom2, BriteSmile, and NiteWhite dental teeth whitening systems. (Giniger, Tr. 448); (Haywood, Tr. 2436, Tr. 2452). Zoom!, Zoom2, and Bright Smile are in-office teeth whitening products made by Discus Dental. (Haywood, Tr. 2452; CX0535 at 001).

Response to Finding No. 201:

Respondent has no specific response.

202. Dentists in North Carolina use Discus Dental’s teeth whitening systems. (Owens, Tr. 1559-1560); Hardesty, Tr. 2808; CX0556 at 039 (Burnham, Dep. 146-147); CX0565 at 024 (Hardesty, Dep. 99-100); CX0578 at 005 (Parker, Dep. 11)).

Response to Finding No. 202:

Respondent has no specific response.

203. Ultradent Products, Inc. is headquartered in South Jordan, Utah. The company manufactures and markets its products for use nationwide and worldwide. (CX0597 at 063). Ultradent sells the Opalescence teeth whitening system and only sells its products to licensed dentists. (Giniger, Tr. 334-335; CX0590 at 013).

Response to Finding No. 203:

Respondent has no specific response.

204. Dentists in North Carolina use Ultradent's Opalescence teeth whitening system. (Tilley, Tr. at 2002-2003); (CX0572 at 009 (Wester, Dep. at 26)).

Response to Finding No. 204:

Respondent has no specific response.

205. Dentsply is an international dental product distributor based in York, Pennsylvania. Dentsply sells its products to dentists. (CX0597 at 059).

Response to Finding No. 205:

Respondent has no specific response.

206. BleachBright is located in Kenner, Louisiana. BleachBright sells a teeth whitening system for non-dentist (BleachBright has sold its non-dental teeth whitening products in North Carolina). (CX0112 at 001-002; CX0278 at 001; CX0303 at 005).

Response to Finding No. 206:

Respondent disputes this proposed finding of fact. There is no support in the testimony cited by Complaint Counsel for the headquarters location of BleachBright (CX0112 at 001-002; CX0278 at 001; CX0303 at 005).

207. BEKS is headquartered in Jasper, Alabama. BEKS sells and/or has sold teeth whitening products in North Carolina. (Osborn, Tr. 668-670, 682). BEKS sells teeth whitening products to dentists, non-dentist teeth whitening providers, and directly to consumers. (Osborn, Tr. 650).

Response to Finding No. 207:

Respondent disputes this proposed finding of fact. There is no support in the testimony cited by Complaint Counsel for the headquarters location of BEKS. (Osborn, Tr. 668-670, 682).

208. Grater Whiter Smiles is headquartered in Fond du Lac, Wisconsin. Grater Whiter Smiles sells and/or has sold teeth whitening products in North Carolina. (Hughes, Tr. 933-935).

Response to Finding No. 208:

Respondent disputes this proposed finding of fact. There is no support in the testimony cited by Complaint Counsel for the headquarters location of Grater Whiter Smiles. (Hughes, Tr. 933-935).

209. White Science is headquartered in Alpharetta, Georgia. White Science sells teeth whitening products to dentists and non-dentist teeth whitening providers. White Science sells and/or has sold teeth whitening products in North Carolina. (Nelson, Tr. 725, 729, 733-734).

Response to Finding No. 209:

Respondent disputes this proposed finding of fact. There is no support in the testimony cited by Complaint Counsel for the location of WhiteScience's headquarters. (Nelson, Tr. 725, 729, 733-734).

210. WhiteSmile teeth-whitening products were secured from DaVinci systems in California, a leading seller of bleaching formulations. DaVinci systems sells teeth-whitening products to both dentists and non-dentists. (Valentine, Tr. 520).

Response to Finding No. 210:

Respondent has no specific response.

IV. Teeth Whitening in North Carolina and the Board

A. The Board Becomes Aware of the Entry of Non-dentist Teeth Whiteners Into North Carolina

211. In or around 2003, the Board received its first complaints about non-dentist teeth whitening (CX0562 at 006 (Friddle, IHT at 21)). Dr. Brown opened an investigation of Great White Smiles in September 2003 after Dr. Yeager complained that his staff had informed him that Great White Smiles was selling teeth whitening gel and allegedly making impressions for bleach trays at the "Southern Women's Show" in Charlotte, North Carolina. (CX0033 at 001-005). Subsequently, a Board employee attended the "Southern Women's Show" when it was in Raleigh, North Carolina to investigate the "possible illegal practice of dentistry," but the Great White teeth whiteners were not in attendance (CX0032 at 001-005). After the Board learned that Great White employees

had been told by a dentist that “they were breaking the law and eventually the Dental Board would find out,” the dentist reported that Great White did not intend to return to North Carolina. Dr. Brown then directed Ms. Friddle to close the investigation for “lack of evidence.” (CX0032 at 001-005).

Response to Finding No. 211:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record. The record shows that the dentist who told Great White that they were breaking the law was the ex-husband of “the lady who ran Great White.” (CX32 at 5). Given this relationship, Dr. Brown requested on February 17, 2004, that this information be confirmed. (CX32-5). A Board employee a visit to the Southern Women’s Show on May 2, 2004, and Great White was not in attendance. (CX32 at 3). Based on the employee’s visit to the Southern Women’s Show, Dr. Brown directed that the file be closed for “lack of evidence.” (CX32 at 1-2).

212. Between August and September 2, 2004, four North Carolina dentists complained to the Board that Edie’s Salon Panache advertised that it was the second “salon in North Carolina to offer teeth whitening” provided by non-dentist at prices lower than dentist (CX0036 at 002-004).

Response to Finding No. 212:

Respondent disputes this proposed finding of fact. There are only two dentist complaints in the evidence offered by Complaint Counsel in support of this proposed finding of fact. (CX36 at 2-4). Further, this proposed finding of fact is based on an assumption that the dentists were complaining about the price. The source of the information that the prices charged by this salon was lower than a dentist comes from the advertising forwarded to the Board, or quoted to the Board in an email. (CX36 at 2-3).

213. Dr. Caryn Massari sent an e-mail dated September 2, 2004 to the Board providing information that Edie’s Salon Panache was advertising non-dentist teeth whitening in the Charlotte area for \$149 dollars which she asserted was “[l]ess than dentists charge”. Dr.

Massari further noted that Edie's was the "2nd salon in North Carolina to offer teeth whitening"[emphasis in original] (CX0036 at 002).

Response to Finding No. 213:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record. Dr. Massari did not assert that the salon advertised teeth whitening at was less than dentists charge. (CX36 at 3). Nor did she particularly note that the salon was the second in North Carolina to offer teeth whitening. (CX36 at 2). She merely quoted the wording of the salon's advertising; the salon itself made these assertions. (CX36 at 2-3).

214. On September 11, 2006, Dr. Luiz Arzola faxed the Board a complaint noting that "increasingly large number[s] of spas in the Hickory area are offering their clients dental bleaching." He inquired whether that procedure is legal when performed by unlicensed persons. (CX0619 at 001).

Response to Finding No. 214:

Respondent has no specific response.

215. The Board met on February 9, 2007, and discussed the increasing number of complaints regarding non-dental teeth whitening being provided in spas. (CX0056 at 005). At the same Board meeting "Teeth Whitening Centers" was on the Board's agenda. (CX0274 at 002).

Response to Finding No. 215:

Respondent disputes this finding of fact as based on an assumption. The teeth whitening centers on the Board's agenda for February 9, 2007, were a different issue from the teeth whitening being provided in spas. The teeth whitening centers involved an inquiry whether licensed dental hygienists could provide teeth whitening services in teeth whitening centers without dentist supervision. (CX56 at 5).

216. By February and March of 2008, Board employees Bakewell and Goode recognized that there were non-dentist teeth whitening service providers or "bleaching kiosks" and teeth whitening companies throughout the State of North Carolina (CX0231 at 001; CX0092 at 001).

Response to Finding No. 216:

Respondent has no specific response.

B. The Board and Its Constituents Acknowledge Competition from Non-Dentist Providers of Teeth Whitening

217. At the Board's February 2007 meeting, during a discussion of the increasing number of complaints regarding non-dental teeth whitening being provided in spas, Dr. Hardesty emphasized the need to approach the North Carolina Dental Society with a request about changing the statutory penalty for unlicensed practice of dentistry from a misdemeanor to a felony. (CX0056 at 005). The NCDS did so and Dr. Litaker of the NCDS attributed its consideration to request that the North Carolina legislature increase the severity of the penalty for unlicensed practice of dentistry to three issues: the provision of non-dental teeth whitening in the state; the creation of metal cosmetic prostheses covering the teeth, known as "grills"; and a case involving the unlicensed practice of dentistry in Hickory, North Carolina. (CX0576 at 008-009 (Litaker, Dep. at 25-26)).

Response to Finding No. 217:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record. The Board's minutes from February 2007 state that Dr. Hardesty "reiterated" the need to approach the Dental Society. (CX56 at 5). Dr. Hardesty has testified that "we batted that around for six – since I was in school, and I don't think it pertains specifically to teeth whitening. It's is more from unlicensed practitioners from other countries." (CX566 (Hardesty, IHT at 116)). These discussions occurred "Long before I was on the Board." (CX566 (Hardesty, IHT at 117)). Further, Dr. Litaker's testimony was that the Dental Society discussed the possibility of going to the legislature and asking that the penalties for unlicensed dentistry be made severe based on an incident in Hickory, NC. (CX576 (Litaker, Dep. at 25)). He only mentioned teeth whitening and the fabrication of grills when pressed about the timing of the Society discussion. (CX576 (Litaker, Dep. at 25)).

218. On November 19, 2007, Dr. Harald Heymann complained to the Board about a nondentist bleaching salon in Southpoint Mall in North Carolina, emphasizing that the salon administers gel trays and only “charge(s) 100!” (CX0365 at 002).

Response to Finding No. 218:

Respondent disputes this proposed finding of fact as a mischaracterization of the record and as creating an assumption. In his complaint, Dr. Heymann, a professor with the University of North Carolina School of Dentistry, placed greater emphasis on safety by pointing out that the salon used “44% carbamide peroxide administered [by] a ‘gel tray’!!” (CX365 at 2).

219. After receiving a February 18, 2008 complaint from Dr. Casey of Raleigh, North Carolina about a teeth whitening kiosk in Crabtree Valley Mall, the Board’s Executive Director responded that the Crabtree Valley whitening kiosk “is one of many such ‘bleaching kiosks’ with which we are currently going forth to do battle,” and that the Board had sent out “numerous cease and desist orders throughout the state.” (CX0404 at 001-002).

Response to Finding No. 219:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. This correspondence was not an acknowledgment of competition; rather, the writer expressed a concern about the “potential effects on the gingiva leading to cervical sensitivity.” (CX404 at 2). It was an inquiry into the non-dentist bleaching kiosks from a state official (Dr. Casey is the Dental Director of the North Carolina Division of Medical Assistance). (CX404 at 1-3).

220. In a letter dated February 27, 2008, Dr. Nicole LeCann also complained to the Board about a bleaching kiosk in Crabtree Valley Mall. Dr. LeCann noted that the kiosk’s prices started at \$99 and wrote that the presence of kiosks “cheapens and degrades the dental profession.” Dr. LeCann requested that the Board investigate the matter “quickly.” (CX0278 at 001; White, Tr. 2317-2319).

Response to Finding No. 220:

Respondent disputes this proposed finding of fact as a mischaracterization of the record and as containing an assumption. Mr. White testified in relation to the complaint by Dr. LeCann that it would not be relevant to the Board that a dentist may charge more for take-home trays and in-office bleaching than a bleaching kiosk in terms of analyzing a complaint against a non-dentist teeth whitener. (White, Tr. 2319). Mr. White further testified he has not heard other dentists express the same sentiment as expressed by Dr. LeCann in regards to the dental profession. (White, Tr. 2318-2319).

221. In an e-mail sent March 7, 2008, dental assistant Jill Elliott complained to the Board about a teeth bleaching kiosk in a mall in Wilmington, North Carolina. Ms. Elliott mentioned that the kiosk charged \$99 to \$100 for the teeth whitening procedure and noted that "I am not affected by this in any financial way but . . . it does affect the local dentist." (CX0626 at 001).

Response to Finding No. 221:

Respondent disputes this proposed finding of fact as a misrepresentation and mischaracterization of the record. The letter writer stated that she had experience as a dental assistant, but for the last seven years was employed "in the dental products field." (CX262 at 1). Also, Complaint Counsel has omitted an important part of the quotation used in this proposed finding of fact that shows where her true concern lies. The entire quote is, "I am not affected by this in any financial way but what they are claiming and doing is wrong and it does affect the local dentist." (CX626 at 2).

222. At the March 2008 Board Meeting, the Board discussed a request from the North Carolina Dental Society to discuss teeth whitening clinics at the April 4, 2008 Tripartite meeting between the Board, the University of North Carolina School of Dentistry, and the North Carolina Dental Society. (CX0109 at 003; Hardesty Tr. 2867).

Response to Finding No. 222:

Respondent disputes this proposed finding of as not being an accurate representation of the record and as creating an assumption not in fact. The record reflects that

representatives from the N.C. Dental Society “will be speaking on retiring dentists, continuing education requirement, the N.C. Caring Dental Professionals and teeth whitening clinics” at the April 4, 2008 Tripartite meeting. It was not a case of the Society making a request of the Board. (CX109 at 3).

223. At the April 4, 2008 tripartite meeting of the Board, the Dental Society, and the University of North Carolina Dental school, the Dental Society members attending complained about the proliferation of non-dentist teeth whitening kiosks and asked the Board what it was going to do about it. The Board assured the Dental Society that it was investigating complaints about non-dentist teeth whiteners. (CX0565 at 067 (Hardesty, Dep. at 259-261); Hardesty, Tr. at 2866; CX0109 at 003).

Response to Finding No. 223:

Respondent disputes this proposed finding of fact as a mischaracterization and misrepresentation of the record. The Tripartite Report for the April 4, 2008 does not mention any discussion of teeth whitening kiosks. (CX176 at 2). Board members and members of the Dental Society have testified that there were no conversations or other communications about the unlicensed practice of dentistry at Tripartite meetings. (RX52 (Burnham, Dep. at 236); RX56 (Feingold, Dep. at 258); RX75 (Oyster, Dep. at 73-74); RX76 (Parker, Dep. at 231)). Further, the portion of Dr. Hardesty’s hearing testimony cited by Complaint Counsel in support of this proposed finding of fact merely describes what a Tripartite meeting is. (Hardesty, Tr. 2866). In his deposition, Dr. Hardesty expressed some uncertainty about whether all of the topics to be presented by the Tripartite meeting were addressed by the Society. (CX259 (Hardesty, Dep. at 259-260)).

224. On June 28, 2010, Dr. Lesan sent an e-mail to Mr. White and, among other things, suggested that the dental profession should collectively file a class action suit against the non-dental teeth manufacturers. In the e-mail, Dr. Lesan stated, “[i]f we as dental

professionals do not take a stand, then it will not be to [sic] long that the patient will be doing their own dental work outside of the dental office.” (CX0422 at 001).

Response to Finding No. 224:

Respondent disputes this proposed finding of fact as a mischaracterization of the record and contains an assumption regarding the sender’s intent. Dr. Lesan stated in his email that the spa teeth whitening businesses “only are concerned about the money not the public safety.” (CX422 at 1).

225. Dr. Haywood, the Board’s industry expert, testified, If we are unable to define what a dentist does based on their training and education, then we have opened the door for the lowest level of ‘mid-level provider,’ the mall bleacher. . . . I believe this bleaching question will be what the definition of the profession hinges on for the future. If you cannot defend the position that it is best to see a dentist, then there is no need for a dentist for any other treatments. (Haywood, Tr. 2914-2915, 2627). See also (CX0278 at 001) (after observing a \$99 teeth whitening, a dentist complains that mall bleaching “cheapens and degrades the profession” and “teaches the public to not value or respect the dental profession.”); CX0141 at 001 (if courts permit unauthorized practice of dentistry in one area, “[b]efore you know it, if we let this stand, lay persons will be into dentures (denturists)” and other areas); CX0422 at 001 (“If we as dental professionals do not take a stand, then it will not be to [sic] long that the patient will be doing their own dental work outside of the dental office.”).

Response to Finding No. 225:

Respondent disputes this proposed finding of fact as a mischaracterization of the record and based upon an assumption. Dr. Haywood testified that he was not an industry expert; he is an academician. (Haywood, Tr. at 2392). Regarding Dr. Haywood’s testimony, when asked by Complaint Counsel whether the statement quoted by Complaint Counsel in support of this proposed finding of fact accurately reflected his views at the time he formulated his opinion in this matter, he responded, “That, and the rest of the body of this letter [CX836] in context.” (Haywood, Tr. at 2915). Further, regarding Exhibit CX278, the complainant dentist did not observe the teeth whitening procedure. (CX278 at 1). Regarding Exhibit CX141, it was clear that the dentist had grave concerns about the

customers' safety in the areas of sterilization and infection control, and that the dentist had no intent to totally close down the jewelry store. (CX141 at 1-2). Again, the concern expressed by the dentist in Exhibit 422 was "public safety" – not competition. (CX422 at 1).

C. The Board Alleges That Non-Dentist Teeth Whiteners and the Makers of Mouth Jewelry Are Engaged in the Unauthorized Practice of Dentistry

226. In 2003 and 2004, the Board was investigating the makers of mouth jewelry "grillz and fangs" for alleged violations of the Dental Practice Act. The Board considered whether mouth jewelry makers were engaged in the unauthorized practice of dentistry on two distinct possible theories of violation. First, the Board considered whether the impressions taken by "unlicensed persons," such as mouth jewelry makers, violated the Dental Practice Act prohibition of "taking an impression." Second, the Board considered whether the actual creation by "unlicensed persons" of jewelry to be worn on teeth violated the Dental Practice Act prohibition on the "fabrication of a dental appliance." (CX0338 at 001-002; CX0149 at 001; CX0148 at 001; CX0337 at 001; CX0363 at 001; CX0140 at 001; CX0141 at 001; CX0142 at 001; CX0143 at 001).

Response to Finding No. 226:

Respondent has no specific response.

227. In 2003 and 2004, the Board also considered whether non-dentists teeth whiteners were engaged in the unauthorized practice of dentistry. The Board considered whether the impressions taken by "unlicensed persons" used to create "bleaching trays" violated the Dental Practice Act prohibition of "taking an impression." (CX0041 at 001; CX0554 at 038 (Allen, Dep. 142-144); CX0041 at 003; CX0437 at 001).

Response to Finding No. 227:

Respondent disputes this proposed finding of fact.

1. The Brunson Jewelry Litigation

228. In late December of 2003 and early 2004, the Board investigated a business known as Brunson Jewelry for potential violations of the Dental Practice Act. Mr. Brunson was in the business of manufacturing mouth jewelry ("grillz and fangs") designed to be worn over a customer's teeth. During the process of fabricating mouth jewelry, Mr. Rodriguez would take an impression of the customer's teeth. (CX0159 at 001-002; CX0337 at 001; CX0363 at 001).

Response to Finding No. 228:

Respondent has no specific response.

229. The Board brought a civil suit wherein it alleged that Rodriguez Brunson was fabricating dental devices such as the mouth jewelry he had made for a Board investigator in violation of the Dental Practice Act. The Board further alleged that Brunson was engaged in the unauthorized practice of dentistry by taking an impression of the human teeth. The Board sought a permanent injunction to prohibit the defendant from fabricating and selling metal devices and taking impressions of teeth (CX0159 at 001-002) (Order and Judgment in North Carolina Board of Dental Examiners vs. Rodriguez Brunson ("*Brunson*") March 31, 2005).

Response to Finding No. 229:

Respondent has no specific response.

230. On August 4, 2004, Mr. White informed the Board that the judge in the *Brunson* case had issued a preliminary injunction against Mr. Rodriguez for making impressions but had not issued a preliminary injunction against the making and selling of mouth jewelry. Mr. White further informed the Board that there was a mediated settlement conference scheduled for September 23, 2004. (White, Tr. 2328; CX0140 at 002). In a series of email exchanges between August 4, 2004 and August 5, 2004, Board members Drs. Allen, Brown, Morgan, and Burnham exchanged their views about settling the *Brunson* case rather than pursuing a decision on the merits. (CX0140 at 001; CX0141 at 001; CX0142 at 001; CX0143 at 001). In one e-mail, Dr. Morgan wrote: Well, if the judge says that patients can take their own impressions and then ANYBODY no matter what name you want to use, can then fabricate a dental appliance, (teeth whitening tray, overlay crowns, bridges, dentures, partials, orthodontics, etc.) without a dentists prescription for such an appliance, then that's the practice of dentistry!! Before you know it, if we let this stand, lay persons will be into dentures (denturists), ortho (inivisalign), etc. they will just then be called, denture spa's, ortho spas, hyg. spas (CX0141 at 001; White, Tr. 2329-2330).

Response to Finding No. 230:

Respondent disputes this proposed finding of fact as a misrepresentation and mischaracterization of the record. The exhibit cited by Complaint Counsel in support of this proposed finding of fact does not reflect communication with the Board by Mr. White on August 4, 2004 about the *Brunson* case, nor were there any back and forth communications on that date about this case. (CX140 at 2). Further, when questioning

Dr. Morgan about what he said during this email exchange, Complaint Counsel characterized Dr. Morgan as “concerned very much apparently about the safety implications ... of what Brunson was doing or you believed he was doing,” to which Dr. Morgan affirmatively responded. (CX569 (Morgan, Dep. at 223)).

231. Dr. Morgan opined that he could not suggest a settlement of the case because the appliances (e.g. mouth jewelry) “could kill or seriously injure” someone, and because there were “sterilization and infection control concerns” whether or not Rodriguez or others took impressions. Dr. Burnham agreed with Drs. Morgan, Holland and Brown that Brunson Jewelry should not be allowed to continue offering grills even if consumers take their own impressions and noted there similar businesses “opening up all over” and one in High Point that advertises it is legal because the “patients” take their own impressions. (CX0142 at 001). The Board did not settle the *Brunson* case, but proceeded to trial. (CX0159; White, Tr. 2331).

Response to Finding No. 231:

Respondent disputes this proposed finding of fact as a mischaracterization of the exhibit offered by Complaint Counsel in support of it. There is no indication in Exhibit CX142 of the positions taken by Drs. Morgan, Holland and Brown, and Dr. Burnham does not discuss their positions other than to say that he agrees. (CX142 at 1).

2. The Criminal Case Against Brandi Temple of “The Temple”

232. On August 10, 2004, Bobby White sent an e-mail to Board members concerning his review of a Hollywood Smiles teeth whitening brochure from “The Temple” stating that he believed the company was “smart enough to know the taking of an impression would place them unquestionably in violation of the DPA. So, they are dancing around this issue by keeping their fingers out of the mouths of their clients.” White suggested to the Board that he believed that “this is stretching the definition of taking an impression too far.” He stated that the if they were “mixing and/or pouring material, supervising, encouraging, directing, etc. a client in the taking of an impression in their spa, then they are in fact taking an impression of human teeth whether or not any fingers enter the mouth.” (CX0041 at 001).

Response to Finding No. 232:

Respondent has no specific response.

233. The Board believed that from a legal standpoint its only recourse for prosecuting the Brandi Temple case was to prove that Ms. Brandi Temple was taking impressions in violation of the Dental Practice Act. (CX0554 at 038 (Allen, Dep. at 142-144); CX0041 at 003).

Response to Finding No. 233:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record and it contains an assumption. As shown in the investigative report of the Board staff member who visited Ms. Temple's spa, Ms. Temple's teeth whitening services consisted of taking impressions of her customer's teeth, providing them with a custom teeth whitening tray that was made on the premises, and selling the customer a teeth whitening kit for at-home use. (RX15 at 9-10). The only possible violation of the Dental Practice Act evidenced by Ms. Temple's activities was the taking of impressions. (RX15 at 9-10).

234. On November 23, 2004, an arrest warrant in the name of the State of North Carolina was issued for Brandi Temple of the Temple Rejuvenating Spa from Davidson County, North Carolina. (CX0040 at 008). Board investigator Sean Kurdys alleged on behalf of the Board that Ms. Temple was engaged in the unauthorized practice of dentistry because she had taken or made impressions of human teeth (CX0040 at 008).

Response to Finding No. 234:

Respondent has no specific response.

235. In January 2005, the District Attorney of Davidson County entered a voluntary dismissal of the criminal charges of unauthorized practice of dentistry against Brandi Temple, Assistant District Attorney Kinsey informed the Board that he had taken a voluntary dismissal based upon Ms. Temple's affidavit wherein Ms. Temple did not admit guilt and noted that the affidavit was "given in compromise of a doubtful and disputed criminal charge." Ms. Temple further stated that "she will not take or make an impression of the human teeth, gums or jaws in regards to the sale and distribution of teeth whitening kits to the general public" (CX0040 at 002-004).

Response to Finding No. 235:

PART B

Respondent disputes this proposed finding of fact based on the assumptions contained therein and mischaracterization of the record. The Dismissal filed with the court by the prosecutor on January 4, 2005, indicates that the reason for the dismissal was the matter was "corrected." (CX40 at 4). On the Dismissal form, the prosecutor did not indicate the reason for the dismissal was "no crime is charged" or "insufficient evidence to warrant prosecution." (CX40 at 4).

3. The Criminal Case Against Marcia Angelette Of Edie's Salon Panache

236. During August and September 2004, four North Carolina dentists complained to the Board about an advertisement from Edie's Salon Panache that advertised non-dentist teeth whitening for \$149 dollars in the Charlotte area. The advertisement also noted that Edie's was the second salon in North Carolina to offer teeth whitening. (CX0036 at 002-004).

Response to Finding No. 236:

Respondent disputes this proposed finding of fact. There are only two dentist complaints in the evidence offered by Complaint Counsel in support of this proposed finding of fact. (CX36 at 2-4). Further, this proposed finding of fact is based on an assumption that the dentists were complaining about the price. The source of the information that the prices charged by this salon was lower than a dentist comes from the advertising forwarded to the Board, or quoted to the Board in an email. (CX36 at 2-3).

237. Terry Friddle submitted an investigative report of Edie's Salon Panache to Dr. Allen on October 7, 2004 (CX0284 at 001). Dr. Allen responded that Board should definitely pursue the Edie's Salon Panache case and he directed Ms. Friddle to place her report on the agenda for the next Board meeting (CX0437 at 001).

Response to Finding No. 237:

Respondent disputes this finding of fact as incomplete and containing an assumption. Complaint Counsel does not incorporate the entirety of Ms. Friddle's investigative report

in support of this proposed finding of fact, which would show the safety and sanitation issues presented in Ms. Friddle's report and which would cause Dr. Allen to respond that the Board should definitely pursue this case. (CX284 at 1-2; CX437 at 1).

238. An arrest warrant in the name of the State of North Carolina was issued on October 27, 2004 for Marcia Angelette of Edie's Salon Panache in Cabarrus County, North Carolina. Board Investigator Mr. Kurdys alleged, on behalf of the Board, that Ms. Angelette was engaged in the unauthorized practice of dentistry because she had taken or made impressions of human teeth (CX0034 at 007). The criminal cases was disposed of before a trial on the merits of the claim that the defendants had engaged in the unauthorized practice of dentistry by making impressions (CX0034 at 003).

Response to Finding No. 238:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record. The exhibit cited by Complaint Counsel in support of this proposed finding of fact shows that there was a "not guilty" plea by Ms. Angelette on the date of trial, January 5, 2005. (CX34 at 3). It also shows that there was a guilty verdict. (CX34 at 3). Further, it shows that Judge "WGH" granted a prayer for judgment provided that the defendant not practice dentistry anymore. (CX34 at 3). Ms. Friddle also testified about attending and testifying at trial, as well as the guilty verdict. (RX57 (Friddle, Dep. at 128-129)).

4. The Aftermath of the *Brunson* Case and the Dismissal of the Criminal Cases Against Non-dentist Teeth Whiteners

239. The Board viewed the January 2005 dismissal of the Brandi Temple matter as evidence that "the court ruled that whitening in and of itself wasn't violating the Dental Practice Act." (CX0554 at 037 (Allen Dep. 140-141)). Dr. Allen acknowledged that Ms. Temple's affidavit did not prohibit her from offering teeth whitening services. Dr. Allen interpreted the court's dismissal of the Brandi Temple case based on the Temple affidavit to mean that the court ruled that teeth whitening in and of itself did not violate the Dental Practice Act. (CX0554 at 037 (Allen Dep. 139-141); CX0040 at 005).

Response to Finding No. 239:

Respondent disputes this proposed finding of fact as containing an assumption, a misrepresentation of the record, and an incomplete statement of fact. With all due respect to Dr. Allen, the record shows that Ms. Temple was charged with violation of the Dental Practice Act by the taking of impressions in connection with the sale of teeth whitening kits; she was not actually offering teeth whitening services at her spa. (RX15 at 9-10; CX40 at 8). Further, the Board successfully obtained a guilty verdict in another case involving the taking of impressions in connection with the sale of teeth whitening kits in January 2005. (CX34 at 3; RX57 (Friddle, Dep. at 128-129)).

240. In March 2005, the Board received a partial adverse ruling relating to the *Brunson* case. The court rejected the Board's assertion that making and selling of grillz, fangs, or "mouth jewelry" violated the Dental Practice Act prohibition of fabrication of a dental device without a license, but found that Mr. Brunson had been taking impressions of teeth in violation of the Dental Practice Act. (CX0159 at 001; White Tr. 2331). The Court stated, "[w]hile important public health concerns attend the marketing, fabrication and sale of any product or device that is inserted in a persons' mouth, and while N.C.G.S. 90-29(b)(8) should be liberally construed so as to serve the remedial purpose of the licensing statute, the fang device and similar devices offered and sold by Brunson are not substitutes for the wearer's natural teeth (or prosthetic teeth, if the wearer has a crown, bridge or plate) but temporary, removable adornments loosely referred to as 'jewelry.'" The judge also stated that "[t]he extension of the definition of 'practice of dentistry' to include such devices, or otherwise providing for regulation and control of the fabrication and sale thereof, is best left to the legislature." (CX0159 at 006).

Response to Finding No. 240:

Respondent disputed this proposed finding of fact as it contains a conclusion of law as to a "partial adverse ruling."

241. After the *Brunson* decision, the Board believed that courts would be "narrowly interpreting the Dental Practice Act relating to unlicensed practice of dentistry when it came to those areas." (CX0554 at 035, Allen Dep. at 133). In an e-mail relating to an investigation of another maker of mouth jewelry, Mr. Grillz, Dr. Burnham advised Ms. Friddle in February of 2006 that there "is not much we can do about it" if Mr. Grillz's clients were "taking their own impressions." (CX0243 at 001). Subsequently, Dr. Brown informed Dr. Litaker of his opinion that the judge had ruled the fabrication of "grills" to be no different than a child wearing a set of wax teeth. (CX0576 at 012, 023-024 (Litaker, Dep. 39-40, 85-87)). The Board has not proposed legislation and there has been

no change in the Dental Practice Act relating to the fabrication of appliances such as mouth jewelry. (White, Tr. 2332).

Response to Finding No. 241:

Respondent disputes this proposed finding of fact as a misrepresentation of the record and an assumption of facts. Mr. White testified that the Board did not decide to use cease and desist letters rather than go to the court system in teeth-whitening cases because of the Board's lack of success in using the court system. (White, Tr. at 2338). This is plainly evidenced by the fact that the Board brought two civil actions in court after the verdict was handed down in *Brunson*. (RX25 at 9-14, Complaint for Declaratory Judgment and Temporary and Permanent Injunctive Relief, filed Nov. 21, 2006; RX8 at 1-8, Complaint for Declaratory Judgment and Injunctive Relief, filed Jan. 22, 2008)). Further, Dr. Morgan testified that he had no recollection of any discussions between Board members of between Board members and staff about the implications of the *Brunson* decision. (RX65 (Morgan, Dep. at 214-2146)). He also testified that he could not say that the *Brunson* decision made the Board cautious about returning to court for an interpretation of the Dental Practice Act as to the unauthorized practice of dentistry. (RX65 (Morgan, Dep. at 238-239)).

242. During the NCDS consideration to request that the North Carolina legislature increase the severity of the penalty for unlicensed practice of dentistry, Lisa Piercey, lobbyist for the NCDS, requested an opinion from the North Carolina Attorney General, Roy Cooper, as to whether provision of non-dental teeth whitening or fabrication of "grills" constituted the unlicensed practice of dentistry. In Mr. Cooper's opinion, neither of these constituted the unlicensed practice of dentistry. (CX0576 at 008-009 (Litaker, Dep. at 25-28)).

Response to Finding No. 242:

Respondent disputes this proposed finding of fact as having no basis in fact. The Attorney General's office provided Respondent's Counsel with a letter stating that the

Attorney General's office has issued no written opinions as to whether or not non-dentists providing teeth whitening services may or may not be in violation of the provisions of the Dental Practice Act. (RX48 at 1). Per the letter, there were no advisory letters or opinions issued on this topic either. (RX48 at 1). Further, pursuant to N.C. Gen. Stat. § 114-2(5), the North Carolina Attorney General may only provide "his opinion upon all questions of law submitted to him by the General Assembly, or by either branch thereof, or by the Governor, Auditor, Treasurer, or any other State officer." In other words, a private association could not have obtained such an opinion.

D. No North Carolina Court Has Issued a Decision on the Merits Finding That Non-dentist Teeth Whitening Providers Are Engaged in the Unauthorized Practice of Dentistry

243. On four occasions since 2004, the Board has sought civil or criminal relief in North Carolina courts alleging that teeth whitening service providers were engaged in the unauthorized practice of dentistry under the Dental Practice Act. (CX0073 at 004 (complaint for declaratory judgment and injunctive relief against Carmel Day Spa & Salon (filed January 17, 2008)); CX0103 at 003-016 (complaint for temporary restraining order and permanent injunction against Signature Spas of Hickory (filed November 21, 2006)); CX0040 at 008 (arrest warrant issued for Brandi Temple (issued November 23, 2004)); CX0034 at 007 (arrest warrant issued for Marcia Angelette (issued October 27, 2004))).

Response to Finding No. 243:

Respondent has no specific response.

244. There have been no decisions on the merits in a North Carolina court relating to the Dental Board's enforcement of the Dental Practice Act with respect to non-dental teeth whitening. (Response to RFA ¶ 22; CX0573 at 017 (White, Dep. at 58-59)).

Response to Finding No. 244:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record. Complaint Counsel cites Respondent's Response to RFA ¶22 as support for this proposed finding of fact. This request for admission stated "[a]dmit that there has been

no decision on the merits in a North Carolina court relating to the Dental Board's enforcement of the Dental Practices Act with respect to non-dental teeth whitening." Respondent's admission of this request was truthful. There was a guilty verdict entered in the case of Ms. Angelette, but she was charged with violation of the Dental Practice Act by taking impressions – not for providing teeth whitening services. (CX34 at 3; RX11 at 4; RX57 (Friddle, Dep. at 128-129)). Further, Mr. White's testimony cited in support of this proposed find of fact simply relates to the two civil cases pursued by the Board in the North Carolina courts. (White, Tr. at 58-50).

245. The two criminal cases involving Ms. Temple and Ms. Angelette were dismissed before a trial on the merits. (CX0034 at 003); (CX0040 at 002-003).

Response to Finding No. 245:

Respondent disputes this proposed finding of fact as a blatant misrepresentation of the record as it pertains to Ms. Angelette. The exhibit cited by Complaint Counsel in support of this proposed finding of fact shows that there was a "not guilty" plea by Ms. Angelette on the date of trial, January 5, 2005. (CX34 at 3). It also shows that there was a guilty verdict. (CX34 at 3). Further, it shows that Judge "WGH" granted a prayer for judgment provided that the defendant not practice dentistry anymore. (CX34 at 3). Ms. Friddle also testified about attending and testifying at trial, as well as the guilty verdict. (RX57 (Friddle, Dep. at 128-129)).

246. The Board has sought relief in the civil courts of North Carolina on two occasions alleging that teeth whitening service providers were engaged in the unauthorized practice of dentistry under the Dental Practice Act. (CX0073 at 004 (complaint for declaratory judgment and injunctive relief against Carmel Day Spa & Salon (filed January 17, 2008)); CX0103 at 003-016 (complaint for temporary restraining order and permanent injunction against Signature Spas of Hickory (filed November 21, 2006)).

Response to Finding No. 246:

Respondent has no specific response.

247. On November 21, 2006, the Board filed a civil action against the Signature Spas of Hickory seeking a motion for a restraining order. The Board alleged that the non-dentist teeth whitening service providers had engaged in the unlicensed practice of dentistry by “removing stains, accretions, and deposits from human teeth and by circulating brochures and otherwise representing that they are capable of removing stains, accretions, and deposits from human teeth at a time when no employee of Signature Spas was licensed to practice dentistry in North Carolina” in violation of N. C. Gen. Stat. §§ 90-92(b)(2), 90-92(b)(13). (CX0103 at 003-012).

Response to Finding No. 247:

Respondent disputes this proposed finding of fact as a misrepresentation of the record.

The Board’s civil action against Signature Spas of Hickory sought a declaratory judgment, a temporary restraining order, and a permanent restraining order. (RX25 at 914).

248. The proprietors of Signature Spas of Hickory offered to settle the matter by agreeing to stop providing teeth whitening services. In fact, Signature Spas of Hickory had already stopped providing teeth whitening services. (CX0231 at 001; CX0215 at 001).

Response to Finding No. 248:

Respondent has no specific response.

249. The Board was unwilling to accept a consent unless the proprietors of Signature Spas of Hickory admitted that they were engaged in the unlawful practice of dentistry. (CX0214 at 001) Dr. Hardesty wrote to Drs. Burnham, Owens & Feingold, Bobby White, and Ms. Carolin Bakewell, “I personally think that we need to play hardball and have them admit to the illegal practice as we are in other litigation. I also think that we should have them taxed for us having to take this to court.” (CX0212 at 001; CX0556 at 035 (Burnham, Dep. at 130-131); CX0211 at 001).

Response to Finding No. 249:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and as containing an assumption. Ms. Bakewell testified that it would not be fair to say that

the Board wanted a settlement only if there was an admission of a violation of the Act by Signature Spas. (RX50 (Bakewell, Dep. at 243-244)). Although individual members of the Board at various times expressed a reluctance to enter into a consent order without such an admission, they ultimately accepted a consent order under those terms. (RX25 at 25-28).

250. The Board wanted the Signature Spas defendants to admit to the unauthorized practice of dentistry because they wanted to use it as precedent against other teeth whitening businesses. (CX0216 at 001-002). Based upon a conversation with Dr. Brown, Dr. Litaker indicated that the Board was hoping to get statements from non-dentist teeth whitening providers admitting guilt in order to set a precedent for future cases and for other states. (CX0576 at 012-013, 023-024, 030-031 (Litaker, Dep. at 40-42, 85-87, 113-115)).

Response to Finding No. 250:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and as containing an assumption that the Board pursued this case in the courts only for that purpose. Dr. Feingold, the case officer, testified that the “precedential side of it and all would just be something nice that could have happened along with it; we were just out to handle the complaint as it came into the Board. (RX56 (Feingold, Dep. at 162)). Dr. Litaker’s testimony is hearsay.

251. The Board was concerned about its likelihood of success on the merits of the case against Signature Spas of Hickory. As Mr. White stated, “[l]itigation is a roll of the dice and there is no guarantee we will come away with the finding we want.” (CX0211 at 001)). Even though the Board’s counsel advised the Board that a settlement would not provide legal precedent in other teeth whitening cases, the Board settled the matter. (CX0581 at 063-065 (Bakewell, Dep. at 243-251)).

Response to Finding No. 251:

Respondent disputes this proposed finding of fact as an misrepresentation of the complete record. Ms. Bakewell testified that she was not concerned about the “risk factor of losing” the Signature Spas case. (RX50 (Bakewell, Dep. at 248)). Ms. Bakewell

testified, "I didn't think there was any chance we were going to lose. The trial judge was nodding when he was looking at the statute." (RX50 (Bakewell, Dep. at 248)). Dr. Feingold, the case officer, also testified that he did not have a concern that the Board would not win on the merits; rather, settlement was in the interest of time and resources. (RX56 (Feingold, Dep. at 158-159)). Complaint Counsel also mischaracterizes Ms. Bakewell's testimony cited in support of this proposed finding of fact. Ms. Bakewell testified that "[t]he settlement would give the same precedential value as a case if we litigated it out because the lower courts don't – I mean they don't rule over anything other than their own cases." (CX581 (Bakewell, Dep. at 245)).

252. The Board filed for a civil action for a declaratory Judgment and injunctive relief against the proprietors of the Carmel Day Spa on January 17, 2008. The Board alleged that the defendants had engaged in the unlicensed practice of dentistry because they "offered teeth whitening services to members of the public" which included the "removal of stains, accretions and deposits from human teeth" in violation of N. C. Gen. Stat. §§ 90-92(b)(2), 90-92(b)(13). (CX0073 at 004-006).

Response to Finding No. 252:

Respondent has no specific response.

253. The Board settled the Carmel Day Spa litigation prior to a decision on the merits by entry of a consent order in July 2008. (RX00008 at 015-017).

Response to Finding No. 253:

Respondent disputes this proposed finding of fact as containing an assumption that is not supported by the record and as an incomplete statement of the record. The record shows that the consent order signed by the parties and the presiding superior court judge stated in the conclusions of law: "The Rafie defendants and Carmel Day Spa, through its employees, have engaged in the unlicensed practice of dentistry by removing stains, accretions and deposits from human teeth and by circulating brochures and otherwise

representing that it or they are capable of removing stains, accretions and deposits from human teeth at a time when no employee of Carmel Day Spa was licensed to practice dentistry in North Carolina.” (RX8 at 16).

V. The Board’s Exclusion of Non-dentist Teeth Whiteners

A. The Board Sends Cease and Desist Orders To Non-dentists Providing Teeth Whitening Services

1. The Development of the Cease and Desist Orders Sent to Non-dentists Providing Teeth Whitening Services

254. After the voluntary dismissal in the Brandi Temple matter, and the partial loss of the *Brunson* case, Board Investigator Mr. Line Dempsey sent a September 30, 2005 e-mail to Board member Dr. Brown and several Board staff stating that Cease and Desist Orders could be used in cases where there was an allegation of the unauthorized practice of dentistry, even though there was insufficient evidence to support the allegation. (CX0080 at 002; White Tr. 2335-2336; CX0555 at 60 (Brown Dep. 231)).

Response to Finding No. 254:

Respondent disputes this proposed finding. Mr. White testified that the Board did not decide to use cease and desist letters as a consequence of their “lack of success” with the courts. (White, Tr. 2338). Further, Mr. Dempsey specifically suggested the use of a cease and desist letter in his email – not a cease and desist order. (CX80 at 2). Further, Complaint Counsel has omitted a very important clause from Mr. Dempsey’s email – “at least now we can put them on notice that we know something is going on.” In other words, the Board had evidence of some sort of unauthorized practice of dentistry. (CX80 at 2). In the case of this particular jewelry store, Mr. Dempsey conducted an on-site investigation on July 9, 2004 (prior to the email referenced in Complaint Counsel’s proposed finding of fact) and was informed that the proprietor of the store took impressions of the teeth for the mouth jewelry. (CX358).

255. In his e-mail of September 30, 2005, Board investigator Dempsey suggested that the Board use a Cease and Desist Order developed by Ms. Casie Goode and Mr. Bobby White in connection with a jewelry store case he was investigating (CX0080 at 002; White, Tr. 2334-2335). Mr. Dempsey informed the case officer and other Board staff that:

I also must say that I really do like the Cease and Desist letter . . . I think in the past, we have had several of these type of cases [person is allegedly treating patients without a license] that ended up getting closed because we didn't have evidence . . . This might work well with the "gold teeth" type cases as well." (CX0080 at 002; White Tr. 2338-2339; CX0080 at 002).

Response to Finding No. 255:

Respondent disputes this proposed finding. Mr. Dempsey specifically suggested the use of a cease and desist letter in his email – not a cease and desist order. (CX80 at 2).

Further, Complaint Counsel has omitted a very important clause from Mr. Dempsey's email – "at least now we can put them on notice that we know something is going on." In other words, the Board had evidence of some sort of unauthorized practice of dentistry. (CX80 at 2). In the case of this particular jewelry store, Mr. Dempsey conducted an on-site investigation on July 9, 2004 (prior to the email referenced in Complaint Counsel's proposed finding of fact, and was informed that the proprietor of the store took impressions of the teeth for the mouth jewelry. (CX358).

256. Friddle forwarded the draft of the Cease and Desist Order to Dr. Brown, Mr. White, and Mr. Dempsey. Dr. Brown replied later that day that he would support such an approach if the rest of the Investigative Panel wanted to try the approach (CX0080 at 001). On November 7, 2005, a draft Cease and Desist Order was circulated to Dr. Brown, Dempsey and Mr. White. Dr. Brown approved the use of the Cease and Desist Order in the New York Jewelry investigation subject to Mr. White's approval. Mr. White subsequently approved the use of the letter (CX0080 at 001).

Response to Finding No. 256:

Respondent has no specific response.

257. On November 14, 2005, the Board sent a Cease and Desist Order to New York Jewelry at 2200 West Meadowview Road, Greensboro, North Carolina. The letter informed New York Jewelry that the Board was investigating a report that it was engaging in the unlicensed practice of dentistry and that violation of the Dental Practice Act was a crime. The Board further stated that “[y]ou are hereby ordered to CEASE AND DESIST” all activity constituting the practice of dentistry under the Dental Practice Act. The Board requested that New York Jewelry call the office and arrange an interview with a Board Investigator. (CX0063 at 001).

Response to Finding No. 257:

Respondent has no specific response.

2. The Cease and Desist Orders Sent To Non-dentist Teeth Whitening Providers

258. The Board starting using Cease and Desist Orders in the non-dentist teeth whitening investigations after the voluntary dismissal of the Brandi Temple criminal case and the *Brunson* decision. (White, Tr. 2338-2339).

Response to Finding No. 258:

Respondent disputes this proposed finding. Mr. White testified that the Board did not decide to use cease and desist letters as a consequence any previous teeth whitening cases that were pursued through the court system. (White, Tr. 2338).

a. Cease and Desist Orders Sent by the Board in 2006

259. The record shows that the Board sent two Cease and Desist Orders to non-dentist teeth whitening providers in 2006. (CX0038 at 001; CX0044 at 004-005). The first of many Cease and Desist Orders issued by the Board was to Serenity Day Spa, located at 814 C Old Spartanburg Highway, Hendersonville, North Carolina. (CX0038 at 001) A second Cease and Desist Order was sent to Stephanie Keith of Star-Bright Whitening Systems at her place of business known as the Cutting Crib Hair Salon in Sanford, North Carolina. (CX0044 at 003-005).

Response to Finding 259:

Respondent disputes this proposed finding and the characterization of the cease and desist letter that was sent to Serenity Day Spa as the “first of many.” Further, the two letters referenced by Complaint Counsel specifically cite that the unlicensed activity engaged in

by both recipients was the taking of impressions – not the removal of stains from teeth.

(CX38 at 1; CX44 at 4).

b. Cease and Desist Orders Sent by the Board in 2007

260. After sending a total of two Cease and Desist Orders in 2006, the record indicates that the Board sent at least twelve Cease and Desist Orders in 2007. (CX0050 at 001-003; CX0065 at 001; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; CX0094 at 0015-006; CX0096 at 001-002; CX0097 at 001-002; CX0100 at 001; CX0256 at 002-003; CX0279 at 001-002; CX0386 at 001-002).

Response to Finding No. 260:

Respondent disputes this finding of fact. Two of the exhibits cited by Complaint Counsel are styled as notices and do not use the word “order” or “ordered.” (CX65; CX100).

Several of the cease and desist letters cited by Complaint Counsel are addressed to the same establishment, evidencing multiple attempts at delivery. (CX65 and CX97; CX74 and 256).

261. In 2007 and 2008, the number of complaints about teeth whitening increased, and the Board began sending out Cease and Desist Orders without conducting an investigation because they did not have the resources to conduct the investigations. (CX0562 at 012 (Friddle, IHT at 43)).

Response to Finding No. 261:

Respondent disputes this finding of fact. In response to a follow-up question from Complaint Counsel about the complaints starting to come in in large numbers and the lack of time to go out and perform an onsite visit, Ms. Friddle further testified that “[t]hat was part of it, and part of it was just if we knew what was going on by virtue of the information that was sent to us, we could go ahead and handle it with a cease and desist. If we weren’t, didn’t have enough evidence to know one way or the other, we’d try to always send somebody out to take a look firsthand to find out what they were doing.” (CX562 at 51-52).

262. Because he believed that the Board was having a difficult time getting the time to send staff to do undercover work, Dr. Hardesty directed Ms. Friddle to “write [non-dentist teeth whitening businesses] a Cease and Desist Order the first go round. If we find out they are still doing it, then we move in with the big guns.” This occurred around March 2007. (CX0070 at 001; CX0561 at 022-023 (Friddle, Dep. at 81-83)).

Response to Finding No. 262:

Respondent disputes this proposed finding. Complaint Counsel mischaracterizes Dr. Hardesty’s intent. The email cited by Complaint Counsel does not state that this is Dr. Hardesty’s belief that the Board was having a difficult time with staff availability; it is merely Ms. Friddle’s observation. (CX70 at 1).

263. On March 22, 2007, Ms. Friddle sent an e-mail to Dr. Holland regarding the necessity of sending an undercover investigator to a non-dental teeth whitening provider, whom the Board might send a Cease and Desist Order. Ms. Friddle explained that the Board was too busy to send a private investigator to the “spa deals,” and therefore, “Dr. Hardesty has pretty much taken the stance that we write them a Cease and Desist Order the first go round.” The Board would only “move in with the big guns,” if the Board discovered that a Cease and Desist Order recipient persisted in providing non-dentist teeth whitening services. (CX0070 at 001).

Response to Finding No. 263:

Respondent disputes this proposed finding. Complaint Counsel has mischaracterized this email communication. Ms. Friddle stated that the Board was having a difficult time sending staff to perform uncover investigations; there was no mention in Ms. Friddle’s communication about a private investigator. (CX70 at 1).

264. When Dr. Hardesty directed Ms. Friddle around March 2007 to “write [non-dentist teeth whitening businesses] a Cease and Desist Order the first go round,” Ms. Friddle understood that to mean to send a Cease and Desist Order when a complaint initially came in. On at least five occasions, she followed Dr. Hardesty’s directions. (CX0070 at 001; CX0561 at 022-023 (Friddle, Dep. at 81-84)).

Response to Finding No. 264:

Respondent disputes this finding of fact. Complaint Counsel mischaracterizes the quotation by indicating in brackets that it referred to “non-dentist teeth whitening businesses.” This particular quotation omits the word “them,” which actually refers to the “spas” referenced in the previous sentence. (CX70 at 1). Complaint Counsel also mischaracterized Ms. Friddle’s testimony so as to imply that she automatically sent out cease and desist letters when the complaint initially came. She further testifies in the same line of questioning that it was the case officer’s decision to send the cease and desist. (CX561 (Friddle, Dep. at 84-85)). The number of times that she set cease and desist letters was a speculation on Ms. Friddle’s part. (CX561 (Friddle, Dep. at 84)).

265. Ms. Friddle testified that in 2007 and 2008, Cease and Desist Orders were sent “fairly quickly, like shortly after the case was set up.” (CX0562 at 013 (Friddle, IHT at 47)). Ms Friddle further testified that “if it is unclear as to whether or not, or if it appears that there’s a violation, then we would send a cease and desist.” (CX0562 at 012 (Friddle, IHT at 43-44)).

Response to Finding No. 265:

Respondent has no specific response.

266. Dr. Hardesty authorized sending a Cease and Desist Order to a business without having first sent an investigator to determine precisely what that business was doing. (Hardesty, Tr. 2856). Dr. Hardesty also authorized the sending of a Cease and Desist Order to a salon solely based on an e-mail from a dentist and his review of the website for the whitening product that the salon was considering using. (CX0565 at 043 (Hardesty, Dep. at 163-165); CX0293 at 001). Dr. Owens often sent out C&D letters within minutes or hours of receiving notice of a complaint, and often without any investigation. (CX0297 at 001 (Dec. 1, 2008) (Dr. Owens authorized cease and desist 12 minutes after being assigned case); CX0311 at 001 (Dr. Owens authorized cease and desist same day as receiving assignment)).

Response to Finding No. 266:

Respondent disputes this proposed finding of fact. Respondent objects to the undefined term “often” as used by Complaint Counsel and notes that Complaint Counsel has only provided two examples of such conduct. Complaint Counsel also mischaracterizes DR.

Owens' conducted as being undertaken without any investigation. In the two examples provided by Complaint Counsel, Dr. Owens was able to review the spa's advertising that was attached to the email assigning the case to him prior to directing that a cease and desist letter be sent. (CX297 at 7; CX311 at 2).

c. Cease and Desist Orders Sent by the Board in 2008

267. In 2008, the record indicates that the Board sent at least twelve Cease and Desist Orders to non-dentist teeth whitening providers. (CX0042 at 039-041; CX0059 at 001-002; CX0068 at 001-002; CX0079 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX123 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002).

Response to Finding No. 267:

Respondent has no specific response.

d. Cease and Desist Orders Sent by the Board in 2009

268. In 2009, the record indicates that 22 Cease and Desist Orders that were sent by the Board to non-dentist teeth whitening providers. (CX0042 at 001-002; CX0042 at 005-006; CX0042 at 008-009; CX0042 at 010-011; CX0042 at 012-013; CX0042 at 014-015; CX0042 at 016-017; CX0042 at 018-019; CX0042 at 020-021; CX0042 at 022-023; CX0042 at 024-025; CX0042 at 026-027; CX0042 at 028-029; CX0042 at 030-031; CX0042 at 032-033; CX0042 at 034-035; CX0058 at 001-002; CX0112 at 001-002; CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002; CX0272 at 001-002).

Response to Finding No. 268:

Respondent has no specific response; however, several of the letters were sent to the same recipients (CX42 at 1-2 and CX42 at 39-41).

269. The last three Cease and Desist Orders 2009 of contained slightly different language than the other Cease and Desist Orders sent in 2009 and in 2008. (CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002) These three Cease and Desist Orders were captioned, "NOTICE OF APPARENT VIOLATION AND DEMAND TO CEASE AND DESIST" instead of being captioned "NOTICE AND ORDER TO CEASE AND DESIST." In addition, rather than stating "you are hereby ordered to CEASE AND DESIST any and all activity constituting the practice of dentistry . . ." these three Cease and Desist Orders stated that the Board "hereby demands that you CEASE AND DESIST any and all activity constituting the practice of dentistry . . ." (CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002).

Response to Finding No. 269:

Respondent has no specific response.

3. The Total Number of Cease and Desist Orders Sent To Non-Dentist Providing Teeth Whitening

270. The Board has sent at least 47 Cease and Desist Orders to non-dental teeth whitening manufacturers and providers since it began the practice in 2006. (CX0038-001; CX0042 at 001-002, 005-007, 008-009, 010-011, 012-013, 014-015, 016-017, 018-019, 020-021, 022-023, 024-025, 026-027, 028-029, 030-031, 032-033, 034-035; CX0044 at 004-005; CX0050 at 002-003; CX0058 at 001-002; CX0059 at 001-002; CX0065 at 001-002; CX0068 at 001-002; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; X0079 at 001-002; CX0094 at 005; CX0096 at 001-002; CX0097 at 001-002; CX0100 at 001-002; CX0112 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0351 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002; Joint Stipulations of Law and Fact ¶ 30.).

Response to Finding No. 270:

Respondent has no specific response.

4. Complaints by North Carolina Dentist and Board Members That Led To The Issuance of Cease and Desist Orders To Non-dentist Teeth Whitening Providers

271. Almost all of the complaints to the Board about non-dentist teeth whitening service providers in North Carolina have come from licensed North Carolina dentist or their employees (CX0276 at 001; Kwoka Tr. at 1077-1079; Owens Tr. 1576-1579 (approx. 90% of teeth whitening complaints from dentists or employees of dentists)).

Response to Finding No. 271:

Respondent disputes this proposed finding of fact as containing an undefined term –

“almost all.”

272. The Board admits that “only three investigations it opened included a report of harm or injury to an individual.” (Response to RFA ¶ 22). Two of these stem from consumer complaints and one from a dentist on behalf of his patient. (CX0055 at 001-002; CX0462 at 003; CX0477 AT 001-005).

Response to Finding No. 272:

Respondent disputes this proposed finding of fact as containing an assumption. There is no requirement in the Dental Practice Act that harm or injury must occur before a complaint is received and accepted by the Board. (CX19 at 1-26).

273. In contrast to the three consumers who filed complaints with the Board regarding nondentist teeth whitening operations, the record contains evidence of at least 47 individual dentists who filed complaints with the Board about non-dentist teeth whitening operations. (CX0032 at 001-008; CX0035 at 001-002; CX0036 at 002-018; CX0043 at 001-013; CX0045 at 002-006; CX0054 at 002-006; CX0092 at 001; CX0102 at 001-003; CX0111 at 002-004; CX0198 at 001-002; CX0245 at 001; CX0251 at 001-002; CX0265 at 001; CX0276 at 001-002; CX0278 at 001; CX0281 at 001; CX0282 at 001; CX0293 at 001-002; CX0304 at 001; CX0365 at 001-022; CX0404 at 001-003; CX0411 at 001-004; CX0465 at 001; CX0477 at 003-005; CX0524 at 001-003; CX0619 at 001-002; CX0620 at 001).

Response to Finding No. 273:

Respondent disputes this proposed finding of fact as containing an assumption in regards to the phrase "in contrast."

274. At least 29 non-dentist teeth whitening providers were sent Cease and Desist Orders by the Board in instances where a North Carolina dentist had filed a complaint with the Board.

Complaints: CX0043 at 001-013 (BleachBright); CX0092 at 001 (Port City Tanning); CX0245 at 001 (Celebrity Smiles); CX0251 at 001-002 (Inspire Skin & Body); CX0198 at 001-002 (Movie Star Smile); CX0276 at 001 (*various*); CX0278 at 001 (BleachBright); CX0281 at 001 (Champagne Taste/Lash Lady); CX0304 at 001-002 (Bailey's Lightening Whitening); CX0365 at 001-002 (Celebrity Smiles); CX0404 at 001-003 (BleachBright); CX0411 at 003 (Whitening on Wheels).

Cease and Desist Order: CX0042 at 001-002 (BleachBright/James & Linda Holder); CX0042 at 005-007 (BleachBright/Skin Sense); CX0042 at 008-009 (BleachBright/Electric Beach Pleasant Valley); CX0042 at 010-011 (BleachBright/Exotic Tan); CX0042 at 012-013 (BleachBright/Skin Sense Apex); CX0042 at 014-015 (BleachBright/Cris Scott Hair Studio); CX0042 at 016-017 (BleachBright/Douglas Carroll Salon); CX0042 at 018-019 (BleachBright/Electric Beach Cary); CX0042 at 020-021 (BleachBright/Electric Beach Mission Valley); CX0042 at 022-023 (BleachBright/Electric Beach North Market Drive); CX0042 at 024 at 025 (BleachBright/Cary Massage Therapy Center); CX0042 at 026-027 (BleachBright/Skin Sense Falls of Neuse Road); CX0042 at 028-029 (BleachBright/Modern Enhancement); CX0042 at 030-031 (BleachBright/Life's Little Pleasures); CX0042 at 032-033 (BleachBright/La Therapie Spa); CX0042 at 034-035 (BleachBright/Electric Beach Six

Forks); CX0059 at 001-002 (Port City Tanning); CX0077 at 001-002 (Champagne Taste/Lash Lady); CX0079 at 001-002 (Movie Star Smile); CX0112 at 001-002 (BleachBright/Jason & Shanon Rabon); CX0120 at 001-002 (Fantiaticians); CX0153 at 001-002 (Serenity Total Body Care/BleachBright); CX00272 at 001-002 (Inspire Skin & Body); CX0351 at 001-002 (Celebrity Smiles at The Street of Southpoint); CX0386 at 001-002 (Details, Inc); CX0387 at 001-002 (Bailey's Lightning Whitening); CX0389 at 001-002 (Triad Body Secrets); CX0390 at 001-002 (Whitening on Wheels); CX0391 at 001-002 (The Extra Smile, Inc.).

Response to Finding No. 274:

Respondent has no specific response.

275. A common element of the dentists' complaints to the Board about non-dentist teeth whitening is that the dentists do not represent that any consumer had actually been harmed. (CX0032 at 001-002; CX0035 at 003; CX0036 at 001-002, 005-006, 007-018; CX0043 at 004-008, 009-010, 011-013; CX0054 at 002-006; CX0092 at 001-002; CX0111 at 001-004; CX0198 at 001-002; CX0245 at 001-002; CX0251 at 001-002; CX0278 at 001; CX0281 at 001; CX0293 at 001-002; CX0304 at 001; CX0365 at 001; CX0404 at 001-003; CX0411 at 001, 003; CX0465 at 001; CX0524 at 001-003; CX0619 at 001-002; CX0620 at 001-002).

Response to Finding No. 275:

Respondent disputes this proposed finding of fact as containing an assumption. There is no requirement in the Dental Practice Act that harm or injury must occur before a complaint is received and accepted by the Board. (CX19 at 1-26).

276. Many of the dentists' complaints to the Board about non-dentist teeth whitening referenced the price being charged by or attached advertisements showing the prices charged by non-dentist teeth whitening service providers. (CX0035 at 003; CX0036 at 001-002, 005-006, 007-018; CX0043 at 004-008, 009-010, 011-013; CX0054 at 002-006; CX0198 at 001-002; CX0411 at 001, 003; CX0619 at 001-002).

Response to Finding No. 276:

Respondent disputes this proposed finding of fact. Further, Complaint Counsel mischaracterizes each and every exhibit cited in support of this proposed finding. In the complaints cited by Complaint Counsel where advertising was attached, not a single dentist referenced the price charged by the non-dentist service providers. The only

mention of price was in the advertising attached to the complaint. (CX35 at 3; CX36 at 1-2, 5-6, 7-18; CX43 at 4-8, 9-10, 11-13; CX54 at 2-6; CX198 at 1-2; CX619 at 1-2). In one instance where the price information happened to be conveyed to the Board by any other means that the provision of the actual advertising used by the non-dentist teeth whitening service provider, the dentist quoted verbatim the contents of the advertising. (CX36 at 2). Finally, Respondent notes that there is no pricing information mentioned in CX411 at 1, 3.

277. North Carolina dentist who filed complaints or inquiries that led to Board investigations of the unauthorized practice of dentist derived income from the provision of teeth whitening services in recent years: Dentist A (CX0600 at 003; CX0304 at 001) (over \$150,000); Dentist B (CX0599 at 003; CX0524 at 001) (over \$100,000); Dentist C (CX0602 at 002; CX0035 at 001-002) (over \$100,000); Dentist D (CX0603 at 003; CX0092 at 001) (over \$100,000); Dentist E (CX0605 at 003; CX0245 at 001) (over \$50,000); Dentist F (CX0616 at 021; CX0043 at 011-013) (over \$50,000); Dentist G (CX0601 at 008; CX0276 at 001) (over \$50,000); Dr. H (CX0608 at 002; CX0276 at 001) (over \$50,000); Dentist I (CX0611 at 002, 004; CX0576 at 007-008 (Litaker, Dep. at 20-22, 24-25)); (CX0054 at 003) (over \$50,000); Dentist J (CX0617 at 001, 012; CX0111 at 001-006) (over \$50,000); Dentist K (CX0610 at 002; CX0265 at 001) (over \$15,000); Dentist L (CX0607 at 001; CX0276 at 001) (over \$15,000); Dentist M (CX0609 at 001-002; CX0043 at 003-010) (over \$15,000); Dentist N (CX0613 at 004-005; CX0102 at 001-002) (over \$15,000).

Response to Finding No. 277:

Respondent disputes this finding of fact as an incomplete statement of the record. The same documents cited by Complaint Counsel in support of this finding also show that the income derived from teeth whitening services by these dentists amounts to a relatively small fraction of the total revenues derived from their practices as a whole: Dentist A (CX600 at 3) (10%); Dentist B (CX599 at 3) (6%); Dentist C (CX602 at 2) (2%); Dentist D (CX603 at 3) (<1%); Dentist F (CX616 at 21) (<1%); Dentist G (CX601 at 8) (2 1/2%); Dentist I (CX611 at 2) (1%); Dentist J (CX617 at 12) (1%); Dentist K (CX610 at

2) (<2%); Dentist L (CX607 at 1) (1%); Dentist M (CX609 at 1) (1 1/2%); Dentist N (CX613 at 4) (1 1/2%).

Respondent further notes that some of the dollar figures provided by Complaint Counsel in this proposed finding are mischaracterizations of the information provided in response to a *subpoena duces tecum* by these dentists. The revenues reported by the majority of these dentists actually represent the revenues of the entire practice – not the revenues of an individual dentist: Dentist A (CX600 at 1) (3 dentists); Dentist B (CX599 at 1) (2 dentists); Dentist C (CX602 at 1) (2 dentists); Dentist D (CX603 at 1) (2 dentists); Dentist F (CX616 at 25) (2 dentists); Dentist J (CX617 at 1) (4 dentists); Dentist K (CX610 at 7) (2 dentists).

278. Sitting Board members Drs. Owens and Hardesty also submitted information that led to the opening of investigations into non-dental teeth whitening providers. (CX0041 at 003; CX0128 at 001; CX0567 at 055-057 (Holland, Dep. at 215-218, 226)). Dr. Owens contacted Bobby White in October of 2008 and sent a brochure to the Board from “the WOW wagon teeth whitening mobile van.” (CX0411 at 003) The Board sent a “Notice and Order to Cease and Desist” dated November 12, 2008, to Mr. Nathaniel Vinke of Whitening on Wheels at 17111 Kenton Drive, Cornelius, North Carolina. (CX0390 at 001-002); Dr. Hardesty filed a complaint with the Board on February 18, 2009 against Tom Jones Drug regarding the business offering non-dentist teeth whitening services. On the same day, Dr. Hardesty was assigned as the Case Officer of the Tom Jones investigation. (CX0128 at 001; CX0160 at 001-007; CX0567 at 057-059 (Holland, Dep. at 221-226)).

Response to Finding No. 278:

Respondent disputes this finding of fact, and Complaint Counsel has mischaracterized evidence offered in support of it. The brochure that Dr. Owens forwarded to the Board about the mobile teeth whitening van was evidence in support of a complaint that was previously made by another dentist whose office is located in Huntersville, North Carolina, a small town very close to Cornelius, where the mobile teeth whitening business was reported in operation. (RX32 at 3). Regarding Dr. Hardesty and the

complaint against the drug store, Complaint Counsel cites Dr. Holland's testimony in support. Dr. Holland testified that though this situation was an usual occurrence, "the unauthorized practice of dentistry doesn't really need a signed complaint, so it's not a person versus a respondent. It's – it's the board. The board is representing the public rather than a particular patient or complainant." (CX567 (Holland, Dep. at 226)).

279. Complaints filed with the Board regarding non-dentist teeth whitening operations also came from individuals in the dental field. (CX0626 at 001-002 ("dental assisting" for 21 years); CX0228 at 001-002 (Registered Dental Hygienist); CX0368 at 005 ("anonymous telephone call from an individual who worked at a dental office")).

Response to Finding No. 279:

Respondent has no specific response.

5. Cease and Desist Orders Sent To Non-Dentist Teeth Whitening Providers by Type of Business

280. 22 of the 47 Cease and Desist Orders were sent to North Carolina salons and spas that were providing whitening services. (CX0038-001; CX0042 at 005-006, 012-013, 014-015, 016-017, 024-025, 026-027, 028-029, 030-031, 032-033; CX0044 at 004-005; CX0050 at 002-003; CX0069 at 001-002; CX0077 at 001-002; CX0096 at 001-002; CX0153 at 001-002; CX0156 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0389 at 001-002).

Response to Finding No. 280:

Respondent has no specific response.

281. Seven of the 47 Cease and Desist Orders were sent to North Carolina teeth whitening businesses located in mall kiosks. (CX0074 at 001-002; CX0079 at 001-002; CX0103 at 001-002; CX0112 at 001-002; CX0123 at 001-002; CX0256 at 001-002; CX0388 at 001-002).

Response to Finding No. 281:

Respondent has no specific response.

282. Eleven of the 47 Cease and Desist Orders were sent to North Carolina tanning facilities. (CX0042 at 008-009, 010-011, 018-019, 020-021, 022-023, 034-035; CX0059 at 001-002; CX0065 at 001-002; CX0094 at 005; CX0097 at 001-002; CX0120 at 001-002).

Response to Finding No. 282:

Respondent has no specific response.

283. Two of the 47 Cease and Desist Orders were sent to teeth whitening product manufacturers (CX0100 at 001 (WhiteScience); CX0122 at 001-002 (Florida White Smile)).

Response to Finding No. 283:

Respondent disputes this proposed finding of fact as a misrepresentation of the contents of the exhibits cited in support of it by Complaint Counsel. Exhibit CX100 is a cease and desist notice; the word "order" does not appear anywhere in the letter. (CX100 at 1).

Regarding the second instance cited by Complaint Counsel, the Board was in receipt of complaint that the company was performing teeth whitening services at a Sams Club in Southern Pines, North Carolina, and sent a cease and desist letter. (CX361 at 3).

284. Three of the 47 Cease and Desist Orders were sent to other locations including a drug store that was providing non-dentist teeth whitening services (CX0058 at 001-002); a non-dentist teeth whitening business employing a mobile van to provide whitening services (CX0390 at 001-002 (WOW)); and a flower shop. (CX0042 at 001-002 (Holders)).

Response to Finding No. 284:

Respondent has no specific response.

285. Two of the 47 Cease and Desist Orders were sent to what appears to be home-based businesses. (CX0391 at 001-002 (The Extra Smile); CX0155 at 001-002 (Buena Vista Smiles)).

Response to Finding No. 285:

Respondent has no specific response.

6. The Content of the Cease and Desist Orders Are Clearly Orders

286. The 47 Cease and Desist Orders sent to non-dentist teeth whitening service providers were sent on the letterhead of the North Carolina State Board of Dental

Examiners. The letterhead also contains each Board members name, the Past President of the Board and the name of the Chief Operations Officer. (CX0038-001; CX0042 at 001-002, 005-007, 008-009, 010-011, 012-013, 014-015, 016-017, 018-019, 020-021, 022-023, 024-025, 026-027, 028-029, 030-031, 032-033, 034-035; CX0044 at 004-005; CX0050 at 002-003; CX0058 at 001-002; CX0059 at 001-002; CX0065 at 001-002; CX0068 at 001-002; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; CX0079 at 001-002; CX0094 at 005; CX0096 at 001-002; CX0097 at 001-002; CX0100 at 001-002; CX0112 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0351 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002).

Response to Finding No. 286:

Respondent has no specific response.

287. Most (42) of the Cease and Desist Orders sent to non-dentist teeth whiteners contain bold, capitalized headings that state: "NOTICE AND ORDER TO CEASE AND DESIST" or "NOTICE TO CEASE AND DESIST." (CX0038-001; CX0042 at 001-002, 005-007, 008-009, 010-011, 012-013, 014-015, 016-017, 018-019, 020-021, 022-023; 024 at 025, 026-027, 028-029, 030-031, 032-033; 034-035; CX0050 at 002-003; CX0058 at 001-002; CX0059 at 001-002; CX0065 at 001-002). "CEASE AND DESIST NOTICE." (CX0068 at 001-002; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; CX0079 at 001-002; CX0094 at 005; CX0096 at 001-002; CX0097 at 001-002; CX0100 at 001-002; CX0112 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0351 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002; Joint Stipulations of Law and Fact ¶ 30).

Response to Finding No. 287:

Respondent has no specific response.

288. In addition to the headings, the Cease and Desist Orders sent to 39 non-dentist teeth whitening service providers state:

You are hereby ordered to CEASE AND DESIST any and all activity constituting the practice of dentistry or dental hygiene as defined by North Carolina General Statutes § 90-29 and § 90-233 and the Dental Board Rules promulgated thereunder.

Specifically, G.S. 90-29(b) states that "A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:"

“(2) Removes stains, accretions or deposits from the human teeth;”

“(7) Takes or makes an impression of the human teeth, gums or jaws:”

“(10) Performs or engages in any of the clinical practices included in the curricula of recognized dental schools or colleges.” (CX0042 at 001-002, 005-007, 008-009, 010-011, 012-013, 014-015, 016-017, 018-019, 020-021, 022-023, 024-025, 026-027, 028-029, 030-031, 032-033, 034-035; CX0050 at 002-003; CX0058 at 001-002; CX0059 at 001-002; CX0068 at 001-002; CX0069 at 001-002; CX0077 at 001-002; CX0079 at 001-002; CX0094 at 005; CX0096 at 001-002; CX0097 at 001-002; CX0112 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0351 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002)

Response to Finding No. 288:

Respondent has no specific response.

289. Three of the Cease and Desist Orders contain a bold , capitalized heading that states: “NOTICE OF APPARENT VIOLATION AND DEMAND TO CEASE AND DESIST.” These three letters also state:

The Dental Board hereby demands that you CEASE AND DESIST any and all activity constituting the practice of dentistry as defined by North Carolina General Statutes § 90-29 and the Dental Board Rules promulgated thereunder.

Specifically, G.S. 90-29(b) states that “A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:”

“(2) Removes stains, accretions or deposits from the human teeth;”

“(7) Takes or makes an impression of the human teeth, gums or jaws:”

“(10) Performs or engages in any of the clinical practices included in the curricula of recognized dental schools or colleges.” (CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002).

Response to Finding No. 289:

Respondent has no specific response.

290. All 47 of the Cease and Desist Orders sent to non-dentist teeth whitening service providers were signed by the Board's Deputy Operations Officer Friddle, the Board's Attorney, or the Board's Assistant Director of Investigations. (CX0038-001; CX0042 at 001-002, 005-007, 008-009, 010-011, 012-013, 014-015, 016-017, 018-019, 020-021, 022-023, 024-025, 026-027, 028-029, 030-031, 032-033, 034-035; CX0044 at 004-005; CX0050 at 002-003; CX0058 at 001-002; CX0059 at 001-002; CX0065 at 001-002; CX0068 at 001-002; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; CX0079 at 001-002; CX0094 at 005; CX0096 at 001-002; CX0097 at 001-002; CX0100 at 001-002; CX0112 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0351 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002).

Response to Finding No. 290:

Respondent has no specific response.

291. 46 of the 47 Cease and Desist Orders sent to non-dentist teeth whitening service providers, indicate that the Case Officer and the Board's Attorney were copied on the Order. (CX0042 at 001-002, 005-007, 008-009, 010-011, 012-013, 014-015, 016-017, 018-019, 020-021, 022-023, 024-025, 026-027, 028-029, 030-031, 032-033, 034-035; CX0044 at 004-005; CX0050 at 002-003; CX0058 at 001-002; CX0059 at 001-002; CX0065 at 001-002; CX0068 at 001-002; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; CX0079 at 001-002; CX0094 at 005; CX0096 at 001-002; CX0097 at 001-002; CX0100 at 001-002; CX0112 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002; CX0272 at 001-002; CX0279 at 001-002; CX0351 at 001-002; CX0386 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002). Only the very first identified Cease and Desist Order, sent to Serenity Day Spa in Hendersonville, North Carolina dated January 11, 2006, does not indicate that the Case Officer and the Board's Attorney were copied on the Order. (CX0038 at 001).

Response to Finding No. 291:

Respondent has no specific response.

292. Cease and desist orders sent to non-dentist teeth whiteners were formally served either by return receipt mail (CX0042 at 001-002), by sheriff's service, (CX0095), by handdelivery by a private investigator (CX0094 at 005), or personal service by a Board investigator (CX0044 at 004-005).

Response to Finding No. 292:

Respondent has no specific response.

B. The Cease and Desist “Letters” Sent by the Board Were Intended to Be Orders

293. In its decision on the Motion for Partial Summary Decision, the Commission found as an undisputed fact that these letters were meant as and taken as Orders from the Board. State Action Opinion at 5.

Response to Finding No. 293:

Respondent disputes this proposed finding of fact as stating an opinion rather than fact.

1. Testimony of the Board Members and Staff Support That the Cease and Desist “Letters” Were Orders

294. Testimony of Board members and Board staff confirm that these Cease and Desist Orders were intended as orders from a state agency to stop teeth whitening activities. (CX0572 at 016 (Wester, Dep. at 57); CX0554 at 034 (Allen, Dep. at 126)).

Response to Finding No. 294:

Respondent disputes this proposed finding of fact. See its responses to PFOFs 295 and 296, *infra*, which more fully respond to the testimony cited by Complaint Counsel in support of this proposed finding of fact.

295. Dr. Wester testified that the Cease and Desist Order was a message that “they should stop” or “cease and desist” from engaging in teeth whitening activities. (CX0572 at 016 (Wester, Dep. at 57)).

Response to Finding No. 295:

Respondent disputes this proposed finding of fact. Dr. Wester also testified that this was based on his understanding as a layperson. (CX572 (Wester, Dep. at 57)).

296. Dr. Allen testified that he agreed that with a Cease and Desist Order, the “board [is] saying that you not only are ordered but you have the responsibility to comply with this order.” (CX0554 at 034 (Allen, Dep. at 126-127)).

Response to Finding No. 296:

Respondent disputes this proposed finding of fact. Complaint mischaracterizes by omission Dr. Allen's testimony cited in support of this proposed finding of fact. After initially agreeing with the question posed by Complaint Counsel, Dr. Allen continued his testimony as follows: "[I]n other words, the board has within its purview the right to – the board cannot in and of itself enforce that, but it is legally bound to on behalf of the people of North Carolina [to] apply the proper authorities to a situation like that with someone that's breaking the law." (CX554 (Allen, Dep. at 126)).

297. Dr. Allen further testified that a Cease and Desist Order from the Board is "an order in the same sense that the board as the State's designee to regulate the practice of dentistry and protect the public is – is telling you not to do this anymore I mean, the letter implies that if you continue to do it you'll either be fined or in prison if you continue." (CX0554 at 034 (Allen, Dep. at 127-128)).

Response to Finding No. 297:

Respondent disagrees with this proposed finding of fact as mischaracterization on the part of Complaint Counsel. Dr. Allen first responded to Complaint Counsel's question that the letter was both a warning and an order. "It's a warning in the sense that this is what's going to happen to you if you continue." (CX554 (Allen, Dep. at 127)).

298. Dr. Burnham believes that the Board sending a Cease and Desist Order to a non-dentist teeth whitener is "the same thing as filing a lawsuit." (RX0052 at 31 (Burnham, Dep. At 117-118)).

Response to Finding No. 298:

Respondent disputes this finding of fact; Complaint Counsel has blatantly mischaracterized the testimony cited in support of this proposed finding of fact. Dr. Burnham testified that "I would think that sending out a cease and desist letter would not be the same thing as filing a lawsuit." (RX52 (Burnham, Dep. at 117-118), emphasis added).

299. Wester testified that he treats a Cease and Desist Order sent by a case officer as essentially the same thing as an injunction or a court order, because the expected impact of a Cease and Desist Order is that the recipient will stop doing what the Board wants them to stop doing. (Wester, Tr. 1337-1338, 1352-1353).

Response to Finding No. 299:

Respondent disputes this proposed finding. Dr. Wester demonstrated in his testimony that he clearly did not have an understanding of the legal ramifications of a cease and desist letter and was not involved in the sending of any cease and desist order during his tenure as a case officer. (Wester, Tr. 1352).

300. Mr. White testified that a Cease and Desist Order issued by the Board is "ordering [the recipient] either to stop whatever activity is or to demonstrate why what they're doing is not a violation of the Act." (CX0573 at 007 (White, Dep. 19-20)).

Response to Finding No. 300:

Respondent disputes this finding of fact as an incomplete statement of fact. Mr. White's complete answer to Complaint Counsel's question was that the cease and desist letter was patterned after "a number of letters that [state that] the Board has [a] belief that the person receiving the letter has violated the Dental Practice Act." (CX573 (White, Dep. at 19)). The Board is not ordering them to stop that activity; the Board is instead requesting that they "either stop whatever activity is or to demonstrate why what they're doing is not a violation of the Act." (CX573 (White, Dep. at 19-20)).

301. Mr. White testified that he understands that in common parlance, "an order is viewed as a command to stop." (CX0573 at 010 (White, Dep. at 31)).

Response to Finding No. 301:

Respondent has no specific response.

2. **Contemporaneous Documents of the Board Members and Staff Support the Proposition That the Cease and Desist "Letters" Were Orders**

302. Contemporaneous e-mails, letters, and reports drafted by Board members and Board staff confirm that the documents sent were Cease and Desist Order. (CX0254 at 001; CX0258 at 001-002; CX0347 at 001).

Response to Finding No. 302:

Respondent disputes this proposed finding of fact. The evidence shows that Board members and Board staff have referred to these cease and desist letters alternately as both "letters" and "orders." (CX462 at 3-5; RX19 at 5; RX28 at 1). Further, in one of the exhibits used to support this proposed finding of fact by Complaint Counsel, both terms were used. (CX258 at 1).

303. On November 26, 2007, Board Investigator Line Dempsey wrote in an e-mail to Dr. Owens, Terry Friddle, Carolin Bakewell, Bobby White and Casie Goode, that he "was able to serve the Cease and Desist Order to Ms. Heather York" of Celebrity Smiles. The next day, on November 27, 2007, Ms. Carolin Bakewell wrote in an e-mail that the Board "has recently issued Cease and Desist Orders to an out of state company that has been providing bleaching services in a number of malls in the state." (CX0254 at 001).

Response to Finding No. 303:

Respondent disputes this proposed finding of fact. Complaint Counsel has cited no evidence in support of the first sentence of this proposed finding of fact. Respondent also disputes the inference that the two events recounted in this proposed finding of fact are related.

304. On January 18, 2007, Board Investigator Line Dempsey wrote that the Amazing Grace Spa was sent "a Cease and Desist Order." (CX0347 at 001).

Response to Finding No. 304:

Respondent disputes this proposed finding of fact. In the exhibit used to support this proposed finding of fact, Mr. Dempsey also referred to the letter as simply a "Cease and Desist." (CX347 at 1).

305. On January 17, 2008, Board Investigator Line Dempsey wrote in an Investigative Memo regarding a kiosk teeth whitening vendor that "Mr. Cogan explained that he had

not officially received a Cease & Desist Order. I explained that Mr. Nelson [the President of the company that manufactured Mr. Cogan's teeth whitening products] said that he had, and I was informing him verbally that he needed to cease and desist Before leaving, I explained, once again, that I was a representative of the North Carolina State Board of Dental Examiners and that he was practicing dentistry without a license and that he should cease and desist." (CX0258 at 001-002).

Response to Finding No. 305:

Respondent disputes this proposed finding of fact. In the exhibit used by Complaint Counsel to support this finding of fact, Mr. Dempsey also referred to the letter as a "Cease and Desist letter." (CX258 at 1).

306. On February 20, 2008, Mr. Bobby White wrote in an e-mail in response to a dentist's complaint, "We've sent out numerous Cease and Desist Orders throughout the state." (CX0404 at 001).

Response to Finding No. 306:

Respondent has no specific response.

307. Any claim by the Board that it was prepared to engage recipients of Cease and Desist Orders in a dialogue about non-dentist teeth whitening is contradicted by the Board's contemporaneous responses to requests to discuss the legal issues involved. (CX0098 at 001; CX0257 at 001; CX0370 at 001).

Response to Finding No. 307:

Respondent disputes this proposed finding. The exhibits cited by Complaint Counsel in support of this proposed finding of fact demonstrate willingness by Mr. White and Dr. Hardesty to entertain a request from Mr. Algis Augustine, Esq. to meet with the Board on March 4, 2008. (CX370 at 1). They also show that Board Counsel wrote to Mr. Augustine on March 10, 2008, and indicated a willingness to communicate with him provided that he "obtain a written opinion from the North Carolina State Bar, indicating that your participation does not constitute the unauthorized practice of law. Or, alternatively, if you retain North Carolina Counsel." (CX257 at 1). The last exhibit cited

by Complaint Counsel, CX98, is a letter dated April 18, 2008, in which Ms. Bakewell declines an in-person meeting by Mr. Augustine with the Board and alludes to “present circumstances.” There is testimony in the record that the “present circumstances” referred to by Ms. Bakewell was the initiation of the investigation of the Board by the Federal Trade Commission. (Hardesty, Tr. 2875-2877).

308. On April 18, 2008, Ms. Carolin Bakewell wrote a letter to Algis Augustine, Esq., declining to meet with a manufacturer, WhiteScience, because “the Board does not believe that an in person meeting would be productive.” (CX0098 at 001).

Response to Finding No. 308:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized Ms. Bakewell’s statement in her letter to Mr. Augustine. The entire sentence reads, “[u]nder the present circumstances, the Board does not believe that an in person meeting would be productive.” (CX98 at 1). There is testimony in the record that the “present circumstances” referred to by Ms. Bakewell was the initiation of the investigation of the Board by the Federal Trade Commission. (Hardesty, Tr. 2875-2877).

309. On March 10, 2008, Ms. Carolin Bakewell wrote a letter to Algis Augustine, Esq., of Chicago, Illinois declining to communicate with him regarding the interpretation of North Carolina law unless he or his client first obtained a written opinion of a North Carolina-licensed lawyer. (CX0257 at 001).

Response to Finding No. 309:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized the communication in the exhibit cited in support of this proposed finding of fact. Ms. Bakewell offered Mr. Augustine two alternatives if he wanted to communicate with the Board about this issue – “obtain a written opinion from the North Carolina State Bar, indicating that your participation does not constitute the unauthorized practice of law. Or, alternatively, if you retain North Carolina Counsel.” (CX257 at 1).

310. On March 4, 2008, Mr. Bobby White wrote an e-mail to Board Member Dr. Hardesty recommending that a meeting be held with a teeth whitening product manufacturer solely for appearance's sake to defeat a claim "that 'the Board would not listen to us' if they choose later to litigate." (CX0370 at 001).

Response to Finding No. 310:

Respondent disputes this finding of fact as Complaint Counsel mischaracterizes the exhibit that they offered in support of this proposed finding of fact. Nowhere in the email does Mr. White use the words "solely for appearance sake" or intimate that the meeting would be solely for this purpose. (CX370 at 1).

311. In an e-mail sent on February 12, 2008, Ms. Carolin Bakewell told Mr. Craig Francis, a student interested in opening a teeth whitening kiosk, that: "Pursuant to North Carolina law, the 'removal of stains, accretions or deposits' from human teeth constitutes the practice of dentistry. See N.C. Gen. Stat. 90-29(b)(2). That means that you may not operate a whitening kiosk except under the supervision of a licensed North Carolina dentist. . . . The prohibition remains the same even if the customer inserts the whitening tray themselves." (CX0523 at 001).

Response to Finding No. 311:

Respondent has no specific response.

3. Recipients of Cease and Desist Orders Understood Them to Be Orders to Stop Providing Teeth Whitening Services

312. Recipients of the Cease and Desist Orders also believed it was an order from a state agency to stop teeth whitening activities. For example, in a letter from Tonya Norwood, received by the Board on February 9, 2009, the owner of Modern Enhancement Salon stated that she would "no longer perform this service as per your order to stop and will no longer perform teeth whitening services unless told otherwise by the North Carolina Board of Dental Examiners." (CX0162 at 001).

Response to Finding No. 312:

Respondent disputes this proposed finding of fact as is contains an assumption that more than one recipient understood that the letter was an order from a state agency. Complaint Counsel only cites one instance in support of this proposed finding of fact.

313. On March 27, 2007, Ms. Pamela Weaver of the Amazing Grace Spa responded to a Cease and Desist Order from the Board (CX0347 at 001) by stating that she had received the order and “immediately removed it [teeth whitening machine] from the salon where I rent and have not used it since that time.” (CX0050 at 001).

Response to Finding No. 313:

Respondent disputes this proposed finding of fact as Complaint Counsel has mischaracterized its contents. Ms. Weaver stated in her letter that she had already stopped use of the BriteWhite teeth whitening machine prior to her receipt of the cease and desist letter. (CX50 at 1).

314. Mr. George Nelson of WhiteScience understood the Cease and Desist Orders sent by the Board as “ordering businesses to close. [The Board] issue[s] a cease and desist and they order [non-dentist teeth whitening operations] to close and not to continue in the teethwhitening business with no other discussion or options . . . I personally haven’t heard and been advised about any type of permitting or other type of option. I’ve only heard about ordering the close of the business.” (Nelson, Tr. 850).

Response to Finding No. 314:

Respondent disputes this proposed finding of fact. Mr. Nelson characterizes the Board’s cease and desist letters as ordering businesses to close with no other discussions or options. (Nelson, Tr. 850). To the contrary, the majority of the Board’s cease and desist letters invite the recipient to engage in further dialog with the Board by “submitting a written response to this notice and order within fifteen (15) days of the receipt of this letter.” (CX42 at 2; CX42 at 4; CX42 at 6; CX42 at 9; CX42 at 13; CX42 at 15; CX42 at 17; CX42 at 19; CX42 at 21; CX42 at 23; CX42 at 25; CX42 at 27; CX42 at 29; CX42 at 31; CX42 at 33; CX42 at 35; CX42 at 40).

D. The Board Takes Action Against Property Owners and Mall Operators

- 1. The Board Sent at Least Eleven Letters to Mall Operators Stating That Non-dentist Teeth Whitening Without Dentist Supervision Was Illegal**

315. On November 21, 2007, the Board sent at least 11 nearly identical letters to third parties, including mall management and out-of-state mall property management companies, stating that "the Board has learned that an out of state company has leased kiosks in a number of shopping malls in North Carolina for the purpose of offering teeth whitening services to the public." (CX0203 at 001-002; CX0204 at 001-002; CX0205 at 001-002; CX0259 at 001-002; CX0260 at 001-002; CX0261 at 001-002; CX0262 at 001-002; CX0263 at 001-002; CX0323 at 001-002; CX0324 at 001-002; CX0325 at 001-002; CX0326 at 001-002).

Response to Finding No. 315:

Respondent disputes this proposed finding of fact as a mischaracterization of the evidence cited in its support. The letter specifically states that "[t]he unauthorized practice of dentistry is a misdemeanor" and the lack of supervision of teeth whitening services by a licensed North Carolina dentist is illegal. (CX203 at 1; CX204 at 1; CX205 at 1; CX259 at 1; CX260 at 1; CX261 at 1; CX262 at 1; CX263 at 1; CX323 at 1; CX324 at 1; CX325 at 1; CX326 at 1).

316. The November 21, 2007 letters sent to mall management and out-of-state property management companies stated:

North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry. See N.C. Gen. Stat. 90-29(b)(2), a copy of which is enclosed. The unauthorized practice of dentistry is a misdemeanor. See N.C. Gen. Stat. 90-40, a copy of which is also enclosed. (CX0203 at 001-002; CX0204 at 001-002; CX0205 at 001-002; CX0259 at 001-002; CX0260 at 001-002; CX0261 at 001-002; CX0262 at 001-002; CX0263 at 001-002; CX0323 at 001-002; CX0324 at 001-002; CX0325 at 001-002; CX0326 at 001-002).

Response to Finding No. 316:

Respondent has no specific response.

317. The November 21, 2007 letters sent to mall management and out-of-state property management companies further stated:

It is our information that the teeth whitening services offered at these kiosks are not supervised by a licensed North Carolina dentist. Consequently, this activity is illegal. (Joint Stipulations of Law and Fact 31; CX0560 at 051 (Feingold, Dep. at 195-196); CX0203 at 001-002; CX0204 at 001-002; CX0205 at 001-002; CX0259 at 001-002; CX0260 at 001-002; CX0261 at 001-002; CX0262 at 001-002; CX0263 at 001-002; CX0323 at 001-002; CX0324 at 001-002; CX0325 at 001-002; CX0326 at 001-002).

Response to Finding No. 317:

Respondent has no specific response.

318. The Board unanimously voted to send the November 21, 2007 letters to mall operators, notifying them that non-dentist teeth whiteners operating in mall kiosks were violating the Dental Practice Act. (CX0565 at 054 (Hardesty, Dep. at 206-208)).

Response to Finding No. 318:

Respondent disputes this proposed finding of fact. There is nothing in Dr. Hardesty's testimony cited in support of this proposed finding of fact by Complaint Counsel that states that Board voted to send the letters to mall operators; Dr. Hardesty's testimony merely states that there were unanimous deliberations about sending out the letters to the malls. (CX565 (Hardesty, Dep. at 208)).

319. It was the Board's intention to send "quite a number" of letters to mall operators warning them that kiosk teeth whiteners were violating the Dental Practice Act by offering teeth whitening services. (CX0565 at 055 (Hardesty, Dep. at 210); CX0203 at 001)).

Response to Finding No. 319:

Respondent has no specific response.

320. There is nothing in the Board's letters to mall operators in November 2007 that would help them distinguish between lawful non-dentist teeth whitening and unlawful nondentist teeth whitening other than the fact that kiosk teeth whitening would be lawful if a 49 dentist was supervising. (CX0565 at 056 (Hardesty, Dep. at 215-216); CX0203 at 001-002).

Response to Finding No. 320:

Respondent disputes this proposed finding of fact. The last sentence invites the recipient to contact Board Counsel if the recipient had any questions; there is also reference to the applicable statutes. (CX565 (Hardesty, Dep. at 215-216); CX203 at 2).

2. One Purpose of the Board Letters to Mall Operators Was to Induce Mall Operators to Refuse to Rent Space to Non-dentist Teeth Whiteners

321. Ms. Bakewell suggested sending the letters to mall operators as a way of depriving nondentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services. (CX0581 at 067-071 (Bakewell, Dep. at 259-264, 266-277)).

Response to Finding No. 321:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized Ms. Bakewell's testimony. She testified as to the reasons why she wrote one particular letter in particular: One, to let the mall know that to the extent that the folks were performing teeth whitening services, the Board regarded that as a violation of the Dental Practice Act. (CX581 (Bakewell, Dep. at 262)). (The Board was getting feedback from people that the "tooth-operators were saying that they had approval from the Board to do this and of course that was not the case.) (CX581 (Bakewell, Dep. at 262)). Reason two was the Board wanted to make sure the mall people knew the Board's position in case the Board took action against a mall kiosk operator and the lease "went bad." (CX581 (Bakewell, Dep. at 262-263)). The third reason was to simply carry out the Board statutory duty to enforce the Dental Practice Act. (CX581 (Bakewell, Dep. at 263)).

322. In a letter dated January 23, 2008, Board counsel Carolin Bakewell informed Dr. Kyle Taylor - a dentist that had complained of teeth whitening in a kiosk in Carolina Place Mall - of the actions that the Board had taken in regard to teeth whitening in Carolina Place Mall. As proof of the Board's diligence, Ms. Bakewell enclosed a copy of the letter that the Board had sent to General Growth Properties - the company that owned

Carolina Place Mall - informing them that the Board viewed the teeth whitening services being performed in Carolina Place Mall as being illegal. (CX0102 at 001-003).

Response to Finding No. 322:

Respondent disputes this proposed finding of fact. There is no evidence in the record of Dr. Taylor reporting a teeth whitening kiosk in Carolina Place Mall to the Board. (Entire record).

323. In a letter dated January 23, 2008, Board counsel Carolin Bakewell informed Dr. Michael Catanese - a dentist that had complained of teeth whitening in a kiosk in Carolina Place Mall - of the actions that the Board had taken in regard to teeth whitening in Carolina Place Mall. As proof of the Board's diligence, Ms. Bakewell enclosed a copy of the letter that the Board had sent to General Growth Properties - the company that owned Carolina Place Mall - informing them that the Board viewed the teeth whitening services being performed in Carolina Place Mall as being illegal. (CX0524 at 001-003).

Response to Finding No. 323:

Respondent disputes this proposed finding of fact. There is no evidence in the record of Dr. Catanese reporting a teeth whitening kiosk in Carolina Place Mall to the Board. (Entire record).

324. Dr. Feingold confirms that the purpose of the November 21, 2007 letters sent by the Board to mall operators was to induce the malls to refuse to rent space to non-dental teeth whiteners. (CX0560 at 052 (Feingold, Dep. at 199-200)).

Response to Finding No. 324:

Respondent disputes this proposed finding of fact. This is a mischaracterization of Dr. Feingold's testimony. Dr. Feingold at first testified that he viewed the letters "as an incentive to not break the law." When pressed by Complaint Counsel whether he agreed that the purpose of the letters was to induce the malls to refuse to rent space to nondental tooth whiteners, Dr. Feingold replied "[t]o nondental tooth whiteners and anybody else who would be breaking the law." (CX560 (Feingold, Dep. at 199-200)).

325. Ms. Friddle testified that the Board sent the letters to malls and mall property management groups "in hopes of trying to prevent further expansion" with respect to non-dentist teeth whitening. (CX0562 at 019-020 (Friddle, IHT at 72, 75-76 ("So not to have them there"))).

Response to Finding No. 325:

Respondent disputes this proposed finding of fact as an incomplete statement of fact. Ms.

Friddle also testified that the letters were sent "just to let the owners of the malls know what we believed to be the practice of dentistry so they could be on the lookout for it and take whatever steps they deemed appropriate." (CX562 (Friddle, IHT at 72)).

326. The Board's purported objective of sending the November 2007 letters to mall management and out-of-state mall property management companies was to seek their assistance to ensure that the property they managed was not being used for improper activity that could create a risk to the public health or safety. (CX0203 at 001-002; CX0204 at 001-002; CX0205 at 001-002; CX0259 at 001-002; CX0260 at 001-002; CX0261 at 001-002; CX0262 at 001-002; CX0263 at 001-002; CX0323 at 001-002; CX0324 at 001-002; CX0325 at 001-002; CX0326 at 001-002; CX0581 at 066-068 (Bakewell Dep. at 259, 264)).

Response to Finding No. 326:

Respondent disputes this finding of fact as a mischaracterization of the Board's objective and an assumption, in particular the use of the term "purported."

327. Dr. Burnham is not aware of any instance of the Board contacting the owner of property where potential unlicensed practice of dentistry teeth whitening was taking place. (CX0556 at 046 (Burnham, Dep. at 177)).

Response to Finding No. 327:

Respondent disputes this proposed finding of fact as a misrepresentation of the record.

Dr. Burnham's testimony complete response to the question was – "Not to my knowledge. I don't know." (CX556 (Burnham, Dep. at 177)).

328. Dr. Burnham believes that the Board could not open an investigation or send warning letters to malls without first receiving a complaint. (CX0556 at 045-046 (Burnham, Dep. at 171, 174); CX0203 at 001-002).

Response to Finding No. 328:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

Dr. Burnham did testify that the Board could not open an investigation without a complaint; however, he did not testify that a complaint was necessary for a letter to be sent to a mall. (CX556 (Burnham, Dep. at 171, 174)).

329. Other than the November 21, 2007 letters sent by the Board to the mall operators regarding kiosk teeth whitening, Dr. Feingold cannot remember any instance where the Board contacted property owners to discourage leasing space to people engaged in certain businesses or practices. (CX0560 at 055 (Feingold, Dep. at 211); CX0203 at 001-002).

Response to Finding No. 329:

Respondent disputes this proposed finding of fact as mischaracterizing Dr. Feingold's testimony. Dr. Feingold's answer was that he did not remember any other instances of the Board contacting property owners, nor was he aware of the letters to the malls at the time, so he definitely did not know of other times that it might have happened. (CX560 (Feingold, Dep. at 211)).

3. The Board Letters to the Mall Operators Caused Mall Operators to Refuse to Rent Space to Non-dentist Teeth Whiteners

330. As a direct result of the Board's November 21, 2007 letters to mall companies, mall management companies, and malls, mall operators were reluctant to lease space to nondentist teeth whitening service providers in North Carolina. In fact, some companies refused to lease space and cancelled existing leases. (Wyant, Tr. 876-884; Gibson, Tr. 627-628, 632-633; CX0255 at 001; CX0525 at 001; CX0629 at 001-002; CX0647 at 002).

Response to Finding No. 330:

Respondent disputes this proposed finding of fact as an incomplete finding of fact and misrepresentation of the record. The exhibits cited by Complaint Counsel in support of

this proposed finding of fact also show that malls whose management companies received the November 21, 2007 letters had teeth whitening kiosks as tenants as of August 28, 2009 and September 27, 2010. (CX629 at 3; CX647 at 2).

i. Hull Story Gibson Companies

331. Mr. John Gibson is a partner and Chief Operating Officer of Hull Storey Gibson Companies, L.L.C. ("HSG"). HSG is a retail property management company that owns 11.5 million square feet of retail space in seven states, including North Carolina. Mr. Gibson became the COO of HSG in 1999. (Gibson, Tr. 613, 615).

Response to Finding No. 331:

Respondent has no specific response.

332. Cathy Mosley is the Specialty Leasing Manager & Leasing Representative. She reports to John Gibson indirectly through the Vice President for Leasing; however, because Mr. Gibson signs all leases, he has frequent direct contact with her. (Gibson, Tr. 616).

Response to Finding No. 332:

Respondent has not specific response.

333. HSG operates five malls in North Carolina, including the Blue Ridge Mall in Hendersonville, North Carolina; the Cleveland Mall in Shelby, North Carolina; The Carolina Mall in Concord, North Carolina; the New Bern Mall in New Bern, North Carolina, and the Wilson Mall in Wilson, North Carolina. (Gibson, Tr. 613-614).

Response to Finding No. 333:

Respondent has no specific response.

334. HSG had a successful non-dentist teeth whitening event at its Lake City Mall. (Gibson, Tr. 624-625).

Response to Finding No. 334:

Respondent disputes this proposed finding of fact. The testimony cited by Complaint Counsel in support of this proposed finding states that an event was held; there is no cited testimony as to the success of the event. (Gibson, Tr. 624-625).

335. HSG's Blue Ridge Mall received a letter dated November 21, 2007, "Re: Tooth Whitening Kiosks," that was brought to Mr. Gibson's attention by Cathy Mosley. HSG's Cleveland Mall received a virtually identical letter. (Gibson, Tr. 626-627; CX0203 at 001-002; CX0259 at 001-002).

Response to Finding No. 335:

Respondent has no specific response.

336. The letters received by HSG advised HSG that:

North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry. See N.C. Gen. Stat. 90-29(b)(2), a copy of which is enclosed. The unauthorized practice of dentistry is a misdemeanor. See N.C. Gen. Stat. 90-40, a copy of which is also enclosed.

It is our information that the teeth whitening services offered at these kiosks are not supervised by a licensed North Carolina dentist. Consequently, this activity is illegal.

The Dental Board would be most grateful if your company would assist us in ensuring that property owned or managed by your company is not being used for improper activity that could create a risk to the public health and safety.

Mr. Gibson understood from these letters that the Board took the position that non-dentist teeth whitening would be a violation of North Carolina law. (Gibson, Tr. 629; CX0203 at 001-002; CX0259 at 001-002).

Response to Finding No. 336:

Respondent disputes this proposed finding of fact as a mischaracterization of Mr.

Gibson's testimony. Mr. Gibson testified that he understood "that the person who would be operating the kiosks and providing the service [emphasis added] would be doing so in violation of the law. That's what I certainly understood." (Gibson, Tr. 629).

337. On March 21, 2008, Lisa Schaak sent an e-mail to Cathy Mosley indicating that Mr. Craig wanted to talk to Ms. Mosley about space for teeth whitening. On March 21, 2008, Ms. Mosley replied to Ms. Schaak stating "Mr. Craig will need to provide us with proof that the Board of Dental Examiners will approve this." (CX0255 at 001-002).

Response to Finding No. 337:

Respondent disputes this finding of fact as an incomplete statement of fact. The evidence cited by Complaint Counsel in support of this proposed finding of fact shows that Ms. Moseley, who had received “feedback from several Developers letting me know that this use is illegal in several states and that their operators have been shut down in their malls,” wanted to verify Mr. Craig’s claim to Lisa Schaack that North Carolina’s Board had observed his procedure and had no issues with it. (CX255 at 1-2; Gibson, Tr. 637).

338. Ms. Mosley brought the mall letter (CX0203 at 001-002) to Mr. Gibson's attention because she had been told that a prospective kiosk tenant insisted that the Board had approved its teeth whitening procedure. (Gibson, Tr. 627-631; CX0525 at 001).

Response to Finding No. 338:

Respondent has no specific response.

339. On March 21, 2008, Ms. Mosley e-mailed Ms. Bakewell to confirm representations that she had received from BleachBright of Carolina to the effect that its teeth bleaching process had been approved by the Board. (Gibson, Tr. 629-631; CX0525 at 001).

Response to Finding No. 339:

Respondent has no specific response.

340. Ms. Bakewell's March 24, 2008, response to Ms. Mosley's inquiry "confirmed . . . to her that it was illegal" for a lay person to operate a teeth-bleaching facility in North Carolina. (Gibson, Tr. 631-632; CX0525 at 001).

Response to Finding No. 340:

Respondent disputes this proposed finding of fact as mischaracterization of Ms.

Bakewell’s response to Ms. Mosley’s inquiry. In her March 24, 2008 response, Ms.

Bakewell stated that the Board “has not issued any sort of blanket approval for the

operation of teeth whitening kiosks by BleachBright.” (CX525 at 1). Mr. Gibson also

testified that Ms. Bakewell's March 24, 2008 response did not communicate to Ms.

Mosley about the illegality of non-dentist teeth whitening activities. (Gibson, Tr. 643).

341. HSG would have leased retail space to non-dentist teeth whiteners in North Carolina but for its receipt of the Board's letter to the mall operators and Ms. Bakewell's e-mail to Ms. Mosley. (Gibson, Tr. 622-623, 632-633).

Response to Finding No. 341:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and a mischaracterization of Mr. Gibson's testimony. Mr. Gibson also testified that HSG would have provided leasing space to other non-dentist providers of teeth-bleaching products and services "[s]o long as they were lawful." (Gibson, Tr. 633). He also testified that he would not object to leasing space to a kiosk that sold over-the-counter teeth whitening products. (Gibson, Tr. 633-634).

342. HSG would be willing to rent in-line or specialty space in its North Carolina malls today, if the Board withdrew its letters to HSG. (Gibson, Tr. 624).

Response to Finding No. 342:

Respondent disputes this proposed statement of fact as it is an incomplete statement of fact and mischaracterizes Mr. Gibson's testimony. Mr. Gibson also testified that HSG would have provided leasing space to other non-dentist providers of teeth-bleaching products and services "[s]o long as they were lawful." (Gibson, Tr. 633). He also testified that he would not object to leasing space to a kiosk that sold over-the-counter teeth whitening products. (Gibson, Tr. 633-634).

343. Ms. Mosley continued to receive inquiries from non-dentist teeth whiteners, but she declined to consider leasing space to them. (Gibson, Tr. 633).

Response to Finding No. 343:

Respondent has no specific response.

ii. General Growth Properties and Simon Group Properties

344. Angela Wyant had a license agreement for a kiosk for her WhiteScience teeth whitening business at Carolina Place Mall, which was owned or managed by General Growth Properties, Inc. (CX0665 at 001-011).

Response to Finding No. 344:

Respondent has no specific response.

345. Ms. Angela Wyant signed a license agreement for kiosk space in Carolina Place Mall with General Growth Properties, owner of the mall, on December 7, 2008. Mr. Brian Wyant wrote a note to himself that the lease was signed, and that the business - a nondental teeth whitening kiosk using the WhiteScience system - opened December 7, 2008. (CX0664 at 001; CX0665 at 001-011).

Response to Finding No. 345:

Respondent has no specific response.

346. In late January 2008, General Growth Properties' leasing agent informed Mr. Wyant that his licensing agreement would not be renewed and that his teeth whitening business would have to leave Carolina Place Mall by February 1, 2008. Wyant was told that the North Carolina State Board of Dental Examiners had sent a letter stating that the business was the illegal practice of dentistry. In a subsequent meeting with Carolina Place Mall General Manager Michael Payton, Wyant was shown the Board's letter to General Growth Properties and was told that it meant Wyant would have to close his business in Carolina Place Mall. Despite Wyant's protests and arguments, Payton insisted that Wyant would have to leave Carolina Place Mall at the end of the month. (Wyant, Tr. 874-880, 884, 902-903; CX0629 at 001-003).

Response to Finding No. 346:

Respondent disputes this proposed finding of fact as it contains an assumption and an incomplete statement of fact. Mr. Wyant testified that he was under a month-to-month licensing agreement at Carolina Place Mall. (Wyant, Tr. 872). Mr. Wyant also acknowledged that, under the licensing agreement's terms, it could be revoked at will or without cause. (Wyant, Tr. 900).

347. On January 28, 2008, Mr. Wyant called Concord Mills Mall in Concord, North Carolina, a Simon Group Properties Mall, to inquire about the possibilities of locating his business there. Wyant was told by Ms. Christy Sparks that the Concord Mills Mall would not rent to non-dentist teeth whiteners due to the North Carolina State Board of Dental Examiners. Wyant also contacted SouthPark Mall, another Simon mall, about relocating his business there, and was told by Ada Nosowicz that no Simon mall would rent to him. (Wyant, Tr. 881-884; CX0629 at 001-003).

Response to Finding No. 347:

Respondent has no specific response.

iii. Southpoint Mall Referred Prospective Non-dentist Teeth Whiteners to the Board

348. On February 11, 2008, Craig Francis e-mailed Bobby White at the Board inquiring about what approvals he would need from the Board to lawfully open up a teeth whitening kiosk. Mr. Francis was intending to sell the BleachBright teeth whitening system, but the leasing office at Southpoint Mall stated he needed to contact the Board about the "laws associated with the kiosk." (CX0542 at 001).

Response to Finding No. 348:

Respondent has no specific response.

349. On February 12, 2008, Board counsel Carolin Bakewell responded to an e-mail from Craig Francis inquiring about what he needed to do in order to lawfully operate a mall whitening kiosk. Ms. Carolin informed Mr. Francis he "may not operate a whitening kiosk except under the direct supervision of a licensed North Carolina dentist. The prohibition remains the same even if the customer inserts the whitening tray themselves." (CX0523 at 001).

Response to Finding No. 349:

Respondent has no specific response.

350. In an e-mail dated February 13, 2008, Ms. Alissa Neal inquired to Line Dempsey "about the teeth whitening businesses that are growing in malls and salons in our area." Ms. Neal related that someone employed at The Streets at Southpoint Mall had informed her that a teeth whitening business at that location had been "shut down very quickly" by the Board. (CX0354 at 001).

Response to Finding No. 350:

Respondent disputes this proposed finding of fact as it contains an assumption. Ms. Neal does not state in her email that she had an interest in opening a teeth whitening business at the Streets of South Point Mall. (CX354 at 1).

E. The Board and the North Carolina Board of Cosmetic Art Examiners

351. In February 2008, the Board asked the North Carolina Board of Cosmetic Art Examiners ("Cosmetology Board") to post a statement that cautioned their licensees about performing certain teeth whitening procedures because they violated the Dental Practice Act. The Board targeted salons because of the influx of non-dentist teeth whitening procedures being offered in those locations. (CX0566 at 030 (Hardesty, IHT at 115-116); CX0056 at 005).

Response to Finding No. 351:

Respondent disputes this finding of fact in that it contains a mischaracterization of testimony. The portion of Dr. Hardesty's testimony used by Complaint Counsel in support of this fact as to the "influx of non-dentist teeth whitening procedures" is posited as a "guess." Further, Board Counsel testified that contact was made with the Cosmetology Board because of "tearful calls" that the Board was receiving from "young ladies who had purchased expensive equipment and found upon investigating the matter further that they probably wouldn't be allowed to use it, and they – some of them were very angry about the way they had been treated by the distributors." (RX50 (Bakewell, Dep. at 307)).

352. Ms. Friddle testified that the Board contacted the Cosmetology Board and wrote an article for that Board, because a number of people contacted the Board stating that they understood that it was legal for licensees of the Cosmetology Board to provide teeth whitening services. (CX0561 at 032 (Friddle, Dep. at 119-120)).

Response to Finding No. 352:

Respondent disputes this proposed finding of fact as a mischaracterization of Ms.

Friddle's testimony. Ms. Friddle actually testified that Ms. Bakewell wrote an article for

the Cosmetology Board individuals who were offering teeth whitening in spas and salons indicated to the Board that they were told by the manufacturer that it was “perfectly fine for me to do this.” (CX561 (Friddle, Dep. at 120)). Ms. Friddle further testified that the letters were informational; “the Board felt that it might be helpful if we let their licensees know that our office considered it the illegal practice of dentistry depending, of course, on the specifics of what they were doing.” (CX561 (Friddle, Dep. at 120)).

353. Dr. Hardesty instructed Board attorney Carolin Bakewell to prepare an article for the Cosmetology Board to post on its website regarding teeth whitening after discussing the issue with the other Board members at a Board meeting. (Hardesty, Tr. 2861-2862).

Response to Finding No. 353:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and as containing an assumption. Dr. Hardesty testified that the decision to prepare an article for the Cosmetology Board was undertaken in a closed session of a Board meeting where the Board consulted with legal counsel. (CX565 (Hardesty, Dep. at 238-239)).

354. Ms. Bakewell conceived the idea of inserting a warning message in the Cosmetology Board's newsletter. (CX0067 at 001, 003 (text of newsletter article transmitted to the Cosmetology Board by Bakewell's e-mail of February 7, 2007)). The text of article stated that teeth whitening by non-dentists was a crime in North Carolina. The text of the draft would have been reviewed by at least Mr. White before it was sent out. (CX0581 at 079-081 (Bakewell, Dep. at 308-310, 311-316)).

Response to Finding No. 354:

Respondent disputes this proposed finding of fact as containing a mischaracterization of the record. Contrary to Complaint Counsel's assertions, the text of the article stated that “[t]he unlicensed practice of dentistry in our state is a misdemeanor.” (CX67 at 3).

355. The Board contacted the Cosmetology Board about the subject of non-dentist teeth whitening services and provided that Board with a notice in February 2007 that stated:

Cosmetologists should be aware that any device or process that "removes stains, accretions or deposits from the human teeth" constitutes the practice of dentistry as defined by North Carolina General Statutes 90-29(b)(2). Taking impressions for bleaching trays also constitutes the practice of dentistry as defined by North Carolina General Statutes 90-29(b)(7).

Only a licensed dentist or dental hygienist acting under the supervision of a licensed dentist may provide these services. The unlicensed practice of dentistry in our state is a misdemeanor." (Joint Stipulations of Law and Fact 33).

Response to Finding No. 355:

Respondent disputes this finding of fact as an incomplete statement of fact. The notice concluded with the following sentence: "Anyone with questions about who can provide teeth whitening and bleaching services may call the N.C. State Board of Dental Examiners at 919-678-8223." (CX67 at 3).

356. Ms. Bakewell is not credible with her testimony that the terms of the teeth whitening article published in the Cosmetology Board newsletter clearly distinguished the illegal provision of teeth whitening services from the lawful sale of teeth whitening products, and that her use of the word "device" clearly connoted a distinction between products and services (CX0581 at 081 (Bakewell Dep. at 314-315)). First, it is self-serving; and second, it contradicts the plain meaning of the words used in the article, and the common meaning of the word "device"- "a piece of equipment or a mechanism designed to serve a special purpose or perform a special function," such as teeth whitening. MERRIAMWEBSTER'S COLLEGIATE DICTIONARY 316 (10th ed. 2002). The article in the Cosmetology Board's newsletter read in relevant part, "Cosmetologists should be aware that any device or process that '[r]emoves stains, accretions or deposits from human teeth' constitutes the practice of dentistry. . . . Only a licensed dentist or dental hygienist acting under the supervision of a licensed dentist may provide these services. The unlicensed practice of dentistry in our state is a misdemeanor." (CX0067 at 003 (emphasis added)).

Response to Finding No. 356:

Respondent disputes this proposed finding of fact because it contains an assumption and it is an opinion – not a fact – as to Ms. Bakewell's credibility, and there is no basis in the record. Ms. Bakewell testified that if read in its entirety, the article conveys to the reader that "the thing that we're talking about, the prohibition, is on provision of services."

(CX581 (Bakewell, Dep. at 315)). Ms. Bakewell further testified that she never received a call from anyone saying that the article was unclear. (CX581 (Bakewell, Dep. at 315)).

357. The Cosmetology Board also informed cosmetologists that they were not permitted to practice teeth whitening because of the Board's position. (CX0050 at 001 (letter from Ms. Pamela Weaver, dated March 27, 2007: I "found out . . . that it was not legal to use [teeth whitening machine] from the state board of cosmetology and immediately removed it from the salon where I rent and have not used it since that time"); CX0347 (January 16, 2007 e-mail from Mr. Line Dempsey to Board members confirming that he made an onsite visit to confirm that Weaver no longer offered teeth whitening services)).

Response to Finding No. 357:

Respondent disputes this proposed finding of fact as a mischaracterization of the exhibit cited in support by Complaint Counsel. Ms. Weaver's letter states that she "found out" from the Cosmetology Board about the legality of her use of the teeth whitening equipment. (CX50 at 1). She does not provide any details about how she "found out," so there is an assumption on the part of Complaint Counsel that she was personally "informed" by the Cosmetology Board. (CX50 at 1).

358. Dr. Hardesty came up with the idea for Board counsel to send a letter asking the Cosmetology Board to post an article about teeth whitening. Dr. Hardesty came to the realization that many of the non-dentist teeth whitening complaints were against salons and spas regulated by the Cosmetology Board. (CX0565 at 060-061 (Hardesty, Dep. at 231-233, 236); CX0067 at 003)).

Response to Finding No. 358:

Respondent has no specific response.

359. The Board approved the sending of the letter to the Cosmetology Board regarding unlicensed teeth whitening by consensus after five minutes' discussion with Board counsel. (CX0565 at 062 (Hardesty, Dep. at 238-240)).

Response to Finding No. 359:

Respondent has no specific response.

F. The Board's Interaction with Manufacturers and Suppliers of Teeth Whitening Materials

360. The Board communicated to out-of-state manufacturers and distributors of teeth whitening products and equipment that the provision of teeth whitening services is illegal in North Carolina. (CX0100 at 001; CX0122 at 001; Nelson, Tr. 850; CX0371 at 001; CX0110 at 001; CX0066 at 001).

Response to Finding No. 360:

Respondent disputes this proposed finding of fact as mischaracterizing the evidence cited in support thereof by Complaint Counsel. Exhibits CX100, CX110, and CX371 state that engaging in the unauthorized practice of dentistry is a misdemeanor. (CX100 at 1; CX110 at 1; CX371 at 1). Exhibit CX66 states that it is improper for anyone other than a dentist or trained individual under dentist supervision to assist patient with the removal of stains or accretions from their teeth. (CX66 at 1). Exhibit CX122 states that practicing dentistry without a license in North Carolina is a crime. (CX122 at 1).

1. The Board Sent Cease and Desist Orders and Letters Advising Manufacturers That It Regarded Non-dentist Teeth Whitening to Be Illegal

361. The Board sent Cease and Desist Orders to manufacturers of teeth whitening products used by non-dentist teeth whiteners in North Carolina. (CX0100 at 001 (December 4, 2007, Cease and Desist Order to WhiteScience, Roswell, GA); CX0122 at 001-002 (October 7, 2008, Cease and Desist Order to Florida White Smile in Orlando, FL)).

Response to Finding No. 361:

Respondent disputes this proposed finding of fact as a misrepresentation of the contents of the exhibits cited in support of it by Complaint Counsel. Exhibit CX100 is a cease and desist notice; the word "order" does not appear anywhere in the letter. (CX100 at 1).

Regarding the second instance cited by Complaint Counsel, the Board was in receipt of

complaint that the company was performing teeth whitening services at a Sams Club in Southern Pines, North Carolina, and sent a cease and desist letter. (CX361 at 3).

362. George Nelson of WhiteScience understood the Cease and Desist Orders sent by the Board as "ordering businesses to close. [The Board] issue[s] a cease and desist and they order [non-dentist teeth whitening operations] to close and not to continue on the teeth whitening business with no other discussion or options . . . I personally haven't heard and been advised about any type of permitting or other type of option. I've only heard about ordering the closing of the business." (Nelson, Tr. 850).

Response to Finding No. 362:

Respondent disputes this proposed finding of fact. Mr. Nelson characterizes the Board's cease and desist letters as ordering businesses to close with no other discussions or options. (Nelson, Tr. 850). To the contrary, the majority of the Board's cease and desist letters invite the recipient to engage in further dialog with the Board by "submitting a written response to this notice and order within fifteen (15) days of the receipt of this letter." (CX42 at 2; CX42 at 4; CX42 at 6; CX42 at 9; CX42 at 13; CX42 at 15; CX42 at 17; CX42 at 19; CX42 at 21; CX42 at 23; CX42 at 25; CX42 at 27; CX42 at 29; CX42 at 31; CX42 at 33; CX42 at 35; CX42 at 40).

363. On February 13, 2007, Ms. Bakewell wrote Enhanced Light Technologies regarding its present and future sales of non-dental teeth whitening systems in North Carolina. On behalf of the Board, Ms. Bakewell represented to the company that those who purchased and provided its systems to the public may be practicing unlicensed dentistry, and that Enhanced Light Technologies should "accurately inform current and potential customers of the limitations on the provision of teeth whitening services in North Carolina." (CX0371 at 001).

Response to Finding No. 363:

Respondent disputes this proposed finding of fact as mischaracterizing the contents of Ms. Bakewell's letter. Ms. Bakewell actually wrote that the "individuals who use your products to provide teeth whitening services to the public may be engaging in the unauthorized practice of dentistry." (CX371 at 1, emphasis added).

364. On February 13, 2007, Ms. Bakewell wrote WhiteScience, a company in Roswell, GA, regarding its present and future sales of non-dental teeth whitening systems in North Carolina. On behalf of the Board, Ms. Bakewell represented to WhiteScience that those who purchased and provided WhiteScience's systems to the public may be practicing unlicensed dentistry, and that WhiteScience should "accurately inform current and potential customers of the limitations on the provision of teeth whitening services in North Carolina." (CX0110 at 001).

Response to Finding No. 364:

Respondent disputes this proposed finding of fact as mischaracterizing the contents of Ms. Bakewell's letter. Ms. Bakewell actually wrote that the "individuals who use your products to provide teeth whitening services to the public may be engaging in the unauthorized practice of dentistry." (CX110 at 1, emphasis added).

2. The Board Counsel's Communications to Manufacturers Discouraged Teeth Whitening Manufacturers from Operating in North Carolina

365. On May 9, 2007, Ms. Bakewell replied to a letter sent by Mr. Frank Recker on April 26, 2007. Ms. Bakewell informed Mr. Recker that non-dentists may not apply bleaching gels or similar materials to a customer's teeth or use curing lights, which all are tantamount to the practice of dentistry according to North Carolina statute. (CX0101 at 001).

Response to Finding No. 365:

Respondent disputes this finding of fact as a mischaracterization of the content of Ms. Bakewell's letter. The procedures that Ms. Bakewell mentioned were mentioned in the context of being included in the prohibition against a non-dentist assisting in the removal of stains, accretions or deposits from the teeth of other humans found in N.C. Gen. Stat. § 90-29. (CX101 at 1).

366. On July 24, 2007, Mr. Frank Recker replied to Ms. Bakewell's May 9, 2007 letter regarding his client, Whitescience. Mr. Recker stressed that his client, and subsequently his client's vendors, sold the non-dental teeth whitening system as a product and not a service, and that the consumer completely self-administered the product. Third-party verbal support by a given vendor was the most involved a provider might become in the whitening process. Mr. Recker sought Ms. Bakewell's concurrence that the

abovedescribed practices did not violate North Carolina General Statute 90-29. (CX108 at 001-002).

Response to Finding No. 366:

Respondent disputes this proposed finding of fact as a misrepresentation and incomplete statement of Mr. Recker's communication with Ms. Bakewell. The material attached to Mr. Recker's July 24, 2007 reply belies his representation that WhiteScience, at least as offered in a spa or salon setting, is a completely self-administered product. The application instructions include the following assistance services that the "vendor" is to provide to the consumer: explain possible side effects, place a bib around the client's neck, determine the client's tooth shade, fill mouthpiece with whitening gel, spray Photo Initiator into trays, provide protective eyewear, adjust whitening light, check and start timer, and provide post-treatment instructions. (CX108 at 10-12).

367. In a letter dated December 4, 2007, Ms. Bakewell sent a Cease and Desist Order to WhiteScience, a manufacturer of teeth whitening kits, and threatened to sue WhiteScience for offering teeth whitening services to the public in spite having received multiple representations from WhiteScience's counsel that it was not engaged in or offering teeth whitening services to the public; it was only selling teeth whitening kits to non-dentist teeth whiteners, and in spite of her claims that the Board was not interested in people who were only selling teeth whitening products. (CX0100 at 001; CX0581 at 071-073 (Bakewell, Dep. at 277-281, 283-285)).

Response to Finding No. 367:

Respondent disputes this proposed finding of fact in that it provides an incomplete statement and a misrepresentation of the record. As more fully stated above in the response to Finding 367, the material attached to Mr. Recker's July 24, 2007 reply belies his representation that WhiteScience, at least as offered in a spa or salon setting, is a completely self-administered product. (CX108 at 10-12). Ms. Bakewell's letter of

December 4, 2007, also indicates that WhiteScience "vendors" were "assisting clients to accelerate the whitening process with an LED light." (CX100 at 1).

368. In a letter dated December 27, 2007, Board counsel Ms. Bakewell informed Algis Augustine, counsel for WhiteScience, that the Board had "never taken the position that the sale or distribution of the WhiteScience kits constitutes the impermissible practice of dentistry." Ms. Bakewell informed Mr. Augustine that it was impermissible for an unsupervised non-dentist to remove stains and accretions from teeth, which "includes the provision of instructions and assistance, bleaching trays, bleaching solution, and the use of an LED light by" non-dentists. (CX0066 at 001).

Response to Finding No. 368:

Respondent has no specific response.

369. In a letter dated January 24, 2008, Algis Augustine wrote Board counsel Carolin Bakewell asking for an explanation for what "assisting" people to remove stains or accretions meant. (CX0099 at 001).

Response to Finding No. 369:

Respondent disputes this finding of fact as a mischaracterization of Mr. Augustine's letter. Although Mr. Augustine stated that an answer to this question would allow "us to reach an accord," his letter did not request an explanation. (CX99 at 1).

370. In a letter dated February 27, 2008, to Board counsel Carolin Bakewell, Algis Augustine reiterated his request that the Board meet with himself and his client, WhiteScience, to resolve the issues between the Board and WhiteScience. Mr. Augustine wrote that Ms. Bakewell had not responded to Mr. Augustine's last letter requesting a meeting. (CX0521 at 001).

Response to Finding No. 370:

Respondent disputes this proposed find of fact as containing an assumption and an incomplete statement of fact. Mr. Augustine did not request a meeting in the material that was received by the Board on January 29, 2008. (CX99 at 1-2).

371. In a letter dated March 10, 2008, Board counsel Carolin Bakewell informed Algis Augustine, counsel for Joe Willet and BleachBright, that the Board would not communicate with him regarding its interpretation of the Dental Practice Act unless he hired North Carolina counsel or obtained a written opinion from the North Carolina State

Bar that Mr. Augustine's participation in a discussion about the Dental Practice Act does not constitute the unauthorized practice of law. (CX0257 at 001).

Response to Finding No. 371:

Respondent has no specific response.

372. In an April 18, 2008, letter Carolin Bakewell informed Algis Augustine that "the Board does not believe that an in person meeting would be productive." (CX0098 at 001).

Response to Finding No. 372:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized Ms. Bakewell's statement in her letter to Mr. Augustine. The entire sentence reads, "[u]nder the present circumstances, the Board does not believe that an in person meeting would be productive." (CX98 at1). There is testimony in the record that the "present circumstances" referred to by Ms. Bakewell was the initiation of the investigation of the Board by the Federal Trade Commission. (Hardesty, Tr. 2875-2877).

373. Ms. Bakewell recommended to the Dental Board that it not meet with a lawyer for WhiteScience, Mr. Augustine from Illinois, because he was not licensed to practice law in North Carolina, "had not taken steps to be admitted pro hac vice," and wanted to discuss with the Board the interpretation of a North Carolina statute - "that constitutes the unauthorized practice of law." She further indicated that he could have asked for a declaratory ruling but did not attempt to reconcile that statement with her earlier unlicensed-practice-of-law claim, or the Board's written policy regarding non-dentist teeth whitening that it could not give legal opinions regarding the legality of particular methods of teeth whitening. (CX0475 at 001; CX0581 at 024 (Bakewell, Dep. at 87-88)).

Response to Finding No. 373:

Respondent disputes this proposed finding of fact as a mischaracterization of Ms. Bakewell's testimony. Ms. Bakewell testified that she did not remember making such a recommendation to the Board. (CX475 (Bakewell, Dep. at 88)). This proposed finding of fact also contains an assumption of a fact not in evidence in regard to her failure to reconcile her statement.

374. In a fax dated November 20, 2006, Joyce Osborn, President of BriteWhite Teeth Whitening system, wrote to Board counsel Carolin Bakewell regarding the communication Ms. Bakewell had with Mr. Tickle of Signature Spas of Hickory. Ms. Osborn assured Ms. Bakewell that the BriteWhite System did not constitute the practice of dentistry because there was no touching of the customer's mouth, and that the BriteWhite System was very safe. Ms. Osborn stated that she would be willing to give a demonstration of the system, send a training manual, or answer any other questions Ms. Bakewell had. (CX0052 at 005-007).

Response to Finding No. 374:

Respondent disputes this proposed finding of fact as an expression of an opinion by Ms. Osborn – not fact – in regards to the BriteWhite System not constituting the practice of dentistry because there was not touching of the customer's mouth and because the system was "very safe." (CX52 at 5).

375. In a series of e-mails sent May 13 and 14, 2007, between Joyce Osborn and Carolin Bakewell, Ms. Osborn reiterated the steps that she had taken to bring the BriteWhite Teeth Whitening System into compliance with North Carolina law as she understood it, and asked Ms. Bakewell whether the Board was going to notify her about whether those steps were sufficient. Ms. Bakewell informed Ms. Osborn that the Board did not intend on making any ruling on BriteWhite's modified system because the Board was waiting for the outcome of its case against a salon for using the BriteWhite system. (CX0047 at 035-038).

Response to Finding No. 375:

Respondent has no specific response.

██████████ Board Has No Authority to Send Letters to Manufacturers

376. Dr. Hardesty was not able to identify any provision in the Dental Practice Act, or any other specific provision of law, that makes "aiding and abetting" the unlicensed practice of dentistry unlawful. (CX0565 at 057 (Hardesty, Dep. at 219); CX0019 at 001-002 (Dental Practice Act § 90-22(b)); CX0100 at 001).

Response to Finding No. 376:

Respondent disputes this proposed finding of fact as containing an assumption that Dr. Hardesty was fully aware of the meaning of "aiding and abetting" as a term of art.

377. As a result of the Board's communications, manufacturers of teeth whitening products used by non-dentist teeth whiteners have not been able to create or maintain a distribution network for their products in North Carolina or the facilities within which such distribution might be accomplished. (Nelson, Tr. 735-736, 775-776, 778, 785-787; CX0814 at 001; CX0389 at 001; Valentine, Tr. 563-564, 575; Osborn, Tr. 671-675).

Response to Finding No. 377:

Respondent disputes this proposed finding of fact as it contains an assumption and conclusion of law (“as a result of the Board’s communications.”) In addition Respondent disputes this proposed finding of fact because “distribution network” is an undefined term.

G. The Board’s Interaction with Prospective Entrants

378. On at least six occasions, the Board communicated to non-dentists considering opening teeth whitening businesses that teeth whitening services could only be legally provided by dentists or by dental hygienists supervised by dentists. (CX0106 at 005; CX0206 at 004-005; Valentine, Tr. 564-567; CX0056 at 005; CX0291 at 002-003; CX0523 at 001). In other situations, the Board evasively avoided answering the question or simply sent the inquiring party the Board's unauthorized practice law policy relating to teeth whitening, which expressly stated that Board members would not answer questions about whether a specific teeth whitening practice violated the law. (CX0544 at 001-002; CX0446 at 001-002; CX0266 at 001; CX0472 at 001; CX0414 at 001; CX0426 at 001; CX0421 at 002-003).

Response to Finding No. 378:

Respondent disputes this proposed finding of fact as containing an assumption about the tone of the Board’s response to the inquiring party as evasive. Complaint Counsel’s proposed finding of fact also mischaracterizes the Board’s response in respect to the unauthorized practice of dentistry policy that was forwarded to those to inquired. The policy cited the particular North Carolina statute to consult and advised “[a]ny person without an appropriate license who engages in any of the action[s] outlined above should

seek the advice of legal counsel to determine if his or her actions would constitute the unauthorized practice of dentistry.” (CX236 at 2; CX475 at 1).

1. **The Board Told Prospective Teeth Whiteners That Any Service Associated with Teeth Whitening Not Performed or Supervised by a Dentist Is Unlawful.**

379. The Board discussed teeth whitening in open session during its August 10-11, 2007 Board meeting. Jim Valentine of WhiteSmileUSA inquired into whether his company could market a teeth whitening product and procedure known as LightWhite to spas and salons operated by non-dentists. Mr. Valentine stated that he adequately explained to the Board that the WhiteSmile process was self-application by the customer with no touching of the patient's mouth by the WhiteSmile operator. "Upon review of the literature, it was determined that the application of this product constituted the practice of dentistry and must be provided by a licensed dentist . . . Only dentists and properly licensed and supervised auxiliaries may assist in the removal of stains, accretions or deposits from the teeth of other humans. This would include the application of bleaching gels or similar materials to a customer's teeth and using curing lights or similar methods to speed the process." (CX0106 at 005; CX0206 at 004-005; Valentine, Tr. 564-567).

Response to Finding No. 379:

Respondent has no specific response.

380. At the August 10-11, 2007 Board meeting, the Board also discussed an inquiry by Frank Recker, an attorney representing Whitescience, into whether Whitescience could market its teeth whitening product to spas and salons operated by non-dentists. Very similarly to its reply to Mr. Valentine, the Board responded that "[u]pon review of the literature, it was determined that the application of bleaching gels or similar materials to human teeth and the use of a light to speed the curing process constituted the practice of dentistry. . . ." (CX0106 at 005; CX0206 at 005).

Response to Finding No. 380:

Respondent disputes this proposed finding of fact. The exhibits cited in support by Complaint Counsel establish that an inquiry was discussed at the Board meeting and that staff was directed to respond, but do not reference the content of the response. (CX106 at 5; CX206 at 5).

381. In a Board meeting on February 9, 2007 Board members discussed a letter from Mr. Chad Hinrichs requesting the Board's interpretation of "with supervision" and "without supervision" with regard to licensed dental hygienists. Mr. Hinrichs planned to

open teeth whitening centers in North Carolina where dental hygienists would perform whitening procedures without dentist supervision. The Board directed Mr. White to reply to Mr. Hinrichs with the Board's definition of "supervision." (CX0056 at 005).

Response to Finding No. 381:

Respondent has no specific response.

382. On January 16, 2008 a person contacted Ms. Friddle of the Board to ask if North Carolina law required a license to operate a teeth whitening business catering to the public. The understanding the person had was that because the teeth whitening product being offered was similar to OTC products currently being sold, and since the customer handles the product themselves without contact by the store operator, a license was not required. (CX0522 at 001).

Response to Finding No. 382:

Respondent has no specific response.

383. In an e-mail dated January 17, 2008, Board counsel Carolin Bakewell informed a nondentist teeth whitener - in response to the teeth whitener's inquiries into the legality of teeth whitening in North Carolina - that the Dental Practice Act defines the practice of dentistry to include the "removal of stains and accretions." Ms. Bakewell informed the inquiring teeth whitener that his or her whitening business, which provides customers with a personal tray with a whitening solution and use of a whitening light, violated the statute because it was designed to remove stains from human teeth. Ms. Bakewell further told the inquiring teeth whitener that the statute is not limited to situations where the nondentist touches the customer's mouth. (CX0291 at 002-003).

Response to Finding No. 383:

Respondent has no specific response.

384. On February 11, 2008, Mr. Chris Francis e-mailed Mr. Bobby White at the Board inquiring about what he would need as far as approval from the Board to lawfully open up a teeth whitening kiosk. Mr. Francis was intending to sell the BleachBright teeth whitening system, and the leasing office at Southpoint Mall suggested he contact the Board. (CX0542 at 001).

Response to Finding No. 384:

Respondent has no specific response.

385. On February 12, 2008, Board counsel Carolin Bakewell responded to an e-mail from Craig Francis inquiring about what he needed to do in order to lawfully operate a

mall whitening kiosk. Ms. Bakewell informed Mr. Francis he "may not operate a whitening kiosk except under the direct supervision of a licensed North Carolina dentist. The prohibition remains the same even if the customer inserts the whitening tray themselves." (CX0523 at 001).

Response to Finding No. 385:

Respondent has no specific response.

386. In an e-mail sent on March 4, 2008, Mr. Bobby White told Dr. Hardesty and Ms. Carolin Bakewell that a teeth bleaching company wanted to meet with the Board, and that Mr. White recommended giving the bleaching company that opportunity because "[t]hat would negate any potential allegation that 'the Board would not listen to us.'" (CX0370 at 001).

Response to Finding No. 386:

Respondent disputes this finding of fact as Complaint Counsel mischaracterizes the exhibit that they offered in support of this proposed finding of fact. The potential allegation referred to by Mr. White is solely for purposes of of any potential lawsuit related to the teeth whitening issue as evidence by the complete quote of what he wrote: "This would negate any potential allegation that 'the Board would not listen to us' if they choose later to litigate." (CX370 at 1).

2. The Board Created Uncertainty for Non-dentists Considering Entering the Market by Refusing to Communicate Clear Enforcement Standards

387. On March 17, 2008, Bobby White wrote that the Board had been receiving "a number of inquiries from people who own or are contemplating owning" a teeth whitening kiosk. (CX0237 at 001).

Response to Finding No. 387:

Respondent has no specific response.

388. On March 17, 2008, Bobby White circulated to Board members, Ms. Bakewell, and Ms. Friddle a proposed memorandum on unauthorized practice as it related to teeth whitening. The memo stated that the "Board will investigate complaints regarding unlicensed individuals who assist members of the public in removal of stains, deposits, or accretions by the application of chemical bleaching agents to the teeth." The memo

further stated that actions taken by the Board would be on a “case-by-case” basis, and that the Board could not give advice about whether a particular type of method of teeth whitening violated the statute. (CX0236 at 001-002).

Response to Finding No. 388:

Respondent disputes this proposed statement of fact as an incomplete statement of fact.

The proposed memo also advised “Any person without an appropriate license who engages in any of the action[s] outlined above should seek the advice of legal counsel to determine if his or her actions would constitute the unauthorized practice of dentistry.” (CX236 at 2).

389. On March 24, 2008, Mr. Chris Craig e-mailed Ms. Carolin Bakewell inquiring about what the Board would consider lawful non-dentist teeth whitening. (CX0255 at 001).

Response to Finding No. 389:

Respondent disputes the characterization of this proposed finding of fact. Mt. Craig’s actual inquiry was “what specific criteria the dental board looks at when deciding whether or not a teeth whitening kiosk is in breach of any rules or regulation that would cause the dental board to take action to shut that operation down.” (CX255 at 1).

390. On March 24, 2008, Mr. Bobby White sent to Mr. Carl Barrister by e-mail a copy of the Board’s statement on the Unauthorized Practice of Dentistry. The policy recited North Carolina General Statute §§ 90-29(2); 90-29(7); and 90-29(13). It stated “[i]t is the duty of the North Carolina State Board of Dental Examiners to investigate all complaints received from the public. . . . The Board is unable to give legal advice regarding whether a particular type or method of chemical bleaching is in violation of the statute. Any person without an appropriate license who engages in any of the action [sic] outlined above should seek the advice of legal counsel to determine if his or her actions would constitute the unauthorized practice of dentistry.” (CX0544 at 001-002).

Response to Finding No. 390:

Respondent has no specific response.

391. On May 8, 2008, Algert Agricola of Ryals, Plummer, Donaldson, Agricola, & Smith in Montgomery, Alabama sent an e-mail to Bobby White seeking information about the Board's teeth whitening decisions, policies, and Board minutes. Bobby White appears to have forwarded a copy of the Board's policy statement to Mr. Agricola. (CX0446 at 001-002).

Response to Finding No. 391:

Respondent has no specific response.

392. On March 21, 2009, Mr. Ronald Haynes of Pro White, Inc., in New York, asked Mr. White for information regarding laws defining parameters within which a non-dental teeth whitening kiosk might operate. Mr. Haynes was interested in expanding his business to North Carolina and considered abiding by state law a priority. (CX0267 at 001-005).

Response to Finding No. 392:

Respondent has no specific response.

393. On March 23, 2009, Ms. Carolin Bakewell responded to Mr. Haynes's inquiry by evasively stating that the Board had recently filed two lawsuits against spas that offered teeth whitening without a supervising dentist. When Mr. Haynes followed-up by asking why those two spas were singled out for lawsuits when others were still operating in North Carolina, Ms. Bakewell stated in a March 24, 2009 e-mail that she "was not in a position to answer that question." (CX0266 at 001).

Response to Finding No. 393:

Respondent disputes this proposed finding of fact as containing an assumption about the tone of Ms. Bakewell's response to Mr. Haynes. Complaint Counsel's proposed finding of fact also mischaracterizes Ms. Bakewell's response because she directly responded to Mr. Haynes' inquiry by referring him to the particular North Carolina statute that he should consult. (CX266 at 1).

394. In an e-mail sent on November 13, 2009, Ms. Regina Jenkins inquired to the Board about the legality of purchasing and using a teeth whitening accelerator in her spa; Ms. Jenkins stated that the customers would be "doing the treatment to themselves." (CX0473 at 002). In an e-mail sent on November 18, 2009, Bobby White responded to Ms. King's email by explaining that the Board would be formulating a policy regarding

teeth whitening at its upcoming meeting, and the Ms. King should contact him again in a month for an answer to her question. (CX0472 at 001).

Response to Finding No. 394:

Respondent has no specific response.

395. On March 24, 2010, the Board received correspondence from Mr. Joshua Granson, Vice President and International Marketing Director of Beyond Dental & Health, teeth whitening product manufacturers. Mr. Granson requested a formal statement relating the Board's policy on non-dental teeth whitening provision. He stressed the potential economic loss posed by unclear policy, citing a \$12.8 billion nationwide market to which North Carolina contributed. (CX0412 at 001).

Response to Finding No. 395:

Respondent has no specific response.

396. On March 31, 2010, Mr. White forwarded Mr. Granson's request the Board received on March 29, 2010 to Drs. Morgan, Holland, and Owens. Mr. White recommended sending the matter to "Noel", referring to Mr. Noel Allen of Allen & Pinnix, PA, for a response and copying Ms. Bakewell on the forward. (CX0414 at 001).

Response to Finding No. 396:

Respondent has no specific response.

397. On April 7, 2010, Dr. Owens asked Mr. White who sent requests to the Board in his email regarding whitening policy. Later that day, Mr. White informed Dr. Owens that both the Beyond Spa group and Ms. Kaya Salwin, counsel for a non-dental teeth whitening company in Michigan, sent requests to the Board. (CX0426 at 001).

Response to Finding No. 397:

Respondent has no specific response.

398. On April 7, 2010, Ms. Kaya Salwin, an attorney based in Toledo, Ohio, e-mailed Mr. White thanking him for agreeing to send the Board's policy on non-dental teeth whitening provision. On April 9, 2010, Ms. Salwin again e-mailed Mr. White, informing him that she had scheduled an April 12, 2010 meeting with the Cosmetology Board to discuss non-dental teeth whitening provision. She again requested the Board's policy on the issue in hopes of receiving it in time to discuss it during said meeting. (CX0421 at 002-003).

Response to Finding No. 398:

Respondent disputes this proposed finding of fact as it contains an assumption that Ms. Salwin's request was ignored by the Board. Although the exhibit cited in support of this proposed statement of fact was redacted for attorney-client communications, it clearly shows four emails between Board Counsel and the Board's Chief Operating Officer after the receipt of Ms. Salwin's email. (CX421 at 1-2).

399. The Board refused to meet with members of the cosmetic teeth whitening industry. (Osborn, Tr. 692; Nelson, Tr. 783-784; CX0521 at 001).

Response to Finding No. 399:

Respondent disputes this proposed finding of fact as containing an assumption and an incomplete statement of fact. Regarding Complaint Counsel's citation of exhibit CX521 in support of this proposed finding of fact, Ms. Bakewell has testified that she did not think it appropriate for Mr. Algis Augustine, an out-of-state attorney, to "come down and argue to the Board an interpretation of North Carolina statute because that constitutes the unauthorized practice of law. He could have asked for other ways to be heard such as a declaratory ruling." (RX50 (Bakewell, Dep. at 87-88)). The testimony of Mr. Nelson in support of this proposed finding of fact referenced Mr. Augustine's letter. (Nelson, Tr. 783-784; CX521 at 1).

VI. Jurisdiction and Related Matters

A. The Board Is a Person Within the Meaning of the Federal Trade Commission Act

400. The Board is an agency of the State of North Carolina, and is charged with regulating the practice of dentistry in the interest of the public health, safety, and welfare of the citizens of North Carolina. (Joint Stipulations of Law and Fact 1; State Action Opinion at 4).

Response to Finding No. 400:

Respondent has no specific response.

401. The Dental Board is a "person" within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. (State Action Opinion at 5-6).

Response to Finding No. 401:

This is not a statement of fact. It is a conclusion of law and is placed improperly within Complaint Counsel's Proposed Findings of Fact.

B. The Acts and Practices of the Board Are In or Affect Commerce

402. The acts and practices of the Dental Board, including the acts and practices alleged herein, are in commerce or affect commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44. (Commission Complaint ¶ 6).

Response to Finding No. 402:

This is not a statement of fact. It is a conclusion of law and is placed improperly within Complaint Counsel's Proposed Findings of Fact.

403. Dentists and non-dentist teeth whiteners in North Carolina compete to provide teeth whitening services to consumers in North Carolina. (Kwoka, Tr. 982, 994, 996-997, 998, 1172; RX0078 at 010; CX0826 at 034 (Baumer, Dep. at 126-127)).

Response to Finding No. 403:

This is not a statement of fact. It is a conclusion of law and is placed improperly within Complaint Counsel's Proposed Findings of Fact. Respondent does not disagree that non-dentist teeth whiteners attempt to compete with dentists. However, unlicensed teeth whitening is an illegal service in North Carolina.

404. OTC teeth whitening products are competitive alternatives available for North Carolina consumers. (Kwoka, Tr. 983; CX0654 at 004; Giniger, Tr. 118-121, 208-210; CX0560 at 030 (Feingold, Dep. at 111-113)).

Response to Finding No. 404:

Respondent has no specific response.

405. OTC teeth whitening products are manufactured outside the State of North Carolina and are distributed and sold in North Carolina through a wide variety of retail outlets. (CX0560 at 030 (Feingold, Dep. at 111-113); CX0566 at 016 (Hardesty, IHT at 58-59); Kwoka, Tr. 983).

Response to Finding No. 405

Respondent has no specific response.

406. Manufacturers of teeth whitening equipment and products used by dentist and non-dentist teeth whiteners are located outside the State of North Carolina. (Joint Stipulations of Law and Fact 21 (non-dentist teeth whiteners in North Carolina bought brand name products, including WhiteSmileUSA, BriteWhite, Beyond White Spa, Beyond Dental & Health, and Spa White) and 25 (dentist teeth whiteners in North Carolina used products by Zoom! and Bright Smile); Valentine, Tr. 520, 561, 567 (sells and licenses a whitening system manufactured by DaVinci in California, and once operated in North Carolina)).

Response to Finding No. 406:

Respondent has no specific response.

407. WhiteScience, a manufacturer of non-dentist teeth whitening systems located in Alpharetta, Georgia, sells its products nationally, and has sold some of its products into North Carolina. (Nelson, Tr. 733-734).

Response to Finding No. 407:

Respondent has no specific response.

408. WhiteScience operates in over 40 states. (Nelson, Tr. 800).

Response to Finding No. 408:

Respondent has no specific response.

409. BriteWhite, a manufacturer of non-dentist teeth whitening systems located in Jasper, Alabama, sells its products nationally, and has sold some of its products into North Carolina. (Osborn, Tr. 668-670).

Response to Finding No. 409:

Respondent has no specific response.

410. BriteWhite's products have been sold to customers in Florida, California, New York, Illinois, Ohio, Indiana, Texas, North Carolina and other states. (Osborn, Tr. 668-670).

Response to Finding No. 410:

Respondent has no specific response.

411. Dr. Hardesty originally purchased the Zoom! in-office whitening system from Discus Dental in 2002 or 2003, but no longer actively uses this product in his office. (CX0565 at 027 (Hardesty, Dep. at 98-100)).

Response to Finding No. 411:

Respondent has no specific response.

412. Dentist and non-dentist teeth whiteners in North Carolina used instrumentalities of interstate commerce and communication in the conduct of their businesses, including without limitation, the telephone and the internet to communicate with manufacturers of teeth whitening equipment and products located outside the State of North Carolina. (CX0268 at 001-002; CX0313 at 001-002; CX0605 at 003-004; CX0610 at 001-005; CX0036 at 003; CX0119 at 001-002; CX0620 at 001; CX0045 at 003; CX0054 at 006; CX0281 at 001; CX0312 at 001; Hughes, Tr. 934-936; Wyant, Tr. 861, 863-866).

Response to Finding No. 412:

This is not a statement of fact. It is a conclusion of law and is improperly placed within

Complaint Counsel's Proposed Findings of Fact.

413. Dentist and non-dentist teeth whiteners in North Carolina purchase and receive products and equipment that are shipped across state lines by manufacturers and suppliers located outside the State of North Carolina. (CX0050 at 001; CX0565 at 027 (Hardesty, Dep. at 98-100); Osborn, Tr. 668-670; Nelson, Tr. 733-734; Hughes, Tr. 934-936; CX0655 at 001 to 003; Wyant, Tr. 861, 863-864, 868-869, 891).

Response to Finding No. 413:

Respondent objects to Complaint Counsel's reliance on CX050 at 001 and on CX0655 at 001 to 003 in support of this Proposed Finding of Fact because it is hearsay.

414. Dentist and non-dentist teeth whiteners in the State of North Carolina transfer money and other instruments of payment across state lines to pay for teeth whitening equipment and products received from manufacturers located outside the State of North

Carolina. (CX0050 at 001; CX0565 at 027 (Hardesty, Dep. at 98-100); Osborn, Tr. 668-670); Nelson, Tr. 733-734; Wyant, Tr. 861, 863-864, 868-869, 891).

Response to Finding No. 414:

Respondent objects to Complaint Counsel's reliance on CX050 at 001 in support of this Proposed Finding of Fact because it is hearsay.

415. The Board sent at least 40 Cease and Desist Orders to non-dentist teeth whiteners in North Carolina that contained various headings in bold capital letters, such as the following: "NOTICE AND ORDER TO CEASE AND DESIST" or "NOTICE TO CEASE AND DESIST." (Joint Stipulations of Law and Fact 30; CX0042 at 001 to 041; Kwoka, Tr. 990; RX0078 at 008; CX0050 at 002-003; CX0069 at 001-002; CX0074 at 001-002; CX0077 at 001-002; CX0096 at 001-002; CX0097 at 001-002; CX0386 at 001-002; CX0654 at 005). Some recipients of Cease and Desist Orders sent copies of those Orders to their out-of-state suppliers of products, equipment, or facilities. (CX0119 at 001-002; CX0052 at 005).

Response to Finding No. 415:

Respondent has set at least 40 cease and desist letters to non-dentist teeth whiteners.

Some, but not all, of the letters were styled as cease and desist orders. Others were styled as "Notice of Apparent Violation and Demand to Cease and Desist." (CX153; CX155; CX 156). Respondent objects to Complaint Counsel's reliance on CX0654 at 005; CX0119 at 001-002; and CX0052 at 005 in support of this Proposed Finding of Fact because it is hearsay.

416. The Dental Board sent at least eleven letters to third parties, including out-of-state property management companies that indicated:

North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry. See N.C. Gen. Stat. 90-29(b)(2), a copy of which is enclosed. The unauthorized practice of dentistry is a misdemeanor. See N.C. Gen. Stat. 90-40, a copy of which is also enclosed

It is our information that the teeth whitening services offered at these kiosks are not supervised by a licensed North Carolina dentists. Consequently this activity is illegal.

(Joint Stipulations of Law and Fact ¶ 31; CX0203 at 001; CX0204 at 001 (CBL & Associates, Chattanooga, Tennessee); CX0205 at 001; CX0259 at 001; CX0260 at 001 (General Growth Properties, Chicago, Illinois); CX0261 at 001 (Hendon Properties, Atlanta, Georgia); CX0262 at 001; CX0263 at 001; CX0323 at 001; CX0323 at 001; CX0325 at 001). As the result of the mall letters and the Cease and Desist Orders, out-of-state mall operators would not rent kiosks or in-line stores to non-dentist teeth whiteners in North Carolina. (Gibson, Tr. 627-628, 632-633; Wyant, Tr. 876-880, 881-884; CX0629 at 001-002; CX0255 at 001-002; CX0647 at 002; CX0525 at 001).

Response to Finding No. 416:

Respondent objects to Complaint Counsel's reliance on CX0629 at 001-002; CX0255 at 001-002; CX0647 at 002; CX0525 at 001; and Wyant, Tr. 876-80, 881-84 in support of this Proposed Finding of Fact because it is hearsay. Additionally, Complaint Counsel blatantly misrepresents CX0255, as the mall operator indicated she based her decision on "feedback from several Developers letting [her] know that this use is illegal in several states and that their operators have been shut down in their malls." Complaint Counsel blatantly misrepresents CX0647, as the mall operator indicated that: (1) at the mall called Streets at Southpoint, a non-licensed teeth whitening tenant closed down its business on its own accord in 2007 and that in 2009, the mall still had a teeth-whitening tenant; (2) at the mall called Valley Hills Mall, a non-licensed teeth whitening tenant operated through the end of his lease and the mall did not take any action to close the tenant; and (3) the mall operator did not know whether the Carolina Place mall had taken steps to close down a tenant in response to a letter from Respondent, but that in 2009, Carolina Place mall still had a teeth-whitening tenant. Complaint Counsel misrepresents CX0525 at 001, as there is no indication therein that the mall operator refused to lease a kiosk to a non-licensed teeth whitening provider based on Respondent's indication that no "blanket approval" for BleachBright kiosks had been granted.

417. The Board sent Cease and Desist Orders to out-of-state manufacturers of teeth whitening products used by non-dentist teeth whiteners in North Carolina. (CX0100 at 001 (December 4, 2007, Cease and Desist Order to WhiteScience, Roswell, GA); CX0122 at 001 (October 7, 2008, Cease and Desist Order to Florida White Smile in Orlando, FL)).

Response to Finding No. 417:

Respondent objects to the mischaracterization of the two letters sent to certain manufacturers of teeth whitening products. The December 4, 2007 letter sent to WhiteScience is styled as "Notice to Cease and Desist." It provides that: "The Board hereby directs your company to cease its activities unless they are performed or supervised by a properly licensed North Carolina dentist. If the Board determines that you or your employees continue offering whitening services to the public after receiving this Notice, it will have no choice but to seek relief in the courts of this State." The October 7, 2008 letter sent to Florida White Smile is styled "Notice and Order to Cease and Desist." It provides that the State Board "is investigating a report that you are engaged in the unlicensed practice of dentistry" and "may use any legal means at its disposal to conduct this investigation." It provides that the recipient should "cease and desist any and all activity constituting the practice of dentistry or dental hygiene as defined by North Carolina General Statutes § 90-29 and § 29-233 and the Dental Board Rules promulgated thereunder."

VII. Economic Analysis of the Board's Conduct

A. Market structure

418. There are four alternative methods of accomplishing teeth whitening: (1) in-office dentist provided teeth whitening; (2) dentist provided take-home teeth whitening kits; (3) OTC teeth whitening strips; and (4) non-dentist teeth whitening provided in spas or mall kiosks. (CX0822 at 003; Kwoka, Tr. 981-984, 1168; Baumer, Tr. 1845).

Response to Finding No. 418:

Respondent notes that the fourth category, non-dentist teeth whitening provided in spas or mall kiosks, is illegal in North Carolina and not safe for consumers to use.

Respondent also notes that this is a duplicate fact that is word-for-word identical to Complaint Counsel's Proposed Finding Nos. 466 and 493.

419. Each of the alternative methods of teeth whitening satisfies different preferences among consumers as to how they want to accomplish the teeth whitening - preferences regarding price, speed, convenience, and the availability of assistance. (Kwoka, Tr. 994-995).

Response to Finding No. 419:

Respondent has no specific response.

420. Dentist in-office teeth whitening employs a relatively high concentration of peroxide that necessitates the use of protective measures to prevent damage to the gums during the whitening process. (RX00078 at 006). The advantage of dentist in-office whitening is that consumers can obtain effective teeth whitening with one visit to the dentist. The disadvantages to dentist in-office teeth whitening are that it is relatively expensive compared to the alternatives, and it requires making an appointment with the dentist that may not be at a convenient time for the consumer. (Kwoka, Tr. 981-982).

Response to Finding No. 420:

Respondent disputes that dentist in-office treatment is relatively expensive compared to non-dentist kiosk/spa teeth whitening. Dr. Haywood testified that, even though non-dentist bleaching is advertised as being cost-effective, the prices non-dentist teeth whiteners advertise is generally for one treatment. Research has shown that to provide an effective teeth bleaching treatment one must have an average of at least three teeth bleaching based on concentrations generally used by dentists. (Haywood, Tr. 2508-2509). Many dentists actually charge only one price for teeth whitening that includes multiple visits to the dentist for teeth whitening, including a medical history and an oral exam. (Wester, Tr. 1292-1293).

421. Dentist in-office teeth whitening ranges widely in price, but charges between \$400 and \$500 are common. (Kwoka, Tr. 982; RX00078 at 006-007).

Response to Finding No. 421:

This statement is a word-for-word duplicate of Proposed Finding No. 496. Otherwise, Respondent has no specific response.

422. Dentists also offer take-home whitening kits that consumers self-administer after a consultation with the dentist. "Take-home kits offer the consumer the convenience of whitening with a lower concentration of hydrogen peroxide, safe enough to use at home, as well as the consultation with the dentist." Take-home kits are less expensive than the dentist in-office procedure and are also relatively effective at whitening teeth. On the other hand, the consumer is required to apply the product at home a number of times without assistance. (Kwoka, Tr. 982-983; CX0654 at 004).

Response to Finding No. 422:

This statement is a word-for-word duplicate of Proposed Finding No. 497. Otherwise, Respondent has no specific response.

423. "An innovative and simpler [alternative] for whitening teeth involves the use of over-the-counter (OTC) strips that customers can purchase from drug stores and other merchants much as they purchase toothpaste." Consumers self-apply the OTC strip, which contains a relatively low concentration of peroxide, directly to their teeth. The OTC strips have the advantages of the convenience of at-home treatment as well as low cost compared to the other alternatives - between \$25 and \$75. The OTC strips are effective when used over a period of days or weeks. The disadvantage is that OTC strips require diligent and repeated application by the consumer. (Kwoka, Tr. 983; CX0654 at 004).

Response to Finding No. 423:

There is no basis for the statement that non-dentist teeth whitening is an innovative product/service. This statement is one of opinion, not a statement of fact. Dr. Baumer noted that teeth whitening products/services are not innovative; arguably, non-dentists merely charge a lower price. (Baumer, Tr. 1723-1724). Further, this statement is a word-for-word duplicate of Proposed Finding No. 498.

424. The most recent alternative method of teeth whitening is non-dentist provided whitening at spas, salons, and mall kiosks. This involves the provision of a kit to the consumer and assistance in the form of instruction and guidance from the operator on-site. Non-dentist whitening has the advantage of one-stop whitening at a reasonable level of peroxide concentration. It is also effective at whitening teeth but with a significantly lower cost in comparison to in-office dentist teeth whitening. (Kwoka, Tr. 983-984; CX0654 at 004).

Response to Finding No. 424:

Respondent notes that the "provision" of teeth whitening services to consumers "in the form of instruction and guidance from the operator" does not consistently follow the so-called "self-administration" guidelines touted by teeth whitening industry representatives. *See* Respondent's Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves). Further, this statement is a word-for-word duplicate of Proposed Finding No. 499.

425. The cost of non-dentist teeth whitening varies but seemingly ranges between \$75 and \$150. (Kwoka, Tr. 984; CX0654 at 004).

Response to Finding No. 425:

This statement is a word-for-word duplicate of Proposed Finding No. 500. Otherwise, Respondent has no specific response.

426. Because each alternative method of teeth whitening offers consumers unique characteristics, there is no "best product" capable of being the dominant preference for all consumers. (Kwoka, Tr. 1002-1003).

Response to Finding No. 426:

This is not a fact, it is an opinion stated by Dr. Kwoka. There is no basis in the record for this statement. Further, this statement is a word-for-word duplicate of Proposed Finding No. 501.

1. Dentist, In-Office Teeth Whitening Services

427. Dentist provided in-office bleaching, also known as dental chair-side bleaching, typically uses highly concentrated hydrogen peroxide (25% to 35%), applied multiple times during a single office visit. At these concentrations, using a gingival barrier is recommended to prevent gingival irritation. (Giniger, Tr. 169, 172; CX653 at 021).

Response to Finding No. 427:

Respondent has no specific response.

428. Dental chair-side bleaching can be done with or without the use of an accelerator light, which emits heat and ultra-violet radiation (UV) to accelerate whitening. (Giniger, Tr. 169; CX0653 at 021, 027).

Response to Finding No. 428:

Respondent has no specific response.

429. To complement the accelerator light, dental chair-side formulations may also contain a photo or thermal activator, a chemical designed to interact with the light or heat to cause the peroxide to break down more quickly. (Giniger, Tr. 169, 172; CX0653 at 021; CX0809A; CX0809B).

Response to Finding No. 429:

Respondent has no specific response.

430. Many dentists today use lights, such as light emitting diode (LED) lights, which generate neither appreciable UV nor heat, above the ambient temperature. (Giniger, Tr. 187-188; CX0632 at 011).

Response to Finding No. 430:

Respondent has no specific response.

431. Consumers of in-office whitening wear protective glasses to prevent eye injury from the spatter of hydrogen peroxide as it is applied directly to the teeth or from UV in the event the dentist uses a UV-emitting light. (Giniger, Tr. 181-191).

Response to Finding No. 431:

Respondent has no specific response.

432. CX809 is a dentist teeth whitening kit that contains 35% hydrogen peroxide. The package contains four syringes and two applicator tips. One syringe has a black color and contains the light-activated gingival barrier material. The second and third syringes

contain the thickening agent and peroxide, which are mixed together moments before it is applied onto the teeth. The fourth syringe contains a desensitizer, such as potassium nitrate or fluoride, that is applied to teeth after the bleaching to prevent or lessen sensitivity. The package also contains two clear curved applicator tips; these would be affixed to the end of the syringe to allow the efficient placement of the gel onto the tooth surface. (CX0809A; CX0809B; Giniger, Tr. 174-177).

Response to Finding No. 432:

Respondent has no specific response.

433. The ingredients contained in CX0809, or any other professional teeth whitening product, are listed on the product's material safety data sheet (MSDS). The MSDS is available by request from the manufacturer. (Giniger, Tr. 178).

Response to Finding No. 433:

Respondent disputes this statement. Dr. Haywood points out that one of the issues with non-dentist teeth bleaching products is that the ingredients of many of the products being put on the market is not known. Haywood, Tr. 2572). For instance, one of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product: under the Section labeled "Composition", the MSDS sheet states only that it's percentage of carbamide peroxide is "proprietary" and does not disclose what other ingredients are in the product. (CX108 at 4).

Further, the implication made by Copmlaint Counsel that this product is safe merely because its ingredients are disclosed (which as noted above is not true) is belied by the potential safety issues with the product. The MSDS for White Science contains a warning under "Section III: Risks" warning of "Potential health effects" as follows:

"Eyes: May cause damage with ulceration of the cornea and/or irritation of the eye lids could occur. Prolonged contact with the eyes may cause irreversible eye damage."

(CX108 at 4).

“Skin: Overexposure by contact with the product may cause mild to severe irritation and/or burns of the skin and mucous membrane.” (CX108 at 4).

Under “Section IV: First Aid” the MSDS states “Eyes: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical aid without delay, preferably from an ophthalmologist.” (CX108 at 4).

Additionally, under Section XVI, entitled “Additional Information”, the MSDS states

“For dental use only.” (CX108 at 5).

434. Dental chair-side bleaching is performed by a dentist or supervised assistant in a dental chair at the dentist's office. The procedure usually takes one to two hours to complete. From the dentist's perspective, this is a resource intensive procedure. (Giniger, Tr. 179-180; CX653 at 039).

Response to Finding No. 434:

Dental chair-side bleaching also includes a dental exam by the dentist, which is crucial to identifying whether or not a patient is an appropriate candidate for teeth whitening.

(Haywood, Tr. 2472 (noting American Dental Association's position that a person who undergoes teeth whitening without a dental exam is at risk)). Non-dentists are not qualified to conduct such examinations. (Haywood, Tr. 2459; Osborn, Tr. 705-706 (“[w]e're not in any way licensed or qualified to do any of that”).

435. During a lengthy preparatory time of up to a 30 minutes, the patient's teeth are exposed using cheek retractors and the gums are isolated using a brushed-on plastic polymer that is hardened by a curing light so as to prevent the gums from being exposed to the high peroxide concentration of the whitening gel. The gel is painted on the front surface of the teeth and left to work, usually for a 20 minute period. At this point an accelerator light, such as the ones in the Sapphire, BriteSmile, LumaArch, or Zoom2 (the most popular among dentists) systems, may be employed to hasten the chemical reaction of the bleaching process. After 20 minutes, the gel is usually suctioned off the teeth using a dental vacuum. The gel is reapplied, the light (if used) is set again, and the treatment is repeated up to two more times for a total of 60 minutes of actual bleaching time. (Giniger, Tr. 164-172; CX0653 at 040).

Response to Finding No. 435:

Respondent has no specific response.

436. The principal benefits of in-office bleaching are that it is quick, convenient, and provides immediate results. Additional benefits include professional service, guidance, and support. (Giniger, Tr. 180-181).

Response to Finding No. 436:

Respondent has no specific response.

437. Dentist provided chair-side bleaching is the most costly bleaching alternative, often costing between \$400 and \$800. (Giniger, Tr. 119-120 (\$400 to \$700); CX0653 at 040 (\$500 to \$800); Valentine, Tr. 552 (\$600 to \$800); Wyant, Tr. 860 (approximately \$900); CX0570 at 043-044 (Owens, Dep. at 167-168) (approximately \$500)).

Response to Finding No. 437:

Dentists providing testimony at this hearing have testified that chair-side bleaching costs closer to \$500. (Owens, Dep. at 167-168). The higher estimates cited by Complaint Counsel are provided by Mr. Valentine and Mr. Wyant, who are not dentists but have interests adverse to dentists in this proceeding, and by Dr. Giniger, who has interests adverse to the Board in this proceeding.

2. Dentist, Take-Home Teeth Whitening

438. Dentist provided at-home bleaching regimens typically use low concentrations of hydrogen peroxide or carbamide peroxide, applied daily for as long as overnight or over a period of weeks or months. (Giniger, Tr. 119-121; CX0652 at 019-020).

Response to Finding No. 438:

Respondent has no specific response.

439. The delivery system for a dentist provided take home system is a custom fabricated bleaching tray. The tray is created either by the dentist, hygienist or technician, and takes roughly 30-45 minutes to fabricate. This type of system generally costs between \$350 and \$500, which includes the examination and teeth whitening materials used in conjunction with the tray. (Giniger, Tr. 200).

Response to Finding No. 439:

Respondent has no specific response.

440. CX0806 comprises the Whiter Image Teeth Whitening Gel Syringes - Premium Strength. It is a dentist provided take-home product containing gel-filled syringes that would be sent home with a patient along with the custom fabricated bleaching tray. (Giniger, Tr. 202-203).

Response to Finding No. 440:

Respondent has no specific response.

441. Dentist provided take-home products are usually more expensive than any non-dentist provided alternative. (Compare CX0653 at 043 (non-dentist take home product costs between \$40 and \$80) with Giniger, Tr. 201 (typical price of dentist provided take home kit is \$350 to \$500)).

Response to Finding No. 441:

Respondent has no specific response.

3. Over-the-Counter Products

442. OTC products typically use relatively low concentrations of hydrogen peroxide or carbamide peroxide, applied daily for as long as overnight. OTC products are sold in a variety of locations including pharmacies, groceries, over the internet, and even by dentists. (Giniger, Tr. 205-206).

Response to Finding No. 442:

Respondent has no specific response.

443. In recent years, manufacturers have developed unique tray-less methods for OTC at-home bleaching. Crest Whitestrips from Proctor and Gamble (P&G) was one of the first OTC teeth bleaching products on the market, and it remains the number one selling product today. When first made available to consumers in the year 2001, Whitestrips contained approximately 5% hydrogen peroxide. Now, the bleaching agent in the most popular Whitestrips is nearly three times as strong as ten years ago. Other manufacturers have also developed generic whitening strips as well, and the concentration of hydrogen peroxide in these strips has also increased significantly over the years. (CX0653 at 041).

Response to Finding No. 443:

Respondent has no specific response.

444. CX0808 is a box of Crest Whitestrips using 9% hydrogen peroxide. (Giniger, Tr. 204-205).

Response to Finding No. 444:

Respondent has no specific response.

445. Strip delivery systems are relatively inexpensive, usually costing between \$25 and \$80 per box, depending on the amount of strips supplied in the kit and the concentration of the bleach. The whitening results with these strips are highly variable because user compliance is variable; a great many consumers will not complete the whitening regimen, which may require as much as 30 days of daily use. (CX0653 at 041-042).

Response to Finding No. 445:

Respondent has no specific response.

446. OTC whitening products are available in a delivery system where gels are applied to the teeth by trays that are filled with peroxide material with tubes or syringes. This was the OTC option available to consumers before the more popular "strips" became available. The issue with tray products is that "people get bored and oftentimes they don't complete the whole regimen." (Giniger, Tr. 206-207; CX0653 at 041-042).

Response to Finding No. 446:

Respondent has no specific response.

4. Non-Dentist Teeth Whiteners

447. Non-dentist provided chair-side bleaching, also called non-dentist bleaching or nondentist teeth whitening, typically use a mid-level hydrogen peroxide/carbamide peroxide concentration, typically equivalent to 16% or less of hydrogen peroxide. The product is usually applied once during a single visit. (Giniger, Tr. 182-183; CX0653 at 021).

Response to Finding No. 447:

Respondent has no specific response.

448. Lay-operated bleaching centers may use lights during the procedure. However, unlike dentists, lay operated facilities exclusively use LED lights, which produce no UV radiation and little heat above the ambient temperature. (Giniger, Tr. 182-183; CX0653 at 021).

Response to Finding No. 448:

Respondent notes that, in response to a question from the Administrative Law Judge, Dr.

Giniger testified that the LED lights used by kiosks/spas have no effect other than a

“motivational” one for the customer to keep their mouth open. (Giniger, Tr. 479).

449. In most, if not all jurisdictions, operators are not permitted to touch the consumer. (Giniger, Tr. 184). To accommodate this, most manufactures use a tray delivery system, which is often pre-impregnated with peroxide. (Giniger, Tr. 187, 385).

Response to Finding No. 449:

Respondent notes that despite the prohibition against touching the customer (which has been self-imposed by the teeth whitening industry to avoid regulation), kiosk/spa operators and their employees do not consistently follow these so-called “self-administration” guidelines. See Respondent’s Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves).

450. CX0805 is the Whiter Image Prefilled Teeth Whitening Tray - single use; it is a product that would be used in a non-dentist chair-side bleaching procedure. The product is supplied in a sterile pouch, and is a one-size-fits-all mouth tray containing 26% hydrogen peroxide. Inside the tray is a sponge which is pre-impregnated with the peroxide to prevent its unwanted dispersal into the oral cavity. Finally, there is a lens on the outside of the mouthpiece to concentrate the LED light used in the Whiter Image system. (Giniger, Tr. 183-186, CX0805).

Response to Finding No. 450:

Respondent has no specific response.

451. CX0817 is the WhiteScience box containing the SpaWhite single use products that would be used in a non-dentist chairside bleaching procedure. (CX0817-A is the customer information document that is contained inside CX0817.) The box's contents include, for use prior to bleaching, customer-administered products to clean residue of the teeth and a mouth rinse. The bleaching tray is supplied in a sterile pouch which the customer opens by tearing at the notch in the Mylar bag. Inside the tray is a foam strip which contains 27% to 28% carbamide peroxide. The customer, having placed the tray in the mouth, adjusts the LED light, which is automatically set for 20 minutes, and turns the light on. (Nelson, Tr. 730-731, 757-768).

Response to Finding No. 451:

Respondent has no specific response.

452. CX0811 is an LED light manufactured by Lightnew that could be used in a non-dentist bleaching center. (Giniger, Tr. 186-188).

Response to Finding No. 452:

Respondent has no specific response.

453. In a typical non-dentist bleaching procedure, the operator will instruct the consumer to unseal the pouch and insert the tray containing bleaching gel into their mouth. The consumer will thereafter position the LED light, sit in an operator provided chair, and let the whitening gel work for between 15 minutes and one hour. Afterwards, the bleaching tray is removed by the consumer and thrown away, and the light is disinfected. (Giniger, Tr. 188-189).

Response to Finding No. 453:

Respondent has no specific response.

454. In Dr. Giniger's experience, lay bleaching facility operators do not touch the mouth of the customer during the whitening procedure. (Giniger, Tr. 189, 386).

Response to Finding No. 454:

There is no basis in the record for this statement; it is merely an opinion stated by Dr. Giniger, who admitted that he has only observed one kiosk and one spa in North Carolina, and that even then he "really didn't check into sanitary conditions that much" (Giniger, Tr. 359). Further, Respondent notes that despite Dr. Giniger's testimony that lay bleaching facility operators do not touch the mouth of the customer during bleaching procedures, kiosk/spa operators and their employees do not consistently follow these "self-administration" guidelines. See Respondent's Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves); RX11 at 6 (teeth whitening spa employee touched investigator's face

with her hands during teeth whitening procedure and admitted to having touched poison ivy).

455. Consumers of non-dentist chair-side bleaching do not have to wear protective glasses because there is no risk of spatter from the products (due to the nature of the delivery system) and any LED light emits little UV radiation. (Giniger, Tr. 191-192).

Response to Finding No. 455:

Respondent notes that the Material Safety Data Sheet for WhiteScience's non-dentist chair-side bleaching product contains a warning under "Section III: Risks" warning of "Potential health effects" as follows: "Eyes: May cause damage with ulceration of the cornea and/or irritation of the eye lids could occur. Prolonged contact with the eyes may cause irreversible eye damage." (CX108 at 4). Under "Section IV: First Aid" the MSDS states "Eyes: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical aid without delay, preferably from an ophthalmologist." (CX108 at 4).

456. A gingival barrier is not required in a non-dentist bleaching procedure because the concentration of peroxide used is non-caustic, and often the delivery system, such as a sponge in the mouthpiece that is pre-impregnated with peroxide, prevents unwanted dispersal of peroxide into the oral cavity. (Giniger, Tr. 192; CX0653 at 020-021).

Response to Finding No. 456:

Respondent notes that the Material Safety Data Sheet for WhiteScience's non-dentist chair-side bleaching product contains a warning under "Section III: Risks" warning of "Potential health effects" as follows: "Skin: Overexposure by contact with the product may cause mild to severe irritation and/or burns of the skin and mucous membrane." (CX108 at 4).

457. Dr. Giniger demonstrated the use of a typical non-dentist teeth whitening system. Dr. Giniger stated that a typical lay-provided teeth whitening system would generally use a lower strength peroxide than used in dental chair-side teeth bleaching, and contain a mouthpiece, that is impregnated with the bleaching material in a sealed and sterile pouch. Then, using CX0805 to demonstrate, Dr. Giniger described the following steps to using

this non-dentist teeth whitening product: (1) the consumer opens the sterile pouch; (2) the consumer inserts the tray into his or her own mouth; (3) the consumer often is provided with a cool, LED light that the consumer can place near his or her mouth; (4) the allotted time passes per the product's instructions and the mouth piece is removed by the consumer and thrown away; and (5) the light is disinfected. The customer's mouth is never touched during this process by the lay operator. (Giniger, Tr. 182-189; CX0805 (admitted into evidence as a demonstrative); CX0811 (admitted into evidence as a demonstrative)). Dr. Giniger placed this bleaching product in his mouth as he demonstrated this process, and testified that no gingival barrier was necessary because of the low concentration of peroxide being used. (Giniger, Tr. 185-186).

Response to Finding No. 457:

As noted above, kiosk/spa operators and their employees do not consistently follow these "self-administration" guidelines. See Respondent's Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves).

458. Mr. George Nelson of WhiteScience also demonstrated the use of his company's nondentist teeth whitening system. Using CX0817 to demonstrate, Mr. Nelson described the following steps to using the WhiteScience SpaWhite system: (1) open the sealed package, (2) read the enclosed instructions; (3) use the provided "finger toothbrush" referred to as a "Fresh Up" to remove residue from the teeth and rinse the mouth with the enclosed "Brilliance rinse; (4) open the sealed sterile package containing the mouth piece; (5) insert the tray into the mouth; (6) placed an LED light near the mouth; (7) allow the allotted time to pass and then remove and dispose of the mouth piece; (8) rinse again with the Brilliance rinse. The mouth of the customer is never touched by the lay operator. (Nelson, Tr. 757-766; CX0817 (admitted into evidence as a demonstrative)). Mr. Nelson inserted the mouth piece from CX0817 into his own mouth while discussing the use of the system. (Nelson, Tr. 764).

Response to Finding No. 458:

As noted above, kiosk/spa operators and their employees do not consistently follow these "self-administration" guidelines. See Respondent's Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves).

459. Mr. Nelson also testified about a video clip that shows this same process. (Nelson, Tr. 746-754; CX0820; CX0820-A (admitted into evidence as a demonstrative)).

Response to Finding No. 459:

As noted above, kiosk/spa operators and their employees do not consistently follow these “self-administration” guidelines. *See* Respondent’s Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves).

460. Non-dentist chair-side bleaching is highly accessible, located most often in large shopping malls. No appointment is required. Many operators offer both light-activated, single session chair-side systems and OTC take home products for the consumer to choose from. The key difference between this option and the OTC option is that in layoperated teeth bleaching centers, consumers are offered professional or near-professional strength products that can be self-applied in ways similar to those used by dental professionals. (CX0653 at 042).

Response to Finding No. 460:

As noted above, kiosk/spa operators and their employees do not consistently follow these “self-administration” guidelines. *See* Respondent’s Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves).

461. Non-dentists typically provide service, support, advice as allowable (based on training by the manufacturers of the bleaching products/services they provide) and their own experience, which may be considerable in that teeth bleaching may be the sole service they offer. (CX0653 at 022; Nelson, Tr. 752; Wyant, Tr. 865-868; Valentine, Tr. 532-544).

Response to Finding No. 461:

Testimony at trial indicated that the “training” of non-dentist teeth whiteners ranged from a five- to ten-minute instructional DVD to a half-day course in Atlanta. (Hughes, Tr. 953-954; Wyant, Tr. 865-866, 911-912). Even the more involved training course in Atlanta did not involve anything close to the type of training possessed by dentists, including training in such areas as dental anatomy, compliance with HIPAA or CDC

regulations, how to take a medical history of a customer, or how to conduct a proper dental exam. (Wyant, Tr. 912-914).

462. Chair-side bleaching from a non-dentist is "quick and convenient," completed in only a single bleaching session. The cost of a complete chair-side teeth bleaching session in a lay-operated bleaching center is typically about between \$75 and \$150. (CX0653 at 022, 043; Kwoka, Tr. 984; CX0654 at 004).

Response to Finding No. 462:

Respondent has no specific response.

463. The lay-operated bleaching centers may also sell a line of take home bleaching kits, some of which include self-adapted bleaching trays, and others of which are sold with silicone stock trays. These kits typically include a moderate strength carbamide peroxide gel or a hydrogen peroxide gel, which are therefore pH neutral to slightly acidic. They typically are only slightly more expensive than Crest Whitestrips®, usually costing between \$40 and \$80. Consumers most frequently are instructed to use the at-home kits for up to 30 minutes per day for 14 days, however they will begin to see a "notable" whitening within three days. (CX0653 at 053; Giniger, Tr. 201-202).

Response to Finding No. 463:

Respondent has no specific response.

464. CX0810 comprises the Whiter Image Teeth Whitening Kit - Deluxe Home Addition. It is a take-home bleaching product containing four syringes of 12% hydrogen peroxide gel, a silicone stock tray, an instruction booklet, and a tray storage case. After customizing the bleaching tray, the consumer must insert the gel into each tooth depression, and wear it for between 15-30 minutes a day for fourteen days. (Giniger, Tr. 193-196).

Response to Finding No. 464:

Respondent has no specific response.

B. Dentists and Non-dentists Compete in the Sale of Teeth Whitening Products and Services

465. Except to the extent that competition has been restrained as alleged herein, and depending on their geographic location, dentists and non-dentists providing teeth whitening services in North Carolina compete between and among themselves, and with dentists serving on the Board. (Finding 466-544).

Response to Finding No. 465:

This is not a statement of fact, it is a conclusion of law, and is improperly placed within
Complaint Counsel's Proposed Findings of Fact.

466. There are four alternative methods of accomplishing teeth whitening: (1) in-office dentist-provided teeth whitening; (2) dentist-provided take-home teeth whitening kits; (3) OTC teeth whitening strips; and (4) non-dentist teeth whitening provided in spas or mall kiosks. (CX0654 at 003; Kwoka, Tr. 981-984, 1168; Baumer, Tr. 1845).

Response to Finding No. 466:

Respondent notes that the fourth category, non-dentist teeth whitening provided in spas or mall kiosks, is illegal in North Carolina and not safe for consumers to use.

Respondent also notes that this is a duplicate fact that is word-for-word identical to
Complaint Counsel's Proposed Finding Nos. 418 and 493.

467. Many of the non-dentist services have been specifically used and/or endorsed by dentists. For example, the WhiteScience product is endorsed by Dr. Mills, Dr. First and Dr. Verber, and the BEKS system has been endorsed by Dr. Trella Dutton. (Nelson, Tr. 731-733; Osborn, Tr. 658-659).

Response to Finding No. 467:

Respondent has no specific response.

468. Teeth bleaching provided by (1) dentist in-office whitening and at-home whitening trays, (2) non-dentists in their facilities and using at-home trays, and (3) consumers using OTC products purchased at retail, all share characteristics and differ in ways that are important to consumers, including immediacy of results, ease of use, provider support, and price. (Giniger, Tr. 118-121; Haywood Tr. 2915-2917; Kwoka, Tr. 994-995; CX0653 at 005).

Response to Finding No. 468:

Respondent has no specific response.

469. Chair-side bleaching, whether provided by dentists or non-dentists, is quick and convenient, usually limited to a single bleaching session. In contrast, take-home products require numerous bleaching sessions over many days or weeks. (Giniger, Tr. 118-119; CX0653 at 005).

Response to Finding No. 469:

Respondent has no specific response.

470. If consumers want a brighter, whiter smile within 24 hours because they have an event the next day, their choices are to go to a dentist for a treatment like Zoom! or to go to a non-dentist kiosk or salon for whitening. (CX0560 at 048 (Feingold, Dep. at 184-185); Nelson, Tr. 766-767).

Response to Finding No. 470:

Respondent has no specific response.

471. The amount of time it takes to whiten the teeth is important to some consumers of teeth whitening services. (Hardesty, Tr. 2812-2813; Nelson, Tr. 766).

Response to Finding No. 471:

Respondent has no specific response.

472. Dentists provide professional service, support, and advice. Non-dentists typically provide service, support, and advice - as allowable under applicable laws - based on training by the manufacturers of the bleaching products/services they provide and their own experience, which may be considerable in that teeth bleaching may be the sole service they offer. Take-home products come with instructions and little, if anything, more. (Giniger, Tr. 119; CX0653 at 005).

Response to Finding No. 472:

Testimony at trial indicated that the "training" of non-dentist teeth whiteners is not "considerable" at all. It ranged from a five- to ten-minute instructional DVD to a half-day course in Atlanta. (Hughes, Tr. 953-954; Wyant, Tr. 865-866, 911-912). Even the more involved training course in Atlanta did not involve anything close to the type of training possessed by dentists, including training in such areas as dental anatomy, compliance with HIPAA or CDC regulations, how to take a medical history of a customer, or how to conduct a proper dental exam. (Wyant, Tr. 912-914).

473. Consumers are best served by having a variety of safe teeth bleaching alternatives. Some consumers appreciate the quick results from chairside teeth whitening, want more or less support and advice, and are more or less cost sensitive. (Giniger, Tr. 126-128; CX0653 at 009).

Response to Finding No. 473:

The first sentence is a statement of pure opinion without any evidence in support and is not a fact.

474. Dentist provided teeth bleaching (\$400-\$800) is typically more expensive than nondentist teeth bleaching (\$100-\$150). However, non-dentist chair-side teeth bleaching is a particularly good substitute for dentist-provided chair-side teeth bleaching for consumers interested in getting quick results. (Giniger, Tr. 119-120, 181, CX0653 at 005, 040).

Response to Finding No. 474:

As noted above, dentists providing testimony at this hearing have testified that chair-side bleaching costs closer to \$500. (Owens, Dep. at 167-168). The higher estimates cited by Complaint Counsel are provided by Mr. Valentine and Mr. Wyant, who are not dentists but have interests adverse to dentists in this proceeding, and by Dr. Giniger, who has interests adverse to the Board in this proceeding. The second is a statement of opinion without any basis in the record, particularly considering the health and safety risks associated with teeth whitening.

475. There is an inverse correlation between the necessity of a dental procedure and a patient's decision against requesting it due to economic pressure. Therefore, cosmetic dental procedures have been requested less frequently during the economic recession. (RX0076 at 044 (Parker, Dep. at 170-172)).

Response to Finding No. 475:

The first sentence has no support cited and is not supported by Dr. Parker's testimony. Thus Complaint Counsel has not identified any basis in the record for this statement. The second sentence misrepresents Mr. Parker's testimony as fact, when the question only called for his speculation.

476. A price-driven consumer, in times of economic pressure, will more likely request teeth whitening at a kiosk or salon than at a dentist's office. (CX0578 at 045 (Parker, Dep. at 172)).

Response to Finding No. 476:

This statement misrepresents Dr. Parker's testimony as being certain and factual, whereas the question asked of Dr. Parker called for speculation and he said it could arguably be true but he did not have any "specific data that addressed that question." (CX0578 (Parker, Dep. at 172)).

477. Dentist provided take-home products are usually more expensive than any non-dentist provided alternative. (Compare CX0653 at 043 (non-dentist take-home product costs between \$40 and \$80) with Giniger, Tr. 201 (typical price of dentist provided take-home kit is \$350 to \$500)).

Response to Finding No. 477:

Respondent has no specific response.

478. OTC products (\$20-\$60) are the least expensive alternative for consumers. These products are good for cost-conscious consumers who are willing to self-apply bleaching products over several days or weeks aided only by written instructions. However, it is not a good substitute for chair-side teeth bleaching for those consumers intent on quick results or wary about self-application of OTC products without supervision or support. (Giniger, Tr. 120-121; CX0653 at 005).

Response to Finding No. 478:

Respondent does not dispute the first sentence. The second two sentences are statements of opinion unsupported by evidence and are not facts.

479. Non-dentist providers of teeth whitening services in North Carolina have advertised that they charge lower prices for their services than dentists charge for their teeth whitening services, and generally do so. (CX0054 at 006 (Signature Spa of Hickory: \$199.99); (CX0043 at 005 (Bleach Bright salon: \$99); CX0198 at 002 (Movie Star Smile salon: \$99); CX0365 at 002 ("They charge \$100!"); CX0030 at 007 (One West Salon & Aesthetics Day Spa: \$169); CX0556 at 040 (Burnham, Dep. at 151-152)).

Response to Finding No. 479:

Respondent has no specific response.

480. Non-dentist providers of teeth whitening services in North Carolina have compared their services to those provided by dentists with respect to price stating that their prices are lower than the prices charged by dentists. (CX0096 at 004; CX0103 at 014-015; CX0043 at 005; CX0108 at 009; Kwoka, Tr. 999).

Response to Finding No. 480:

Respondent has no specific response.

481. Dr. Burnham discussed with other Board members that consumers may choose to go to a kiosk teeth whitener to get their teeth whitened rather than a dentist. (CX0556 at 040 (Burnham, Dep. at 152)).

Response to Finding No. 481:

The statement is incomplete as stated. Dr. Burnham actually stated that this would have been discussed in the course of talking about a teeth whitening complaint, and that the concern of the Board that consumers may choose to go to a teeth whitener instead of a dentist was based on his and other Board members' concerns about the risk to the consumer of non-dental teeth whitening. (CX556 (Burnham, Dep. at 152-153). This is also a restatement of Proposed Finding No. 526.

482. Dentists in North Carolina often make claims in advertisements that they practice "Cosmetic Dentistry," including the provision of teeth whitening services. (CX0641 at 001-002, 004, 013, 015-018, 020, 024-027, 029-032, 039, 043-044, 048-049, 052, 059-060, 063-067).

Response to Finding No. 482:

This statement is based on inadmissible hearsay, and should be disregarded.

483. Teeth whitening is a frequently requested procedure in dentist offices. (CX0555 at 027 (Brown, Dep. at 100)).

Response to Finding No. 483:

First, this is a generalization based on one mere citation. In fact, most dentists testifying in connection with this case stated that teeth whitening accounted for less than 2% of their revenues, and that the procedure is very rarely requested. (Hardesty, Tr. 2777 (does

not even do in-office teeth whitening anymore because no one asks for it); Owens, Tr. 1452 ("less than two percent"); Wester, Tr. 1289-1290 ("between a half and three-quarters of 1 percent"). Second, Dr. Brown actually stated that he was uncertain of the numbers regarding requests for tooth whitening. (CX0555 (Brown, Dep. at 100)).

484. Consumers want their teeth whitened because "anything cosmetic sells." (CX0555 at 034 (Brown, Dep. at 129)).

Response to Finding No. 484:

Respondent has no specific response.

485. Non-dentist providers of teeth whitening services in North Carolina have compared their services to teeth whitening provided by dentists with respect to efficacy. (CX0041 at 006-007; CX0096 at 004; CX0108 at 009).

Response to Finding No. 485:

Respondent has no specific response.

486. Non-dentist teeth whiteners in North Carolina also have distinguished themselves from dentists in terms of time and convenience. (CX0108 at 009; CX0054 at 006).

Response to Finding No. 486:

This statement is a statement of opinion unsupported by evidence, and is not a fact.

There is also no basis in the record for this statement.

487. Non-dentist providers of teeth whitening services have advertised that they can whiten teeth in one hour or less. (CX0308 at 007; CX0043 at 002; CX0078 at 002; CX0108 at 008; CX0054 at 006; CX0103 at 009).

Response to Finding No. 487:

Respondent has no specific response.

488. Dentists differentiate themselves from non-dentist teeth whiteners in terms of training, privacy, and professional ethics. (CX0595 at 003; CX0185 at 001).

Response to Finding No. 488:

Differentiate is an undefined term, and is too vague here to make this a meaningful statement. Further, there is no basis in the record for the statement that dentists actively differentiate themselves from teeth whiteners.

489. A non-dentist teeth whitener operating within two miles of a dentist could affect the volume of teeth whitening services provided by the dentist. (CX0565 at 024 (Hardesty, Dep. at 87)).

Response to Finding No. 489:

This statement is a hypothetical opinion statement, not a factual statement, and it misrepresents Dr. Hardesty's testimony. The question was asked as a complete hypothetical to Dr. Hardesty during his deposition, and he only said that it could "possibly" have an effect. Dr. Hardesty pointed out, though, that general dentists do not derive the majority of their income from teeth whitening, and that at his highest level he derived less than a percent of his revenue from teeth whitening. (CX0565 (Hardesty, Dep. at 87-88)).

490. A dental practice that sought to do teeth whitening as an important part of its revenue stream might react to the price charged by a nearby non-dentist teeth whitener by reducing its own prices for teeth whitening. (CX0565 at 024 (Hardesty, Dep. at 87-88)).

Response to Finding No. 490:

This statement is a hypothetical opinion statement, not a factual statement. The question was asked as a complete hypothetical to Dr. Hardesty during his deposition, and he only said that a dentist could "possibly" react to a nearby teeth whitener's prices. Dr. Hardesty pointed out, though, that general dentists do not derive the majority of their income from teeth whitening, and that at his highest level he derived less than a percent of his revenue from teeth whitening. (CX0565 (Hardesty, Dep. at 87-88)).

491. Dentists promote teeth whitening in their offices. (CX0565 at 027 (Hardesty, Dep. at 98); Hardesty, Tr. 2869; CX0580 at 007 (Tilley, Dep. at 19); Tilley, Tr. 1999-2000; Owens, Tr. 1452-1453).

Response to Finding No. 491:

This statement is not an accurate reflection of the record evidence. The testifying dentists stated that they did not actively market their teeth whitening services. Although they would typically have brochures or posters visible in their office, they would only discuss the possibility of teeth whitening if asked about it by a patient or in relation to dental work such as crowns. (Wester, Tr. 1290; Owens, Tr. 1452-1453; Tilley, Tr. 1999-2000; Hardesty, Tr. 2777).

492. Dr. Parker does not find Crest Whitestrips to either be competitive with dentists or to affect dentist income. Dr. Parker occasionally recommends Crest Whitestrips to patients. (CX0578 at 046-047 (Parker, Dep. at 177-178)).

Response to Finding No. 492:

Dr. Parker's testimony regarding the current state of the market is of limited significance given that he has not practiced as a dentist since 2007. (CX0578 (Parker, Dep. at 9)).

493. There are four alternative methods of accomplishing teeth whitening: (1) in-office dentist-provided teeth whitening; (2) dentist-provided take-home teeth whitening kits; (3) OTC teeth whitening strips; and (4) non-dentist teeth whitening provided in spas or mall kiosks. (CX0654 at 003; Kwoka, Tr. 981-984, 1168; Baumer, Tr. 1845).

Response to Finding No. 493:

Respondent notes that the fourth category, non-dentist teeth whitening provided in spas or mall kiosks, is illegal in North Carolina and not safe for consumers to use.

Respondent also notes that this is a duplicate fact that is word-for-word identical to

Complaint Counsel's Proposed Finding Nos. 418 and 466.

494. Each method of teeth whitening satisfies different preferences among consumers as to how they want to accomplish the teeth whitening - preferences regarding price, speed, convenience, and the availability of assistance. (Kwoka, Tr. 994-995).

Response to Finding No. 494:

This is a statement of opinion and not a fact. Also, there is no basis in the record for this statement – Complaint Counsel did not offer the testimony of a single consumer in this matter.

495. Dentist in-office teeth whitening employs a relatively high concentration of peroxide that necessitates the use of protective measures to prevent damage to the gums during the whitening process. (RX0078 at 006). The advantage of dentist in-office whitening is that consumers can obtain effective teeth whitening with one visit to the dentist. The disadvantages to dentist in-office teeth whitening are that it is relatively expensive compared to the alternatives, and that it requires making an appointment with the dentist that may not be at a convenient time for the consumer. (Kwoka, Tr. 981-982).

Response to Finding No. 495:

Respondent has no specific response.

496. Dentist in-office teeth whitening ranges widely in price, but charges between \$400 and \$500 are common. (Kwoka, Tr. 982; RX0078 at 006-007).

Response to Finding No. 496:

This statement is a word-for-word duplicate of Proposed Finding No. 421.

497. Dentists also offer take-home whitening kits that consumers self-administer after a consultation with the dentist. "Take-home kits offer the consumer the convenience of whitening with a lower concentration of hydrogen peroxide, safe enough to use at home, as well as the consultation with the dentist." (CX0654 at 004). Take-home kits are less expensive than the dentist in-office procedure and are also relatively effective at whitening teeth. On the other hand, the consumer is required to apply the product at home a number of times without assistance. (CX0654 at 004; Kwoka, Tr. 982-983).

Response to Finding No. 497:

This statement is a word-for-word duplicate of Proposed Finding No. 422.

498. "An innovative and simpler [alternative] for whitening teeth involves the use of OTC (OTC) strips that customers can purchase from drug stores and other merchants much as they purchase toothpaste." (CX0654 at 004). Consumers self-apply the OTC strip, which contains a relatively low concentration of peroxide, directly onto their teeth. The OTC strips have the advantage of being a convenient at-home treatment and being low cost compared to the other alternatives - between \$25 and \$75. The OTC strips are

effective when used over a period of days or weeks. The disadvantage is that OTC strips require diligent and repeated application by the consumer. (CX0654 at 004; Kwoka, Tr. 983).

Response to Finding No. 498:

There is no basis for the statement that non-dentist teeth whitening is an innovative product/service. This statement is one of opinion, not a statement of fact. Dr. Baumer noted that teeth whitening products/services are not innovative; arguably, non-dentists merely charge a lower price. (Baumer, Tr. 1723-1724). Further, this statement is a word-for-word duplicate of Proposed Finding No. 423.

499. The most recent alternative method of teeth whitening is nondentist-provided whitening at spas, salons, and mall kiosks. This involves the provision of a kit to the consumer and assistance in the form of instruction and guidance from the operator on-site. Non-dentist whitening has the advantage of being a one-stop whitening at a reasonable level of peroxide concentration. It is also effective at whitening teeth but at a significantly lower cost in comparison to in-office dentist teeth whitening. (Kwoka, Tr. 983-984; CX0654 at 004).

Response to Finding No. 499:

Respondent notes that the "provision" of teeth whitening services to consumers "in the form of instruction and guidance from the operator" does not consistently follow the so-called "self-administration" guidelines touted by teeth whitening industry representatives. *See* Respondent's Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves). Further, this statement is a word-for-word duplicate of Proposed Finding No. 424.

500. The cost of non-dentist teeth whitening varies but seemingly ranges between \$75 and \$150. (Kwoka, Tr. 984; CX0654 at 004).

Response to Finding No. 500:

This statement is a word-for-word duplicate of Proposed Finding No. 425. Otherwise, Respondent has no specific response.

501. Because each alternative method of teeth whitening offers consumers unique characteristics, there is no "best product" capable of being the dominant preference for all consumers. (Kwoka, Tr. 1002-1003).

Response to Finding No. 501:

This is not a fact, it is an opinion stated by Dr. Kwoka. There is no basis in the record for this statement. Further, this statement is a word-for-word duplicate of Proposed Finding No. 426.

502. Non-dentist and dentist teeth whitening compete with each other. (Kwoka, Tr. 994, 996-997, 1172; RX0078 at 010 ("The fact that unauthorized teeth whitening operators compete with legal alternatives [including dentists] is not surprising.")).

Response to Finding No. 502:

Respondent does not disagree that non-dentist teeth whiteners attempt to compete with dentists. But unlicensed teeth whitening is an illegal service in North Carolina.

503. First, the alternative methods of teeth whitening have a number of common characteristics. All of the methods use some form of peroxide - hydrogen peroxide or carbamide peroxide - and all involve application of that chemical in gel or strip form directly onto the teeth. All of the methods trigger the same chemical process that results in whiter teeth. These common features make the methods substitutes for each other. (Kwoka, Tr. 997; Baumer, Tr. 1925).

Response to Finding No. 503:

The term "substitutes" is not defined, which makes the last sentence too indefinite to be meaningful. Respondent has no specific response to the rest of this statement.

504. Teeth whitening alternatives "that are more similar are closer substitutes and so compete more closely." (CX0654 at 007). "[I]t seems like you have a similar lineup [of attributes] with the kiosk versus the dentist." (CX0826 at 034 (Baumer, Dep. at 126-27)).

Response to Finding No. 504:

Respondent has no specific response.

505. Dentist and non-dentist teeth whitening products tend to have greater concentrations of hydrogen peroxide than do OTC products. (Giniger, Tr. 204-205).

Response to Finding No. 505:

Respondent does not disagree.

506. Second, consumers choose among the alternative methods based on the characteristics they prefer, as well as price, and by choosing reveal their preference for the diverse alternatives. (Kwoka, Tr. 994-995).

Response to Finding No. 506:

Respondent has no specific response.

507. Non-dentist teeth whitening is typically priced in between dentist and OTC teeth whitening. (Baumer, Tr. 1926; CX0826 at 034 (Baumer, Dep. at 128)).

Response to Finding No. 507:

Respondent has no specific response.

508. Consumers with the paramount priority of low cost will likely choose OTC strips over the other alternative methods of teeth whitening. Their next best choice would likely be non-dentist teeth whitening services. (Kwoka, Tr. 995).

Response to Finding No. 508:

This is a statement of opinion and not of fact. There is no basis in the record for this statement, and it falls outside of Dr. Kwoka's area of expertise to opine on consumer preference for teeth whitening products.

509. Consumers that place the highest priority on speed of whitening results could prefer inoffice dentist whitening because it offers the highest concentration of peroxide and delivers the quickest results. (Kwoka, Tr. 996). The closest substitute in terms of

speed is non-dentist teeth whitening. (Kwoka, Tr. 998 (consumers must choose between dentists and non-dentist teeth whiteners for procedures limited to one treatment)).

Response to Finding No. 509:

This is a statement of opinion and not of fact. There is no basis in the record for this statement, and it falls outside of Dr. Kwoka's area of expertise to opine on consumer preference for teeth whitening products.

510. The amount of time it takes to whiten the teeth is important to some consumers of teeth whitening services. (Hardesty, Tr. 2812-2814; Nelson, Tr. 766-767).

Response to Finding No. 510:

Respondent has no specific response.

511. Other characteristics which non-dentist and dentist services share include a third party that provides information to the consumer, and the consumer being provided the product by the third party. (Baumer, Tr. 1926; CX0826 at 033-034 (Baumer, Dep. at 125-126)). If a consumer wants an effective "one-shot" teeth whitening the only ways to getting it would be to go to a dentist or a non-dentist teeth whitener, such as those located in mall kiosks. (Kwoka, Tr. 982-984, 998).

Response to Finding No. 511:

Respondent has no specific response to the first sentence. The second sentence is a statement of opinion and not of fact. There is no basis in the record for this statement, and it falls outside of Dr. Kwoka's area of expertise to opine on consumer preference for teeth whitening products.

512. If consumers want a brighter, whiter smile within 24 hours because they have an event the next day, their choices are to go to a dentist for a treatment like Zoom! or to go to a non-dentist kiosk or salon for whitening. (CX0560 at 048 (Feingold, Dep. at 184); Nelson, Tr. 766-767).

Response to Finding No. 512:

Respondent has no specific response.

PART C

513. Despite their diverse characteristics, the alternative methods of teeth whitening address the same consumer need - whiter teeth. (Kwoka, Tr. 996, 1171).

Response to Finding No. 513:

This is a statement of opinion and not of fact. There is no basis in the record for this statement, and it falls outside of Dr. Kwoka's area of expertise to opine on consumer preference for teeth whitening products.

514. Many consumers want their teeth whitened and are seeking the "cosmetic" effect of whiter teeth. (CX0555 at 034 (Brown, Dep. at 129)).

Response to Finding No. 514:

Respondent has no specific response.

515. Third, there is general recognition in the teeth whitening profession that the four alternative methods of teeth whitening are substitutes for each other. Dentists are aware that there is commonality and substitution between the methods of teeth whitening. (Kwoka, Tr. 997-998; CX0392 at 002).

Response to Finding No. 515:

There has been no testimony presented in this hearing indicating that there is any such thing as the "teeth whitening *profession*". In fact, dentists are the only professionals that have testified in this proceeding with any professional expertise related to teeth whitening.

516. Dentists differentiate themselves from non-dentist teeth whiteners in terms of training, privacy, and professional ethics. (CX0595 at 003; CX0185 at 001).

Response to Finding No. 516:

Dentists do not differentiate themselves from non-dentist teeth whiteners. In fact, they do not even actively market their services outside of some dentists that have brochures or posters visible in their reception areas. *See* Respondent's Proposed Findings of Fact No. 611.

517. Fourth, the business behavior of kiosk, spa, and salon providers of teeth-whitening evidences competition between the different methods. For example, non-dentist providers target advertisements to consumers who would or are considering going to the dentist for teeth whitening. The advertisements boast similar results as dentists but for a lower price, indicating a belief that consumers will substitute between the alternatives. (Kwoka, Tr. 999).

Response to Finding No. 517:

Respondent has no specific response.

518. Non-dentist providers of teeth whitening services in North Carolina have advertised that they charge lower prices for their services than dentists charge for their teeth whitening services, and generally do so. (CX0054 at 006; CX0043 at 002; CX0198 at 002; CX0365 at 002; CX0556 at 040; CX0096 at 0004; CX0108 at 009; CX0308 at 007; CX0043 at 002; CX0078 at 002; CX0103 at 009, 015).

Response to Finding No. 518:

Respondent has no specific response.

519. Non-dentist providers of teeth whitening services in North Carolina have compared their services to teeth whitening provided by dentists with respect to efficacy. (CX0096 at 004; CX0108 at 009). Non-dentist teeth whiteners in North Carolina also distinguish themselves in terms of time and convenience, and advertise that they can whiten teeth in one hour or less. (CX0108 at 009; CX0054 at 006).

Response to Finding No. 519:

Respondent has no specific response.

520. Any testimony from non-dentist teeth whitening providers that they identify their competitors as both dentists and OTC strips would also be relevant to the finding that the alternative products are substitutes for each other. (Kwoka, Tr. 1001).

Response to Finding No. 520:

Respondent has no specific response.

521. Fifth, there is substantial cross-elasticity of demand between dentist and non-dentist teeth whitening services. (Kwoka, Tr. 999; RX0078 at 009).

Response to Finding No. 521:

Although Dr. Baumer acknowledged the elements of cross-elasticity of demand between dentist and non-dentist teeth whitening services, he pointed out that it is not fair to compare these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1726-1727).

522. Cross-elasticity is an economic term measuring the degree of substitution between alternative products, defined as the percentage change in quantity and demand of one product as the price of a different product changes. (Kwoka, Tr. 999-1000).

Response to Finding No. 522:

Respondent does not disagree with this statement.

523. Dr. Baumer agrees with Professor Kwoka that there is substantial cross-elasticity - or substitution - between dentist and non-dentist teeth whitening services. (Kwoka, Tr. 999-1000; Baumer, Tr. 1842, 1844; RX0078 at 009). Dr. Baumer believes that nondentist teeth whitening and dentist teeth whitening could be closer substitutes than dentists teeth whitening and OTC products. (Baumer, Tr. 1925).

Response to Finding No. 523:

Although Dr. Baumer did agree with Professor Kwoka that there is cross-elasticity between dentist and non-dentist teeth whitening services, he pointed out that there is not much data here to quantify this and that it is not fair to compare these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1731, 1726-1727).

524. There is an inverse correlation between the necessity of a dental procedure and a patient's decision against requesting it due to economic pressure. Consumer that are sensitive to economic conditions but nonetheless desire teeth whitening may be likely to react by migrating from more expensive dentist teeth whitening to less expensive kiosk or salon whitening. (RX0076 at 044 (Parker, Dep. at 170-172)).

Response to Finding No. 524:

This is not a statement of fact. It is an unsupported opinion by Complaint Counsel that cites mere speculation by a witness in response to a hypothetical question. Accordingly, there is no basis in the record for this statement.

525. A Board member has recognized that a non-dentist teeth whitener operating within two miles of a dentist could affect the volume of teeth whitening services provided by the dentist. (CX0565 at 024 (Hardesty, Dep. at 87)).

Response to Finding No. 525:

This statement is a hypothetical opinion statement, not a factual statement. The question was asked as a complete hypothetical to Dr. Hardesty during his deposition, and he only said that it could “possibly” have an effect. Dr. Hardesty pointed out, though, that general dentists do not derive the majority of their income from teeth whitening, and that at his highest level he derived less than a percent of his revenue from teeth whitening. (CX0565 (Hardesty, Dep. at 87-88)). Also, this Proposed Finding is a nearly identical rephrasing of Proposed Finding No. 489.

526. Board members have discussed the fact that consumers may switch from dentist teeth whitening to non-dentist teeth whitening. (CX0556 at 040 (Burnham, Dep. at 152)).

Response to Finding No. 526:

The statement is incomplete as stated and therefore misleading. Dr. Burnham actually stated that this would have been discussed in the course of talking about a teeth whitening complaint, and that the concern of the Board that consumers may choose to go to a teeth whitener instead of a dentist was based on his and other Board members’ concerns about the risk to the consumer of non-dental teeth whitening. (CX556 (Burnham, Dep. at 152-153)). This is also a restatement of Proposed Finding No. 481.

527. A dental practice that sought to do teeth whitening as an important part of its revenue stream might react to the price charged by a nearby non-dentist teeth whitener by reducing its own prices for teeth whitening. (CX0565 at 024 (Hardesty, Dep. at 87-88)).

Response to Finding No. 527:

This statement merely rephrases Proposed Finding No. 489. Further, it is a hypothetical opinion statement, not a factual statement. The question was asked as a complete hypothetical to Dr. Hardesty during his deposition, and he only said that it could "possibly" have an effect. Dr. Hardesty pointed out, though, that general dentists do not derive the majority of their income from teeth whitening, and that at his highest level he derived less than a percent of his revenue from teeth whitening. (CX0565 (Hardesty, Dep. at 87-88)).

528. The presence of substitution between each alternative method means that they must strive to maintain or improve the quality of their service, keep costs under control, and price accordingly. Each alternative teeth-whitening method must aggressively seek out and maintain its customers; otherwise, customers will migrate to a different method. The effect of substitution is therefore to put sellers in direct competition with each other. (Kwoka, Tr. 1001-1002).

Response to Finding No. 528:

This is a statement of opinion and not of fact. There is no basis in the record for this statement, and it falls outside of Dr. Kwoka's area of expertise to opine on consumer preference for teeth whitening products.

529. Competition among differentiated products is the norm for many consumer products. This competition reflects the fact that there is no single product/price combination that appeals to all consumers. (Kwoka, Tr. 1004).

Response to Finding No. 529:

Respondent has no specific response.

530. The degree of substitution between dentist and non-dentist teeth whitening means that dentists have a financial interest in excluding non-dentists from the market. This is so because if dentists succeed in excluding non-dentists, an alternative that some fraction of consumers prefer, the exclusion will shift demand in favor of the alternatives, including dentists themselves. (Kwoka, Tr. 1002).

Response to Finding No. 530:

This statement is not a fact, it is hypothetical speculation by Dr. Kwoka.

531. For example, Board member Dr. Hardesty's dental practice is located less than two miles from the Crabtree Valley Mall where the Board took action against a non-dentist teeth whitener. (CX0565 at 024 (Hardesty, Dep. at 87); CX0068 at 001; CX0326 at 001).

Response to Finding No. 531:

Although Dr. Hardesty did testify that his dental practice is located less than two miles from Crabtree Valley Mall where there was a non-dentist teeth whitener, there is no basis in the record for the assertion that this is an example of the preceding Proposed Finding.

532. Many of the Board members offer and perform teeth whitening services in their private practice and derive income from it. (State Action Opinion at 14; CX0560 at 047 (Feingold, Dep. at 183); CX0567 at 016 (Holland, Dep. at 58); CX0572 at 009 (Wester, Dep. at 26-28); CX0564 at 010-011 (Hall, Dep. at 33-34); CX0554 at 007 (Allen, Dep. at 18); CX0569 at 009 (Morgan, Dep. at 27-28); CX0467 at 001; CX0606 at 005; CX0614 at 001; CX0378 at 005).

Response to Finding No. 532:

Although it is true that some Board members offer and perform teeth whitening services, they have also testified that less than 2% of their revenues came from teeth whitening, and that such services were rarely requested. (Hardesty, Tr. 2777 (does not even do in-office teeth whitening anymore because no one asks for it); Owens, Tr. 1452 ("less than two percent"); Wester, Tr. 1289-1290 ("between a half and three-quarters of 1 percent").

533. "[T]he existence of a financial interest of dentists in the exclusion of kiosk/spa operators does not require that dentists be the only substitutes for kiosk/spa operators It requires only that they compete with each other to a significant degree." (CX0654 at 009).

Response to Finding No. 533:

This statement is one of opinion, not fact, and merely quotes Dr. Kwoka's report.

Further, it contains an assumption that dentists compete with non-dentist teeth whiteners to a significant degree. There is no basis in the record for the validity of this assumption.

534. Board members have a significant, nontrivial financial interest in the business of their profession, including teeth whitening. (Kwoka, Tr. 1114; CX0826 at 029 (Baumer, Dep. at 107) (Board members "may well be influenced by the impact on the bottom line, "including the financial interest of dentists, in deciding whether to ban non-dentist teeth whitening)). They are in a position to enhance their incomes and those of their constituents. (Kwoka, Tr. 1115-1116).

Response to Finding No. 534:

The citation of Dr. Baumer's deposition testimony for the first sentence blatantly misrepresents his testimony. Dr. Baumer only said that is "possible" that the financial interests of dentists could affect the Board's judgment as to whether or not to ban teeth whitening. He then went on to point out that doing so would be a breach of their duty as sworn public servants, but allowed that for some degree of it is human nature. But he pointed out that Board members have gone to great lengths to avoid the appearance of impropriety by not assigning cases to case officers in the same geographic area, and also noted that for a member of the Board that derived less than 1 percent of their revenue from teeth whitening, their financial interest is far less significant than if they derived 25 percent of their revenue from it. (Baumer, Tr. 107-108). Nowhere in Dr. Baumer's cited testimony does he define the Board members interest as a "nontrivial financial interest."

535. In keeping with its interest, "[t]he Board has acted vigorously to prohibit non-dentist teeth whitening in North Carolina." (CX0654 at 001).

Response to Finding No. 535:

This is not a fact, it is a statement of opinion (using rather dramatic language) by Dr. Kwoka. There is no basis in the record for this statement. The evidence only reflects that the Board acted in accordance with its statutory duty to prevent the unlicensed practice of dentistry.

536. The magnitude of the price effect of exclusion depends upon the substitutability of the alternative products, and both Professor Kwoka and Dr. Baumer agree that there is high cross-elasticity between non-dentist and dentist teeth whitening. (Kwoka, Tr. 1029-1031; Baumer, Tr. 1842; CX0826 at 029 (Baumer, Dep. at 106)).

Response to Finding No. 536:

This is merely a restatement of Proposed Finding Nos. 521 and 523. As stated before, although Dr. Baumer did agree with Professor Kwoka that there is cross-elasticity between dentist and non-dentist teeth whitening services, he also pointed out that there is not much data here to quantify this and that it is not fair to compare these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1842, 1726-1727).

537. Dr. Baumer agrees with Professor Kwoka that there is substantial cross-elasticity - or substitution - between dentist and non-dentist teeth whitening services. (Kwoka, Tr. 999-1000; Baumer, Tr. 1842, 1844; RX0078 at 009). Dr. Baumer believes that non-dentist teeth whitening and dentist teeth whitening could be closer substitutes than dentists teeth whitening and OTC products. (Baumer, Tr. 1925).

Response to Finding No. 537:

This is a word-for-word restatement of Proposed Finding No. 523. As stated before, although Dr. Baumer did agree with Professor Kwoka that there is cross-elasticity between dentist and non-dentist teeth whitening services, he pointed out that there is not much data here to quantify this and that it is not fair to compare these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1842, 1726-1727).

538. Dr. Baumer agrees that a reduction in supply of teeth whitening will have an upward impact on price. (Baumer, Tr. 1700).

Response to Finding No. 538:

Although it is true that Dr. Baumer stated this area of agreement, he noted that this is an unremarkable fact and is a "basic foundation of economics."

539. Dr. Baumer agrees that it is "obvious" that dentists in North Carolina have a financial interest in excluding non-dentist teeth whitening. (RX0078 at 008; Baumer, Tr. 1856; CX0826 at 028 (Baumer, Dep. at 105)). Dr. Baumer agrees that Board members have a financial interest in prohibiting teeth whitening by non-dentists. (Baumer, Tr. 1875).

Response to Finding No. 539:

The use of quotations here is misleading because Dr. Baumer never used the word "obvious" in any of the cited portions of the documents cited by Complaint Counsel. In fact, the cite to his report is blatantly incorrect – Dr. Baumer never stated that dentists have a "financial interest" in excluding non-dental teeth whitening. He said that dentists have a "material interest [in] policing the profession." (RX0078 at 008).

540. Dr. Baumer admits that if a consumer needed their teeth whitening within 24 hours, and did not previously have an appointment with a dentist, he or she would need to use a nondentist teeth whitener. (Baumer, Tr. 1975-1976). A consumer who wanted same-day whitening and was able to go to a dentist would potentially need to pay between \$400 and \$500, which Dr. Baumer admits is a lot of money to most people. (Baumer, Tr. 1976-1977).

Response to Finding No. 540:

Respondent has no specific response.

541. Economists evaluate the economic consequences of illegal activity like they do legal activity. Whether certain activity is legal or illegal is independent from the question of economic impact. (Kwoka, Tr. 1168; Baumer, Tr. 1711 ("[T]he fact that [the product is] illegal doesn't mean there isn't cross-price elasticity.")).

Response to Finding No. 541:

The fact is incomplete as stated in quoting Dr. Baumer's testimony. Dr. Baumer added "On the other hand, when I have been involved in antitrust cases, we only considered the legal portion of the market for purposes of calculating market share and things of this nature."

542. Dr. Baumer agrees that there is cross-elasticity between non-dentist teeth whitening and dentists teeth whitening, but that in his admittedly anecdotal experience it is primarily limited to the "young" and "lower income" people who would go to a non-dentist teeth whitener for "unnaturally white teeth." Dr. Baumer implies that because - in his opinion - it is primarily the young and poor that are in the market for non-dentist teeth whitening that the cross-elasticity impact of the elimination of non-dentist teeth whitening is not as a great a concern. (Baumer, Tr. 1730-1731; CX0826 at 029 (Baumer, Dep. at 106)).

Response to Finding No. 542:

This statement is a word-for-word duplicate of Proposed Finding No. 688. In comparing dentist-provided and non-dentist teeth whitening, Dr. Baumer stated that "I think the substitution is more substantial at the lower income levels among young people."

(Baumer, Tr. 1730).

543. Dr. Baumer agrees that the essence of the exclusion model is that there is some effective barriers to entry. (Baumer, Tr. 1840; CX0826 at 019 (Baumer, Dep. at 66)). Dr. Baumer agrees that the Board is in a position to impose entry barriers. (Baumer, Tr. 1840; CX0826 at 019 (Baumer, Dep. at 66-67)).

Response to Finding No. 543:

Respondent has no specific response. Respondent notes that this is a word-for-word duplicate statement of Proposed Finding No. 554.

544. "[T]he fact that the Board does not attempt to exclude OTC strips tells us nothing about the Board's motivation with regard to eliminating kiosk/spa providers" because "the Board views the sale of OTC whitening kits as outside its jurisdiction (much as the sale of toothpaste)." (CX0631 at 004). Dr. Baumer agrees that the fact that the Board is not trying to change the statute in order to combat OTC whitening could mean that the Board members view non-dentist teeth whitening as a closer substitute for dentist provided teeth whitening than OTC strips. (CX0826 at 033 (Baumer, Dep. at 125)).

Response to Finding No. 544:

Respondent has no specific response.

C. The Board's Conduct Is Presumptively Anticompetitive

1. Under the Exclusion Model, the Conduct of a Dental Board Can Be Considered Presumptively Anticompetitive

545. The exclusion model - whereby incumbent sellers seek to deter or exclude market rivals from the market - is not controversial in economics and can be found in standard textbooks. (Kwoka, Tr. 1018-1019; CX0631 at 007; CX0826 at 015 (Baumer, Dep. at 50)). Both economic experts agree that the exclusion model is the correct model to apply in this case. (Kwoka, Tr. 1004-1005, 1154; Baumer, Tr. 1839-1840; CX0826 at 027 (Baumer, Dep. at 100)).

Response to Finding No. 545:

Respondent has no specific response.

546. Dr. Baumer agrees that the exclusion model is a fairly straightforward analysis, and that the model holds that exclusion limits supply and increases price. (Baumer, Tr. 1840; CX0826 at 048 (Baumer, Dep. at 183)).

Response to Finding No. 546:

Respondent has no specific response.

547. There is no hierarchy of economic models that begins with cartelization and runs to exclusion; economists choose the model that fits the conduct. (Kwoka, Tr. 1152-1153).

Response to Finding No. 547:

Respondent has no specific response.

548. Both economic experts agree that the fact that there are a large number of dentists does not preclude the competitive harm under the exclusion model in this case. (Kwoka, Tr. 1026-1028; Baumer, Tr. 1840-1841, 1847). Dr. Baumer agrees that there is no need for secrecy in order to implement an exclusionary practice, and that there is no need for there to be any minimum price set. (Baumer, Tr. 1845, 1847).

Response to Finding No. 548:

Dr. Baumer conceded that the lack of a high concentration of a product or service does not preclude that there could be harm to consumers in terms of price and choice, (Baumer, Tr. 1841), but as he points out elsewhere, there is also value to consumers in preventing the harm created by having an unregulated, illegal product on the market. (Baumer, Tr. 1708). Further to this point, Dr. Baumer states: "I think you need to look at the economic as well as the health aspects, and I think you can reduce most health aspects

to a number. I know people don't want to value their life, they don't want to value their pain, but we do that all the time, and clearly to ignore the health dimension is not justified." (Baumer, Tr. 1777).

549. Dr. Baumer agrees that the cartel model is not applicable to the conduct in this case, and that Dr. Baumer misread Professor Kwoka's report on this point. (Baumer, Tr. 1839, 1896). Dr. Baumer also apologized for exaggerating Professor Kwoka's views on the cartel issue. (Baumer, Tr. 1799, 1808).

Response to Finding No. 549:

Respondent has no specific response.

550. This case involves a product variant that some consumers prefer. This preference is clear because they purchase it in the market. That product variant, if excluded, makes those consumers and perhaps other consumers worse off as a result. (Kwoka, Tr. 1004-1005).

Response to Finding No. 550:

This is a statement of opinion and not of fact. There is no basis in the record for this statement, and it falls outside of Dr. Kwoka's area of expertise to opine on consumer preference for teeth whitening products.

551. The pre-exclusion market for teeth-whitening consisted of the four teeth whitening alternatives. Consumers were free to choose among the alternatives and pick the one that best met their preferences. At the end of the choosing process the market reached equilibrium, meaning that the consumers have made their first best choice between the alternatives and there is no further migration by the consumers among the alternatives. (Kwoka, Tr. 1005-1006).

Response to Finding No. 551:

Respondent notes that the fourth category, non-dentist teeth whitening provided in spas or mall kiosks, is illegal in North Carolina and not safe to for consumers to use.

552. In the post-exclusion market, one alternative - non-dentist teeth whitening - has been reduced or eliminated in the market. Consumers in the market whose first preference was non-dentist teeth whitening must switch to one of the alternatives or forgo teeth whitening altogether. (Kwoka, Tr. 1006-1007).

Response to Finding No. 552:

As noted above, the fourth category, non-dentist teeth whitening provided in spas or mall kiosks, is illegal in North Carolina and not safe for consumers to use.

553. The mechanism that ties the pre- and post-exclusion markets is the incentive of dentist to exclude non-dentist teeth whitening. The Board represents the interests of dentists and has the power and ability to exclude non-dentists from the teeth whitening market. (Kwoka, Tr. 1007). Accordingly, "[t]he [Board] has sought to prohibit the provision of teeth whitening by kiosks, spas, and other enterprises operated by non-dentists." (CX0654 at 003).

Response to Finding No. 553:

The first sentence is a conclusion of law, not a statement of fact, and is improperly placed in Complaint Counsel's Proposed Findings of Fact. Moreover, there is no factual basis in the record for this statement, it merely cites to the opinions of Dr. Kwoka. The other two sentences in the statement are likewise not factual statements, but merely opinions of Dr. Kwoka that do not accurately reflect the record.

554. Dr. Baumer agrees that the essence of the exclusion model is that there are some effective barriers to entry. (Baumer, Tr. 1840; CX0826 at 019 (Baumer, Dep. at 66)). Dr. Baumer agrees that the Board is in a position to impose entry barriers. (Baumer, Tr. 1840; CX0826 at 019 (Baumer, Dep. at 66-67)).

Response to Finding No. 554:

Respondent has no specific response. Respondent notes that this statement is a word-for-word duplicate of Proposed Finding No. 543.

555. There is no such thing as a "limited exclusion model" within the economic literature. (Kwoka, Tr. 1152). Dr. Baumer testified that there is no difference between a "limited exclusion model" and an absolute exclusion. (Baumer, Tr. 1778).

Response to Finding No. 555:

The first sentence of this statement blatantly and egregiously misrepresents the record because it only cites a portion of Dr. Kwoka's testimony (which does not fully support

the statement), and does not take into account clear testimony on this issue from Respondent's cross-examination of Dr. Kwoka. In the portion of the transcript cited by Complaint Counsel, Dr. Kwoka stated that he had not seen the specific term "limited exclusion model" in economics literature, but during the course of his cross-examination he accepted the definition of it provided by Respondent's counsel, and also accepted that the exclusion model takes many different forms in economic literature. In fact, Dr. Kwoka clearly accepted the limited exclusion model and described its place in economic literature, including in instances studying licensing:

Q. Is there not more than one model of exclusion?

A. Of course there are. Yes. There are any number of models of exclusion in the literature. That's true.

Q. Well, in the instance of licensing can there be a model of unjustified limited exclusion and a model of justified limited exclusion?

A. May I ask what you mean by "justification"? I have, as you know, looked at justifications in this case.

Q. I was asking about a model, not this case.

A. Forgive me. Yes, there are -- there are reasons to look at justifications in these contexts, yes.

Q. And within the licensing arena, are there models for justified limited exclusion?

A. Yes.

(Kwoka, Tr. 1105-1106). Dr. Kwoka also described other instances of the justifiable limited exclusion model: "in this analysis and in others that I've done, for example, in the optometry study, and in the literature generally, researchers examine the justifications for

the restrictions that they find, so that's a routine part of the analysis. Where possible, quality measures or other justifications are examined to see whether they represent economically justifiable reasons for restrictions." (Kwoka, Tr. 1108). In fact, in the portion of the transcript cited by Complaint Counsel Dr. Kwoka never even said "there is no such thing" as a limited exclusion model, he merely disagreed with whether the Board's conduct here was consistent with a "limited" exclusion, and stated his belief that the Board's exclusion of a class of providers was "wholesale".

556. As Dr. Baumer testified, "exclusion causing higher prices" is an "Econ 101 observation." (Baumer, Tr. 1726-1727, 1763; CX0826 at 029 (Baumer, Dep. at 106)).

Response to Finding No. 556:

Respondent has no specific response.

557. Other things being equal, the exclusion of a product will result in a reduction in consumer surplus and an increase in price. (Baumer, Tr. 1726-1727; RX0078 at 010; CX0826 at 033 (Baumer, Dep. at 122-123)).

Response to Finding No. 557:

Respondent has no specific response.

558. Dr. Baumer agrees that a reduction in supply of teeth whitening will have an upward impact on price. (Baumer, Tr. 1700).

Response to Finding No. 558:

This statement as cited mischaracterizes Dr. Baumer's testimony. He stated here that the general proposition that reducing supply will have an upward impact on price, noting that this is "a basic foundation of microeconomics." But he did not state anything about the reduction in supply of teeth whitening, nor state that this basic proposition of microeconomics applied here.

559. Exclusion of competition will result in competitive consequences, one of which is a price increase. (CX0826 at 045 (Baumer Dep. at 171)).

Response to Finding No. 559:

Respondent has no specific response.

560. Dr. Baumer agrees that exclusion can result in harm to consumers in terms of both price and choice. (Baumer, Tr. 1841; CX0826 at 033 (Baumer, Dep. at 124)).

Response to Finding No. 560:

Respondent has no specific response.

561. Consumer surplus is an economic measure of the extent of satisfaction that consumers obtain from a product after subtracting the price they have to pay for it. Well functioning markets maximize consumers surplus. (Kwoka, Tr. 1009). The loss of consumer surplus is therefore a measure of the degree of competitive harm from the restraint. (Kwoka, Tr. 1009-1010).

Response to Finding No. 561:

Respondent has no specific response.

562. Other things being equal, the exclusion of a product will result in a reduction in consumer surplus and an increase in price. (Baumer, Tr. 1726-1727, 1762-1763; Kwoka, Tr. 1019-1020, 1022-1023; RX0078 at 010; CX0826 at 033 (Baumer, Dep. at 122-123)). As Dr. Baumer testified, "exclusion causing higher prices" is an "Econ 101 observation." (Baumer, Tr. 1726-1727, 1763; CX0826 at 029 (Baumer, Dep. at 106)-107). Dr. Baumer agrees that exclusion can result in a harm to consumers in terms of price and choice. (Baumer, Tr. 1841; CX0826 at 033 (Baumer, Dep. at 124)).

Response to Finding No. 562:

While Dr. Baumer agreed with the proposition in the last sentence, he points out elsewhere that there is also value to consumers in preventing the harm created by having an unregulated, illegal product on the market. (Baumer, Tr. 1708). Further to this point, Dr. Baumer states: "I think you need to look at the economic as well as the health aspects, and I think you can reduce most health aspects to a number. I know people don't

want to value their life, they don't want to value their pain, but we do that all the time, and clearly to ignore the health dimension is not justified." (Baumer, Tr. 1777).

563. The type of horizontal restraint at issue here is presumed in economics to be anticompetitive absent some compelling justification because the restraint necessarily results in a decrease in total consumer surplus. (Kwoka, Tr. 1009-1010, 1195). All consumers are worse off as a result of exclusion, no consumer is better off. (Kwoka, Tr. 1010).

Response to Finding No. 563:

This is not a statement of fact, it is Dr. Kwoka's opinion. The opinion makes a number of assumptions for which there is no basis in the record. For instance, it assumes that there is no compelling justification for selective exclusion of a class providing illegal services that have been shown to be harmful to people. It also presumes to measure harm to consumers only by price, and not by health and safety concerns. In short, this and the above findings present an incomplete picture of the testimony offered by Dr. Kwoka and Dr. Baumer, in that they fail to provide any information from the substantial discussion of both experts regarding the justification for exclusion (other than a misrepresentation of the record stating that there was no such thing in the literature, which is not a fair recount of Dr. Kwoka's testimony) or the limited basis for the exclusion. The only people being excluded here are people for whom there are health concerns about their provision of teeth whitening services. (Baumer, Tr. 1784-1785, 1813).

564. The exclusion of non-dentist teeth whiteners represents a loss of innovation in the marketplace - a niche in the market that some consumer preferred above the alternatives. (Kwoka, Tr. 1011; CX0631 at 014). Non-dentist teeth whitening is innovative because it offers a new and different mix of products and services to what had previously existed in the market. (Kwoka, Tr. 1184-1185). The suppression of an innovative new product desired by consumers causes economic harm. (Kwoka, Tr. 1185).

Response to Finding No. 564:

There is no basis in the record for the statement that non-dentist teeth whitening is an “innovative” product/service nor does Complaint Counsel provide a definition of what it means by “innovative”. Further, this statement is one of opinion, not a statement of fact. Dr. Baumer noted that teeth whitening products/services are not innovative; arguably, non-dentists merely charge a lower price. (Baumer, Tr. 1723-1724).

565. The anticompetitive effects of a licensing board's restrictions are the same regardless of whether the board adopts the restriction through a rule or is mandated to enforce the restriction through statute. Economic analysis of a restriction is unaffected by the origins and locus of the power to restrict competition. (Kwoka, Tr. 1149, 1173-1174, 1228-1229).

Response to Finding No. 565:

Respondent notes that Dr. Kwoka's analysis and Complaint Counsel's argument both fixate myopically on economic harm, and even then in such a limited manner that looks only at price and choice. Both fail to consider the policy justifications for excluding an illegal and unsafe class of competitors as well as the value to consumers of such health and safety concerns. *See* Respondent's Proposed Findings of Fact Nos. 558-577.

566. The consumer harm that occurs from the elimination of a product that consumers desire is the same regardless of whether the market is regulated or unregulated. (Kwoka, Tr. 1196).

Response to Finding No. 566:

As noted above, the consumer harm considered by Dr. Kwoka only considers such elements as price and choice. He admitted that his analysis was limited in this way and that he was not asked to evaluate other considerations such as policy. (Kwoka, Tr. 1108-1109). Dr. Baumer found that Dr. Kwoka failed to account for significant health considerations in his discussion. (Baumer, Tr. 1817).

567. Economists evaluate the economic consequences of illegal activity like they do legal activity. Whether certain activity is legal or illegal is independent from the question of economic impact. (Kwoka, Tr. 1168; Baumer, Tr. 1711 ("The fact that [the product] is illegal doesn't mean there isn't cross-price elasticity.")).

Response to Finding No. 567:

While Dr. Baumer acknowledged the elements of cross-elasticity here, he also found that, in his opinion, it is not fair to compare these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1726-1727).

568. Consumer surplus can be measured regardless of whether the product is legal or illegal. (Kwoka, Tr. 1188-1189, 1197).

Response to Finding No. 568:

Respondent has no specific response.

2. Economic Studies Support the Exclusion Model Theory

569. Dr. Baumer mistakenly suggested in his deposition that exclusion of non-licensed teeth whitening may stimulate demand for teeth whitening generally, citing an article by Klein and Leffler and an article by Kenneth Arrow. Neither article provides a justification for the Board's exclusion. (Kwoka, Tr. 1093-1094, 1096-1097).

Response to Finding No. 569:

There is no basis in the record for the statement that Dr. Baumer was "mistaken." In fact, Dr. Baumer testified to his view that the Klein and Leffler article applied because it raises the question of "how do you guarantee high-quality product where low-quality products are available and consumers really can't tell the difference until after they purchase the product[?]" (Baumer, Tr. 1774). This clearly applies to the concerns Respondent has raised in this hearing regarding the dangers of teeth whitening services being provided by non-dentists who put themselves out as dental professionals by wearing lab coats and using dental equipment. Dr. Baumer also described the relevance of the article by Kenneth Arrow: "The point is that -- that Arrow was making, both in this article and in

1963 in his ADR article, which is quoted on the last page, is that the public and the policy makers are not willing to tolerate an unlicensed provision of medical services and I would add dental services.” (Baumer, Tr. 1774-1775).

570. The Klein and Leffler article develops a model elucidating a mechanism by which high-quality products can persist in the market in competition with low-quality products. It does not in any way show or claim to show that consumers are made better off by prohibiting low-quality products. (Kwoka, Tr. 1094-1095).

Response to Finding No. 570:

Respondent refers to its response to Finding No. 569 for why the Klein and Leffler article applies here.

571. The article by Kenneth Arrow deals with how consumers of health care services can secure high-quality care when there is uncertainty about the quality of different providers. The best way to deal with this problem need not be exclusion of lower quality products, but rather can involve less restrictive alternatives such as certification or labeling. (Kwoka, Tr. 1095-1097). Professor Baumer agrees with Arrow's statement that "The choice among these alternatives in any given case depends on the degree of difficulty consumers have in making the choice unaided, and on the consequences of errors of judgment," and he also agrees that "costly physician time may be employed at specific tasks for which only a small fraction of their training is needed and which could well be performed by others less well trained and therefore less expensive." (Baumer, Tr. 1966-1967).

Response to Finding No. 571:

This statement presents only part of Dr. Baumer's testimony and is therefore misleading. Dr. Baumer also stated his point that non-dentist teeth whiteners do not have the training necessary to provide such services and are distinguishable from the discussion in the Arrow article: "I would say that my understanding of the non-dentists are that they don't have to pass any test and that these are [the] kind of businesspeople that look at this as a business opportunity. The other people that we're talking about here, Kenneth Arrow, they're all in medicine. They passed tests. They're physician assistants. They're dental hygienists, et cetera." (Baumer, Tr. 1967).

572. A number of economists have in the past conducted studies of restrictions in the professions that are comparable to the Board's actions. These studies examined a variety of restriction regimes and their effects on both price and quality. (Kwoka, Tr. 1035-1036, 1039).

Response to Finding No. 572:

Dr. Baumer found that Dr. Kwoka relied on outdated literature in the form of these studies, which are from the 1970s and 1980s. (Baumer, Tr. 1733, 1743-1744). Dr. Kwoka himself admitted that the model of licensing boards on a whole does not resemble the widespread model of 20 years ago because licensing practices have changed. (Kwoka, Tr. 1121).

573. The studies also examined the effects of restriction on non-price aspects such as measures of outcomes, which include complaint rates and malpractice insurance rates. (Kwoka, Tr. 1040).

Response to Finding No. 573:

Respondent refers to its Response to Finding No. 572.

574. The studies of restrictions on professions examined restrictions in up to two-dozen occupations, including dentists, lawyers, optometrists, veterinarians, real estate agents, plumbers, and electricians. (Kwoka, Tr. 1036-1037).

Response to Finding No. 574:

Respondent refers to its Response to Finding No. 572.

575. "With regard to financial interest, this [profession's] literature shows numerous occasions in which professionals, given the means and opportunity, have adopted rules of practice that benefit the financial interest of the profession." (CX0631 at 012; CX0826 at 011 (Baumer, Dep. at 36-37) ("[T]here's no doubt that self-interest was - had an impact" on the decisions of licensing boards. "The public lost at the expense of the professional.")).

Response to Finding No. 575:

This statement is misleading for incompleteness. The first sentence is a quote from Dr. Kwoka's report that describes his outdated literature from the 1970s and 1980s. Complaint Counsel completely mischaracterizes this quote by inserting the word "profession" into the quotation to make it appear that the statement is intended to apply to the dental profession. In reality, Dr. Kwoka was referring to the literature of "several different professions." (CX0631 at 012). The quotation from Dr. Baumer's deposition takes two statements made by Dr. Baumer out of context without fairly considering the immediate context in which they were uttered. Dr. Baumer pointed out that the studies were old and outdated, and that they have had an impact in shaping public policy and the type of regulations that they studied. (CX0826 (Baumer, Dep. at 37) ("Many of the [regulations] have been ameliorated in the interim period, and . . . there has been an education process going on and economists have contributed significantly to that education.")). He also made the point that even when the studies were done on old regulations, self-interest was not the only factor that motivated members of the studied licensing boards. (CX0826 (Baumer, Dep. at 37)).

576. Dr. Baumer agrees that at the time these studies were published they were valid as to both their methodologies and their conclusions. (Baumer, Tr. 1896-1897, 1897 ("top notch economists with blind refereed acceptances in top journals")). Dr. Baumer agrees that the type of analysis used in the studies would still be a valid type of analysis if used today because nothing has changed in terms of economic theory or empirical study. (Baumer, Tr. 1897-1898; CX0826 at 032 (Baumer, Dep. at 120)).

Response to Finding No. 576:

While it is true that Dr. Baumer admitted that the methodologies were sound, he still maintained that the studies were outdated and not valid today. Respondent refers to its Response to Finding Nos. 572 and 575.

577. Dr. Baumer himself relied on some of the healthcare professions studies for an article he published in 2007 on an organization composed of state pharmacist licensing boards. (Baumer, Tr. 1901, 1903). In this study, Dr. Baumer noted his concern that pharmacy boards could be engaging in anticompetitive activity that resulted in consumer harm, and that the actions of the pharmacy boards could simply be disguising "economic protectionism." (Baumer, Tr. 1903; CX0826 at 050 (Baumer, Dep. at 191-92)). Dr. Baumer stated in this article that organizations similar to the pharmacy board had been "dismantled . . . after it became apparent that state regulation did little but disguise economic protectionism." (CX0826 at 050 (Baumer, Dep. at 191). Further, Dr. Baumer noted in his article that even laws designed to protect the public health could also be used to insulate the licensed professionals from competition, and cited one authority who remarked that "contemporary state licensure justifies local professional fiefdoms, perpetuates parochialism, and encourages anticompetitive protectionism." (CX0826 at 051 (Baumer, Dep. at 194). Dr. Baumer based his opinions partially on the professions studies from the 1970s and 1980s. (Baumer, Tr. 1903). At the time he wrote his 2007 report, Dr. Baumer believed the professions studies had continued relevance. (Baumer, Tr. 1903).

Response to Finding No. 577:

Dr. Baumer acknowledged that he partially relied on some of the studies from the 1970s and 1980s in a previous article that he wrote, but testified that he stood by his statement that for purposes of the analysis in this proceeding that the studies are outdated.

(Baumer, Tr. 1910).

578. Dr. Baumer only came to his opinion that these healthcare professions studies are too old to be valid during the process of writing his paid expert report for the Board. (Baumer, Tr. 1908-1909). Despite relying on studies he now believes are outdated, Dr. Baumer stands by his 2007 study and has no intention of retracting or correcting the article. (Baumer, Tr. 1910).

Response to Finding No. 578:

Respondent refers to its Response to Finding No. 577.

579. The studies on restrictions in the professions generally looked at three major categories of restrictions: (1) whether states have reciprocity with other states in licensing; (2) the states' use of high fail rates on licensing examinations to control the flow of new practitioners into the state; and (3) restrictions on the form of practice, such as the number of offices a professional might own or whether the professional can be employed by a nonprofessional. (Kwoka, Tr. 1037-1038; CX0631 at 013).

Response to Finding No. 579:

Respondent refers to its Response to Finding Nos. 572 and 575.

580. These restrictions were defended as being in the public interest or in the interest of the consumers of the profession involved in the restriction. The restrictions were often adopted at the behest of the incumbent providers of these professional services. (Kwoka, Tr. 1038).

Response to Finding No. 580:

Respondent refers to its Response to Finding Nos. 572 and 575.

581. The studies on restrictions in the professions generally concluded that these restrictions had the effect of increasing the price of services within the states with the most stringent restraints. (Kwoka, Tr. 1041; CX0631 at 012). The studies did not find any systematic benefits in quality to consumers due to the restrictions. (Kwoka, Tr. 1041; CX0654 at 017-018; CX0631 at 012).

Response to Finding No. 581:

Respondent refers to its Response to Finding Nos. 572 and 575.

582. Some studies focused on restrictions in dentistry specifically. Like the other studies, the dentist-specific studies focused on (1) reciprocity; (2) restriction on scope of practice dealing with limits on the number of dental hygienists and the functions they can perform; and (3) stringency of licensing standards. (Kwoka, Tr. 1042). The dental studies came to the same conclusions as the studies of the other professions. (Kwoka, Tr. 1046; CX0654 at 015-016).

Response to Finding No. 582:

Respondent refers to its Response to Finding Nos. 572 and 575.

583. "Boulier examined restrictions on interstate mobility of dentists and found them to be associated with higher dentists' fees and net income in states that restricted competition. Shepard analyzed detailed data on specific dental services and found that 11 of 12 services had significantly higher fees in states without licensing reciprocity. Conrad and Emerson reported that state limits on the number of dental offices, lack of reciprocity, restraints on the number of hygienists, and advertising prohibitions were each related to higher fees and/or higher net incomes for dentists." (CX0654 at 015-016).

Response to Finding No. 583:

Respondent refers to its Response to Finding Nos. 572 and 575.

584. The Laing and Ogur study examined restrictions on the use of auxiliaries such as hygienists and dental assistants. States had restrictions on the number of auxiliaries that the dentists could employ and on the functions that the auxiliaries could perform. The study found that in states that limited the number of hygienists, the price of a dental visit was from 5% to 7% higher than in states that had no such restrictions. The study also found that in states that restricted the number of functions that dental assistants could perform, the price of a dental visit was 6% higher than in states that did not. (Kwoka, Tr. 1043-1044; CX0654 at 016).

Response to Finding No. 584:

Respondent refers to its Response to Finding Nos. 572 and 575.

585. The Kleiner and Kudrle study, published in 2000, examined whether stringent licensing standards were a barrier to entry for new dentists for the benefit of incumbent dentists, or whether the stringent standards had the purpose of assuring consumers about the quality of new dentists. If simply a barrier to entry, prices for dental services should be higher in those states that had more restrictions on entering the practice of the profession. The study collected both price data and data untreated dental deterioration. The study found that states with the most stringent licensing standards had prices of dental visits 11% higher than states with low licensing stringency. The study also found that licensing stringency produced no benefits in terms of dental health. (Kwoka, Tr. 1044-1046; CX0654 at 016).

Response to Finding No. 585:

Respondent refers to its Response to Finding Nos. 572 and 575. Dr. Baumer admitted that this study was relatively newer than the studies from the 1970s and 1980s, though he pointed out that it is still 10 years old and he is not sure when the data for the study was gathered prior to its publication. (Baumer, Tr. 1971-1972).

586. Dr. Baumer admits that the Kleiner and Kudrle article is not subject to the same criticism he levels against the other professions studies - that they are too old to be relevant. (Baumer, Tr. 1971-1972). Indeed, Dr. Baumer agrees that he does not have any reason to criticize the Kleiner and Kudrle study. (Baumer, Tr. 1971). Dr. Baumer admits that the study found that individuals from states with more restrictive dental practice provisions had greater untreated dental problems than individuals from states with less restrictive provisions. (Baumer, Tr. 1971).

Response to Finding No. 586:

This statement blatantly mischaracterizes Dr. Baumer's testimony. He did say that the article was not as old as the other articles, but he explicitly said that it was "less" subject to criticism for being outdated, not that it was not subject to criticism at all. (Baumer, Tr. 1971-1972) ("it's less subject to it. It's ten years old.").

587. The profession's studies supply empirical evidence supporting the theoretical conclusions that (1) exclusion will work to the benefit of the incumbents, (2) exclusion will harm consumers, and (3) exclusion generates no systematic benefits in terms of improvement in quality of services. Exclusion causes an unjustified transfer of income or surplus from the consumers to the producers, including the imposition of higher prices for the professional services. (Kwoka, Tr. 1047).

Response to Finding No. 587:

Respondent refers to its Response to Finding Nos. 572 and 575.

588. The members of the Board, and North Carolina licensed dentists generally, are considered incumbent providers. (Kwoka, Tr. 1209; Baumer, Tr. 1761-1762 ("people already providing and are licensed and authorized to provide the service"))).

Response to Finding No. 588:

Although Dr. Kwoka said he considers the members of the Board as dentists to be incumbent providers, he said he has not seen in the economic literature he has reviewed the term "incumbent provider board." (Kwoka, Tr. 1209-1210).

589. There is a long history of licensing boards in different professions asserting that they are engaging in actions for the benefit of the public and consumers of a particular service, and in repeated instances those assertions are belied by the economic evidence. The economic evidence suggests that private interests rather than public or consumer interest is dominating the conduct. (Kwoka, Tr. 1048; CX0631 at 009).

Response to Finding No. 589:

This paraphrase of Dr. Kwoka's testimony is misleading because Dr. Kwoka admitted that the studies generally described in the above statement are irrelevant in this case. Dr. Kwoka actually conceded on cross that studies of medical licensing professions, such as dentists and optometrists, that he has reviewed do not indicate that the financial interest

of those professions “dominates” their public interest or consumer interest. Instead, he reads those studies to only suggest that the financial interest represents a significant factor among those other interests. (Kwoka, Tr. 1115).

590. Dr. Baumer agreed that state regulatory boards can be used to exclude competition and augment the incomes of licensed practitioners. (Baumer, Tr. 1763; RX0078 at 008-010).

Response to Finding No. 590:

This statement misleadingly paraphrases Dr. Baumer’s report and additionally takes his statements, which stated conclusions made by Dr. Kwoka for the sake of argument, out of context. Dr. Baumer stated in his report that “It is true that state regulatory boards can be used to exclude competition and augment incomes of licensed practitioners. Excluding competition from untrained and unlicensed quacks is precisely the reason that these boards were created and why they still enjoy support from the public and from legislators.” (RX0078 at 9). Additionally, the cite made above by Complaint Counsel to the hearing transcript does not support the statement at all.

591. Dr. Baumer agreed that members of these professional boards acted in ways calculated to enhance their own income and the income of the constituents of the boards, to the detriment of patients and the general public. (Baumer, Tr. 1848-1850, 1855, 1912-1913).

Response to Finding No. 591:

This statement misleadingly paraphrases Dr. Baumer’s testimony. A review of his testimony reveals that he stated that some boards were aware of their income-enhancing potential and made use of that, but not all boards did that:

Q. So in the ‘80s that state board members acted on behalf of the interest of the regulated; correct?

A. That’s the question?

Q. Right. Correct.

A. All right. I think that the effect of their actions may have promoted the interest of those regulated. Whether they viewed what they were doing as enhancing the income of those being regulated I don't know.

Q. Well, isn't it your view that 30 or 40 years ago that the state board members realized that they had this authority to exclude and that they could take advantage of it to their benefit?

A. I think there are certainly some boards that were aware of the income-enhancement potential and made use of it, yes. I'm not saying all boards did that.

Q. And not all of the actions of a board that did that would necessarily be motivated by income enhancement; correct?

A. Right.

Q. So boards could at some times be operating to enhance income, sometimes be operating strictly in the public interest; correct?

A. That's correct.

(Baumer, Tr. 1847-1848).

592. Dr. Baumer agrees that professional boards, including dental boards, have supported anticompetitive restrictions in the past. (Baumer, Tr. 1884).

Response to Finding No. 592:

This statement is not an accurate recount of Dr. Baumer's testimony. In the portion of the transcript cited by Complaint Counsel, Dr. Baumer did not testify that professional boards "supported anticompetitive restrictions" 30-40 years in the past, he merely

testified that some boards were aware of their income-enhancing potential and others were not. He did not specifically say that such boards included dental boards. The portion of the transcript cited by Complaint Counsel is as follows:

Q. Well, isn't it your view that 30 or 40 years ago that the state board members realized that they had this authority to exclude and that they could take advantage of it to their benefit?

A. I think there are certainly some boards that were aware of the income-enhancement potential and made use of it, yes. I'm not saying all boards did that.

Q. And not all of the actions of a board that did that would necessarily be motivated by income enhancement; correct?

A. Right.

Q. So boards could at some times be operating to enhance income, sometimes be operating strictly in the public interest; correct?

A. That's correct.

(Baumer, Tr.1848).

593. Dr. Baumer agreed that the professions studies generally show that consumers were harmed by restrictions imposed by medical boards through higher prices and less choices. (Baumer, Tr. 1852). Dr. Baumer agrees that the licensing board restrictions examined in the professions studies were unwarranted and harmful to consumers. (Baumer Tr. 1764; CX0631 at 006-007).

Response to Finding No. 593:

The first sentence is misleading because it is an incomplete description of Dr. Baumer's testimony. He actually stated that the studies found consumers were harmed in terms of higher prices and less choice, but that the restricted practices were justified based on health and safety. The portion of the transcript cited by Complaint Counsel is as follows:

Q. And you're familiar with the result that these studies gradually show -- excuse me.

You're familiar with the fact that these studies generally show that consumers were harmed on many occasions by restrictions imposed by these medical boards; correct?

A. The consumers were harmed in the sense that there were higher prices, perhaps less choices. Some of these practices, restricted practices, were justified based on health and safety. Others had no health and safety foundation. Some were based on possible fraud, which allegedly was due to advertising would promote. So I agree.

Q. So when you're saying they were justified, you're not saying -- you're saying that the board members attempted to justify them on the basis of health and safety; correct?

A. Well, I say both, that they were justified by health and safety and the board members attempted to justify them by health and safety.

(Baumer, Tr. 1852).

594. Dr. Baumer agreed that the professions studies showed that in many cases the health and safety justifications proffered by the boards turned out to be false. (Baumer, Tr. 1852-1853).

Response to Finding No. 594:

Respondent has not specific comment.

595. "Legal challenges to these abuses [by licensing boards] have resulted in numerous instances where restrictive practices have been banned or modified, with substantial consumer benefits in terms of lower prices, better information, and more alternative from which to choose." (CX0631 at 006). Dr. Baumer agrees that "the Goldfarb case of 1974," as well as other "court decisions," had an impact on abuses by licensing boards. (CX0826 at 012 (Baumer, Dep. at 38)).

Response to Finding No. 595:

The first sentence is not a statement of fact, it is a quotation from Dr. Kwoka's Rebuttal Report (to which Respondent was not permitted any reply under Commission rules until the hearing). There is no factual basis for this statement in the record other than Dr.

Kwoka's unsubstantiated statement. Dr. Baumer agreed that the Goldfarb case had an impact in terms of licensing boards setting minimum prices, which is irrelevant and not at issue in this hearing. (CX0826 (Baumer, Dep. at 38)).

596. The licensing board restrictions existing today are generically similar to those studied in the past, even if there may be some differences. (Kwoka, Tr. 1122-1123).

Response to Finding No. 596:

This testimony by Dr. Kwoka was rebutted by Dr. Baumer during his testimony at trial.

Complaint Counsel on cross stated in a question to Dr. Baumer:

Q. Now, in terms of moving to the present, again, it's -- you believe that some -- some or many practices that were anticompetitive of the boards have been eliminated over time as a result of the work of yourself and Professor Kwoka and others; correct?"

A. Right. I think we're in agreement on that.

(Baumer, Tr. 1900-1901).

Additionally, Dr. Kwoka himself admitted that licensing board practices have changed on the whole:

Q. Has there not been a continued evolution with respect to occupational licensing in response to that literature?

A. Well, public policy has intervened in lots of instances and remedied problems that have been found based on that literature and based on individual experiences. So has licensing practices changed? Sure, they certainly have, and the long history of action against restrictions I think is proof of that.

(Kwoka, Tr. 1121)

597. The empirical findings of the professions studies are applicable to the actions of the Board even though those studies involved exclusion of licensees and the Board's actions excluded non-licensed persons. Although one study did examine harm caused by

the exclusion of non-licensed chair assistants, from an economic perspective the important fact is that there has been exclusion – harm follows from exclusion regardless of whether the excluded group is licensed or unlicensed. (Kwoka, Tr. 1050-1051; CX0631 at 013). In fact, many boards studied based their exclusionary conduct on the fact that using the “other” licensed occupation (e.g., dental assistant) was unsafe. (Kwoka, Tr. 1041, 1043-1044; CX0631 at 009).

Response to Finding No. 597:

Respondent refers to its Response to Finding No. 572.

598. Dr. Baumer agrees that economists can learn from other types of exclusionary conduct to make inferences about new exclusionary conduct. (Baumer, Tr. 1982).

Response to Finding No. 598:

Respondent has no specific response.

599. The Board’s exclusion of non-dentist teeth whiteners is even more restrictive than the practices examined in the professions studies. The professions studies examined restrictions that were narrower in scope than outright exclusion, but the harm found in those cases – raising the price of the service without a quality benefit to the consumer – will result from outright exclusion as well. (Kwoka, Tr. 1051-1053, 1123).

Response to Finding No. 599:

First, there is no basis in the record to characterize the Board’s actions as “outright exclusion.” As Dr. Baumer points out, teeth whitening in North Carolina has not been banned, the only thing eliminated has been provision of such a service by people who have absolutely no training in dentistry. (Baumer, Tr. 1734). Further, the record clearly contradicts any contention that non-dentist teeth whiteners provide as high a quality service as dentists. *See* Respondent’s Proposed Findings of Fact Nos. 375-400; (Baumer, Tr. 1786) (“The idea that a dentist who has three years of postgraduate work wouldn’t provide a better service than people who have no training, have not passed any license examination and are not subject to having their license removed for unethical behavior, that that has no impact on quality, that just seems so farfetched.”).

Also, Dr. Kwoka never said that the Board's alleged exclusion of non-dentist teeth whiteners was "even more restrictive", he merely claimed that the professions studies involved restrictions that were narrower in scope. (Kwoka, Tr. 1052).

600. The fact that most of the professions studies were conducted 25 years ago does not mean that the studies are outdated. Three of the articles cited by Professor Kwoka were published since 2000. The recent lack of interest in publishing on the subject results from the fact that all of the studies came to similar conclusions - higher prices due to restrictions without a corresponding increase in quality. There have been no studies in recent years that challenge this conventional and consensus view. (Kwoka, Tr. 1054-1055, 1120-1121, CX0631 at 012-013).

Response to Finding No. 600:

Respondent refers to its Response to Finding No. 572.

601. Dr. Baumer admits that he may have exaggerated in describing the professions studies as outdated. (Baumer, Tr. 1766).

Response to Finding No. 601:

This statement clearly mischaracterizes Dr. Baumer's testimony. In the portion of the transcript cited, Dr. Baumer stated: "Now, I may have exaggerated slightly, but basically Dr. Kwoka is relying on -- I think 'outdated' is an appropriate adjective."

602. Dr. Baumer "provides no theoretical or empirical basis for disregarding the academic literature" cited by Professor Kwoka. (CX0631 at 013).

Response to Finding No. 602:

This sentence is not a statement of fact, it is a quotation from Dr. Kwoka's Rebuttal Report (to which Respondent was not permitted any reply under Commission rules until the hearing). There is no factual basis for this statement in the record other than Dr. Kwoka's unsubstantiated statement. Dr. Baumer also pointed out that Dr. Kwoka does not present much data here to quantify his methodology or conclusions. (Baumer, Tr.

1731, 1726-1727). It is interesting that Dr. Kwoka would find fault with Dr. Baumer for providing no empirical basis when Dr. Kwoka provides no empirical basis in the first for the conclusions he reaches here.

603. Public policy intervention, in part through the actions of the FTC and state legislatures, has addressed some of the anticompetitive licensing restrictions identified by the professions studies and by individual experiences. (Kwoka, Tr. 1121-1122).

Response to Finding No. 603:

Respondent has no specific response.

604. Dr. Baumer agrees that not all of the anticompetitive conduct undertaken by the healthcare professional boards in the 1970s and 1980s has been eliminated, and that there is "absolutely" "continuing potential for abuse by state boards," and that "it certainly does occur." (Baumer, Tr. 1898, 1901; CX0826 at 012 (Baumer, Dep. at 39); CX0826 at 036 (Baumer, Dep. at 136); CX0826 at 055 (Baumer, Dep. at 211-212)).

Response to Finding No. 604:

Respondent has no specific response.

605. Dr. Baumer agrees that healthcare reciprocity restrictions are often needlessly restrictive in a manner than harms consumers. (Baumer, Tr. 1916). Dr. Baumer agrees it would be prudent to maintain a healthy skepticism for restraints on reciprocity that are justified by the need to keep dangerous healthcare professionals out of the state, given the history of reciprocity restrictions imposed by healthcare licensing boards. (Baumer, Tr. 1916-1917; CX0826 at 018-19 (Baumer, Dep. at 65-66) ("health and safety" rationale just a "smokescreen" for the "true motive" of "income enhancement for dentists in the state"))).

Response to Finding No. 605:

The quotation in parentheses misleadingly suggests that such quotations are Dr. Baumer's actual opinion, when in fact he was having conversation with deposing counsel about academic points and merely stated that the health and safety rationale comment with respect to reciprocity restrictions is a "plausible point."

606. It is a standard assumption in economics that people watch out for their own interests even if they have other objectives as well. (Kwoka, Tr. 1181; CX0826 at 011 (Baumer, Dep. at 34)).

Response to Finding No. 606:

Respondent has no specific response.

607. The professions studies have indisputably shown that the fact that board members are sworn state officials or ethical in their own conduct does not contravene the fact that their practices have been unduly restrictive and harmful to consumers. (Kwoka, Tr. 1112-1113). The financial interest of board members does not necessarily dominate their interests, but it does represent a significant part in how board members proceed. (Kwoka, Tr. 1115).

Response to Finding No. 607:

This is not a fact, it is an opinion statement by Dr. Kwoka. Further, there is no basis in the record for finding that the Board members were motivated more by their own financial interests than their sworn duty to uphold the laws of North Carolina and protect the health, safety and welfare of the public. In fact, they testified to the contrary. (Wester, Tr. 1280; Owens, Tr. 1440, 1474-1475; Hardesty, Tr. 2763-2766). Further, Dr. Kwoka conceded that Board members acted based in part on their sworn duty as public officials and are also motivated by ethical and professional standards of behavior. (Kwoka, Tr. 1111-1113).

608. Dr. Baumer agreed that professional boards have sometimes operated to enhance income, and sometimes operated strictly in the public interest. (Baumer, Tr. 1848).

Response to Finding No. 608:

Respondent has no specific response.

609. Dr. Baumer admits that because of human nature, board members might be influenced by the impact of their decisions on the financial bottom line of dentists. (Baumer, Tr. 1871). The fact that the Board sent a mail letter to a mail operator only two miles from the location of a Board member's dental practice would influence Dr. Baumer's opinion of whether the Board had tried to eliminate financial conflicts of interest. (Baumer, Tr. 1870-1871).

Response to Finding No. 609:

Dr. Baumer merely said that letters sent to mall operators would be "one factor [he] would take into account." (Baumer, Tr. 1870-1871).

610. For the purposes of his analysis, Professor Kwoka does not assume that dentists are solely motivated by profit maximization. Dentists practice in honest and ethical ways, but nonetheless clearly understand their financial interest in various restrictions that may be put in place. (Kwoka, Tr. 1053; CX0631 at 003, 009).

Response to Finding No. 610:

Dr. Baumer rebutted this testimony by pointing out that Dr. Kwoka states "time and time again that the state board represents dentists, they have a material interest in excluding competition" and that that is their motivation with respect to teeth whitening. (Baumer, Tr. 1765). He conceded that he could eliminate the word "solely", but maintained that Dr. Kwoka's analysis was dominated by its reference to profit maximization as a motive of Board members. (Baumer, Tr. 1765).

611. Dr. Baumer admits that he should not have claimed that Professor Kwoka argued that dentists are "solely" motivated by profit maximization. (Baumer, Tr. 1765).

Response to Finding No. 611:

Respondent refers to its response to Finding No. 610.

612. The fact that Board members swear an oath in order to serve on the Board does not change the fact that they represent their own financial interests and the interests of their constituent North Carolina dentists. (Kwoka, Tr. 1111-1112).

Response to Finding No. 612:

This is not a fact, it is an opinion statement by Dr. Kwoka. Further, there is no basis in the record for finding that the Board members were motivated more by their own financial interests than their sworn duty to uphold the laws of North Carolina and protect the health, safety and welfare of the public. In fact, they testified to the contrary. (Wester, Tr. 1280; Owens, Tr. 1440, 1474-1475; Hardesty, Tr. 2763-2766). Further, Dr. Kwoka

conceded that Board members acted based in part on their sworn duty as public officials and are also motivated by ethical and professional standards of behavior. (Kwoka, Tr. 1111-1113).

613. Dr. Baumer agrees that it is well recognized that medical professional board members engaged in conduct that harmed consumers despite their oaths to protect the public health. (Baumer, Tr. 1915). One of Dr. Baumer's concerns about licensing boards holding the power to exclude is the financial interests of the regulated in excluding competition. (CX0826 at 037 (Baumer, Dep. at 138)).

Response to Finding No. 613:

Dr. Baumer agreed that these were the findings of studies from the 1970s and 1980s that he considers to be outdated literature for purposes of this matter. The second sentence mischaracterizes Dr. Baumer's deposition testimony. He actually only stated that one of his concerns with respect to having the power to exclude is "**related to** the financial interests of the regulated in excluding competition." He did not state that it was his actual belief, only that the two were related. (CX0826 (Baumer, Dep. at 138)). He also states in this discussion that

Their intent in excluding a class of products may not be to make more money. It may be due to ignorance. It may be an effect of that exclusion that they do make more money, but they may be of the opinion that the product was unsafe when, in fact, it wasn't unsafe, and they ended up excluding it because they thought it was unsafe but not directly because it would add 5 percent more to their gross incomes.

(CX0826 at 037 (Baumer, Dep. at 138)).

614. The fact that Board members have the interest of the public in mind is not in conflict with the fact that the Board members also have the interest of dentists in mind. (Kwoka, Tr. 1177; CX0826 at 039 (Baumer, Dep. at 146) ("[M]ost professionals, including dentists, are intrigued with what they do. . . . They also like money, want money.")). Dr. Baumer agrees that there could be anticompetitive effects of Board conduct if there were a mixed motive in terms of pecuniary self-interest and concern for health and safety. (CX0826 at 024 (Baumer, Dep. at 87)).

Response to Finding No. 614:

The last sentence of this statement is misleadingly incomplete in that it omits Dr. Baumer's follow-up explanation to his statement regarding mixed motives, in which he stated how he thinks one could distinguish anticompetitive actions from actions that are not anticompetitive where such mixed motives exist. In that explanation, he stated that if one looks at all the factors, such as "statements of the Board themselves as to the reason for this action, e-mails that might have taken place or other evidence of correspondence between the Board members, et cetera", then one would have to look to whether or not the Board was acting within an area that is defined by the statute that it is charged with enforcing. (CX0826 (Baumer, Dep. at 87-88)).

615. Dr. Baumer agrees that if the Board does not follow statutory requirements and procedures in proceeding against the unlicensed practice of dentistry that it "would be a factor that would suggest they're not being completely objective." (CX0826 at 047 (Baumer, Dep. at 179)).

Response to Finding No. 615:

Respondent refers to its response to Finding No. 614. Also, Respondent notes that the record reflects that the Board acted within its statutory requirements and procedures. *See* Respondent's Proposed Findings of Fact Nos. 11-74.

616. Professor Kwoka's critique of professional licensing is limited to those cases where licensing is unnecessary or unduly restrictive, such as the actions of the Board. Professor Kwoka is not attacking professional licensing generally. (Kwoka, Tr. 1055-1056, 1109-1114, 1250; CX0631 at 006). Professor Kwoka does not in any way advocate for the deregulation of the professions. (Kwoka, Tr. 1260).

Response to Finding No. 616:

Respondent notes that there is no basis in the record for the statement that "the actions of the Board" are "unnecessary or unduly restrictive" and that this statement contains an improper assumption. Further, Dr. Baumer found that Dr. Kwoka's critique of professional boards is clearly an argument for deregulation: "I don't see how else you can

look at it. Yes, it's an argument for deregulation." (Baumer, Tr. 1772). Dr. Baumer added that "the board is not a candidate for deregulation. No economist that I'm aware of has come out and said that." (Baumer, Tr. 1809-1810).

617. Dr. Baumer admits that he cannot point to anything that explicitly demonstrates that Professor Kwoka wants to abolish licensing boards. (Baumer, Tr. 1871-1872, 1965). Dr. Baumer admits that Professor Kwoka explicitly denied that he wanted to abolish licensing boards. (Baumer, Tr. 1871-1872). Dr. Baumer admits that Professor Kwoka does not take issue with the conduct of the Board other than its conduct with reference to non-dentist teeth whiteners. (Baumer, Tr. 1885-1886). It is not Dr. Baumer's view that Professor Kwoka is arguing that there should be no licensing of dentists. (CX0826 at 028 (Baumer, Dep. at 102)).

Response to Finding No. 617:

The last sentence misstates Dr. Baumer's testimony. He actually said that "95 percent of what [Dr. Kwoka] talks about appears to be negative towards licensing, particularly in his initial report," but that after Dr. Baumer's criticism of his initial report Dr. Kwoka "backed off and admitted that where there are significant health concerns, he even says where it's reasonable to have licensing." (CX0826 (Baumer, Dep. at 102)).

618. Dr. Baumer cannot point to anything but the gestalt of Professor Kwoka's report, rebuttal report, and demonstrative exhibit to support his assertion that Professor Kwoka wants to abolish licensing boards. (Baumer, Tr. 1877-1878, 1884-1885).

Response to Finding No. 618:

First, this statement misstates Dr. Baumer's testimony, since he actually said the gestalt "at a minimum" indicates the basis for his finding that Dr. Kwoka is a proponent of abolishing licensing boards. Dr. Baumer also cited the statements made by Dr. Kwoka in his demonstrative exhibit, that is, his slideshow (CX822) itself, not its "gestalt." (Baumer, Tr. 1884-1885 ("I think the PowerPoint notes that he produced kind of speak for themselves, and so that's my evidence.")).

619. Professor Kwoka does not assert that a board like the North Carolina State Board of Dental Examiners is *per se* anticompetitive simply by the way it is structured. (Kwoka, Tr. 1109, 1113-1114, 1117).

Response to Finding No. 619:

Dr. Baumer disagrees with this statement, and found Dr. Kwoka's analysis to be consistent with a *per se* analysis, and not a rule of reason analysis. (Baumer, Tr. 1699). He found that Dr. Kwoka's analysis essentially asserts that the Board's structure is illegal because it is dominated or populated by a majority of professionals. (Baumer, Tr. 1810). Further, Dr. Kwoka made **no assertion at all** regarding whether his analysis was consistent with a "per se" analysis or a "rule of reason" analysis. Neither of those terms appear anywhere in the transcript during his testimony. Dr. Baumer's testimony that Dr. Kwoka applied a *per se* analysis is and continues to be entirely unrebutted by any evidence in the record. The unsupported assertions of Complaint Counsel in the above self-serving statement cannot form a basis for rebutting Dr. Baumer's testimony.

620. Professor Kwoka did not examine the structure of licensing boards within North Carolina, or in the United States generally, other than the North Carolina State Board of Dental Examiners. Professor Kwoka referenced the professions studies to demonstrate that the restrictions by the Board were not a novel or unprecedented occurrence, but did not make conclusions regarding licensing boards generally. (Kwoka, Tr. 1119-1120).

Response to Finding No. 620:

Respondent has no specific comment.

621. Certification would be a less restrictive alternative than a ban and result in a reduction in anticompetitive effects. (Kwoka, Tr. 1124).

Response to Finding No. 621:

Dr. Kwoka also stated that he "didn't advocate certification here." (Kwoka, Tr. 1259).

622. State agencies, private organizations, trade associations, or other professional bodies may offer certifications of a minimal quality standard that can be relied upon by consumers. Certification does not require prohibition of non-certified products and

services, and some consumers may prefer a low-cost provider above a certified provider. (Kwoka, Tr. 1125).

Response to Finding No. 622:

Respondent refers to its response to Proposed Finding No. 621.

623. The certification model is not the abolition of intervention in the market, but it offers a less restrictive alternative to prohibition of products that consumers desire. (Kwoka, Tr. 1125-1126).

Response to Finding No. 623:

Respondent refers to its response to Proposed Finding No. 621.

624. Dr. Baumer proffers no evidence that, with regard to teeth whitening, a licensing regime offers an advantage over methods of market correction. "The market's long and overwhelmingly benign experience with teeth whitening by non-dentists indicates that there is no sensible basis to reserve teeth whitening to licensed graduates of a dental school, any more than the application of cosmetics should be reserved to licensed dermatologists or ear piercing to licensed surgeons." (CX0631 at 011-012).

Response to Finding No. 624:

This statement contains a blatant assumption for which there is no basis in the record.

The record does not at all reflect a "long and overwhelmingly benign experience with teeth whitening by non-dentists." In fact, it reflects that there are a number of dangers to teeth whitening –

the Board provided numerous examples of health and safety issues, including the testimony of an expert in the fields of practical and clinical esthetic and restorative dentistry, the testimony of Mr. Runsick, an actual consumer, the testimony of a dentist that evaluated Mr. Runsick's injury that was caused by teeth whitening, the testimony of licensed dentists regarding the health and safety issues involved with kiosk/spa teeth whitening, and the documentary evidence of other consumers injured by kiosk/spa teeth

whitening. See Respondent's Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531. Additionally, Complaint Counsel's expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466).

Further, Complaint Counsel provides no explanation of what it means by "market correction." Also, Dr. Baumer testified that "[he does not] believe the market solves all problems and that we want to go back to having unregulated provision of medical services", and that the market mechanism argument is "basically[] an argument for deregulation." (Baumer, Tr. 1772).

625. Dr. Baumer was not aware of other state regulatory models where Department of Health oversight over state licensing boards provides a disinterested decision-maker for new regulations or rules, but states "that's an interesting variation" and "removing conflicts of interest . . . other things being equal is a good thing." (CX0826 at 038 (Baumer, Dep. at 142, 144)).

Response to Finding No. 625:

In the same discussion, Dr. Baumer also pointed out that "one of the benefits of the Board of -- the State Board of Dental Examiners is the fact that you have actual practitioners who actually know what goes on when a dentist opens up somebody's mouth. Now, if you have some bureaucrat who has a master of public administration in health, I don't know if they know what's -- what it's like on the front lines or not." (CX0826 (Baumer, Dep. at 144)).

626. Dr. Baumer does not believe that all services need to be provided by licensed professionals. (CX0826 at 046 (Baumer, Dep. at 177)).

Response to Finding No. 626:

Respondent has no specific response.

627. The "lemons" problem, as formulated by economist George Akerlof, is the concern that information differences between consumers and sellers will result in low-quality products driving high-quality products out of the market. (Kwoka, Tr. 1089-1090). Both Professor Kwoka and Dr. Baumer agree that the lemons problem does not apply to nondentist teeth whitening. (Kwoka, Tr. 1090; Baumer Tr. 1772, 1773). The lemons problem is not an issue because consumers have no trouble distinguishing dentists from non-dentists, and can choose dentists if they believe dentists provide a higher quality product. (Kwoka, Tr. 1090-1091).

Response to Finding No. 627:

While it is true that Dr. Baumer conceded that there is not an Akerlof problem here, that was only limited to the proposition that non-dentists have not chased dentists out of the market. Dr. Baumer did not agree with the last sentence made in this statement, because in his view there are still issues with regard to consumer confusion and sanitation problems. Consumers that walk into a kiosk are not necessarily aware of things they should have before undergoing teeth whitening, such as a dental exam, nor are they aware of the level of medical training of these people who happen to be dressed in medical garb. (Baumer, Tr. 1773). Consumer also would not be sufficiently aware of such sanitation issues such as whether there is running water at a kiosk and why that is a necessary sanitation measure. (Baumer, Tr. 1773).

D. The Board's Conduct Excluded Competition from Non-Dentists

1. Non-dentist Teeth Whiteners Were Excluded by the Board Sending Cease and Desist Orders

628. The Board's Cease and Desist Orders were effective in excluding non-dentist teeth whitening from North Carolina. Many of the recipients ceased offering teeth-whitening services. (RX0078 at 008 ("Not surprisingly, the actions of the State Board were effective and many kiosk and spa operated complied" with the Cease and Desist Orders)).

Response to Finding No. 628:

Respondent disputes this proposed finding of fact as it mischaracterizes the material offered in support of it and is also an incomplete statement of fact. The complete

quotation offered by Complaint Counsel in support is as follows: "Not surprisingly, the actions of the State Board were effective and many kiosk and spa operators complied with state law by ceasing their actions that were clearly in violation of state law." (RX78 at 8). In addition, this quotation was not only referring to the cease and desist letters; it was referencing all of the actions of the Board. (RX78 at 8).

629. Businesses stopped providing non-dentist teeth services after receiving a Cease and Desist Order from the Board. In January 2008, Amazing Grace Day Spa stopped offering teeth-whitening services after receiving a Cease and Desist Order from the Board. (CX0347 at 001).

Response to Finding No. 629:

Respondent disputes this proposed finding of fact as a misrepresentation of the record.

The letter recipient clearly states that she had already stopped offering teeth whitening services prior to the receipt of the Board's letter. (CX347 at 1).

630. After receiving a Cease and Desist Order from the Board dated February 8, 2007, the owner of Champagne Taste Salon, also known as "Lash Lady" wrote to the Board stating that "they have now stopped offering [teeth whitening] service[s]." (CX0622 at 003).

Response to Finding No. 630:

Respondent has no specific response.

631. By February 29, 2008, according to a Memorandum to Members of the Board from Terry Friddle regarding Closed Investigative Files, Savage Tan Salon no longer offered teeth whitening after receiving a Cease and Desist Order from the Board. (CX0623 at 003-004).

Response to Finding No. 631:

Respondent disputes this finding of fact as a misrepresentation of the record. The evidence offered by Complaint Counsel in support of this proposed finding of fact shows that after receiving the cease and desist letter, the recipient informed Board staff that he did not intend to stop offering teeth whitening services. (CX623 at 3-4). A follow-up

visit by the Board's investigator revealed that teeth whitening services were not being offered at that location, but it was not known whether the individual was continuing to offer services at another location. (CX623 at 4).

632. In a letter dated February 9, 2009, Modern Enhancement Salon owner Tonya Norwood notified that Board that her salon would "no longer perform this service as per your order to stop and will no longer perform whitening services unless told otherwise by the North Carolina Board of Dental Examiners." (CX0162 at 001).

Response to Finding No. 632:

Respondent has no specific response.

633. Triad Body Secrets was "forced out of business" after receiving a Cease and Desist Order from the Board. (CX0815 at 001).

Response to Finding No. 633:

Respondent disputes this proposed finding of fact as it constitutes hearsay. (CX815 at 1).

634. A Bleach Bright business in Carolina Place Mall was "forced out of business" after receiving a Cease and Desist Order from the Board. (CX0815 at 001).

Response to Finding No. 634:

Respondent disputes this proposed finding of fact as it constitutes hearsay. (CX815 at 1).

635. Margie Hughes of SheShe Studio Spa testified that she stopped offering teeth whitening services immediately upon receiving the Board's Cease and Desist Order dated February 23, 2007. (Hughes, Tr. 946).

Response to Finding No. 635:

Respondent disputes this proposed finding of fact as the testimony offered by Ms. Hughes at the hearing is inconsistent with contemporaneous documents in the Board's investigative file. In a telephone conversation on July 10, 2007, the Board's investigator was told by Ms. Hughes that she "now has a consent form that her clients sign stating that they will take their own impressions" and that she "requires her clients to sign [the] consent form." (CX353 at 2, Investigative Memorandum dated August 7, 2007). Ms.

Hughes also testified that she offered services to family members and friends after receipt of the Board's letter. (Hughes, Tr. at 950-951).

636. After receiving a Cease and Desist Order from the Board dated January 31, 2007, Details, Inc. notified the Board that it had sold its teeth whitening equipment and was no longer providing teeth whitening services. (CX0660 at 003).

Response to Finding No. 636:

Respondent disputes this finding of fact as a misrepresentation of the record and assumption of fact. The letter recipient informed the Board that the teeth whitening equipment had been sold and such services were no longer being provided. (CX660 at 3). Complaint Counsel assumes that the equipment was sold after receipt of the Board's letter.

637. After receiving a Cease and Desist Order from the Board dated July 17, 2008, the owner of Bailey's Lightening Whitening wrote to the Board that "due to [the Cease and Desist Order she] had disposed of the [teeth whitening] product" and "would not be providing any teeth whitening services at her salon." (CX0658 at 005).

Response to Finding No. 637:

Respondent disputes this proposed finding of fact as a misrepresentation of the record. The exhibit cited by Complaint Counsel in support of this proposed finding of fact shows that the teeth whitening product was never used at the salon; they never sold or "even practiced it on themselves." (CX658 at 5).

638. Businesses pared back their advertising and operations after receiving a Cease and Desist Order from the Board. Ms. Margie Hughes of SheShe Studio Spa testified that she stopped advertising her teeth whitening services immediately upon receiving the Board's Cease and Desist Order dated February 23, 2007. (Hughes, Tr. 946).

Response to Finding No. 638:

Again, Respondent disputes this proposed finding of fact as an assumption and a misrepresentation of the record. Ms. Hughes testified that she only advertised her teeth

whitening services in the newspaper for a "week or two," so the cease and desist letter would not have had an effect on her advertising in that manner. (Hughes, Tr. at 837). Further, this proposed statement of fact does not offer any evidence in support of the assertion that businesses scaled back their operations.

639. After receiving a Cease and Desist Order from the Board dated February 18, 2009, Mike Hodges of Tom Jones Drug wrote to the Board stating that "[i]mmediately after receiving your [C&D] notice we have halted advertising, disposed of all postcards, printed flyers and discontinued any verbal communication on making any claim to remove stains from the human teeth." (CX0309 at 001).

Response to Finding No. 639:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and a misrepresentation of the record. This pharmacy still performs teeth whitening and is still advertising. An investigative memorandum about the observations of an investigation performed on March 19, 2010 references a flyer sent to the Board and details the investigator's investigation. (RX30 at 4).

2. Non-dentist Teeth Whiteners Were Excluded as a Result of the Board Sending Letters to Malls and Mall Property Management Groups

640. On November 21, 2007, the Board sent at least 11 nearly identical letters to third parties, including mall management and out-of-state mall property management companies, stating that "[t]he Dental Board has learned that an out of state company has leased kiosks in a number of shopping malls in North Carolina for the purpose of offering teeth whitening services to the public," and that removal of stains was a crime in North Carolina. (CX0203 at 001-002; CX0204 at 001-002; CX0205 at 001-002; CX0259 at 001-002; CX0260 at 001-002; CX0261 at 001-002; CX0262 at 001-002; CX0263 at 001-002; CX0323 at 001-002; CX0324 at 001-002; CX0325 at 001-002; CX0326 at 001-002).

Response to Finding No. 640:

Respondent disputes this proposed finding of fact as a mischaracterization of the evidence cited in its support. The letter specifically states that "[t]he unauthorized practice of dentistry is a misdemeanor" and the lack of supervision of teeth whitening

services by a licensed North Carolina dentist is illegal. (CX203 at 1; CX204 at 1; CX205 at 1; CX259 at 1; CX260 at 1; CX261 at 1; CX262 at 1; CX263 at 1; CX323 at 1; CX324 at 1; CX325 at 1; CX326 at 1).

641. These letters were effective in excluding non-dentist teeth whitening from North Carolina. As a direct result of the Board's November 21, 2007, letters to mall companies, mall management companies, and malls, mall operators were reluctant to lease space to non-dentist teeth whitening service providers in North Carolina. In fact, some companies refused to lease space and cancelled existing leases. (Wyant, Tr. 876-880, 881-884; Gibson, Tr. 627-628, 632-633; CX0255 at 001; CX0525 at 001; CX0629 at 001 to 002; CX0647 at 002).

Response to Finding No. 641:

Respondent disputes this proposed finding of fact as an incomplete finding of fact and misrepresentation of the record. The exhibits cited by Complaint Counsel in support of this proposed finding of fact also show that malls whose management companies received the November 21, 2007 letters had teeth whitening kiosks as tenants as of August 28, 2009 and September 27, 2010. (CX629 at 3; CX647 at 2).

642. Hull Story Gibson's ("HSG") Blue Ridge Mall received the letter from the Board dated November 21, 2007, stating that "[t]he Board has learned that an out of state company has leased kiosks in a number of shopping malls in North Carolina for the purpose of offering teeth whitening services to the public," and that removal of stains was a crime in North Carolina." The letter was brought to the attention of HSG's CEO John Gibson by Ms. Cathy Mosley. HSG's Cleveland Mall received a virtually identical letter. (CX0203; CX0259; Gibson, Tr. 626-627).

Response to Finding No. 642:

Respondent disputes this proposed finding of fact as a mischaracterization of the evidence cited in its support. The letters received by both malls specifically state that "[t]he unauthorized practice of dentistry is a misdemeanor" and the lack of supervision of teeth whitening services by a licensed North Carolina dentist is illegal. (CX203 at 1; CX259 at 1).

643. As a direct result of the Board's November 21, 2007 letter, HSG refused to rent space to non-dentist teeth whiteners and required that any non-dentist that would like to operate in its North Carolina Malls prove that the Board has approved their business model. (Gibson, Tr. 622-624, 632-633; CX0255 at 001).

Response to Finding No. 643:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and a mischaracterization of Mr. Gibson's testimony. Mr. Gibson also testified that HSG would have provided leasing space to other non-dentist providers of teeth-bleaching products and services "[s]o long as they were lawful." (Gibson, Tr. 633). He also testified that he would not object to leasing space to a kiosk that sold over-the-counter teeth whitening products. (Gibson, Tr. 633-634).

644. HSG CEO John Gibson testified that his management company would have rented either in-line or specialty (kiosk) space in its North Carolina properties to non-dentist teeth whitening or bleaching services, prior to its receipt of letters from the North Carolina State Board of Dental Examiners addressed to some its North Carolina malls. (Gibson, Tr. 622-623).

Response to Finding No. 644:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and mischaracterizes Mr. Gibson's testimony. Mr. Gibson further testified that he would have rented retail space to such tenants "on first blush" as they had not leased to a teeth whitening operation before and had no experience with whether it was an appropriate use of their property. (Gibson, Tr. 623-624).

645. Mr. Gibson of HSG further testified that if the Board were to, in effect, withdraw the letter sent to HSG stating that non-dentist teeth whitening operation were illegal, HSG would lease space in its North Carolina properties to non-dentist teeth whitening businesses. (Gibson, Tr. 624).

Response to Finding No. 645:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and a mischaracterization of Mr. Gibson's testimony. Mr. Gibson also testified that HSG would have provided leasing space to other non-dentist providers of teeth-bleaching products and services "[s]o long as they were lawful." (Gibson, Tr. 633). He also testified that he would not object to leasing space to a kiosk that sold over-the-counter teeth whitening products. (Gibson, Tr. 633-634).

646. HSG owns and manages five malls in North Carolina: Blue Ridge Mall in Hendersonville; Cleveland Mall in Shelby; Carolina Mall in Concord; New Bern Mall in New Bern; and Wilson Mall in Wilson. (Gibson, Tr. 613-614).

Response to Finding No. 646:

This is a nearly word-for-word duplicate to Proposed Finding of Fact No. 333.

Respondent has no other specific response.

647. As a direct result of the Board's November 21, 2007 letter, General Growth Properties ("GGP") and Simon Group Properties refused to rent space to, and renew leases for, nondentist teeth whitening businesses, including the Carolina Place Mall in Pineville, North Carolina. (Wyant, Tr. 874-884, 902-903; CX0629).

Response to Finding No. 647:

Respondent disputes this finding of fact as a misrepresentation of the record. An exhibit cited by Complaint Counsel in support of this proposed finding of fact shows that, as of September 27, 2010, there was a teeth whitening kiosk in operation in the same space as Mr. Wyant vacated at Carolina Place Mall. (CX629 at 3). In addition to the kiosk at Carolina Place Mall, there was a teeth whitening tenant at another GGP mall, Streets at Southpoint, as of August 28, 2009. (CX647 at 2). Further, at another GGP mall, Valley Hills Mall, the teeth whitening kiosk had closed, but the mall "did not take any action to close the tenant." (CX647 at 2).

648. GGP manages three other properties in North Carolina - The Streets at Southpoint in Durham; Four Seasons Town Centre in Greensboro; and Valley Hills Mall in Hickory. (CX0647 at 001-002, 008, 014).

Response to Finding No. 648:

Respondent has no specific response.

649. Simon Malls decided not to lease to non-dentist teeth whitening businesses after receiving the mall letter. Simon manages Concord Mills Mall and South Park Mall. (Wyant, Tr. 881, 883).

Response to Finding No. 649:

Respondent disputes this proposed finding of fact as containing an assumption as to the decision process of Simon Malls. There is no basis in the record for the assumption that this decision was based on the receipt of the Board's letter.

3. Non-dentist Teeth Whiteners Were Excluded as a Result of the Board Convincing the North Carolina Board of Cosmetic Arts Examiners to Inform Cosmetologists That It Was Unlawful for Them to Perform Teeth Whitening

650. In February 2008, after learning of the increased number of non-dentist teeth whitening services being offered in salons and spas, the Dental Board contacted the Cosmetology Board, asking that Board to caution its licensees that performing certain teeth whitening procedures violated that Dental Practice Act. (CX0566 at 030 (Hardesty, IHT at 115-116); CX0056 at 005; CX0561 at 032 (Friddle, Dep. at 119-120)).

Response to Finding No. 650:

Respondent disputes this finding of fact in that it contains a mischaracterization of testimony and misrepresentation of the record. The evidence cited by Complaint Counsel in support of this proposed finding of fact shows instead of learning of the increased number of non-dentist teeth whitening services offered in salons and spas, the Board saw "an increase in complaints involving spas that [were] offering teeth whitening services." (CX56 at 5; CX566 (Hardesty, IHT at 115-116); CX561 (Friddle, Dep. at 120). Further, Board Counsel testified that contact was made with the Cosmetology Board because of

“tearful calls” that the Board was receiving from “young ladies who had purchased expensive equipment and found upon investigating the matter further that they probably wouldn’t be allowed to use it, and they – some of them were very angry about the way they had been treated by the distributors.” (RX50 (Bakewell, Dep. at 307)).

651. Dr. Hardesty instructed Board attorney Carolin Bakewell to prepare an article for the Cosmetology Board to post on its website regarding teeth whitening, after discussing the issue with the other Board members at a Board meeting. (Hardesty, Tr. 2861-2862). The Cosmetology Board posted the Dental Board's notice on the Cosmetology Board's website. (Hughes, Tr. 940-941).

Response to Finding No. 651:

Respondent disputes this proposed finding of fact as an incomplete statement of fact and as containing an assumption. Dr. Hardesty testified that the decision to prepare an article for the Cosmetology Board was undertaken after consultation with legal counsel.

(CX565 (Hardesty, Dep. at 238-239)).

652. Cosmetology Board licensees learned of the Dental Board's stance against nontdentists performing teeth whitening services from the Cosmetology Board. (CX0347; CX0050 at 001; CX0814; Hughes Tr. 940-941).

Response to Finding No. 652:

Respondent has no specific response.

653. As a direct result of the Board's actions with respect to the Cosmetology Board, nontdentists stopped providing teeth whitening services. (CX0050 at 001; CX0814; Hughes Tr. 941-943).

Response to Finding No. 653:

Respondent disputes this proposed finding of fact as an assumption. Respondent also disputes this proposed finding of fact as the testimony offered by Ms. Hughes at the hearing is inconsistent with contemporaneous documents in the Board’s investigative file.

In a telephone conversation on July 10, 2007, after her viewing of the Cosmetology

Board's notice on its website, the Board's investigator was told by Ms. Hughes that she "now has a consent form that her clients sign stating that they will take their own impressions" and that she "requires her clients to sign [the] consent form." (CX353 at 2, Investigative Memorandum dated August 7, 2007; Hughes, Tr. at 942-943).

654. In a note dated March 27, 2007, Ms. Pamela Weaver indicated that she no longer provided non-dentist teeth whitening services after she was informed by the Cosmetology Board that it was not legal. (CX0050 at 001). An e-mail from Board investigator Line Dempsey, and a memo from Terry Friddle confirm that Ms. Weaver did in fact stop offering those services after interacting with the Cosmetology Board. (CX0347 at 001; CX0530 at 004).

Response to Finding No. 654:

Respondent disputes this proposed finding of fact as a mischaracterization of the exhibit cited in support by Complaint Counsel. Ms. Weaver's letter states that she "found out" from the Cosmetology Board about the legality of her use of the teeth whitening equipment. (CX50 at 1). She does not provide any details about how she "found out," so there is an assumption on the part of Complaint Counsel that she was personally "informed" by the Cosmetology Board. (CX50 at 1).

655. In an e-mail dated August 31, 2010, Pat Helmandollar notified WhiteScience that her salon "will no longer be doing teeth whitening in our salon/spa as the North Carolina board of cosmetic arts has deemed it unlawful to perform this service in a salon." (CX0814; Nelson, Tr. 786-787).

Response to Finding No. 655:

Respondent has no specific response.

4. Distributors and Manufacturers of Non-dentist Teeth Whitening Products Were Excluded by the Board Sending Cease and Desist Orders, Letters to Malls and Mall Property Management Groups and Contacting the North Carolina Board of Cosmetic Arts Examiners

656. As a result of the Dental Board's actions, manufacturers of teeth whitening products used by non-dentist teeth whiteners have been unable to maintain a distribution

network for their products in North Carolina, or the facilities by which such distribution might be accomplished. (Nelson, Tr. 735-736, 775-778, 785-787; CX0814 at 001; CX0389 at 001; Valentine, Tr. 562-564, 575; Osborn, Tr. 671-675).

Response to Finding No. 656:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Mr. Nelson testified that WhiteScience currently has some business in North Carolina. (Nelson, Tr. 800-801.) Respondent also disputes this finding of fact as containing an assumption that the Board's actions are the only factors allegedly keeping manufacturers out of the market. Ms. Osborn testified that she felt "that it would not be honest of me to sell a machine in a state that prohibited teeth whitening outside the dental industry, and it would create a bad track record for our company." (Osborn, Tr. at 674). Mr. Valentine's testimony was that WhiteSmile's re-entry into North Carolina was not successful due to "the environment at that time, our sales had across the country dropped off significantly due to the economy, so it was just an economic issue." (Valentine, Tr. 575).

a. WhiteScience

657. As a result of the Board's actions, including the issuance of Cease and Desist Orders, WhiteScience's sales in North Carolina "evaporated." (Nelson, Tr. 735-736; 774-778).

Response to Finding No. 657:

Respondent disputes this proposed finding of fact as a mischaracterization of the entire record. Mr. Nelson testified that WhiteScience currently has some business in North Carolina. (Nelson, Tr. 800-801.)

658. Before being "shut down" by the Board, WhiteScience was making close to \$200,000 a year in sales of teeth whitening products in North Carolina. This equates to over a million dollars in lost retail sales in North Carolina. (Nelson, Tr. 734-35).

Response to Finding No. 658:

Respondent disputes this proposed finding of fact as making an assumption and as a mischaracterization of the entire record. Mr. Nelson testified that WhiteScience currently has some business in North Carolina. (Nelson, Tr. 800-801.)

659. Recipients of Cease and Desist Orders operating in North Carolina using WhiteScience teeth whitening systems believed that those letters were orders from the State of North Carolina to stop providing teeth whitening services. (Nelson, Tr. 789).

Response to Finding No. 659:

Respondent disputes this proposed finding of fact as hearsay.

660. As a result of the Board's actions, including the issuance of Cease and Desist Orders, Triad Body Secret ceased selling teeth whitening services. Previously, Triad Body Secrets provided teeth whitening using the WhiteScience product. (Nelson, Tr. 785-786; CX0389 at 001-002).

Response to Finding No. 660:

Respondent disputes this proposed finding of fact as hearsay. Mr. Nelson testified that he spoke to someone at Triad regarding this issue. (Nelson, Tr. 786).

661. Pam Helmendollar, the owner of a salon/spa in North Carolina informed WhiteScience that she stopped providing teeth whitening services at her business because she believed that the North Carolina Board of Cosmetic Arts Examiners deemed it unlawful for salons to provide teeth whitening services. (Nelson, Tr. 786-787; CX0814 at 001).

Response to Finding No. 661:

Respondent has no specific response.

b. BEKS

662. As a result of the Board's actions, including the issuance of Cease and Desist Orders, Ms. Joyce Osborn of BriteWhite Systems stopped selling her products in North Carolina. BriteWhite products have not been sold in North Carolina since 2008. (Osborn, Tr. 671-675; Nelson Tr. 778).

Response to Finding No. 662:

Respondent disputes this proposed finding of fact. The testimony of Mr. Nelson offered by Complaint Counsel in support of the proposed finding of fact does not make reference to BriteWhite. (Nelson, Tr. 778).

663. Ms. Osborn testified that she was "scared of having a risk of getting a cease and desist," and did not sell in North Carolina or through a distributor into North Carolina even though there were a "number of requests" for its product from people in North Carolina. BriteWhite is a family business and cannot afford to take any risk of challenge from the Board. (Osborn, Tr. 671-675).

Response to Finding No. 663:

Respondent disputes this finding of fact as an incomplete statement of fact. Immediately after testifying that BriteWhite was a family-owned business and it could not afford to take any risk, Ms. Osborn testified that she felt "that it would not be honest of me to sell a machine in a state that prohibited teeth whitening outside the dental industry, and it would create a bad track record for our company." (Osborn, Tr. at 674).

664. But for the Board's actions, Ms. Osborn would sell the BriteWhite System in North Carolina. (Osborn, Tr. 674-675).

Response to Finding No. 664:

Respondent disputes this proposed finding of fact as based upon an assumption and as not supported by the the evidence cited by Complaint Counsel. The testimony cited by Complaint Counsel in support of this proposed finding of fact does not attribute Ms. Osborn's decision not to sell her teeth whitening system in the state of North Carolina to the actions of the Board. (Osborn, Tr. 674-675).

c. WhiteSmile USA

665. Mr. Jim Valentine, a principal at WhiteSmile USA, stated that at its peak, WhiteSmile operated in over 60 Sam's Club stores in about 28-29 states. WhiteSmile

averaged \$2,000 each day it operated at a Sam's Club location, and at good stores, could make as much as \$3,500 to \$4,000 a day. WhiteSmile's best-day revenues from its combined Sam's Club operations was \$248,000. (Valentine, Tr. 548-549).

Response to Finding No. 665:

Respondent has no specific response.

666. Mr. Valentine stated that WhiteSmile first marketed its products and services in North Carolina in the spring of 2007 through its "road shows." Road shows are temporary kiosks located in places like Sam's Club for a period of time before moving to the next location. The early shows in Raleigh and Charlotte were considered a big success. (Valentine, Tr. 561).

Response to Finding No. 666:

Respondent has no specific response.

667. Mr. Valentine stated that despite WhiteSmile's early success in North Carolina, and despite the fact that it considered North Carolina to be a good market, WhiteSmile initially chose not to do Sam's Clubs shows in North Carolina. This was because both WhiteSmile and Sam's Club were aware of the actions taken by the Dental Board in North Carolina against non-dentist teeth whiteners. (Valentine, Tr. 562-563; 610).

Response to Finding No. 667:

Respondent has no specific response.

668. Mr. Valentine stated that WhiteSmile was aware of the Board's stance against nondentist teeth whitening through its contacts with potential investors in North Carolina. WhiteSmile learned of the Board's use of Cease and Desist Orders, and counsel for the investors was told by the Board that WhiteSmile's operations would be considered the practice of dentistry, even though providers would not touch their customers' mouths. (Valentine, Tr. 562-564).

Response to Finding No. 668:

Respondent disputes this finding of fact as it mischaracterizes Mr. Valentine's testimony.

Mr. Valentine testified that he was aware of cease and desist letters being sent by the Board. (Valentine, Tr. 563). In addition, Mr. Valentine's testimony about the investors' counsel contacting the Board and what the Board told them is hearsay. (Valentine, Tr. 564).

669. Mr. Valentine stated that because of the Board's representations to the counsel for the potential investors, WhiteSmile's negotiations with the North Carolina investors fell apart. (Valentine, Tr. 563-564).

Response to Finding No. 669:

Respondent disputes this proposed finding of fact as a mischaracterization of Mr.

Valentine's testimony. Mr. Valentine testified that the deal fell through because of the investors' "concern about the legality of it" and because their attorneys advised against it.

(Valentine, Tr. at 563-564).

670. Mr. Valentine testified that he personally contacted to the Board to inquire as to whether WhiteSmile could market its system to non-dentists in North Carolina. Mr. Valentine stated that the Board responded to his query and informed him that it considered WhiteSmile's product and procedures to be the practice of dentistry. (CX0206 at 004-005; Valentine, Tr. 564-567). This was despite the fact that the Board knew that WhiteSmile's process was entirely self-applied. (Valentine, Tr. 566-567).

Response to Finding No. 670:

Respondent disputes this finding of fact as mischaracterizing the record. The minutes of the Board meeting cited by Complaint Counsel in support of this proposed finding of fact clearly indicate that the Board, upon a review of the literature provided to it by Mr.

Valentine, determined that non-dentist following these procedures would be engaged in the practice of dentistry in North Carolina. (CX206 at 4-5).

671. Valentine stated that WhiteSmile did not want to operate in North Carolina because it knew it would have an issue. (Valentine, Tr. 578).

Response to Finding No. 671:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

Mr. Valentine did not testify that WhiteSmile did not want to operate in North Carolina; he testified that WhiteSmile "didn't want to have an issue where we knew there would be an issue." (Valentine, Tr. at 578).

672. Mr. Valentine stated that WhiteSmile would have entered the North Carolina market in January 2008 had it not been for the Board's opposition to non-dentist provided teeth whitening. (Valentine, Tr. 568).

Response to Finding No. 672:

Respondent disputes this proposed finding of fact as it is supported with testimony characterized by Mr. Valentine as his "guess." (Nelson, Tr. 568).

673. Mr. Valentine stated that WhiteSmile eventually entered the North Carolina market in 2009 with Sam's Club road shows. (Valentine, Tr. 567).

Response to Finding No. 673:

Respondent has no specific response.

674. Mr. Valentine stated that as a result of this delay, WhiteSmile likely lost close to half a million dollars in sales revenue. He estimated that WhiteSmile would have done over 60 shows in North Carolina without the Board's interference, at a conservative estimate of \$25,000 per show in sales revenue. (Valentine, Tr. 568-570).

Response to Finding No. 674:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Mr. Valentine testimony does not reflect the amount of lost revenue as indicated in this proposed finding of fact. (Valentine, Tr. 569-570). Mr. Valentine also testified that his estimates of damages that his company suffered in 2008 were irrelevant because "Sam" wouldn't let the company go there. (Valentine, Tr. at 578).

675. Mr Valentine stated that WhiteSmile teams faced interference from North Carolina dentists and dental hygienists at Sam's Club locations. Dentists and dental hygienists attempted to interrupt and interfere with WhiteSmile's teeth whitening operations. (Valentine, Tr. 579).

Response to Finding No. 675:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Mr. Valentine testified that he believed that it had happened; he did not know for a certainty. (Valentine, Tr. at 579).

676. Mr. Valentine stated that there was a perception among some potential customers in North Carolina that non-dentist teeth whitening was illegal. This perception hurt WhiteSmile's sales in North Carolina. (Valentine, Tr. 575).

Response to Finding No. 676:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

Mr. Valentine's testimony was that WhiteSmile's re-entry into North was not successful

due to "the environment at that time, our sales had across the country dropped off

significantly due to the economy, so it was just an economic issue." (Valentine, Tr. 575).

677. The Board used Cease and Desist Orders, as well as letters to mall operators, with the intent, purpose, and effect of causing non-dentist teeth whitening providers in North Carolina to cease business. (Kwoka, Tr. 1007-1008). The letters were effective and consumers were denied their choice when kiosks/spa operations challenged by the Board ceased business. (Kwoka, Tr. 1136-1137, 1219; CX0654 at 005-006). "Mall operators declined to renew leases and refused to rent to interested would-be tenants." (CX0654 at 005-006).

Response to Finding No. 677:

The first two sentences constitute mere opinion statements by Dr. Kwoka and there is no basis in the record regarding the intent, purpose and effect of the letters that he alleges.

The record reflects that the Board sent out letters that would state only that the recipient is to cease and desist "any and all activity constituting the practice of dentistry or dental hygiene," provide the verbatim part of the statute, and request the recipient's cooperation.

(CX42; CX58; CX59; CX68; CX69; CX74; CX96; CX97; CX112; CX279; CX351;

CX386; CX387; CX388; CX389; CX390; CX391). Similar letters are sent out by other

North Carolina state boards to enforce prohibitions on the unauthorized practice of a

licensed profession, including the North Carolina State Bar, the North Carolina Medical

Board, and the North Carolina Board of Pharmacy. (White, Tr. 2226-2227). Such cease

and desist letters are sent by the Board where there is evidence that a person is engaged in

the unauthorized practice of dentistry, not just teeth whitening. (RX59 (Goode, IHT at 56-57); RX63 (Holland, Dep. at 173)). (For example, see CX62, CX63, and CX306). In the absence of an in-person investigation, cease and desist letters were sent because there was credible evidence of a violation, usually advertising, or on the face of the complaint. (RX56 (Feingold, Dep. at 267-277); RX58 (Friddle, IHT at 51-52, 53-54)). In every instance, cease and desist letters were sent by the State Board only when there was *prima facie* evidence from a credible source of a violation. (RX7 at 3) (Body, Mind & Spirit Day Spa, #06-217, spa advertisement offering "laser teeth whitening"); RX58 (Friddle, IHT at 53-54)).

The record evidence reflects that the cease and desist letters were intended to warn the recipient that what they were doing was potentially illegal and requested that they stop. (Owens, Tr. 1451, 1515-1518; White, Tr. 2229; RX49 (Allen, Dep. at 126-127); RX50 (Bakewell, Dep. at 215); RX52 (Burnham, Dep. at 102-103); RX63 (Holland, Dep. at 125-126); RX64 (Kurdys, Dep. at 118)). The Board also intended to inform cease and desist letter recipients about the status of North Carolina's law. (White, Tr. 2230; RX49 (Allen, Dep. at 41-42)). Cease and desist letters were a reasonable, common sense method by which persons were given an opportunity to voluntarily comply without the Board resorting to litigation or criminal prosecution. (RX50 (Bakewell, Dep. at 211-212, 215); RX56 (Feingold, Dep. at 104)). Any person or entity receiving a cease and desist letter has the ability to pursue relief in the courts of the State of North Carolina if they feel they have been aggrieved. (Wester, Tr. 1284; Hardesty, Tr. 2774; White, Tr. 2234; RX50 (Bakewell, Dep. at 214-215)). In certain instances, recipients of cease and desist letters made an informal showing that what they were doing

was not barred by statute (notwithstanding their marketing material or what a witness reported), and the Board closed their file with no further action. (RX20 at 2; RX29 at 1). Any person or entity ordered by the Board to cease and desist any activity may disregard such an order. (Owens, Tr. 1451; Hardesty, Tr. 2774; RX53 (Dempsey, Dep. at 41)).

The third and final sentence of this statement is a quote from Dr. Kwoka's expert report, and is merely opinion testimony lacking any foundation. The actual testimony of a mall operator from the hearing, John Gibson, was that he would have been willing to lease a kiosk at his malls to a teeth whitening operation if he was assured that it could be done legally, but when he heard that the Board considered it the unlicensed practice of dentistry without a licensed dentist supervising, he was not willing to allow it. (Gibson, Tr. 630-631).

678. The Cease and Desist Orders sent by the Board also had the effect of deterring other nondentists from entering into the teeth whitening business in North Carolina, resulting in the continued denial of consumer choice. (Kwoka, Tr. 1129, 1136-1137).

Response to Finding No. 678:

There is no evidence cited in support of this statement other than the opinion statement of Dr. Kwoka. Thus Complaint Counsel has provided no actual evidence in support of this statement. Further, anyone who wishes to challenge North Carolina law concerning the provisions of the Dental Practice Act could have filed a request for a declaratory judgment under the Administrative Procedure Act, but did not do so. (White, Tr. 2232-2233; CX515 at 8, N.C. Gen. Stat. § 150B-4; RX50 (Bakewell, Dep. at 87-88)).

679. The economic significance of the Cease and Desist Orders is that they did in fact cause recipients to cease teeth whitening, as instructed in the letters. The economic response of the recipients of the Cease and Desist Orders clearly demonstrates that they interpreted the letters as an instruction to cease and desist. (Kwoka, Tr. 1132-1133, 1135-1136).

Response to Finding No. 679:

Respondent refers to its response to Finding No. 677.

680. The fact that recipients of the letters may have, in principle, had several options upon receiving the letter other than exiting the market does not change the fact that in practice, they did exit the market. (Kwoka, Tr. 1133-1135).

Response to Finding No. 680:

This statement contains an assumption that is merely supported by Dr. Kwoka's opinion and is not supported by the actual record. Different non-dentist teeth whiteners had a variety of different responses to the letters. Some initially challenged the letters, (Hughes, Tr. 946-947), but after discussing the provisions of the law with representatives of the Board and consulting legal counsel decided not to continue to offer teeth whitening services. (Hughes, Tr. 963-964). Other recipients of the letters told Board representatives that they were only selling products to customers who applied the products themselves, and did not assist customers in the application of the product, which prompted the Board to cease its investigation. (RX3 at 1-5). Dr. Kwoka improperly draws his conclusions after generalizing about how recipients of cease and desist letters responded, but his generalized statements do not reflect the reality that is thoroughly documented in the Board's extensive investigative files.

E. Exclusionary Conduct Results in Harm to Consumers

681. The exclusion of nondentist teeth whitening represents a loss of consumer surplus. (Kwoka, Tr. 1013).

Response to Finding No. 681:

Dr. Kwoka's evaluation of loss of consumer surplus is limited to price considerations.

Dr. Baumer points out that there is also value to consumers in preventing the harm

created by having an unregulated, illegal product on the market. (Baumer, Tr. 1708).

Further to this point, Dr. Baumer states: "I think you need to look at the economic as well as the health aspects, and I think you can reduce most health aspects to a number. I know people don't want to value their life, they don't want to value their pain, but we do that all the time, and clearly to ignore the health dimension is not justified." Dr. Baumer also pointed out that he would agree with Dr. Kwoka concerning the smaller surplus, except to the extent that as a result of clearing non-dentists out of the market, the remaining consumers will feel that the market is safer. (Baumer, Tr. 1723-1724). A point made along these lines by Kenneth Arrow is that "safety has the effect of shifting demand out." (Baumer, Tr. 1723-1724).

682. The exclusion of non-dentists in the North Carolina teeth whitening market necessarily makes consumers worse off. (Kwoka, Tr. 1008-1013). The consumers who have revealed a preference for non-dentist teeth whitening are forced to choose an alternative they regard as inferior, either dentist teeth whitening or OTC strips. (Kwoka, Tr. 1008-1013; CX0631 at 014). These consumers chose non-dentist teeth whitening because they preferred a cheaper alternative to dentists and a quicker alternative to OTC strips, but after exclusion those characteristics are not available to them. (Kwoka, Tr. 1181-1182).

Response to Finding No. 682:

Respondent refers to its response to Proposed Finding No. 681.

683. The exclusion of non-dentist teeth whiteners means that some consumers whose first choice was non-dentist teeth whitening will decline to purchase an alternative method of teeth whitening. For them, the only acceptable teeth whitening method had to have all the characteristics of non-dentist teeth whitening: convenience and speed without the higher price that dentists charge. This represents a loss of all consumer surplus that the consumer would have enjoyed from non-dentist teeth whitening. (Kwoka, Tr. 1011-1013; CX0631 at 014).

Response to Finding No. 683:

Respondent refers to its response to Proposed Finding No. 681.

684. Also, exclusion of non-dentist teeth whitening will result in an increase in demand for dentist teeth whitening. An increase in demand will predictably cause dentists to charge more for the analogous or comparable service, which means that all consumers of dentist teeth whitening will face higher prices as a result of exclusion, including those consumers who originally preferred dentist teeth whitening. (Kwoka, Tr. 1011-1014, 1189-1191; CX0631 at 014).

Response to Finding No. 684:

Respondent refers to its response to Proposed Finding No. 681.

685. Dr. Baumer agrees that one innovative aspect of non-dentist teeth whitening is the ability for consumers to receive a quick teeth whitening in a convenient mall location, on the same day that they desire the whitening, with same-day results. (Baumer, Tr. 1973). The ability to offer same-day procedures fills a niche in the market. (Baumer, Tr. 1974-1975). This advance is good for the consumers. (Baumer, Tr. 1974-1975).

Response to Finding No. 685:

This statement blatantly mischaracterizes Dr. Baumer's testimony. He explicitly stated that he did not consider the convenience factor of non-dentist teeth whitening to be an "innovation", he merely called it a product characteristic, and further that he did not consider it a significant characteristic. (Baumer, Tr. 1973-1974).

686. Dr. Baumer admits that if a consumer needed their teeth whitening within 24 hours, and did not previously have an appointment with a dentist, he or she would need to use a nondentist teeth whitener. (Baumer, Tr. 1975-1976). A consumer who wanted same-day whitening and was able to go to a dentist would potentially need to pay between \$400 and \$500, which Dr. Baumer admits is a lot of money to most people. (Baumer, Tr. 1976-1977).

Response to Finding No. 686:

Respondent has no specific response.

687. The greater the substitution, or cross-elasticity, between dentist and non-dentist teeth whitening, the greater prices will rise for dentist teeth whitening as a result of exclusion. (Kwoka, Tr. 1014-1015, 1190; CX0654 at 007). The magnitude of the price effect of exclusion depends upon the substitutability of the alternative products, and both Professor Kwoka and Dr. Baumer agree that there is high cross-elasticity between nondentist and dentist teeth whitening. (Kwoka, Tr. 1029-1031; Baumer, Tr. 1842; CX0826 at 029 (Baumer, Dep. at 106)). The high cross-elasticity between non-dentist

and dentist teeth whitening indicates that there will be a significant upward price effect after the exclusion of non-dentist teeth whitening. (Kwoka, Tr. 1029, 1031, 1189).

Response to Finding No. 687:

This statement essentially restates Proposed Finding No. 523 only in slightly greater detail. Although Dr. Baumer did agree with Professor Kwoka that there is cross-elasticity between dentist and non-dentist teeth whitening services, he pointed out that there is not much data here to quantify this and that it is not fair to compare these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1731, 1726-1727).

688. Dr. Baumer agrees that there is cross-elasticity between non-dentist teeth whitening and dentists teeth whitening, but that in his admittedly anecdotal experience, it is primarily limited to the "young" and "lower income people" who would go to a non-dentist teeth whitener for "unnaturally white teeth." Dr. Baumer implies that because - in his opinion - it is primarily the young and poor that are in the market for non-dentist teeth whitening, the cross-elasticity impact of the elimination of non-dentist teeth whitening is not as great of a concern. (Baumer, Tr. 1730-1731; CX0826 at 029 (Baumer, Dep. at 106)).

Response to Finding No. 688:

This statement is a word-for-word duplicate of Proposed Finding No. 542. In comparing dentist-provided and non-dentist teeth whitening, Dr. Baumer stated that "I think the substitution is more substantial at the lower income levels among young people." (Baumer, Tr. 1730).

689. Dr. Baumer agrees that a reduction in supply of teeth whitening will have an upward impact on price. (Baumer, Tr. 1700).

Response to Finding No. 689:

Respondent refers to its response to Proposed Finding No. 687.

690. Each of the consequences deriving from the exclusion of non-dentist teeth whitening represents a loss of consumer surplus; this loss of consumer surplus is equivalent to anticompetitive harm. (Kwoka, Tr. 1013, 1015-1017).

Response to Finding No. 690:

Dr. Baumer points out that there is also value to consumers in preventing the harm created by having an unregulated, illegal product on the market. (Baumer, Tr. 1708).

Further to this point, Dr. Baumer states: "I think you need to look at the economic as well as the health aspects, and I think you can reduce most health aspects to a number. I know people don't want to value their life, they don't want to value their pain, but we do that all the time, and clearly to ignore the health dimension is not justified." (Baumer, Tr. 1777).

691. If the Board's exclusion of non-dentist teeth whiteners persists it will result in future effects on competition. Each year that non-dentists are excluded represents another iteration of loss of consumer surplus. (Kwoka, Tr. 1017-1018).

Response to Finding No. 691:

This is not a statement of fact, it is opinion testimony by Dr. Kwoka. Dr. Baumer challenged this opinion, finding that Dr. Kwoka "does not exclude the possibility that non-dentist -- that banning non-dentist teeth whitening may have zero impact on the prices charged by dentists. And again, I think that that does make some sense. There may be no price effect by people that have to switch to dentists because dentists may be pricing based on the time spent on the service rather than in relation to what is charged by these non-dentist teeth whiteners." (Baumer, Tr. 1730). Dr. Baumer also pointed out that, if the conduct is only slightly anticompetitive or if the effect of such conduct is very small, then "it would be bad public policy to intervene when the effects are that small

because there are other consequences of overturning professional boards.” (Baumer, Tr. 1732).

692. Through the use of Cease and Desist Orders, the Board has almost certainly deterred and will continue to deter entry by non-dentists interested in providing teeth whitening services in North Carolina. Although the magnitude of the deterrent effect cannot be directly measured, this means that the loss of consumer surplus that can be observed is just a fraction of the total loss. (Kwoka, Tr. 1018).

Response to Finding No. 692:

Respondent disputes Complaint Counsel’s continuing references to its cease and desist letters as orders, when the record has clearly established that the letters were intended as requests and provided notice of North Carolina law. The statement also contains an assumption regarding the conduct of non-dentist teeth whiteners in response to receiving such letters, which is not supported by the actual record. *See* Response to Proposed Finding No. 680. These non-dentists had, and continue to have, a range of options in response to the Board’s letters, including challenging those letters in court, a fact that many of them have admitted they were aware of. (Valentine, Tr. 585-586; Nelson, Tr. 776; Osborn, Tr. 693-694; Wyant, Tr. 920-921).

693. Despite the fact that the data to perform a precise estimation of the magnitude of the price effects of the exclusion is not available, as an economic matter there are price effects from exclusion of non-dentist teeth whiteners. (Kwoka, Tr. 1029-1030; CX0631 at 014-015). The fact that consumers are worse off as a result of the exclusion of non-dentist teeth whitening does not require empirical or documentary evidence. (Kwoka, Tr. 1185; CX0631 at 014-015).

Response to Finding No. 693:

Dr. Baumer testified that this lack of empirical data undermined Dr. Kwoka’s analysis. (Baumer, Tr. 1731). Dr. Baumer also stated that an outcome of not having this data available is that Dr. Kwoka’s analysis does not exclude the possibility “that banning non-

dentist teeth whitening may have zero impact on the prices charged by dentists.”

(Baumer, Tr. 1730).

694. Although the actual magnitude of the consumer harm cannot be estimated with precision, evidence including the revenue generated by non-dentist teeth whitening operators that would be lost as a result of exclusion, and that a majority of consumers have been satisfied with the estimated millions of non-dentist teeth whitening procedures performed, suggest that the magnitude is substantial. (Valentine, Tr. 548-549 (WhiteSmile sales averaged \$2,000 per day); Nelson, Tr. 734-35 (WhiteScience sales estimated at \$200,000 per year; CX0496 at 001; CX0585 at 009; Giniger, Tr. 122-123, 279, 322-323; 356).

Response to Finding No. 694:

During his testimony, Mr. Valentine admitted that WhiteSmile USA did not enter the North Carolina market until 2009, and that any damages he may have quoted prior to that date are irrelevant. (Valentine, Tr. 567, 578). Mr. Nelson testified that WhiteScience currently has some business in North Carolina. (Nelson, Tr. 800-801). Also, the data that Complaint Counsel has presented at trial of “millions” of non-dentist teeth whitening procedures performed on “satisfied” consumers actually aggregates the statistics from the over-the-counter teeth whitening products with non-dentist teeth whitening offered at spas and kiosks to arrive at Dr. Giniger’s “millions upon millions” figure. There is no data on non-dentist teeth whitening that would show harm. (Haywood, Tr. 2547-2548).

695. The absence of data to show price effects from exclusion is a more frequent occurrence than its availability because such data is difficult to come by. (Kwoka, Tr. 1030).

Response to Finding No. 695:

Respondent refers to its response to Proposed Finding No. 693.

696. Dr. Baumer admits that in order to implement a study that measured the costs and benefits of banning teeth whitening, an economist would need access to published data on the subject, which to his knowledge did not exist. (Baumer, Tr. 1978-1979). Dr. Baumer believes that collecting such data and performing the economic study would require “Herculean assumptions that would be virtually unverifiable.” (CX0826 at 043 (Baumer,

Dep. at 165)). Dr. Baumer did not attempt to undertake such a study. Dr. Baumer does not believe that the absence of data allowing such an economic study requires antitrust law to ignore potentially anticompetitive conduct. (Baumer, Tr. 1980).

Response to Finding No. 696:

Dr. Baumer pointed out that “it would have been relatively easy to send out a survey or to have a focus group or to have something, even to look at the Consumer Price Index, to determine whether there was a price rise. None of that was offered in the Kwoka report.” (Baumer, Tr. 1725). Dr. Baumer also pointed out that, conceptually, such a study would not be difficult at all to do. (Baumer, Tr. 1978; CX0826 at 043 (Baumer, Dep. at 165)). He also stated that, even in the absence of such data, antitrust can have a role, “but I don’t think antitrust has a role if you just simply have the structure and there’s absolutely no objectionable conduct.” (Baumer, Tr. 1980).

697. Dr. Baumer does not produce any evidence that there has not been a price effect due to the exclusion of non-dentist teeth whitening. (Kwoka, Tr. 1031).

Response to Finding No. 697:

Dr. Kwoka does not produce any evidence that there is a price effect, (Baumer, Tr. 1731), and Complaint Counsel has the burden of proof.

698. Dr. Baumer does not cite any study where the exclusion of a service or product that consumers desire led to a decline in prices. (Kwoka, Tr. 1055).

Response to Finding No. 698:

Respondent has no specific response.

699. Dr. Baumer does not cite any study where the exclusion of a product that consumer desire led to a zero price effect. (Kwoka, Tr. 1055; CX0631 at 013).

Response to Finding No. 699:

Respondent has no specific response.

700. Exclusionary conduct can be harmful even if the price effect is small. (CX0631 at 014).

Response to Finding No. 700:

Respondent has no specific response.

701. Dr. Baumer admits that if non-dentist teeth whiteners were just gaining a foothold in the market, and therefore did not have a substantial restraining effect on price, that their exclusion from the market would not necessarily result in a price change. (Baumer, Tr. 1857).

Response to Finding No. 701:

This statement mischaracterizes Dr. Baumer's testimony as certain of this fact. In fact, he only admitted that "it's possible." (Baumer, Tr. 1857).

702. Even in the absence of verifiable price effects, there are other effects demonstrating the anticompetitive nature of the exclusionary conduct; namely, the denial of consumer choice causes loss of consumer surplus for those whose first choice was non-dentist teeth whitening. Even if effects are not precisely quantifiable, an exclusionary practice can only result in decline in consumer surplus. (Kwoka, Tr. 1031-1032).

Response to Finding No. 702:

Dr. Baumer points out that there is also value to consumers in preventing the harm created by having an unregulated, illegal product on the market. (Baumer, Tr. 1708).

Further to this point, Dr. Baumer states: "I think you need to look at the economic as well as the health aspects, and I think you can reduce most health aspects to a number. I know people don't want to value their life, they don't want to value their pain, but we do that all the time, and clearly to ignore the health dimension is not justified." (Baumer, Tr. 1777).

703. Even in a market where there was no measurable price effect due to exclusion there will still be a quantity distortion due to the shift in consumers from non-dentist teeth

whitening to other alternatives, resulting in a decline of consumer surplus. (Kwoka, Tr. 1033).

Response to Finding No. 703:

Dr. Kwoka's evaluation of loss of consumer surplus is limited to price considerations.

Dr. Baumer points out that there is also value to consumers in preventing the harm created by having an unregulated, illegal product on the market. (Baumer, Tr. 1708).

Further to this point, Dr. Baumer states: "I think you need to look at the economic as well as the health aspects, and I think you can reduce most health aspects to a number. I know people don't want to value their life, they don't want to value their pain, but we do that all the time, and clearly to ignore the health dimension is not justified." Dr. Baumer also pointed out that he would agree with Dr. Kwoka concerning the smaller surplus, except to the extent that as a result of clearing non-dentists out of the market, the remaining consumers will feel that the market is safer. (Baumer, Tr. 1723-1724). A point made along these lines by Kenneth Arrow is that "safety has the effect of shifting demand out." (Baumer, Tr. 1723-1724).

704. Dr. Baumer incorrectly asserts that the price effect of exclusion is small simply because dentists derive only a small portion of their revenues from teeth whitening. The relevant comparison is the degree of shifting between alternative teeth whitening providers, particularly from non-dentist teeth whitening to dentist teeth whitening. The adverse effect on competition to consumers is measured by this shift, not by the relative proportion of a dentist's teeth whitening revenues to the dentist's overall revenues. (Kwoka, Tr. 1033-1034; CX0631 at 015).

Response to Finding No. 704:

Dr. Kwoka boldly asserts that Dr. Baumer's analysis of the price effect of exclusion is incorrect, yet himself provides "no estimates of the price effects on teeth whitening services by the exclusion of untrained kiosk or spa providers," and "does not offer even a

ball park estimate of the impact of preventing the unauthorized practice of dentistry by enforcing state law with regard to teeth whitening enterprises. (RX0078 at 9).

705. The argument that there is no economic harm due to exclusion of non-dentist teeth whitening because OTC strips provide a cheaper alternative and dentists provide a higher quality alternative is contrary to modern economics. (Kwoka, Tr. 1100; CX0631 at 015). Consumers make choices based on their own revealed preference for a given alternative. (Kwoka, Tr. 1002-1003). To ask consumers to simply be satisfied with the alternatives is akin to Henry Ford's declaration that "you can have your car in any color you want as long as its black." (Kwoka, Tr. 1225).

Response to Finding No. 705:

Respondent has no specific response.

706. The discipline of economics promotes allowing customers to choose freely among the products unless there is a compelling justification for exclusion. Even if it were true that there is only a minor inconvenience to switching from non-dentist whitening to an alternative method, good economics does not deny consumer choice based on inadequate justifications. (Kwoka, Tr. 1100-1101, 1225-1226).

Response to Finding No. 706:

Respondent does not disagree with this statement.

707. A variety of choices is generally a benefit to consumers. It does not harm consumers to have a choice of both low and high quality products or any other variety of attributes that the consumer desires. (Kwoka, Tr. 1101-1102; Baumer, Tr. 1775-1776; CX0822 at 029).

Response to Finding No. 707:

Respondent does not disagree with this statement.

708. Economists would expect that a market would reach an equilibrium that included both low and high quality products. (Kwoka, Tr. 1101-1102).

Response to Finding No. 708:

Respondent does not disagree with this statement.

709. Exclusion of non-dentist teeth whitening in North Carolina, whether partial or complete, has no economic justification. (Kwoka, Tr. 1127). This unjustified exclusion necessarily harms consumers and is therefore anticompetitive. (Kwoka, Tr. 1102; 1106-1107).

Response to Finding No. 709:

In reaching this conclusion, Dr. Kwoka admits that he failed to take into account public policy considerations. (Kwoka, Tr. 1108-1109). Dr. Baumer found that Dr. Kwoka failed to account for significant health and safety considerations in his discussion. (Baumer, Tr. 1817). Yet the Board has provided numerous examples of health and safety issues resulting from non-dentist teeth whiteners, including the testimony of an expert in the fields of practical and clinical esthetic and restorative dentistry, the testimony of Mr. Runsick, an actual consumer, the testimony of a dentist that evaluated Mr. Runsick's injury that was caused by teeth whitening, the testimony of licensed dentists regarding the health and safety issues involved with kiosk/spa teeth whitening, and the documentary evidence of other consumers injured by kiosk/spa teeth whitening. *See* Respondent's Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531. Additionally, Complaint Counsel's expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466).

710. Absent an efficiency justification, the Board's conduct in excluding non-dentist teeth whiteners was anticompetitive. (Kwoka, Tr. 1075).

Response to Finding No. 710:

Respondent refers to its response to Proposed Finding No. 709.

F. Consumers Were and Are Harmed by the Unavailability of Non-dentist Teeth Whitening Services

711. Complaint Counsel's expert Dr. Giniger has administered numerous consumer satisfaction surveys on teeth bleaching and has observed that most people who undergo the procedure are satisfied with the result. This is because people who go to non-dentist teeth bleaching establishments have lower expectations than if they were going to a

dentist and were paying two or three times the cost. (Giniger, Tr. 322-323, 345; CX0576 at 005 (Litaker, Dep. at 13 (Dr. Litaker was not aware of any patient who had a bad experience from non-dentist teeth whitening))).

Response to Finding No. 711:

Dr. Giniger's claim has been that "[r]elevant literature and experience of millions upon millions of consumers indicate that cosmetic teeth bleaching is safe and effective, whether performed by dentists, non-dentists or consumers." This claim actually aggregates the statistics from the over-the-counter teeth whitening products with non-dentist teeth whitening offered at spas and kiosks to arrive at his "millions upon millions" figure. There is no data on non-dentist teeth whitening that would show harm. (Haywood, Tr. 2547-2548). Of course, this conveniently ignores the evidence of people who have not been satisfied with non-dentist teeth whitening, as described in Respondent's response to Proposed Finding No. 709.

Further, evidence presented by Complaint Counsel at trial indicated that of the 55 percent of the general population engaged in teeth whitening, 14 percent used professional dentist teeth whitening and 86 percent used over-the-counter products. (CX489 at 22). The survey also indicated that 71 percent of the dental patients who used custom-made trays from dentists were either satisfied or very satisfied with the results, whereas only 34 percent of those using over-the-counter products were satisfied or very satisfied with the results. (CX489 at 30).

Additionally, Dr. Giniger was not tendered to the court as an expert in economics, and there is no basis for his testimony as to consumer choice and expectations based on pricing.

712. In contrast, Dr. Haywood expressed "concerns" about the efficacy of non-dentist teeth bleaching, but was unable to cite to any evidence demonstrating that consumers are dissatisfied with non-dentist provided bleachings. (Giniger, Tr. 328; CX0632 at 021).

Response to Finding No. 712:

This blatantly misrepresents the record, since Dr. Haywood testified that there was anecdotal evidence of not just "dissatisfaction", but actual harm to consumers.

(Haywood, Tr. 2520-2521). Further, it is interesting that Complaint Counsel cites to Dr.

Giniger's testimony to claim Dr. Haywood has been unable to cite evidence when Dr.

Haywood did not even testify at trial until after Dr. Giniger had testified.

713. Indeed, given the historical use of high-intensity lights and high concentration of peroxide products used in dental offices, which are known to cause hypersensitivity, it is likely that the greatest expression of consumer dissatisfaction will be from dentist teeth bleaching. (Giniger, Tr. 346).

Response to Finding No. 713:

As noted above, evidence presented by Complaint Counsel at trial indicated that of the 55 percent of the general population engaged in teeth whitening, 14 percent used professional dentist teeth whitening and 86 percent used over-the-counter products, (CX489 at 22), and that 71 percent of the dental patients who used custom-made trays from dentists were either satisfied or very satisfied with the results, whereas only 34 percent of those using over-the-counter products were satisfied or very satisfied with the results. (CX489 at 30).

714. Dr. Haywood claims that a single chair-side treatment often cannot resolve many discolorations. But this is true of chair-side treatments by dentist as well as non-dentists. Furthermore, non-dentist providers may offer free second chair-side bleaching to consumers whose expectations have not been met. (CX0632 at 021-022).

Response to Finding No. 714:

Respondent disputes this statement because no evidence has been presented in this proceeding of non-dentist providers who “may” offer free second chair-side bleaching to customers. However, there has been testimony regarding non-dentist teeth whitening service-providers who require that their customers sign liability waivers, (Valentine, Tr. 597), or have threatened to have their dissatisfied customers thrown off the premises. (Runsick, Tr. 2116-2117). There has also been testimony that dentists will provide four teeth whitening appointments for a single charge. (Wester, Tr. 1293).

715. Dr. Giniger explained that at its core, non-dentist providers of teeth bleaching services offer consumers value propositions that many consumers want. (CX0632 at 022).

Response to Finding No. 715:

This is mere opinion testimony by Dr. Giniger, and there is no basis in the record evidence for his claim.

VIII. The Board’s Claims of Consumer Harm from Non-dentist Teeth Whitening Are Insubstantial and Unsubstantiated, and Therefore Provide No Justification for the Board’s Actions

A. Teeth Whitening Safety

716. Cosmetic teeth bleaching is safe and effective, whether performed by dentists, nondentists, or consumers. (Giniger, Tr. 356, 453-455).

Response to Finding No. 716:

This is not a fact: it is an opinion stated by Dr. Giniger. It is also an opinion of law, and Dr. Giniger was not qualified as an expert in that area. Dr. Giniger is an expert in the field of "prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products." (Giniger, Tr. 104). See Respondent's Proposed Finding of Fact 339.

Dr. Haywood testified to a contrary opinion. Respondent's Proposed Findings of Fact 363 – 365, 375 - 379 and 395 are incorporated herein by reference:

363. Dr. Haywood testified that he has read and is familiar with the North Carolina Dental Practice Act, including the provision on stain removal. (Haywood, Tr. 2545).

364. Dr. Haywood's reading of the Act, based on his experience as a dentist and dental instructor, is that the Act does not permit stain removal by unlicensed persons. (Haywood, Tr. 2545, 2573).

365. Dr. Haywood testified that a non-dentist providing dental treatment such as teeth whitening is stain removal and is the illegal practice of dentistry. (Haywood, Tr. 2459-2460, 2539, 2573).

375. Dr. Haywood provided the analogy that the difference between over-the-counter products and mall bleaching is analogous to the difference between suicide and assisted suicide. (Haywood, Tr. 2458-2459).

376. Non-dentists who provide teeth bleaching treatments convey the illusion of having dentist supervision by the use of chairs and lights similar to what might be found in a dentist office. (Haywood, Tr. 2458).

377. Because of the equipment used by non-dentist teeth whiteners, there is an illusion of people having dental training. (Haywood, Tr. 2459).

378. Non-dentists who encourage or direct a customer during the bleaching process may give the illusion that they are a dentist who possesses the knowledge of a dental professional about teeth whitening. (Haywood, Tr. 2473-2474).

379. In Dr. Haywood's opinion, non-dentists who perform teeth whitening are presenting themselves as a health professional such as a dentist, with the attendant training and skill to be able to diagnose and treat patients for dental conditions such as tooth discoloration and stains. (Haywood, Tr. 2403).

395. Dr. Haywood had the following concerns regarding the safety of non-dental teeth bleaching: (1) non-dental teeth bleaching does not involve a diagnosis for proper treatment and can mask the pathology for such treatment in the future; (2) non-dental teeth bleaching carries the potential for a less esthetic outcome (e.g., restorations are not identified, root canals are not known); (3) the safety of higher concentrations of teeth whitening solutions is unknown (e.g., there has been no research for concentrations of hydrogen peroxide above 15%); (4) the quality of some products is unknown, especially with respect to issues involving pH, allergic ingredients, or other ingredients; and (5) the patient may not receive any or the maximum benefit available for whitening, and may waste money on ineffective products. (Haywood, Tr. 2571-2572).

Several of the Board/dentists testified to the contrary. See PFOF Nos. 447, 449 – 458.

The American Dental Association (ADA) has adopted a Policy Position about the public safety of teeth whitening by non-dentists. See Respondent's Proposed Findings of Fact 389 – 394.

717. Non-dentist provided bleaching does not harm consumers by masking the sole symptom of progressive pathologies. (Giniger, Tr. 356).

Response to Finding No. 717:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to a contrary opinion. (Haywood Tr. 2547).

718. Teeth bleaching can produce transient adverse side effects, but those are not specific to any class of providers. In fact, the most frequent and pronounced side effects are from dentist provided chair-side bleaching, owing to the greater concentration of

hydrogen peroxide and use of lights that emit UV radiation and heat. (Giniger, Tr. 354-355, 444-447).

Response to Finding No. 718:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified as to potential harm and other effects. See Respondent's PFOF 383. (Haywood, Tr. 2571)
719. Teeth bleaching products do not contain notable allergens. (Giniger, Tr. 355).

Response to Finding No. 719:

This is not a fact; it is an opinion stated by Dr. Giniger. The ADA is issued a report identifying allergens. See CX392 at 8; see also Respondent's PFOF No. 457.

720. Teeth whitening, whether performed by dentists, non-dentists, or consumers, does not cause material damage to the enamel or pulp. (Giniger, Tr. 355).

Response to Finding No. 720:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to the contrary. See Respondent's PFOF # 369. (Haywood Tr. 2404).

721. Teeth whitening, whether provided by dentists, non-dentists, or consumers, does not cause systemic toxicity. (Giniger, Tr. 356).

Response to Finding No. 721:

This is not a fact, it is an opinion stated by Dr. Giniger. In response to this claim by Dr. Giniger, Dr. Haywood stated "The problem here is we don't know what are in the ingredients that non-dentist folks are using," and that the same thing is "true . . . with enamel damage." (Haywood, Tr. 2546). He also said that "knowing the higher concentrations of peroxide, such as cited with the [Procter & Gamble] data, we don't have any data on that. The higher the concentration, the greater concern for systemic problems, so that's why I'm a fan of low concentrations." (Haywood, Tr. 2547).

722. Vital teeth bleaching does not remove stains. (Giniger, Tr. 116-118).

Response to Finding No. 722:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to the contrary. See Respondent's PFOF # 400 (Haywood, Tr. 2438-2439, 2573). In addition, members of the teeth whitening industry testified that their teeth whitening products involved stain removal. (Wyant, Tr. 906; Nelson, Tr. 817-819).

723. There is no evidence that consumers are confused and mistakenly believe that the people providing non-dentist teeth whitening services are actually dentists. (Giniger, Tr. 348).

Response to Finding No. 723:

This is not a fact; it is an opinion stated by Dr. Giniger. Brian Runsick testified to the contrary. See Respondent's PFOF # 4605 (Runsick, Tr. 2105).

724. The Board's effort to exclude non-dentist providers of teeth bleaching is not warranted by health, esthetic, or efficacy considerations. (Giniger, Tr. 353-354).

Response to Finding No. 724:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to the contrary. See Respondent's PFOF # 395 – 399.

725. Since its discovery in 1818, hydrogen peroxide has long been used and regarded as safe in industrial, agricultural, and consumer product applications. Its safety has been reviewed by domestic scientific bodies and regulatory agencies, including the FDA, and its use in those applications has been approved. (Giniger, Tr. 210-212; CX0653 at 24).

Response to Finding No. 725:

Respondent has no specific response.

726. Hospitals used "Proxigel," a 10% carbamide peroxide concentration, with newborn infants to help clear their throats. (Wester, Tr. 1310, 1353; Haywood, Tr. 2578; CX0550 at 002).

Response to Finding No. 726:

Respondent has no specific response.

727. A 30% hydrogen peroxide solution has been sold for dental and other uses in the United States since before 1938, and so it has not been subjected to FDA review. In lower concentrations, however, hydrogen peroxide has been evaluated under the FDA's OTC Drug Review Program and found to be safe for diverse oral and dermatological medical uses, including as an oral debriding agent/wound cleanser, dental first aid antiseptic, and mouthwash. (Giniger, Tr. 212-213; CX0653 at 025, 026).

Response to Finding No. 727:

Respondent has no specific response.

728. Based upon a review by the Life Sciences Review Office of the Federation of American Societies of Experimental Biology, the FDA has found that hydrogen peroxide is generally recognized as safe for use in the production of various foods. (Giniger, Tr. 213; CX0653 at 025).

Response to Finding No. 728:

Respondent has no specific response.

729. The United States Department of Agriculture has determined that hydrogen peroxide is safe and suitable for use in the production of meat and poultry products and may be used in the production of organic crops and livestock. (Giniger, Tr. 211-212; CX0653 at 025).

Response to Finding No. 729:

Respondent has no specific response.

730. The United States Environmental Protection Agency has authorized the application of hydrogen peroxide to foods as a pesticide. (CX0653-025-026).

Response to Finding No. 730:

Respondent has no specific response.

731. Hydrogen and carbamide peroxide have been used as mouth rinses to reduce plaque in individuals with gingivitis and for the treatment of periodontal disease. (Joint Stipulations of Law and Fact 23).

Response to Finding No. 731:

Respondent has no specific response.

732. Teeth bleaching products are labeled and sold to dental professionals and to consumers as a cosmetic, not a drug. (Giniger, Tr. 213, 216; CX0653 at 024).

Response to Finding No. 732:

Respondent has no specific response.

733. Dr. Giniger evaluated the safety of teeth bleaching generally and non-dentist teeth bleaching in particular and concluded that non-dentist teeth bleaching is safe, absolutely and relative to dentist provided teeth bleaching. (Giniger, Tr. 120-122).

Response to Finding No. 733:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to the contrary. See Respondent's PFOF # 395-399. The Response to No. 716 is incorporated herein by reference. Also, the Board provided numerous examples of health and safety issues, including the testimony of an expert in the fields of practical and clinical esthetic and restorative dentistry, the testimony of Mr. Runsick, an actual consumer, the testimony of a dentist that evaluated Mr. Runsick's injury that was caused by teeth whitening, the testimony of licensed dentists regarding the health and safety issues involved with kiosk/spa teeth whitening, and the documentary evidence of other consumers injured by kiosk/spa teeth whitening. See Respondent's Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531 (other consumer harm).

734. Over the last 20 years, millions of consumer have safely bleached their teeth without dental involvement and there is not a single study demonstrating substantial, nontransient harm from non-dentist teeth bleaching. (Giniger, Tr. 121-123, 430-431, 453-455; Haywood Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening), 2729; CX0653 at 007).

Response to Finding No. 734:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to that no research had been done. (Haywood Tr. 2547-2548; 2711-2712. See Respondent's PFOF # 401-409. In addition, Complaint Counsel's expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466). Finally, the Proposed Finding ignores the evidence of the Policy Position of the ADA.

Additionally, the Reponse to Finding No. 733 is incorporated herein by reference.

735. Dr. Haywood expressed "concerns" as to the safety of non-dentist teeth bleaching, but was unable to cite to any current or compelling scientific literature or other information demonstrating actual harm caused by non-dentist teeth bleaching. (Haywood Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening), 2729).

Response to Finding No. 735:

This is not a fact; it is an opinion stated in the form of a proposed Finding. Dr. Haywood testified to that no research had been done. (Haywood Tr. 2547-2548; 2711-2712. See Respondent's PFOF # 401-409.

736. This is in accord with Board members' testimony and other North Carolina dentists. (CX0554 at 026 (Allen, Dep. at 95-96) (little to no evidence of any serious harm or non103 transient effects caused by non-dentist teeth whitening); CX0555 at 026 (Brown, Dep. at 97) (unaware of any evidence that the practice of teeth whitening by non-dentists, has caused any harm other than transient or temporary sensitivity or irritation); Wester, Tr. 1405-1406 (unaware of any evidence that the practice of teeth whitening by non-dentists, has caused any harm other than transient or temporary sensitivity or irritation); CX0560 at 066 (Feingold, Dep. at 254) (not aware of any empirical literature establishing that consumers have been subject to significant non-transient harm from teeth whitening provided by a non-dentist)).

737. Dr. Giniger also explained that there are no reports in the relevant literature showing that dentist bleaching is safer than non-dentist teeth bleaching. (Giniger, Tr. 121-123, 267-268, 278-279; CX0653 at 044, 046). This is consistent with the Board's position. (Response to RFA 18 (Board admits that "it is not aware of studies comparing the safety of teeth whitening services as performed by dentists" versus non-dentists)).

Response to Finding No. 737:

This is not a fact; it is an opinion stated by Dr. Giniger. Dr. Haywood testified to that no research had been done. (Haywood Tr. 2547-2548; 2711-2712. See Respondent's PFOF # 401-409. In addition, Complaint Counsel's expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466). Finally, the Proposed Finding ignores the evidence of the Policy Position of the ADA.

738. In fact, the availability of non-dentist provided teeth bleaching may contribute to dental health by increasing consumer appreciation of oral health and hygiene. (Giniger, Tr. 124).

Response to Finding No. 738:

This is not a fact; it is an opinion stated by Dr. Giniger. Significantly, when he testified as to marketing surveys, he did not mention this as a subject.

1. The Following Terms Are Relevant to the Understanding of the Safety and Efficacy of Teeth Whitening¹

739. Abscess: A puss filled sac that grows over time; it is a common sequelae (symptom) or consequence of irreversible pulpal damage. (Giniger, Tr. 280-281, 284; CX0823 at 029) (Haywood, Dep. at 108-109 (An abscess "creates byproducts of the breakdown of tissue much like a rotting body does[.]")).

Response to Finding No. 739:

Respondent has no specific response.

740. There are two types of abscess: abscess associated with the tooth and abscess associated with gums. (Giniger, Tr. 283). Abscess in the tooth can be caused by caries or trauma. (Giniger, Tr. 281).

Response to Finding No. 740:

Respondent has no specific response.

741. Depending on its severity and stage of development, an abscess may be treated by antibiotics, a root canal, or by extracting the tooth and replacing it with an implant.

¹ A color copy of a tooth which was used as part of a demonstrative exhibit, CX0803 at 022, is attached hereto at Tab 1 for demonstrative purposes.

(Giniger, Tr. 287-288).

Response to Finding No. 741:

Respondent has no specific response.

742. Anaphylactic Reaction: A potentially life-threatening allergic reaction where the airways to the lungs are closed. (Giniger, Tr. 355).

Response to Finding No. 742:

Respondent has no specific response.

743. Avulsion: A condition where the tooth is knocked out of the mouth. (Giniger, Tr. 306).

Response to Finding No. 743:

Respondent has no specific response.

744. Calcific Metamorphosis: A condition caused by pulpal injury. When calcific metamorphosis is present in a tooth, cells fill in the pulp with additional dentin, thereby creating a "natural" root canal. (Giniger, Tr. 285-286).

Response to Finding No. 744:

Respondent has no specific response.

745. The treatment for calcific metamorphosis is either a root canal or a tooth extraction followed by an implant. If the calcific metamorphosis has completely filled in the pulp, treatment is not needed as the body has completed a natural root canal. (Giniger, Tr. 297-298)

Response to Finding No. 745:

Respondent has no specific response.

746. Chromogen: An intrinsic or extrinsic stain on the tooth. (Giniger, Tr. 141; CX0653 at 012; Haywood Tr. 2490-2491). Chromogens typically consist of carbon molecules that are linked by double bonds; the more double bonds, the deeper the color of the stain. (Giniger, Tr. 152-153; CX0653 at 018).

Response to Finding No. 746:

Respondent has no specific response.

747. Dentin: The tooth has three layers: enamel, dentin, and pulp. The dentin is below the enamel and has a yellow color; it is more porous than enamel, and can act like a "sponge" and soak up an intrinsic stain. (Giniger, Tr. 158-159). For example, discoloration from trauma is caused by the dentin soaking up ruptured blood vessels from the pulp.

Response to Finding No. 747:

Respondent has no specific response.

748. Dosimetric Analysis: An analyses that uses available data to make a correlation between a given dosage and its absorption in the human body. (Giniger, Tr. 254-255).

Response to Finding No. 748:

Respondent has no specific response.

749. Enamel: The enamel is the outermost layer of the tooth and has a white color. The enamel is hardest substance in the human body and is nonporous. (Giniger, Tr. 158-159).

Response to Finding No. 749:

Respondent has no specific response.

750. Extrinsic Stain: A chromogen on the enamel, which can be caused by, among others, food and wine. (Giniger, Tr. 161-162; CX0653 at 012).

Response to Finding No. 750:

Respondent has no specific response.

751. Implant: A treatment for an oral pathology where the diseased tooth is extracted and replaced with an implant. Regardless of the pathology treated, implants have a long term success rate of 95%, and are approximately the same price as a root canal. As a result, many people prefer implants to root canals. The consequence of a failed root canal is to remove the tooth and place an implant. (Giniger, Tr. 288-289, 292-293).

Response to Finding No. 751:

Respondent has no specific response.

752. Inclusion/Exclusion Criteria: The minimum conditions necessary for a potential subject to be included in a study. For example, for a clinical study of the efficacy of a teeth bleaching formulation, scientists might require that all participants have natural teeth. (Giniger, Tr. 260-262).

Response to Finding No. 752:

Respondent has no specific response.

753. Intrinsic Stain: A chromogen beneath the enamel which can be caused by, among other things, exposure to tetracycline or fluoride during the tooth's formative period. An intrinsic stain can also be caused by trauma. Staining from trauma is caused by blood vessels within the pulp bursting and flooding the porous dentin with hemoglobin. The pulp cannot re-absorb the blood, so the tooth is permanently stained. As time passes, the discoloration turns from red to brown. (Giniger, Tr. 161-162; CX0653 at 012).

Response to Finding No. 753:

Respondent has no specific response.

754. Teeth bleaching will not completely lighten deeply embedded intrinsic stains like those caused by tetracycline exposure or trauma. For such internal stains, satisfactory whitening may require non-vital bleaching procedures or use of cosmetic restorations, such as crowns or veneers. (Giniger, Tr. 163-164; cf. Haywood, Tr. 2441-2442; CX0653 at 012-013).

Response to Finding No. 754:

Respondent has no specific response.

755. Luxation: A condition where the tooth is dislodged in the socket. (Giniger, Tr. 306-307).

Response to Finding No. 755:

Respondent has no specific response.

756. Malocclusion: A misalignment of the teeth, where "your teeth don't fit together correctly." (CX0823 at 041 (Haywood, Dep. at 154)).

Response to Finding No. 756:

Respondent has no specific response.

757. Nightguard Vital Bleaching: A dentist provided tray-application for vital teeth bleaching that is meant to be used over night. Nightguard Vital Bleaching with 10% carbamide peroxide was first proposed by Drs. Haywood and Heymann in 1989. Today, doctors often use Nightguard Vital Bleaching with formulations that contain a higher carbamide peroxide concentration. (Giniger, Tr. 149-150, 156-157; CX0653 at 024).

Response to Finding No. 757:

Respondent has no specific response.

758. Non-vital Tooth: A dead tooth, where the nerve of the tooth ceases to function, and blood supply is compromised. (Giniger, Tr. 112-113; 287).

Response to Finding No. 758:

Respondent has no specific response.

759. Panoramic X-Ray: An x-ray of the majority of the face, including the teeth, top and bottom jaws, and the sinuses. (Giniger, Tr. 304; Haywood, Tr. 2987-2988).

Response to Finding No. 759:

Respondent has no specific response.

760. Parafunction: A condition where the teeth move or are used in a manner outside or beyond their normal function, causing damage. (CX0823 at 041 (Haywood, Dep. at 154-156)).

Response to Finding No. 760:

Respondent has no specific response.

761. Periapical X-Ray: An x-ray of the entire tooth. (Haywood, Tr. 2987)

Response to Finding No. 761:

Respondent has no specific response.

762. pH: a measure of acidity, with a pH of 7 being roughly neutral, with a lower pH indicating greater than neutral acidity. (Cf. Giniger, Tr. 453; Haywood, Tr. 2855).

Response to Finding No. 762:

Respondent has no specific response.

763. Posterior Bitewings X-Ray: An x-ray of the posterior teeth (molars and premolars of the upper and lower jaw) that will reveal oral pathologies, such as caries, and defective restorations. (Haywood, Tr. 2986-2987).

Response to Finding No. 763:

Respondent has no specific response.

764. Pulp: The pulp is the innermost layer of the tooth, and contains the living tissue comprised of cellular elements including the nerve and blood supply. (Giniger, Tr. 158-159).

Response to Finding No. 764:

Respondent has no specific response.

765. Resorption: A rare consequence of pulpal injury which can take the form of internal or external resorption. (Giniger, Tr. 284-285; 291-293). When a tooth undergoes resorption, cells that line the internal diameter of the pulp eat away at the adjoining dentin, causing the pulp canal to become larger. At the end stage of resorption, the amount of dentin and cementum surrounding the tooth roots becomes very thin, causing the tooth to dislodge. (Haywood, Tr. 2962).

Response to Finding No. 765:

Respondent has no specific response.

766. Resorption is not a cancer. (Giniger, Tr. 292; Haywood, Tr. 2964).

Response to Finding No. 766:

Respondent has no specific response.

767. The treatment for resorption is either a root canal or a tooth extraction followed by an implant. This is true even if the resorption is discovered at the earliest stage of development. (Giniger, Tr. 292-294).

Response to Finding No. 767:

Respondent has no specific response.

768. Root: The portion of the tooth beneath the gum line. (Giniger, Tr. 158-159).

Response to Finding No. 768:

Respondent has no specific response.

769. Root Canal: A treatment for oral pathology by which the nerve and the blood vessels in the pulp are removed. The pulp chamber is thereafter reshaped, and a conical-shaped rubber filing material is placed inside. (Giniger, Tr. 287).

Response to Finding No. 769:

Respondent has no specific response.

770. Root canals are performed on teeth that are non-vital or are about to become non-vital. (Giniger, Tr. 287).

Response to Finding No. 770:

Respondent has no specific response.

771. Regardless of the pathology treated, root canals have a long-term success rate (more than 5 years) of 85%. (Giniger, Tr. 282, 292-293).

Response to Finding No. 771:

Respondent has no specific response.

772. Systemic Toxicity: Side effects that would affect the organs or systems of the body. (Giniger, Tr. 239).

Response to Finding No. 772:

Respondent has no specific response.

773. Vital Tooth: A tooth that is alive. (Giniger, Tr. 112-113).

Response to Finding No. 773:

Respondent has no specific response.

2. Dr. Martin Giniger Credibly Dispelled the Board's Argument That Non-dentist Teeth Whitening Poses Health Risks

774. Dr. Martin Giniger was retained by Complaint Counsel to: assess the likely understanding of the phrase, "the removal of stains" in the 1930s, during which time the North Carolina legislature decreed that the removal of stains constituted "the practice of dentistry"; explain whether vital teeth bleaching removes stains; describe and compare teeth bleaching alternatives available to consumers; assess whether public safety is threatened by non-dentist provided teeth bleaching; and assess whether the public interest is served by the Board's exclusion of lay-operated teeth bleaching businesses in North Carolina. (Giniger, Tr. 76-77).

Response to Finding No. 774:

Dr. Giniger was tendered as an expert in the field of “prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products.” (Giniger, Tr. 104). The above areas are not included within the tender.

Moreover, this testimony was given before he was tendered as an expert witness.

775. Dr. Giniger is extremely well-qualified to provide information and opinion on the subjects with respect to which he was retained. (CX0653 at 051-059).

Response to Finding No. 775:

Dr. Giniger was tendered as an expert in the field of “prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products.” (Giniger, Tr. 104). Any opinion testimony beyond that was excluded by the Administrative Law Judge and should be disregarded.

776. Dr. Giniger has demonstrable expertise of assistance to this tribunal with respect to, among other things, the prevention, diagnosis, and treatment of diseases and conditions that affect the oral cavity; the history and practice of teeth whitening; and the formulation, safety, efficacy, and consumer acceptance of teeth bleaching, and other oral care, products and services. (Giniger, Tr. 104-105, 378; CX653 at 001-003, 051-059).

Response to Finding No. 776:

Dr. Giniger was tendered as an expert in the field of “prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products.” (Giniger, Tr. 104). Any opinion testimony beyond that was excluded by the Administrative Law Judge and should be disregarded.

777. Dr. Giniger is a licensed dentist, having attained the degree of Doctor of Dental Medicine with honors in 1984. (Giniger, Tr. 78-79; CX0653 at 051).

Response to Finding No. 777:

Respondent has no specific response.

778. Dr. Giniger attained the degree Master of Science in Dentistry in the field of Oral Medicine in 1993. (Giniger, Tr. 78-79; CX0653 at 051).

Response to Finding No. 778:

Respondent has no specific response.

779. Dr. Ginger attained the degree Ph.D. in Biomedical Science, specializing in Oral Biology in 1993. (Giniger, Tr. 78-79; CX0653 at 051).

Response to Finding No. 779:

Respondent has no specific response.

780. In addition, Dr. Giniger has had significant additional education and training, including clinical rotations at prestigious institutions in such subjects as physical diagnosis and oral pathology. (CX0653 at 001, 053-054).

Response to Finding No. 780:

Respondent has no specific response.

781. Dr. Giniger has held several highly relevant academic postings. Among other academic postings, Dr. Giniger held a joint appointment at the Schools of Dentistry and Medicine at Louisiana State University, and was Vice Chairman of the Department of Diagnostic Sciences at the University of Medicine and Dentistry of the New Jersey School of Dentistry. (CX0653 at 052).

Response to Finding No. 781:

Respondent has no specific response.

782. Dr. Giniger's teaching responsibilities have ranged from operative dentistry, including the history and practice of teeth whitening, to oral diagnosis and treatment planning, to oral epidemiology. (Giniger, Tr. 80-83, 92-94; CX0653 at 001, 002).

Response to Finding No. 782:

Respondent has no specific response.

783. Dr. Giniger's academic responsibilities have included the direction of various clinical programs including oral diagnosis and treatment planning. (Giniger, Tr. 84-87; CX0653 at 054).

Response to Finding No. 783:

Respondent has no specific response.

784. In addition, Dr. Giniger has held highly relevant hospital appointments, including Director of Diagnostic Services at the University of Medicine and Dentistry of the New Jersey School of Dentistry. (CX653 at 001-002, 053).

Response to Finding No. 784:

Respondent has no specific response.

785. Dr. Giniger has a distinguished record as a scientific researcher on a variety of topics, including both basic and applied science, and has an extensive publication record in prestigious peer reviewed journals. For example, Dr. Giniger reported his discovery of a previously unknown way in which melanoma cells spread using Laminin as a signaling molecule in such prestigious peer-reviewed journals as the Journal of Biological Chemistry. (CX0653 at 002, 056-059; Giniger, Tr. 88).

Response to Finding No. 785:

Respondent has no specific response.

786. Among his researches, Dr. Giniger has directed or conducted numerous clinical trials involving the safety and efficacy of oral care methods/formulations, including teeth bleaching products, the results of which have been published in such peer-reviewed journals as the Journal of American Dental Association and the Journal of Clinical Dentistry. (Giniger, Tr. 88-91; CX0653 at 002, 056-059).

Response to Finding No. 786:

The teeth whitening industry has financed most of the research conducted by Dr. Giniger, as mentioned in his testimony. (Giniger, Tr. 364).

787. Dr. Giniger was instrumental in the development of oral care methods/products for which fourteen patents have been issued, numerous of which relate specifically to teeth bleaching. (Giniger, Tr. 94-95; CX0653 at 055).

Response to Finding No. 787:

Respondent has no specific response.

788. Dr. Giniger is the recipient of numerous grants and awards, including the America Academy of Oral Medicine's Lester Burkett Memorial Award, presented annually to the dentist who best demonstrates excellence in teaching, patient care, and publishing in the field of oral care. (Giniger, Tr. 88-91; CX0653 at 002, 056-059).

Response to Finding No. 788:

789. Dr. Giniger has worked and consulted for numerous oral care companies, developing and/or testing the safety and effectiveness of a variety of oral care products including teeth bleaching products. (Giniger, Tr. 96-98; CX0653 at 002).

Response to Finding No. 789:

The teeth whitening industry has financed most of the research conducted by Dr. Giniger, as mentioned in his testimony. (Giniger, Tr. 364).

790. For example, Dr. Giniger served as Director of Professional and Academic Marketing for Colgate-Palmolive Company and as Vice President of Clinical research for Dexcel Pharma. He provided consulting services to numerous other providers of teeth whitening products including Discus Dental Corporation, the manufacturer of the Zoom! in-office teeth whitening system (among other products), and BriteSmile, formerly a leading independent provider of teeth whitening products/systems to dentists and non-dentist providers (and now a part of Discus Dental). (Giniger, Tr. 96-98; CX0653 at 002).

Response to Finding No. 790:

Dr. Giniger published an article in the Journal of the American Dental Association about the product's effectiveness, but Dr. Giniger's findings were later refuted by a letter to the editor of the Journal written by Dr. John Kanca. In his letter, Dr. Kanca cited Dr. Giniger's invalid scientific method and statistical analyses. (Haywood, Tr. 2416, 2454-2457; Haywood, Dep. 289-290; Giniger, Tr. 447-449). Dr. Giniger never responded to Dr. Kanca's letter refuting all of Dr. Giniger's claims about the Discus Dental product. (Haywood, Tr. 2457). Also, Dr. Giniger has also served as an expert witness in previous litigation for BriteSmile, Procter & Gamble, and Colgate-Palmolive. (Giniger, Tr. 393).

791. Dr. Giniger was instrumental in the development of, among other products, Colgate's Whitening Toothpastes and Systems, Discus' NiteWhite with ACP at-home teeth bleaching product, and Discus' Zoom2 teeth bleaching system for in-dentist-office use. Aggregate sales of these products have exceeded \$10 billion. (Giniger, Tr. 94-96; CX0653 at 002-003).

Response to Finding No. 791:

Respondent has no specific response.

792. Dr. Giniger does not receive royalties from the sale of the these or other oral care products he helped develop for companies by which he was employed or to which he provided consulting services. (Giniger, Tr. 391-392).

Response to Finding No. 792:

While Dr. Giniger may not receive royalties from these products, he clearly has received compensation for Power Swabs. (Giniger, Tr. 366). In addition, he created GRINRx was so that he could benefit. "...I felt in consideration that my products sell billions and billions every year, why shouldn't I be benefiting, you know, why – you know, where's my cut in all this, and in fact, you know, I wasn't receiving much of a cut in all of this, so I decided to strike out on my own." (Giniger, Tr. 394).

793. In his employments and consultancies, Dr. Giniger also has been involved in the assessment of consumer satisfaction and preference with respect to teeth bleaching methods/formulations. (Giniger, Tr. 126).

Response to Finding No. 793:

Dr. Giniger testified that when he did "...a clinical trial studying the safety and efficacy of a product, they will also supply me with pre-use and post-use consumer surveys."

Dr. Giniger did not conduct the surveys. He did administer "...pre-use and post-use attitudinal surveys" and compiled the results. He never specifically testified as to surveys of "consumer satisfaction with respect to teeth bleaching methods."

794. As a result of his involvement in the assessment of consumer satisfaction and preference with respect to teeth bleaching methods/formulations, Dr. Giniger is authoritative in his testimony relating thereto. (Giniger, Tr. 126).

Response to Finding No. 794:

Dr. Giniger was tendered as an expert in the field of “prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products.” (Giniger, Tr. 104). Any opinion testimony beyond that was excluded by the Administrative Law Judge and should be disregarded.

795. Dr. Giniger recently founded and is Chief Scientific Officer of Power Swabs Corp, which manufactures and sells to dentists a detergent-containing formulation applied to the teeth before bleaching to increase whitening effectiveness while reducing bleaching-related gingival sensitivity. (Giniger, Tr. 103-104).

Response to Finding No. 795:

Power Swabs, is based on a theory of bleaching agents and a mechanism of bleaching that is not supported by any scientific evidence whatsoever. (Haywood, Tr. 2525-2526).

See PFOF No. 359.

796. In formulating his opinions in this litigation, Dr. Giniger used due diligence in ascertaining relevant facts. (Giniger, Tr. 106-107).

Response to Finding No. 796:

Respondent notes that Dr. Giniger ignored all evidence of consumer harm, anecdotal or otherwise, that was contained in numerous articles. (Giniger, Tr. 461-466). See PFOF No. 408; RX82 – RX91; RX94 – RX96; RX98 – RX101; RX103; RX114 – RX118; RX120 – RX124; RX126 – RX129; RX133 – RX135).

797. Dr. Giniger reviewed the documents produced by the Board and by third parties, the depositions taken, various pleadings of both Complaint Counsel and the Board, and the Expert Report of Dr. Haywood. (Giniger, Tr. 106-107).

Response to Finding No. 797:

Respondent has no specific response.

798. In addition, Dr. Giniger conducted an extensive review of the relevant scientific literature, including the materials referred to in Dr. Haywood's Report, and also drew on his extensive knowledge and expertise in the field of oral care and teeth bleaching. (Giniger, Tr. 106-107).

Response to Finding No. 798:

Respondent notes that Dr. Giniger ignored all evidence of consumer harm, anecdotal or otherwise, that was contained in numerous articles. (Giniger, Tr. 461-466). See PFOF No. 408; RX82 – RX91; RX94 – RX96; RX98 – RX101; RX103; RX114 – RX118; RX120 – RX124; RX126 – RX129; RX133 – RX135).

799. The information and opinion evidence provided by Dr. Giniger was clear, consistent, and well-supported. Dr. Giniger was authoritative and credible throughout. (Finding 774-798).

Response to Finding No. 799:

The Administrative Law Judge must determine if academic testimony rather than experiential testimony as a dentist makes an expert witness more or less authoritative. He has not seen a dental patient in six years. The last time Dr. Giniger saw patients as a practicing dentist was in 2005. Since then, his only contact with patients has been through clinical trials. (Giniger, Tr. 367-368).

Dr. Ginger's independence and credibility must be scrutinized. Dr. Giniger currently serves as a consultant to the teeth whitening industry. (Giniger, Tr. 364-365). Also, Respondent notes that Dr. Giniger ignored all evidence of consumer harm, anecdotal or otherwise, that was contained in numerous articles. (Giniger, Tr. 461-466).

See PFOF No. 408; RX82 – RX91; RX94 – RX96; RX98 – RX101; RX103; RX114 – RX118; RX120 – RX124; RX126 – RX129; RX133 – RX135).

Moreover, significant questions were raised as to his bias, which impacts on his credibility. The teeth whitening industry has financed most of the research conducted by Dr. Giniger, as mentioned in his testimony. (Giniger, Tr. 364). His expressed desire to make money in non-dental teeth whitening undermines his independence as an unbiased expert. “I wasn’t receiving much of a cut in all of this, so I decided to strike out on my own.” (Giniger, Tr. 394).

3. Dr. Van B. Haywood’s Testimony Is Flawed and Not Credible

800. Dr. Van Haywood was retained by the Board to present his opinions regarding the safety of non-dentist provided teeth bleaching. (Haywood Tr. 2398-2400).

Response to Finding No. 800:

Dr. Haywood was tendered and accepted as an expert “...in the fields of practical and clinical esthetic and restorative dentistry.” (Haywood, Tr. 2391).

801. Dr. Haywood is unquestionably knowledgeable about Nightguard Vital Bleaching by dentists, of which he was a co-developer in 1989. (Haywood Tr. 2579-2580).

Response to Finding No. 801:

Respondent has no response, but does ask., why is the practice of Nightguard Vital

Bleaching is capitalized as if it were a proprietary product or process?

802. But, as more fully described in these findings, Dr. Haywood appears to lack objectivity with respect to his promotion of Nightguard Vital Bleaching by dentists and his profound antipathy toward other means/practitioners of teeth bleaching. (See generally Haywood Tr. 2619-2627).

Response to Finding No. 802:

Dr. Haywood is recognized as a world expert on teeth whitening. (CX507 at 1 (Journal of Professional Excellence/Dimensions of Dental Hygiene; Dr. Haywood “shares his expertise”); CX494 at 1 (Irish Dentist/Sept. 2004, Dr. Haywood characterized as a “world expert”)). In order to preserve his independence and objectivity, Dr. Haywood independently performs grant-sponsored research on teeth whitening products with no strings attached. (Haywood, Tr. 2392-2393). Dr. Haywood does not actively promote teeth whitening products. (Haywood, Tr. 2393). Dr. Haywood has never been granted a financial stake or interest in any of the products about which he has consulted or published. (Haywood, Tr. 2407). Dr. Haywood has never been a salaried employee, owner, stockholder, or member of management of any of the firms that have retained him as a consultant. (Haywood, Tr. 2408). Dr. Haywood testified that for “some” non-dentists doing teeth whitening, they were in it for the money and willing to harm consumers for a dollar.” (Haywood, Tr. 2621-2622).

803. Dr. Haywood's relevant education is that required for licensure as a dentist. He has neither specialized training in oral diagnosis, nor any degree beyond the degree Doctor of Dental Medicine. (Haywood Tr. 2576-2577).

Response to Finding No. 803

In addition to his training as a dentist, Dr. Haywood was a tenured professor at the University of North Carolina School of Dentistry and has been a tenured professor at the Medical College of Georgia. (Haywood, Tr. 2387-2388).

804. Dr. Haywood is a career academic, whose professional esteem is intimately bound with the establishment and expansion of Nightguard Vital Bleaching by dentists as the preeminent form of vital teeth bleaching. (Haywood, Tr. 2580-2589).

Response to Finding No. 804:

PART D

This proposed finding of fact is a mischaracterization of Dr. Haywood's testimony. He testified that he was in private practice for seven years. (Haywood, Tr. 2387). Dr. Haywood also currently practices dentistry in addition to his academic responsibilities. (Haywood, Tr. 2384-2385). Further, Dr. Haywood is an academician who performs independent research in his fields of expertise. (Haywood, Tr. 2392). Dr. Haywood independently performs grant-sponsored research on teeth whitening products with no strings attached. (Haywood, Tr. 2392-2393). Dr. Haywood has never been granted a financial stake or interest in any of the products about which he has consulted or published. (Haywood, Tr. 2407).

805. Dr. Haywood achieved his first tenured position at the North Carolina College of Dentistry, one year after publication of the 1989 article on Nightguard Vital Bleaching by dentists. (Haywood Tr. 2580).

Response to Finding No. 805:

Respondent has no specific response.

806. As Dr. Haywood acknowledged, his co-authorship of the 1989 article on Nightguard Vital Bleaching by dentists "most definitely" played a role in his obtaining tenure. (Haywood Tr. 2580).

Response to Finding No. 806:

Respondent has no specific response.

807. As Dr. Haywood acknowledged, his co-authorship of the 1989 article on Nightguard Vital Bleaching by dentists and his subsequent work refining and extending Nightguard Vital Bleaching by dentists played a significant part in his subsequently gaining tenure at the Medical College of Georgia, where he presently teaches. (Haywood Tr. 2580).

Response to Finding No. 807:

Dr. Haywood never testified to this and this proposed Finding of Fact is without basis in the transcript, or the exhibits of Record.

808. Dr. Haywood has an extensive research/publication record, but it is largely confined to the topic of Nightguard Vital Bleaching by dentists. (Haywood Tr. 2583).

Response to Finding No. 808:

Respondent has no specific response.

809. Dr. Haywood acknowledges that he has become "well-known" in the world of esthetic dentistry for his research on Nightguard Vital Bleaching by dentists. (Haywood Tr. 2583).

Response to Finding No. 809:

Dr. Haywood testified that he became "...well known in the esthetic world for my research on bleaching." (Haywood Tr. 2583).

810. Dr. Haywood has long been a sought-after continuing education speaker on the topic of Nightguard Vital Bleaching by dentists. As a result of his contributions to Nightguard Vital Bleaching by dentists, he often receives travel, lodging, and meal reimbursements and "honoraria" ranging up to \$10,000 for presentations on that topic given at diverse, often interesting and international, destinations. Dr. Haywood has been so-engaged at more than six such conferences in the past year alone. (Haywood, Tr. 2584-2586).

Response to Finding No. 810:

The proposed Finding of Fact implies that Dr. Haywood is a speaker for the money. Dr. Haywood testified that continuing education programs are "...the way we educate dentists." (Haywood Tr. 2583). Dr. Haywood does not actively promote teeth whitening products. (Haywood, Tr. 2393). Dr. Haywood has never been granted a financial stake or interest in any of the products about which he has consulted or published. (Haywood, Tr. 2407). Dr. Haywood has never been a salaried employee, owner, stockholder, or member of management of any of the firms that have retained him as a consultant. (Haywood, Tr. 2408).

If the purpose of the proposed Finding of Fact is to address Dr. Haywood's credibility, then it should be noted that all of Dr. Giniger's research is financed by the teeth whitening industry. (Giniger, Tr. 364). Dr. Giniger is paid by the companies that use Power Swabs for his work in connection with that product. (Giniger, Tr. 366). Dr. Giniger previously served as an expert witness for Procter & Gamble in connection with litigation involving teeth whitening matters. In that litigation, Procter & Gamble challenged the advertising claims of Colgate-Palmolive. (Giniger, Tr. 380-381).

811. As Dr. Haywood acknowledged, for some twenty years he has been passionately committed to the idea that Nightguard Vital Bleaching by dentists is the safest and most effective bleaching alternative. (Haywood, Tr. 2588-2589).

Response to Finding No. 811:

Dr. Haywood admitted to his commitment to teaching dentists about safety in bleaching, "Although I've never used the word "passionate." I don't know about that. (Haywood, Tr. 2588)

812. Dr. Haywood lacks certain experience relevant to the opinions he has expressed in this matter. For example, Dr. Haywood has neither taught any course on oral diagnosis, nor himself had any specialized training therein. (Haywood, Tr. 2576-2577).

Response to Finding No. 812:

Dr. Haywood was tendered and accepted as an expert "...in the fields of practical and clinical esthetic and restorative dentistry." (Haywood, Tr. 2391).

Dr. Haywood was contacted by the FTC almost three years ago to be an expert in this matter, and he refused because of his belief that teeth whitening constitutes the practice of dentistry and that he could not support that. (Haywood, Tr. 2459-2460).

The FTC approached Dr. Haywood a second time, about two years ago to discuss the case with him. This conversation was terminated when he voiced his opinion that there was a difference between over-the-counter teeth whitening methods and non-dental teeth whitening methods. (Haywood, Tr. 2459-2460).

813. Dr. Haywood has no training, expertise, or experience in the formulation of teeth bleaching products. (Haywood, Tr. 2577-2579).

Response to Finding No. 813:

Dr. Haywood was tendered and accepted as an expert "...in the fields of practical and clinical esthetic and restorative dentistry." (Haywood, Tr. 2391).

Dr. Haywood was contacted by the FTC almost three years ago to be an expert in this matter, and he refused because of his belief that teeth whitening constitutes the practice of dentistry and that he could not support that. (Haywood, Tr. 2459-2460).

The FTC approached Dr. Haywood a second time, about two years ago to discuss the case with him. This conversation was terminated when he voiced his opinion that there was a difference between over-the-counter teeth whitening methods and non-dental teeth whitening methods. (Haywood, Tr. 2459-2460).

814. Dr. Haywood has no training, expertise or experience in marketing any product to consumers, nor in evaluating consumer satisfaction/preferences. (Haywood, Tr. 2579).

Response to Finding No. 814:

Respondent has no specific response.

815. Dr. Haywood has never been employed by, managed, or owned a company engaged in commerce of any kind. (Haywood Tr. 2576; cf. RX00077 at 25-50 (Dr. Haywood's curriculum vitae)).

Response to Finding No. 815:

Respondent has no specific response.

816. Dr. Haywood has promoted Nightguard Vital Bleaching by dentists based on limited and sometimes inadequate evidence, including evidence that he feels free to disregard in connection with other methods/practitioners of teeth bleaching. With respect to the latter, Dr. Haywood, early on, insisted that the absence of evidence of harm from dentist provided Nightguard Vital Bleaching is ample evidence of its safety. (CX0402 at 007).

Response to Finding No. 816:

This proposed finding of fact disregards Dr. Haywood's testimony and other statements in CX 402. It is also an opinion rather than a statement of fact as to the characterization of evidence upon which Dr. Haywood relied and his methodologies. Further, the page of the exhibit cited by Complaint Counsel in support of this proposed finding of fact does not appear to address harm in any manner other than in respect to over-the-counter teeth whitening products. (CX402 at 7).

817. For example, in 1991, Dr. Haywood was seeking to obtain acceptance of Nightguard Vital Bleaching within the dental community. He published an article in which he set out to address concerns others had expressed as to the safety of Nightguard Vital Bleaching. (Haywood Tr. 2590-2597). He wrote: "[p]atients could continue [dentist-facilitated at home bleaching] for extended periods, but there is no clinical evidence that this is occurring. There is always the potential for abuse by some persons, but there is the same potential danger of abuse from ingestion of fluoride-containing toothpaste or rinses, alcohol-containing mouthwashes, and aspirin, even when these materials are correctly prescribed." (CX0402 at 007).

Response to Finding No. 817:

Respondent has no specific response.

818. In so writing, Dr. Haywood argued that Nightguard Vital Bleaching was safe despite expressed concerns because, despite increasingly widespread use of Nightguard Vital Bleaching, there was no clinical evidence that the harm of concern had occurred. (Haywood Tr. 2595).

Response to Finding No. 818:

Respondent disputes this proposed finding of fact as containing an assumption. In the testimony cited by Complaint Counsel in support of this proposed finding of fact, there was no reference to "despite expressed concerns" or "increasingly widespread use of nightguard vital bleaching." (Haywood, Tr. 2595). This proposed finding of fact misstates Dr. Haywood's testimony and also ignores other statements in his article, which was introduced as CX 402.

819. Dr. Haywood raises several "concerns" about non-dentist provided teeth bleaching, including consumers' at-home use of OTC products, however, Dr. Giniger summarily rejects the very same argument: that non-dentist provided teeth bleaching is evidently safe because, despite hundreds of millions of applications, there is no clinical evidence that any of the harms of "concern" have occurred. (Haywood, Tr. 2945-2950 (500 million safe uses of OTC products would not allay Dr. Haywood's safety concerns)).

Response to Finding No. 819:

The proposed Finding is actually a conclusion of law and is argumentative of the evidence. The record is clear that Dr. Haywood testified as the concerns about non-

dentist teeth whitening and consumers' use of OTC products. (Haywood, Tr. 2571-2572; see also, RX 146). On the other hand, Dr. Giniger testified as to his lack of concern about non-dentist and OTC teeth whitening. (Giniger Tr. 121; see CX803-11).

820. Dr. Haywood has urged expansion of Nightguard Vital Bleaching by dentists to specialized circumstances and populations based on empirical research that has been criticized by expert commentators as inadequate, and at times using claims that appear untrue. (Haywood, Tr. 2586-2602, 2609-2619).

Response to Finding No. 820:

The proposed Finding is actually a conclusion of law and is argumentative of the evidence.

821. In 1999, Dr. Haywood began recommending long-term use of Nightguard Vital Bleaching by dentists - for periods of up to and beyond six months - to remove tetracycline and other hard-to-lighten internal stains, based on a study he and his colleagues reported on in an article entitled, "Nightguard Vital Bleaching of Tetracycline-Stained Teeth: 54 Months Post Treatment." (Haywood, Tr. 2586-2587, 2595).

Response to Finding No. 821:

Respondent has no specific response.

822. The study purported to examine the safety and efficacy of Nightguard Vital Bleaching by dentists used on tetracycline-stained teeth for roughly six months, with follow up through 54 months post treatment. (Haywood, Tr. 2595-2596).

Response to Finding No. 822:

The use of "purported" is argumentative. The study clearly examined this safety issue.

823. The study, however, had only fifteen subjects who completed the bleaching regimen, and only nine of whom completed the follow-up protocol. (Haywood, Tr. 2596-2597).

Response to Finding No. 823:

The use of "only" is argumentative. Dr. Haywood testified as to any limitations of the number of participants was due to lack of funding. (Haywood, Tr. 2598).

824. The European Commission's Scientific Committee on Consumer Products (SCCP) issued a March 2005 opinion seeking to assess the scientific literature regarding use of peroxides in vital teeth bleaching. In that opinion the SCCP noted the inadequacy of Dr. Haywood's study as support for his recommendation: "[t]here exists a 7.5-year follow-up study on a small group of teeth-whitening product users. SCCP has noted that only 9 of the 15 persons in the long-term study agreed to a clinical examination. . . . As pointed out in the [SCCP's previous] preliminary opinion, for a case-reference study to detect a doubling of the risk for an adverse effect that occurs at a level of 1:1000 in the reference group, the study group must have at least a thousand people." (Haywood, Tr. 2597-2598).

Response to Finding No. 824:

Dr. Haywood testified as to any limitations of the number of participants was due to lack of funding. (Haywood, Tr. 2598).

825. At trial, Dr. Haywood shrugged off the disparity between his exceedingly small sample size and his unqualified recommendation of long-term-use of Nightguard Vital Bleaching by dentists, saying only that small sample size was a frequent limitation in clinical research. (Haywood, Tr. 2598-2599).

Response to Finding No. 825:

Dr. Haywood testified as to any limitations of the number of participants was due to lack of funding. (Haywood, Tr. 2598). He also testified that he made the recommendation "because that is still supervised by a professional..." (Haywood, Tr. 2599).

826. Some time around 2002, Dr. Haywood discovered, and published a case report indicating, that long-term use of Nightguard Vital Bleaching by dentists could cause irreversible "greening" of teeth that had certain amalgam fillings. (Haywood, Tr. 2599-2601).

Response to Finding No. 826:

Respondent has no specific response.

827. Dr. Haywood conducted no further research on the matter, but continued to recommend use of long-term Nightguard Vital Bleaching for removal of tetracycline and other hard-to-lighten stains. (Haywood, Tr. 2599-2602, 2443-2444 (noting recent use of Nightguard Vital Bleaching on tetracycline-stained teeth)).

Response to Finding No. 827:

Dr. Haywood testified that he did “several case reports” (Haywood, Tr. 2603). But, he did not do a clinical study, as he defined it. (Haywood, Tr. 2603, 2606). He also has “...the data of watching those patients for years ...monitored by me, so that was additional study...”

828. Dr. Haywood doesn't "have a clue" as to how many people underwent long-term Nightguard Vital Bleaching by dentists to lighten tetracycline stains between 1999-2002, or how many dentists acted on his recommendation, but Dr. Haywood "would like to think" that many did so. (Haywood, Tr. 2601-2602).

Response to Finding No. 828:

How could he know?

829. In 2007, Dr. Haywood wrote an article urging the use of Nightguard Vital Bleaching by dentists for caries control by seniors for rest of their lives. Dr. Haywood made, and continues to make, that recommendation despite the fact that there is not a single study demonstrating the safety of perpetual use of Nightguard Vital Bleaching by persons of advanced years, whose health may be compromised in numerous ways. (Haywood, Tr. 2615, 2587).

Response to Finding No. 829:

This proposed Finding misrepresents Dr. Haywood's article, which was referenced as CX711, but never introduced into evidence. The use of “not a single study” misrepresents the question which asked about a “clinical study.” Dr. Haywood's testimony as to a “pilot study” was excluded. (Haywood, Tr. 2614).

830. In 2010, Dr. Haywood wrote an article in which he urged use of Nightguard Vital Bleaching by dentists for caries control in people wearing orthodontic appliances, including children as young as ten years of age as well as adolescents and others, for periods as long as 30 months and perhaps longer. (Haywood, Tr. 2586, 2607-2611).

Response to Finding No. 830:

Respondent has no specific response.

831. In his 2010 article, Dr. Haywood acknowledged concerns as to the safety of such longterm use of Nightguard Vital Bleaching, but stated its safety had that "the safety of 10 percent carbamide peroxide has been demonstrated pre-bleaching in use in newborn infants, and in previous long-term uses. . . . [T]he long-term treatment of tetracycline patients has shown no detrimental effects on the teeth." Dr. Haywood based this latter claim on his own prior study of the safety of long-term use of Nightguard Vital Bleaching to lighten tetracycline-stained teeth, (Haywood, Tr. 2609-2610), despite the extreme methodological limitations previously noted by the SCCP.

Response to Finding No. 831:

The article, which was identified as CX702 on page 2608 of the transcript, was not introduced. The proposed finding is an accurate statement from the report, except that last phrase referencing the SCCP report; the phrase "extreme methodological imitations" is argumentative. Dr. Haywood testified as to any limitations of the number of participants in the study was due to lack of funding. (Haywood, Tr. 2598). He also testified that the SCCP reported his study because they were "dentist prescribed treatments." (Haywood, Tr. 2611).

832. In his 2010 article, Dr. Haywood also claimed that the long-term use of Nightguard Vital Bleaching by dentists in children as young as ten years of age was supported by "the more recent review of all the literature on safety by the European market [i.e., by the SCCP]. . . ." (Haywood, Tr. 2610).

Response to Finding No. 832:

Dr. Haywood actually testified on Tr. 2611; he stated that the use of nightguard vital bleaching by adolescents was if "approved by their parents" and because they were "dentist prescribed treatments." His testimony as to "children as young as ten years of age" was in response to a question about permanent teeth. Dr. Haywood did testify as this issue earlier. (Haywood, Tr. 2586).

833. Beyond doubt, however, the SCCP review did not support the use of long-term Nightguard Vital Bleaching for children and adolescents. In fact, the SCCP's March 2006 guidance document states that "[t]ooth whitening procedures are not recommended under the age of 18," and its December 2007 opinion further indicated that, "[i]n the

absence of specific data on the safety of teeth whitening products in children/adolescents, the SCCP is not in a position to assess the potential health risks associated with their use in this population subgroup." (Haywood, Tr. 2612-2613).

Response to Finding No. 833:

The phrase "beyond doubt" is argumentative. The testimony relates to CX 674 which was reference in the transcript on page 2612, but was not introduced. While the quoted language is from the report, the proposed finding ignores Dr. Haywood's consistent testimony that the use of nightguard vital bleaching by adolescents was appropriate if "approved by their parents" and because they were "dentist prescribed treatments."

(Haywood, Tr. 2611-2612).

834. Indeed, in its December 2007 opinion on use of hydrogen peroxide in vital teeth bleaching, the SCCP had concluded more generally that, "[b]ased on the available data, the SCCP is not in a position to define a level of hydrogen peroxide and a frequency of application that would result in exposure which would be considered safe for the consumer." (Haywood, Tr. 2616).

Response to Finding No. 834:

While the quoted language is from the report, the proposed finding ignores Dr. Haywood's consistent testimony that the use of nightguard vital bleaching by adolescents was appropriate if "approved by their parents" and because they were "dentist prescribed treatments." (Haywood, Tr. 2611; 2616). It is also ignores his response to the question as to whether he ignored the recommendations; he stated that he did not.

835. Dr. Haywood continued to claim, in his article presenting the "Bottom Line" on vital teeth bleaching, that "patients are candidates for bleaching when they are ten year olds or older because that is when permanent teeth erupt," despite the fact that he had neither conducted nor was aware of any clinical study of the safety of use of Nightguard Vital Bleaching in children. (Haywood, Tr. 2586, 2604-2607; 2609-2616).

Response to Finding No. 835:

The testimony relates to CX 674 which was referenced in the transcript on page 2612, but was not introduced. While the quoted language is from the report, the proposed finding ignores Dr. Haywood's consistent testimony that the use of nightguard vital bleaching by adolescents was appropriate if "approved by their parents" and because they were "dentist prescribed treatments." (Haywood, Tr. 2611-2612).

836. As Dr. Haywood is aware, other expert commentators have criticized such recommendations. For example, Dr. Haywood's co-developer of Nightguard Vital Bleaching, Dr. Heymann, has written that he "would be reluctant to make such recommendations [two to six months of nightly treatments of adolescents] to dentists . . . because it involves using whitening products well beyond what is known to be safe in a short-term treatment duration with little supporting evidence of safety." (Haywood, Tr. 2618).

Response to Finding No. 836:

The proposed Finding misrepresents Dr. Haywood's response. When read the above quote language from Dr. Heymann's article, Dr. Haywood testified, "I'm not sure that's what he said." (Haywood, Tr. 2618).

837. Dr. Haywood is disturbed by the movement of non-dentists and companies into areas traditionally within the ambit solely of dentists - dentists' privileged place in managing the oral cavity. (Haywood, Tr. 2627).

Response to Finding No. 837:

Dr. Haywood testified that he was "concerned" but did not testify that he was disturbed.

838. Dr. Haywood views the question of whether non-dentists may provide teeth bleaching services or assistance as a wedge issue in dentist control of areas traditionally within the ambit solely of dentists. (Haywood, Tr. 2632).

Response to Finding No. 838:

Dr. Haywood testified that "My view is that this is a battle over licensure and the federal government controlling the licensure and defining dentistry different from what the profession has always defined itself as." (Haywood, Tr. 2632).

839. Dr. Haywood authored a document entitled "Comments on Frequently Asked Questions Document: Dr. Van Haywood 4.25.2010" in which he stated: "[i]f we are unable to define what a dentist does, based on their training and education, then we have opened the door for the lowest level of 'mid level provider', the mall bleacher. . . . That is similar to the other issue the profession has been unable to resolve, that of someone applying 'cosmetic bonded facings' in their home rather than veneers by a dentist, and saying they are not practicing dentistry without a license. As I said earlier, I believe this bleaching question will be what the definition of the profession hinges on for the future. If you cannot defend the position that it is best to see a dentist, then there is no need for a dentist for any other treatments." (Haywood, Tr. 2629-2632, 2914-2915).

Response to Finding No. 839:

The testimony relates to CX 836 which was referenced in the transcript on page 2914-2915, but was not introduced. Dr. Haywood testified that the statement quoted accurately reflected his views as well as "the rest of the body of this letter." (Haywood, Tr. 2915).

840. Along with his view that the question of whether non-dentists may provide teeth bleaching services or assistance is a wedge issue in dentist control of areas traditionally within the ambit solely of dentists, Dr. Haywood maintains an extraordinarily broad opinion as to what constitutes the practice of dentistry. For example, Dr. Haywood believes that the mere sale by a lay-operated teeth bleaching facility of an OTC teeth bleaching product for at-home use is "practicing dentistry." (CX0823 at 015 (Haywood, Dep. at 50)).

Response to Finding No. 840:

The testimony relates to CX 823, but was not introduced. It also references a deposition designation that Complaint Counsel did not make.

841. In other words, the recommendation by a clerk at a drugstore of a particular OTC teeth bleaching product for at-home use in response to a customer's inquiry as to which OTC teeth bleaching product she should buy is "the practice of dentistry." (Haywood, Tr. 2640).

Response to Finding No. 841:

Respondent has no specific response.

842. The scope of "the practice of dentistry" claimed by Dr. Haywood far exceeds that claimed by any other witness in this litigation, including the Respondent. (Haywood, Tr. 2640-2641; CX0823 at 015 (Haywood, Dep. at 50)).

Response to Finding No. 842:

The testimony relates to CX 823, but was not introduced. It also references a deposition designation that Complaint Counsel did not make. The remainder of the proposed Finding is argumentative.

843. Dr. Haywood has a profound antipathy towards non-dentists who provide teeth bleaching services to consumers or who sell teeth bleaching products to consumers for at-home use, reflected in the extremity of his characterizations opinions. (Haywood, Tr. 2716-2717, 2746-2750).

Response to Finding No. 843:

The proposed Finding is argumentative. Dr. Haywood testified that he was aware of consumer harm. (Haywood, Tr. 2716). Dr. Haywood also testified that non-dentist who provide teeth whitening are engaging in the practice of dentistry. (Haywood, Tr. 2459-2460, 2539, 2573).

844. Dr. Haywood believes that a non-dentist's mere offer to provide or assist a consumer in teeth bleaching is irremediably deceptive by implication, wrong, and that all non-dentist providers are "charlatans and quacks."(Haywood, Tr. 2748).

Response to Finding No. 844:

Dr. Haywood did not testify that non-dentist's actions were "deceptive by implication wrong." Dr. Haywood did testify that they confuse and deceive their customers. (Haywood, Tr. 2645). Dr. Haywood also testified that non-dentist who provide teeth whitening are engaging in the practice of dentistry. (Haywood, Tr. 2459-2460, 2539, 2573). He did testify that in his opinion, they were "charlatans and quacks."(Haywood, Tr. 2748).

845. However, Dr. Haywood has not talked with any non-dentist providers, nor is he aware of any evidence that consumers have been deceived in fact by a non-dentist's mere offer to provide or assist a consumer in teeth bleaching. (Haywood, Tr. 2645-2650).

Response to Finding No. 845:

Dr. Haywood testified that he would not contact any retailer and ask for the composition of their products. "If they were practicing illegally dentists, I'm not curious of what they're doing illegally. I just know it's illegal." (Haywood, Tr. 2649).

846. When asked whether any disclosures could prevent consumer confusion as to whether a non-dentist provider was, or was affiliated with a dental professional (for example, the non-dentist provider's having a "big sign that says 'I'm not a dentist or a dental hygienist, nor is any dentist or dental hygienist affiliated with this organization'"). Dr. Haywood replied, "no, because they're still doing the wrong thing. It's kind of like the idea if I - if I robbed a bank and gave all the money to the poor, does that make robbing the bank the correct thing to do." (CX823 at 010 (Haywood Dep. at 30)).

Response to Finding No. 846:

The testimony relates to CX 823, but was not introduced. It also references a deposition designation that Complaint Counsel did not make. Dr. Haywood did testify that, "...it's like robbing a bank and then gave money to the poor, does that mean that robbing the bank is the correct thing to do." (Haywood, Tr. 2747).

847. In the absence of a ban, the American Dental Association has propounded extensive potential notice and disclosure requirements to reduce consumer confusion associated with non-dentist provided bleaching. (CX0487 at 008-009). Even compliance with those requirements, however, would not remedy Dr. Haywood's "concerns." (Haywood, Tr. 2749-2750).

Response to Finding No. 847:

Respondent has no specific response.

848. Dr. Haywood compared non-dentist providers to thieves a second time, and more directly, when replying to a question as whether he had reviewed the operating protocols of any manufacturers of teeth bleaching systems sold for use by non-dentist providers. Dr. Haywood sought to justify the fact that he had not, by responding, "why would I want to review how thieves break into a bank. I'm not interested in that." (Haywood. Tr. 2746).

Response to Finding No. 848:

Respondent has no specific response.

849. Dr. Haywood lacks personal knowledge of any scientific evidence demonstrating that consumers have been harmed in any degree by non-dentist provided teeth bleaching (other than brief and temporary teeth pain or gingival sensitivity, which is caused by dentist provided and non-dentist provided teeth bleaching alike). (Haywood, Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening)).

Response to Finding No. 849:

Dr. Haywood testified that there had been no studies, so there was no way he could know. (Haywood, Tr. 2711-2712). He also testified that “part of the reason” was because it involves the illegal practice of dentistry, they are not doing the research. (Haywood, Tr. 2712). Scientific journals normally do not conduct studies of illegal practices such as the provision of teeth whitening by non-dentists. (Haywood, Tr. 2538-2539). Another reason is that non-dentist bleaching is a new phenomenon in the marketplace, and there has not been time to conduct a formal scientific study of the potential harms. Such studies can take a while to conduct, including the review of relevant literature which can take about two years, and dentists in private practice often do not have the time to do this because it is a very involved procedure. (Haywood, Tr. 2518-2519). Another problem with doing this research is that companies cannot ethically do a proper double-blind scientific study, where one group is treated one way and another group is treated another way. For the study to be ethical, both groups must have a dental exam. (Haywood, Tr. 2517-2518, 2528). When companies such as Procter & Gamble do such studies, they must provide a dental exam initially, which would not properly simulate non-dental teeth whitening. (Haywood, Tr. 2526-2527).

850. Nevertheless, Dr. Haywood has repeatedly analogized customers of lay-operated teeth bleaching facilities to suicides, and the estimated more than 100 million users of OTC Crest Whitestrips and other OTC products to assisted suicides. (Haywood, Tr. 2643-2644).

Response to Finding No. 850:

The proposed Finding of Fact mischaracterizes Dr. Haywood's use of an analogy. Dr. Haywood testified, "You understand by analogy, I don't mean that really happens." (Haywood, Tr. 2645). On direct exam and in his expert report, Dr. Haywood testified, "...when asked what's the difference between mall bleaching and over-the-counter product differences, my comment was that that's the difference between suicide and assisted suicide." (Haywood, Tr. 2458).

851. Dr. Haywood believes that the provision of teeth bleaching services and products, including the mere sale of OTC products for at-home use is simply and terribly "wrong." When asked whether additional hundreds of millions of uses of Crest Whitestrips without reported incident would affect his opinion as to the safety of non-dentist provided teeth bleaching, Dr. Haywood replied: "I just don't know how you can answer that. I-I think it's the wrong thing to do, and so to say it's more wrong if I get-I mean, that's like-what is that like? Abortions? Because you had so many abortions, does that make it right? I don't see that's the right way to analyze the scientific evaluation." (CX0823 at 048, (Haywood. Dep. at 184-185)).

Response to Finding No. 851:

Respondent has no specific response.

852. At trial Dr. Haywood testified that his safety concerns regarding non-dentist provided teeth bleaching would not be affected even if millions of non-dentist provided teeth bleachings had been performed without any evidence of actual harm. (Haywood, Tr. 2679).

Response to Finding No. 852:

Respondent has no specific response.

853. Even 500 million uses of Crest Whitestrips without reported incident would be insufficient to affect Dr. Haywood's opinion regarding the safety of Crest Whitestrips. (Haywood, Tr. 2945-2950).

Response to Finding No. 853:

Respondent has no specific response.

854. Dr. Haywood did not inquire about the legality of non-dentist teeth whitening in other states. (Haywood, Tr. 2640).

Response to Finding No. 854:

Respondent has no specific response.

855. Without support, Dr. Haywood sought to discredit information provided and research sponsored or conducted by P&G relating to non-dentist provided teeth bleaching, and particularly Crest Whitestrips. For example, Dr. Haywood claims that P&G, to regain sales lost to a low-priced paint-on OTC teeth bleaching product that had been introduced by Colgate under the name Simply White, knowingly introduced and marketed an inefficacious low-priced paint-on OTC teeth bleaching product under the Night Effects name. (Haywood, Tr. 2624, 2935-2936).

Response to Finding No. 855:

Dr. Haywood testified, "That's what Proctor & Gamble told me." (Haywood, Tr. 2624).

856. Dr. Haywood alleges that he had been so-informed by a representative of P&G itself. (Haywood, Tr. 2624).

Response to Finding No. 856:

Dr. Haywood testified, "That's what Proctor & Gamble told me." (Haywood, Tr. 2624).

857. At the least, Dr. Haywood is plainly and seemingly inexplicably mistaken about that matter. This Court may take judicial notice of Colgate Palmolive v. P & G, 03-CV-9348. In that litigation, Colgate had sued P&G alleging that P&G's effectiveness and superiority claims for its low-priced paint-on Night Effects product were false. A unanimous jury determined that the P&G product was both efficacious and substantially superior to Colgate's Simply White product. (See Docket #40, Judgment dismissing complaint, attached hereto at Tab 2).

Response to Finding No. 857:

Respondent Board objects to the motion to take judicial [sic] official notice of the litigation. It is irrelevant. Moreover, at trial, Complaint Counsel represented that the case had gone to a jury verdict. (Tr. 2938).

858. Dr. Haywood was at pains to contrast what he apparently regards as the low ethics of the marketplace with what he identifies as the superior ethics of professionals in general and dentists in particular. According to Dr. Haywood, the American Dental

Association's code of ethics distinguishes dentists from lay-providers of teeth bleaching products and services. (Haywood, Tr. 2461-2462).

Response to Finding No. 858:

Dr. Haywood emphasized that unlike non-dentists, dentists "...have a code of ethics, which is to do no harm to patients, to take care of them, do the right thing and be truthful about what we do, so those are different constraints that the profession has from a business about the kind of treatment they render to patients." (Haywood, Tr. 2462).

859. But Dr. Haywood acknowledged that not all dentists satisfy the American Dental Association's ethical standards. (Haywood, Tr. 2625).

Response to Finding No. 859:

This proposed Finding mischaracterizes Dr. Haywood's testimony. He testified that, "I don't have any personal data on that. I hear people talk about it."

860. Indeed, Dr. Haywood has observed, including in his writings, that, "[t]he biggest challenge in esthetic dentistry is to maintain the ethics of the dental profession and to place patient care ahead of financial gain." (Haywood, Tr. 2626).

Response to Finding No. 860:

Respondent has no specific response.

861. At the same time, Dr. Haywood conceded that some nonprofessional, commercial operators of business adopt the high ethical standards notwithstanding that they don't belong to the American Dental Association. (Haywood, Tr. 2626).

Response to Finding No. 861:

Dr. Haywood testified, "That's true of anything. Yes." (Haywood, Tr. 2626).

862. Dr. Haywood lacks knowledge of vital teeth bleaching products, practices, and procedures, and has made no effort even during his engagement in this litigation to obtain such knowledge. (Haywood, Tr. 2647-2648, 2724-2725).

Response to Finding No. 862:

Dr. Haywood sought to justify the fact that he had not, by responding, "why would I want to review how thieves break into a bank. I'm not interested in that." (Haywood, Tr. 2746).

863. In the formulation of his opinion and preparation for testimony in this litigation, Dr. Haywood did not request or review any documents of the Board or any third persons, whether provided during discovery or otherwise. (Haywood, Tr. 2647-2648).

Response to Finding No. 863:

Respondent has no specific response.

864. In the formulation of his opinion and preparation for testimony in this litigation, Dr. Haywood reviewed only one deposition (that of Mr. Runsick), and did not request or review the deposition transcript of present or former members of the Board. (Haywood, Tr. 2648).

Response to Finding No. 864:

Respondent has no specific response.

865. Dr. Haywood has never sought from participants in the industry, any information relating to the safety or effectiveness of non-dentist provided teeth bleaching, whether about nondentist provided teeth bleaching product formulations or characteristics, equipment features or characteristics, operating protocols or procedures, or studies of safety, nor has he visited any non-dentist operated teeth bleaching facilities to observe its products, equipment, and operations. (Haywood, Tr. 2645-2647, 2650-2651, 2654).

Response to Finding No. 865:

Dr. Haywood sought to justify the fact that he had not, by responding, "why would I want to review how thieves break into a bank. I'm not interested in that." (Haywood. Tr. 2746).

866. Dr. Haywood often relied on his extreme characterizations of non-dentist providers of teeth bleaching as the basis for his having failed to become informed about matters relevant to his opinions in this litigation. For example, Dr. Haywood expressed concern as to the composition or characteristics of products used by non-dentist providers. But when asked whether he had inquired of manufacturers or retailers about either, he indicated that he had not: "I don't know why I would do that. If they were practicing illegally dentists [sic], I'm not curious of what they're doing illegally. I just know that it's illegal." (Haywood, Tr. 2649-2650-2651 (never even requested MSDS sheets relating to products marketed for non-dentist provided teeth bleaching)).

Response to Finding No. 866:

The proposed Finding of Fact is argumentative. With mall bleaching, there is someone assisting, guiding, directing, or influencing the customer to do something, which is unwise and constitutes the practice of dentistry. (Haywood, Tr. 2459). In over-the-counter tooth whitening, products are applied by the consumer to themselves; in non-dentist tooth whitening, the service is provided by someone who, in Dr. Haywood's opinion, is presenting themselves as a health professional with the requisite training and skill to diagnose and treat dental conditions. (Haywood, Tr. 2403).

867. For further example, Dr. Haywood expressed concern as to sanitation and infection control procedures at non-dentist operated teeth bleaching facilities. (Haywood, Tr. 2530-2531). Further, he asserted that non-dentist-operated teeth bleaching facilities implicitly misrepresented to consumers their affiliations, qualifications, capabilities, and such. (Haywood, Tr. 2745, 2748). The operating protocols and practices of members of the non-dentist provider community would seem highly informative as to those matters. However, when asked if he had sought information regarding those protocols and practices from any member of the non-dentist provider community or otherwise, Dr. Haywood said that he had not done so, as follows: "why would I want to review how thieves break into a bank. I'm not interested in that." (Haywood, Tr. 2746).

Response to Finding No. 867:

Respondent has no specific response.

868. Dr. Haywood frequently asserted that information that would seem highly informative and relevant to his opinions was unobtainable, when a more candid statement would be that he simply lacked interest in and failed to make any effort to obtain that information. For example, Dr. Haywood expressed concern as to the potential for severe allergic reaction from teeth bleaching at non-dentist-operated facilities. (RX00077 at 010). However, Dr. Haywood appears to have made no effort to obtain information regarding the potential for harm from the ingredients in non-dentist products. When asked whether he knew that manufacturers of non-dentist teeth bleaching products use food-safe ingredients, Dr. Haywood stated, "I know of no way to know about what manufactures do in their businesses. Nor is it my responsibility or job description to do that." (Haywood, Tr. 2650).

Response to Finding No. 868:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions.

869. Dr. Haywood expressed concern as to the potential for harm to the teeth's enamel allegedly associated with possible high acidity (low pH) of formulations used by nondentist providers. However, Dr. Haywood appears to have made no effort to obtain information regarding the potential for harm to the teeth's enamel allegedly associated with possible high acidity (low pH) of formulations used by non-dentist providers. (Haywood, Tr. 2653-2654).

Response to Finding No. 869:

Respondent has no specific response.

870. Dr. Haywood could have taken various actions to obtain information regarding the potential, if any, for harm to the teeth's enamel associated with possible high acidity (low pH) of formulations used by non-dentist providers. (Giniger, Tr. 178 (MSDS available on request from the manufacturer), 218; CX0632 at 008).

Response to Finding No. 870:

Respondent has no specific response.

871. Dr. Haywood never consulted any manufacturers of products used in non-dentist provided teeth bleaching or any non-dentist providers regarding product composition or characteristics, including acidity (low pH). (Haywood, Tr. 2654)

Response to Finding No. 871:

Respondent has no specific response.

872. Dr. Haywood never sought to obtain any MSDS sheets from any manufacturer of products used in non-dentist provided teeth bleaching or from any lay-provider of teeth bleaching products or services. (Haywood, Tr. 2650-2651).

Response to Finding No. 872:

Respondent has no specific response.

873. MSDS sheets contain relevant information regarding product composition and characteristics, and are readily available on request. (Giniger, Tr. 178; CX0632 at 008)).

Response to Finding No. 873:

Respondent has no specific response.

874. Moreover, Dr. Haywood simply ignores the great weight of evidence, including both clinical and experiential evidence, that non-dentist provided teeth bleaching does not pose a material risk of harm to the teeth's enamel. (Finding 945-962).

Response to Finding No. 874:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions.

875. Dr. Haywood expressed concern as to the potential for harm to pulpal function resulting from use of lights in connection with teeth bleaching at non-dentist operated facilities. However, Dr. Haywood appears to have made no effort to obtain information regarding the potential for harm to pulpal function resulting from use of lights in connection with teeth bleaching at non-dentist operated facilities. (Haywood, Tr. 2699-2705).

Response to Finding No. 875:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions.

876. Despite available literature on this subject, Dr. Haywood remains ignorant as to the kinds and qualities of lights that could cause harm to pulpal function and the kinds and qualities of lights used in non-dentist provided teeth bleaching. (CX632 at 011; Haywood, Tr. 2701).

Response to Finding No. 876:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. Dr. Haywood testified that teeth bleaching could cause harm to pulpal function. (Haywood, Tr. 2546). Dr. Haywood also testified that use of certain lights in teeth whitening could cause pulpal damage. (Haywood, 2699).

877. Dr. Haywood does not know what kinds of lights are used in non-dentist provided teeth bleaching. (Haywood, Tr. 2702) (Dr. Haywood does not know whether non-dentist operated facilities use laser lights in teeth bleaching)). In fact, only LED lights are used in non-dentist provided teeth bleaching. (Giniger, Tr. 187-189; CX0632 at 011; Haywood, Tr. 2699-2702).

Response to Finding No. 877:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. Dr. Haywood testified that teeth bleaching could cause harm to pulpal function. (Haywood, Tr. 2546). Dr. Haywood also testified that use of certain lights in teeth whitening could cause pulpal damage. (Haywood, 2699). He testified, "That's a concern in all issues with lights, and why we need it regulated by the profession." (Haywood, Tr. 2699).

878. Dr. Haywood does not know whether LED lights generate enough heat to harm the pulp. (Haywood, Tr. 2704-2705; 2707-2708). In fact, LED lights do not generate heat. (Giniger, Tr. 187-189; CX0632 at 011; Haywood, Tr. 2699-2702).

Response to Finding No. 878:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. Dr. Haywood testified that teeth bleaching could cause harm to pulpal function. (Haywood, Tr. 2546). Dr. Haywood also testified that use of certain lights in teeth whitening could cause pulpal damage. (Haywood, 2699). He testified, "That's a concern in all issues with lights, and why we need it regulated by the profession." (Haywood, Tr. 2699).

879. Dr. Haywood could have taken various actions to obtain information regarding the kinds and qualities of lights that could cause harm to pulpal function and the kinds and qualities of lights used in non-dentist provided teeth bleaching.

Response to Finding No. 879:

Dr. Haywood testified, "That's the responsibility of the manufacturer to defend their product." (Haywood, Tr. 2696)

880. Dr. Haywood never examined nor consulted any manufacturers or users of lights used in non-dentist provided teeth bleaching regarding the kinds and qualities of lights used in non-dentist provided teeth bleaching. (Haywood, Tr. 2701-2705 (Dr. Haywood

never visited a non-dentist-operated teeth bleaching establishment to obtain information or otherwise)).

Response to Finding No. 880:

Respondent has no specific response.

881. Moreover, Dr. Haywood simply ignores the great weight of evidence, including both clinical and experiential evidence, that non-dentist provided teeth bleaching does not pose a material risk of harm pulpal function. (Finding 957-962).

Response to Finding No. 881:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. Dr. Haywood testified that teeth bleaching could cause harm to pulpal function. (Haywood, Tr. 2546). Dr. Haywood also testified that use of certain lights in teeth whitening could cause pulpal damage. (Haywood, 2699). He testified, "That's a concern in all issues with lights, and why we need it regulated by the profession." (Haywood, Tr. 2699).

882. Dr. Haywood's disregard of the great weight of evidence, including both clinical and experiential evidence, that non-dentist provided teeth bleaching is safe puts him sharply at odds with other expert commentators. (Finding 883-885).

Response to Finding No. 882:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. Dr. Haywood had the following concerns regarding the safety of non-dental teeth bleaching: (1) non-dental teeth bleaching does not involve a diagnosis for proper treatment and can mask the pathology for such treatment in the future; (2) non-dental teeth bleaching carries the potential for a less esthetic outcome (*e.g.*, restorations are not identified, root canals are not known); (3) the safety of higher concentrations of teeth whitening solutions is unknown (*e.g.*, there has been no research for concentrations of hydrogen peroxide above

15%); (4) the quality of some products is unknown, especially with respect to issues involving pH, allergic ingredients, or other ingredients; and (5) the patient may not receive any or the maximum benefit available for whitening, and may waste money on ineffective products. (Haywood, Tr. 2571-2572).

In Dr. Haywood's opinion, whitening is best performed in a professionally supervised manner, with a proper examination and diagnosis, using appropriate materials for the patient and situation, with a fair fee for the service. (Haywood, Tr. 2572).

In Dr. Haywood's opinion, low concentrations of carbamide peroxide in a custom-fitted tray are the safest, most cost-effective, and best-researched bleaching treatments available. (Haywood, Tr. 2572).

883. Dr. Haywood played a substantial role in the drafting of a September 2009 American Dental Association position paper intended to "provide information for dentists and to pursue how to protect the public from unsupervised and inappropriate bleaching." (Haywood, Tr. 2463; CX0392 at 001-013 (Teeth Whitening/Bleaching: Treatment Considerations for Dentists and their Patients, ADA Council on Scientific Affairs, September 2009)). A draft of that paper, which identified concerns similar to those identified by Dr. Haywood in this litigation, was critiqued in writing by other well respected experts. (CX0585 at 001-012) ("Possible Edits to CSA Whitening Report: Consultant Comments"); Haywood, Tr. 2673).

Response to Finding No. 883:

Respondent has no specific response.

884. One commentator dismissed some of Dr. Haywood/the draft paper's concerns as unfounded: "[a]t this point at-home bleaching is 23 years old and DTC (direct to consumer) bleaching via CWS is a decade old. At this point tens of millions, if not hundreds of millions, or people worldwide have bleached their teeth. The European Union which was initially extremely cautious about this technique has now moved substantially towards approval of the technique. Probably a majority of people who have bleached their teeth have done so without the supervision of a dental professional. Atin noted that teeth whitening is considered safe based on a lack of clinical reports of

macroscopic damage to teeth or to restorations, so far . . . If indeed concerns over damage were well founded, it seems to me to defy logic that after millions of cases of teeth whitening using products that damage enamel and restorative materials we do not find articles about damage to restoration/enamel surfaces similar to the two cited in the CSA report that resulted from DTC whitening." (CX0585 at 009).

Response to Finding No. 884:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. The Response to Finding No. 882 is incorporated by reference.

885. Dr. Heymann, Dr. Haywood's co-developer of Nightguard Vital Bleaching, likewise criticized the draft paper's views: "I was not aware of the extent of the research that had been done with OTC products until I participated in the comprehensive review of whitening studies in generating the safety report (see Munro et al., papers) and until I participated as a consultant to these companies. Ironically, if FDA approval were required, I assure you P&G's Crest Whitestrips would be among the first whitening products to receive this approval based on the rigorous testing they and other similar ethical companies have done. I have participated in a number of clinical trials here at UNorth Carolina over the past 20 years sponsored by virtually every major manufacturers of whitening products. NO studies are conducted under more rigorous standards than those for P&G and Colgate." (CX0497 at 005) (capitals included).

Response to Finding No. 885:

Dr. Haywood testified that he was unaware of what Dr. Heyman had written. "I don't know if he has commented on the studies." (Haywood, Tr. 2899).

886. Dr. Haywood has claimed that in part the paucity of reports of consumer harm from nondentist provided teeth bleaching is attributable to the lack of a mechanism for consumers to make complaints known. (CX0823 at 15 (Haywood, Dep. at 52)). However, consumers and dentists can and often do make complaints of various sorts known to state agencies, such as Boards of Dental Examiners, Offices of Consumer Affairs, and the American Dental Association and its State and local counterparts. In particular, the American Dental Association Divisions of Government and Public Affairs and Science has recommended to ADA members, "that dentist do the following if their office treats a patient harmed through whitening by retail staff: Submit the information to the U.S. Food and Drug Administration . . .; Encourage the patient to file a complaint with the state dental board; Contact the ADA Division of Science to report the diagnosed harm. Doing so enables the ADA to gauge the extent of reported harm and thus communicate reliable data and information back to the state dental societies. . . ." (CX0469 at 003-004 (Teeth Whitening By Retail Staff, August 2009); Haywood, Tr. 2724)).

Response to Finding No. 886:

The testimony relates to CX 823, but was not introduced. It also references a deposition designation that Complaint Counsel did not make. The remainder of the proposed Finding reflects the evidence of record.

887. Dr. Haywood served as a consultant to the American Dental Association's Council on Scientific Affairs, and in that capacity, played a substantial role in the drafting of a September 2009 ADA position paper intended to "provide information for dentists and to pursue how to protect the public from unsupervised and inappropriate bleaching." (Haywood, Tr. 2463; CX0392 at 001-013 (Teeth Whitening/Bleaching: Treatment Considerations for Dentists and their Patients, ADA Council on Scientific Affairs, September 2009)).

Response to Finding No. 887:

Respondent has no specific response.

888. Despite serving as a consultant to the ADA and being retained by the Board in this litigation, Dr. Haywood never sought consumer complaint files relating to non-dentist provided teeth bleaching from the ADA, the Board, Respondent's counsel, or anyone else. (Haywood, Tr. 2647-2648, 2724-2725).

Response to Finding No. 888:

Respondent has no specific response.

889. Dr. Haywood applies to non-dentist provided teeth bleaching an analytical construct pursuant to which it would be impossible to establish the safety of non-dentist provided teeth bleaching even if it were absolutely safe in fact. To begin, Dr. Haywood insists that the absence of reported actual harm despite extensive experience with non-dentist provided teeth bleaching is insufficient to establish its safety. (Haywood, Tr. 2713-2714).

Response to Finding No. 889:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. The response to Finding No. 882 is incorporated herein by reference.

890. For example, Dr. Haywood testified that the experience of several hundred million uses of Crest Whitestrips over the course of many years without reported actual harm would not be probative of the safety of non-dentist provided teeth bleaching generally or Crest Whitestrips in particular, though perhaps the experience of one billion patients would have some probative value. (Haywood, Tr. 2949-2950).

Response to Finding No. 890:

Respondent has no specific response.

891. Dr. Haywood insists that only empirical studies of non-dentist provided teeth bleaching could establish its safety. (Haywood, Tr. 2729).

Response to Finding No. 891:

Dr. Haywood testified in response to the leading question, "Correct. I guess."

(Haywood, Tr. 2729).

892. However, Dr. Haywood also insists that there are no valid clinical studies of non-dentist provided teeth bleaching, and that it is technically impossible to conduct valid studies of non-dentist provided teeth bleaching. (Haywood, Tr. 2729-2730).

Response to Finding No. 892:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. The Response to proposed Finding No. 849 is incorporated by reference.

893. Dr. Haywood asserted that any study of non-dentist provided teeth bleaching necessarily would violate ethical norms for research involving human subjects, comparing any such study to the infamous Tuskegee Syphilis Experiment in which African-American men with syphilis were denied available and effective treatment so that the ravages of the untreated disease could be observed. (CX0823 at 048 (Haywood, Dep. at 183) (Q: "Is it your position that one cannot ethically conduct a study of unsupervised bleaching?" A: "Yeah, that's correct. I think the Alabama law has provided that when they did the syphilis with the black folks and wouldn't tell them they had it done. So that's an ethical issue"))).

Response to Finding No. 893:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. The Response to proposed Finding No. 849 is incorporated by reference.

894. Applying his analytical construct, Dr. Haywood would deprive consumers of the benefits of non-dentist provided teeth bleaching services even if non-dentist provided teeth bleaching were absolutely safe. (Haywood, Tr. 2730):

Q: You acknowledge that you've created a catch-22w here that would perpetually bar non-dentists from providing teeth whitening even if it were true in fact that that was perfectly safe?

A. That's exactly what I believe, yes, sir.

Response to Finding No. 894:

Respondent has no specific response.

895. Further, Dr. Haywood's insistence that it is technically impossible to conduct valid studies of non-dentist provided teeth bleaching is illogical and extreme. (Giniger, Tr. 257-259; CX0632 at 010).

Response to Finding No. 895:

The proposed Finding of Fact is argumentative because Complaint Counsel disagrees with Dr. Haywood's opinions, and it mischaracterizes his testimony. The Response to proposed Finding No. 849 is incorporated by reference.

896. In fact, there are numerous studies showing the safety and efficacy of non-dentist provided teeth bleaching, including numerous peer-reviewed, published studies of at home use by consumers of OTC products. (Giniger, Tr. 257-259; CX0632 at 009-010; CX0496 at 001-008 (2010 letter from P&G to the FDA appending a list of 42 studies supporting the safety of Crest Whitestrips)).

Response to Finding No. 896:

The proposed Finding is actually a conclusion of law and is argumentative of the evidence. The record is clear that Dr. Haywood testified as the concerns about non-dentist teeth whitening and consumers' use of OTC products. (Haywood, Tr. 2571-2572;

see also, RX 146). On the other hand, Dr. Giniger testified as to his lack of concern about non-dentist and OTC teeth whitening. (Giniger Tr. 121; see CX803-11).

897. These include studies of the safety of at-home use over a period of several weeks of products containing 14% hydrogen peroxide. (CX0496 at 001-008; CX0632 at 009).

Response to Finding No. 897:

Respondent has no specific response.

898. Dr. Haywood dismisses all of the P&G and similarly structured studies, claiming that they are not in the least probative of "unsupervised [by dentists] administration" of bleaching products. He reasons that they cannot be for two reasons: because potential subjects were subject to inclusion and exclusion criteria, and because dentists participated in the studies in some manner. Dr. Haywood did not describe, nor does it appear that he assessed the specific inclusion/exclusion criteria used or the manner of participation of dentists in the studies of interest. (Haywood, Tr. 2731; CX0823 at 047-048 (Haywood, Dep. at 180-183).

Response to Finding No. 898:

Respondent has no specific response.

899. Dr. Haywood's reasoning is deeply flawed. (Giniger, Tr. 257-259; CX0632 at 010; CX0585 at 002-003, 005; CX0497 at 005-006).

Response to Finding No. 899:

This is not a fact, it is an opinion stated by Dr. Giniger. Dr. Haywood testified that Dr. Giniger's reasoning was deeply flawed. See RX 141 and his testimony regarding this Power Point, including rebuttals of Dr. Giniger's opinion. (Haywood, Tr. 2403 – 2573). The Response to Finding of Fact No. 716 is also incorporated herein by reference See also, Respondent's Proposed Findings of Fact 401 – 406.

900. The mere participation of a dentist in a study does not render it methodologically infirm. For example, a participating dentist's participation might be restricted to conducting a baseline examination and making follow-up observations, without other interaction with test subjects. (Giniger, Tr. 260-261; CX0632 at 009).

Response to Finding No. 900:

Participation, particularly financial benefit, does not render a study methodologically infirm, but it does subject the study to potential criticism for bias.

901. Similarly, the mere application of inclusion/exclusion criteria does not render a study methodologically infirm. Inclusion/exclusion criteria can be calibrated to eliminate few, if any, potential participants, thereby avoiding sampling bias. (Giniger, Tr. 260-262; CX0632 at 009).

Response to Finding No. 901:

Respondent disputes this proposed finding of fact as a statement of opinion – not fact.

Dr. Haywood's testimony was that studies that were probative of the safety of non-dental teeth whitening would necessarily breach ethical norms. (Haywood, Tr. 2922-2923).

902. Dentist participation and the application of inclusion/exclusion criteria would be problematic only if the manner of dental participation or the specific inclusion/exclusion criteria selected is poorly designed or executed such that the study is compromised, as a biased sample would do. (Giniger, Tr. 261-262; CX0632 at 009-010).

Response to Finding No. 902:

Respondent disputes this proposed finding of fact as a statement of opinion – not fact.

Dr. Haywood's testimony was that studies that were probative of the safety of non-dental teeth whitening would necessarily breach ethical norms. (Haywood, Tr. 2922-2923).

903. Thus, for example, while it may be true that the findings of a study that excludes children from the subject pool ought not to be extrapolated to children, the absence of children from a subject pool does not preclude extrapolation of the study findings to other groups that were represented in the subject pool. (Haywood, Tr. 2612-2613) (absence of studies including children renders SCCP unable to draw conclusion about the "potential health risks associated with their use in this population subgroup").

Response to Finding No. 903:

Respondent has no specific response.

904. Probative studies of unsupervised bleaching can - and frequently do - include baseline examination and follow-up observations by dentists, without other additional interaction with test subjects, and include at least some inclusion and exclusion criteria. (Giniger, Tr. 262).

Response to Finding No. 904:

Respondent has no specific response.

905. Numerous other experts reject Dr. Haywood's position that the safety of unsupervised bleaching cannot be studied clinically. (CX0496 at 001-008 (2010 letter from P&G to the FDA appending a list of 42 studies supporting the safety of Crest Whitestrips); CX0585 at 002-003 (ADA consultants providing comments on first draft of the 2009 Teeth Whitening statement authored by, among others, Dr. Haywood) (responding to a statement in the report that studies conducted by dental professionals cannot demonstrate the safety of at-home bleaching materials - "Does this mean that research conducted by dental professionals is in some way biased or inherently flawed or that dental professionals are not committed to honest research? That is why studies are peer reviewed both in funding and in publication. I find that statement to be an unnecessary and inaccurate indictment of dental research conducted by dental professionals!").

Response to Finding No. 905:

The Report quoted is a confidential report, and the author is not identified. It is unsubstantiated hearsay. It was used for cross-examination of Dr. Haywood, but it cannot be considered as an expert opinion, because the authors were not qualified and admitted. The report agrees with Dr. Haywood that "dentist-supervised bleaching is the safest approach to all bleaching." (CX0585 at 004). Dr. Haywood noted that Complaint Counsel's questions confused the fact that the report was dealing with non-dentists administration of Crest WhiteStrips. "...the question [of] masking diagnosis is different from harm to enamel and restorative material. (Haywood, Tr. 2676). He went on to testify that "Because you've switched to non-dentists providing it. This [article] is talking about direct-to-consumer issues, and we've already established that this issue is not effects on enamel, the issue is the practice of dentistry and the misdiagnosis of the treatment that needed to come. That's a different issue." (Haywood, Tr. 2677-2678).

906. For example, Dr. Heymann, Dr. Haywood's co-developer of Nightguard Vital Bleaching necessarily rejected Dr. Haywood's claim that non-dentist provided teeth

bleaching cannot be studied clinically: "I was not aware of the extent of the research that had been done with OTC products until I participated in the comprehensive review of whitening studies in generating the safety report (see Munro et al., papers) and until I participated as a consultant to these companies. Ironically, if FDA approval were required, I assure you P&G's Crest Whitestrips would be among the first whitening products to receive this approval based on the rigorous testing they and other similar ethical companies have done." (CX0497 at 005).

Response to Finding No. 906:

When he was read the above quote language from Dr. Heymann's article, Dr. Haywood testified, "...yes. That's his opinion." (Haywood, Tr. 2618). Clearly, Dr. Haywood has testified throughout as to a different opinion. In Dr. Haywood's opinion, "non-dentist teeth bleaching does not have a good risk-benefit or cost-benefit ratio, and misleads the public as to safety and efficacy. (Haywood, Tr. 2573). "...there is no data on the non-dentist bleaching. And on the over-the-counter materials, if it masks pathology, then we don't know the pathology that is there, so at this point we don't know what the outcome will be because we didn't have a baseline exam." (Haywood, Tr. 2548).

C. The Board's Witnesses Testified About the Lack of Evidence of Any Harm Caused by Non-dentist Teeth Whitening

907. There is little to no evidence of any serious harm or non-transient effects caused by nondentist teeth whitening. (Nelson Tr. 771; Osborn Tr. 664-665; CX0554 at 026 (Allen, Dep. at 95-96).

Response to Finding No. 907:

Respondent disputes this proposed finding of fact. First, Complaint Counsel has mischaracterized the evidence in support of this finding by representing that the majority of the evidence cited in support of this proposed finding comes from the "Board's Witnesses" per the heading immediately above. Mr. Nelson and Ms. Osborn are teeth whitening industry representatives and were subpoenaed by Complaint Counsel as its witnesses. (Subpoenas Ad Testificandum, Feb. 3, 2011). Dr. Allen's actual testimony

was that he was not personally aware of anyone who had received any nontransient harm from non-dentist teeth whitening, nor was he aware of any literature regarding the same. (CX554 (Allen, Dep. at 95-96)). He did not testify that there was little to no evidence of any serious harm or non-transient effects caused by non-dentist teeth whitening. (CX554 (Allen, Dep. at 95-96)).

908. Board members testified that they are not aware of any evidence that the practice of teeth whitening by non-dentists has caused any harm other than transient or temporary sensitivity or irritation. (CX0555 at 026 (Brown, Dep. at 97); CX0554 at 026 (Allen, Dep. at 95-96)).

Response to Finding No. 908:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized the testimony cited in support of thereof. In response to a question as to whether he was aware of any evidence that the practice of tooth whitening by non-dentists caused any harms other than transient, Dr. Brown's actual testimony was that he had not made any searches or inquiries to determine whether that has occurred. (CX555 (Brown, Dep. at 97). Dr. Allen's actual testimony was that he was not personally aware of anyone who had received any nontransient harm from non-dentist teeth whitening, nor was he aware of any literature regarding the same. (CX554 (Allen, Dep. at 95-96)).

909. Board members testified that they are not aware of any empirical literature establishing that consumers have been subject to significant non-transient harm from teeth whitening provided by a non-dentist. (CX0560 at 066 (Feingold, Dep. at 254); (CX0554 at 026 (Allen Dep. at 95-96)).

Response to Finding No. 909:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized the testimony of Board members cited in support of this proposed

finding. In the testimony cited by Complaint Counsel in support of this proposed finding, Dr. Feingold was asked whether he had “any knowledge of empirical literature establishing that there even are a material number of adverse outcomes from tooth whitening by nondentists.” He was not asked whether he was aware of any empirical literature establishing that consumers were subject to non-transient harm from teeth whitening. (CX560 (Feingold, Dep. at 254)).

910. Dr. Feingold testified that he was not part of any literature search by the Board to determine whether the practice of teeth whitening by non-dentists leads to a higher incident of adverse outcomes than teeth whitening by dentists. (CX0560 at 065 (Feingold, Dep. at 253)).

Response to Finding No. 910:

Respondent disputes this proposed finding of fact. Dr. Feingold actually testified that he was not aware of any empirical literature “in either direction” as to whether he was aware of “any empirical literature establishing that the practice of teeth whitening by nondentists leads to a higher incidence of adverse outcomes in the practice of teeth whitening by dentists.” (CX560 (Feingold, Dep. at 253)).

911. Dr. Brown testified he has conducted no search to try to determine whether the practice of teeth whitening by non-dentists has caused any non-transient harm to consumers. (CX0555 at 026 (Brown, Dep. at 97)).

Response to Finding No. 911:

Respondent has no specific response. Dr. Brown further testified in this line of questioning, “[t]he law doesn’t say anything about whether – whether it has any effects or not. It just says that they’re not allowed to do it.” (RX51 (Brown, Dep. at 98)).

912. Notwithstanding the lack of evidence, Dr. Feingold testified that as of February 7, 2007, there was a growing problem in North Carolina involving the provision of teeth bleaching services by non-dentists because of health and safety issues. (CX0560 at 065 (Feingold, Dep. at 251-252); CX0067 at 001).

Response to Finding No. 912:

Respondent disputes this proposed finding of fact as argumentative rather than a reflection of Dr. Feingold's actual testimony. Neither the testimony cited by Complaint Counsel in support of this proposed finding of fact, nor Complaint Counsel's questions contained therein, make any reference to a lack of evidence. (CX560 (Feingold, Dep. at 251-252).).

913. The Board admits that "it is not aware of studies comparing the safety of teeth whitening services as performed by dentists" versus non-dentists. (Response to RFA 21).

Response to Finding No. 913:

Respondent disputes this proposed finding of fact. It contains the assumption that there are studies that the Board could be aware of. Dr. Haywood testified that there are no studies on the performance of teeth whitening services performed by non-dentists.

(Haywood, Tr. 2932).

914. The Board admits that it is not aware of "studies comparing the 'patient health issues' that might arise from teeth whitening services as performed by dentists" versus nontentists." (Response to RFA 38).

Response to Finding No. 914:

Respondent disputes this proposed finding of fact. It contains the assumption that there are such studies that the Board could be aware of. Dr. Haywood testified that there are no studies on the performance of teeth whitening services performed by non-dentists.

(Haywood, Tr. 2932).

915. The Board is not aware of any consumer harm due to any of the non-dentist teeth whitening procedures referenced in Response to Complaint Counsel's First Request for Admissions. (Response to RFA ¶¶ 23-28).

Response to Finding No. 915:

Respondent disputes this proposed finding of fact as it is incomplete as a statement of fact, mischaracterizes the Board's responses to Complaint Counsel's First Request for Admissions, and contains an assumption. The non-dentist teeth whitening procedures referenced in this proposed finding of fact are six very specific cases identified in Complaint Counsel's First Set of Requests for Admissions. (Respondent's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, at 10-12). In its responses and objections to these six requests for admissions, Respondent objected to the undefined phrase "consumer harm" as ambiguous and vague, and further objected because the N.C. Dental Practice Act does not require that an injury be suffered before a complaint is made to the Board. Respondent's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, 10/27/2010).

D. There Is a Lack of Evidence of Harm from Non-dentist Teeth Whitening Outside North Carolina

916. Mark Brengelman, an Assistant Attorney General from Kentucky, noted in August 2008 that there had been "no complaints of actual harm. I'm not even sure that any patients themselves have actually complained, only other dentists, et cetera." (CX0562 at 028 (Friddle, IHT at 108); CX0525 at 001).

Response to Finding No. 916:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized Ms. Friddle's testimony. The letter was Mr. Brengelman was mentioned and quoted by Complaint Counsel, but Ms. Friddle was not asked to comment on Mr. Brengelman's letter. (CX562 (Friddle, IHT at 108)). Instead, she was asked if she ever had "any discussions with any members of the Board or any members of the staff of the Dental Board regarding the lack of actual patient harm in these case?" Ms. Friddle responded, "I don't believe so." (CX562 (Friddle, IHT at 108)). The other evidence

cited in support of the proposed finding does not reference Mr. Brengelman at all.

(CX525).

917. Dr. Haywood lacks personal knowledge of any scientific evidence demonstrating that consumers have been harmed in any degree by non-dentist provided teeth bleaching (other than brief and temporary teeth pain or gingival sensitivity, which is caused by dentist provided and non-dentist provided teeth bleaching alike). (Haywood, Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening)).

Response to Finding No. 917:

Respondent disputes this proposed finding of fact. It contains the assumption that there are studies that Dr. Haywood is personally not aware of. Dr. Haywood testified that “[a]s long as you include the phrase ‘non-dental teeth whitening,’ there are no studies for that group.” (Haywood, Tr. 2932).

918. Over the last 20 years, millions of consumer have safely bleached their teeth without dental involvement and there is not a single study demonstrating substantial, nontransient harm from non-dentist teeth bleaching. (Giniger, Tr. 121-123, 430-431, 453-455; Haywood, Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening), 2729; CX0653 at 005).

Response to Finding No. 918:

Respondent disputes this proposed finding of fact. It contains the assumption that because there are no studies, there is no substantial, non-transient harm from non-dentist teeth bleaching. Dr. Haywood testified that “[a]s long as you include the phrase ‘non-dental teeth whitening,’ there are no studies for that group.” (Haywood, Tr. 2932).

919. There is little to no evidence of any serious harm or non-transient effects caused by nondentist teeth whitening. (Nelson, Tr. 771; Osborn, Tr. 664-665).

Response to Finding No. 919:

Respondent disputes this proposed finding of fact. Complaint Counsel has mischaracterized the testimony cited in support of this proposed finding. Mr. Nelson did

not offer any testimony related to non-transience, and he merely responded that he had not received any complaints from consumers regarding serious harm. (Nelson, Tr. 771). The testimony of Ms. Osborn cited by Complaint Counsel contains no reference to non-transience; she simply states that she received complaint, but they were not related to pain or sensitivity. (Osborn, Tr. 664-665).

D. The Potential Side Effects of Teeth Whitening Are Generally Transient

920. Board members and dentists from the North Carolina Dental Society are not aware of incidents of non-transient harm to their patients who received teeth whitening from a non-dentist. (CX0577 at 010 (Oyster, Dep. at 30-31); CX0554 at 026 (Allen, Dep. at 95-96); Wester, Tr. 1405-1406; CX0578 at 007 (Parker, Dep. at 19-21); CX0576 at 005 (Litaker, Dep. at 13)).

Response to Finding No. 920:

Respondent has no specific response.

921. Dentists from the North Carolina Dental Society testified that transient tooth sensitivity and transient gum soreness are the only injuries they have observed in the patients for whom they provide teeth whitening. (CX0576 at 005 (Litaker, Dep. at 13); CX0577 at 010 (Oyster, Dep. at 30); CX0578 at 007 (Parker, Dep. at 19-20) (regarding take-home trays) and CX0578 at 007 (Parker, Dep. at 21) (regarding the Zoom! system)).

Response to Finding No. 921:

Respondent has no specific response.

922. Dr. Wester testified that his dentist peers had not reported to him any instances of harm from teeth whitening beyond transient sensitivity. (Wester, Tr. 1405-1406).

Response to Finding No. 922:

Respondent has no specific response.

923. The only specific instance that Dr. Allen is aware of non-transient harm due to nondentist teeth whitening is the case of Mr. Runsick, but Dr. Allen did not examine Mr. Runsick's file, and only had the information that was provided to him by Board counsel in the context of this litigation. (CX0554 at 046 (Allen, Dep. at 174-175)).

Response to Finding No. 923:

Respondent disputes this proposed finding of fact. Dr. Allen testified that he was aware of "at least one case in particular" – not that Mr. Runsick's case was the only case that he was aware of. (CX554 (Allen, Dep. at 174-175)).

E. Sensitivity Is a Common and Transient Side Effect of All Types of Teeth Whitening

924. Drs. Giniger and Haywood agree that teeth bleaching may cause teeth and gum sensitivity or pain, but such sensitivity or pain is transient, usually resolving within a few days. (Giniger, Tr. 143-147; CX0653 at 012; CX0627 at 002 (2009 interview with Dr. Haywood) (Q: "Can bleaching sensitivity cause damage in the long term?" A: "Although penetration of peroxide through the tooth to the pulp can produce sensitivity, the pulp remains healthy and the sensitivity is completely reversible when treatment is terminated. No long-term sequelae remain after the sensitivity has abated."); CX0402 at 005 (article authored by Dr. Haywood noting studies on application of 35% hydrogen peroxide on teeth "has shown effects which are reversible over time, with no clinical consequence other than immediate but transient sensitivity"). This is in accord with the testimony of Board members. (CX0566 at 019 (Hardesty, IHT at 71) (Hardesty testifies that it is rare for patients to experience sensitivity from teeth whitening for longer than a few days, and they certainly do not longer than a week)).

Response to Finding No. 924:

Respondent has no specific response.

925. Drs. Giniger and Haywood agree that sensitivity is caused by temperature rise in the pulp and by the use of high concentration peroxide. (Giniger, Tr. 214-215; CX0653 at 012; CX0823 at 062 (Haywood, Dep. at 240-241) ("The general rule is the higher the concentration [of bleaching agents], the greater the chance of sensitivity); RX0077 at 17-18).

Response to Finding No. 925:

Respondent has no specific response.

926. Sensitivity is therefore more likely in dentist chair-side bleaching due to greater concentration of hydrogen peroxide and more intense light/heat activation used in dental offices. (Giniger, Tr. 214-215; CX0653 at 027).

Response to Finding No. 926:

Respondent disputes this proposed finding as it states an opinion – not a fact.

927. Regardless of the source, sensitivity from bleaching does not require medical care, and can be resolved by simply discontinuing bleaching or, if needed, through the use of OTC nonsteroidal anti-inflammatory drugs such as aspirin, ibuprofen, or Tylenol. (Giniger, Tr. 143-147; CX0653 at 012).

Response to Finding No. 927:

Respondent disputes this proposed finding of fact. The exhibit cited by Complaint Counsel in support of this proposed finding of fact does not make reference to medical care. (CX653 at 12).

928. It is a rare occurrence that patients experience sensitivity from teeth whitening for longer than a few days after the whitening material is removed, and certainly not more than one week. (CX0566 at 019 (Hardesty, IHT at 71)).

Response to Finding No. 928:

Respondent has no specific response.

929. Without either known exposed root material or a patient's history of oral sensitivity, it is difficult to predict teeth sensitivity to teeth whitening. (Hardesty, Tr. 2814).

Response to Finding No. 929:

Respondent has no specific response.

930. Dr. Wester testified that he could not tell which patients would have post-teeth whitening sensitivity before the patient underwent teeth whitening. (Wester, Tr. 1369).

Response to Finding No. 930:

Respondent has no specific response.

F. Non-dentist Teeth Whitening Poses Little If Any Other Risk Suggested by Dr. Haywood

1. There Is Little or No Risk of Allergic Reaction

931. Teeth bleaching, whether performed by a dentist, a lay-provider, or the consumer using an OTC product at home, poses no risk of anaphylactic reaction. (Giniger, Tr. 222-

225; Haywood, Tr. 2729; CX0823 at 024 (Haywood, Dep. at 89) (Dr. Hardesty [sic] is not aware of any consumer having an anaphylactic reaction from non-dentist teeth whitening).

Response to Finding No. 931:

Respondent disputes this statement because it blatantly mischaracterizes the record evidence. There is no basis in the record for this statement. In fact, none of the evidence cited by Complaint Counsel, including the testimony of its teeth whitening industry expert Dr. Giniger, supports the sweeping statement made here. Dr. Giniger never testified that teeth bleaching “poses no risk of anaphylactic reaction”, he merely responded to questions by Complaint Counsel and stated that gluten, a known allergen, is not in “any of these products”, and that he is not “aware of” banana flavorings being used in teeth whitening products (in response to Dr. Haywood’s testimony that there are concerns about allergies to banana flavorings). (Giniger, Tr. 222-225). The testimony of Dr. Haywood cited by Complaint Counsel merely states that he has not heard of someone having an anaphylactic reaction from non-dental teeth bleaching, not that teeth bleaching poses no risk of anaphylactic reaction. Additionally, Complaint Counsel mistakenly says “Dr. Hardesty” in its parenthetical when it appears to reference Dr. Haywood.

Dr. Haywood’s **actual** testimony is that non-dentist teeth whitening poses serious risks of anaphylactic reactions to consumers using those products because the non-dentists using those products do not have the training or sophistication to be aware of the risks of potentially allergic reactions to the chemicals contained in their products, nor do they have the requisite training to deal with such a reaction should it occur. (CX0823 (Haywood, Dep. at 73-74); Haywood, Tr. 2459). Dr. Haywood also points out that another issue with non-dentist teeth bleaching products is that the ingredients of many of

the products being put on the market is not known. Haywood, Tr. 2572). For instance, one of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product, stating only that it's percentage of carbamide peroxide is "proprietary" and not disclosing what other ingredients are in the product. (CX108 at 4).

932. Hydrogen peroxide is a naturally occurring product of cellular metabolism, and therefore peroxide allergy is extremely rare. (Giniger, Tr. 224).

Response to Finding No. 932:

Hydrogen peroxide is not the only ingredient in teeth bleaching products. Many teeth whiteners, however, do not disclose all of the ingredients of their products, in part because of the lack of regulation in the market. (*See* CX108 at 4 (stating only that it's percentage of carbamide peroxide is "proprietary" and not disclosing what other ingredients are in the product)).

933. Teeth bleaching formulations are made of ingredients that are also used in processed foods and other personal care items. These products are also often listed as United States Pharmacopeia ("USP"), which is the purest chemical form in which they can be purchased, surpassing food-grade quality. (Giniger, Tr. 224-229).

Response to Finding No. 933:

Respondent disputes the relevance of this fact because it fails to establish an adequate level of regulation of teeth whitening products that are used by non-dentists. In fact, no evidence was presented at trial demonstrating that all non-dentist teeth whiteners use FDA-approved teeth whitening products, nor was there any evidence presented that there is a state or federal regulatory entity that ensures that FDA-approved teeth whitening products are used by non-dentists selling the product to consumers. (Entire record). The record did reflect, however, that non-dentist teeth whiteners have sought to avoid

regulation of the provision of their products and services. (Valentine, Tr. 536-541 (admitting that WhiteSmile USA sought to avoid regulation by the State Board and other states by telling its employees to have customers self-administer bleaching products); Osborn, Tr. 666-667 (admitting that she has revised her training, informational and marketing literature to no longer use the word “stains” to describe the teeth whitening process she helped develop, and that she did this in an attempt to avoid state regulations that would view her system as the practice of dentistry); Osborn, Tr. 675-678 (admitting that the Council for Cosmetic Teeth Whitening has developed “best practices” protocols for how to avoid state regulations that could potentially regard teeth whitening as the practice of dentistry, including not touching customers or their mouths and making sure that customers self-administer the teeth whitening products).

934. Propylene glycol is a USP product that is commonly used in American cheese, tobacco, and a variety of different personal care items, including toothpaste. (Giniger, Tr. 225-226).

Response to Finding No. 934:

Respondent refers to its response to Proposed Finding No. 933.

935. Carbomer is commonly used in gelled foods, gelled cosmetic, and toothpaste. (Giniger, Tr. 226).

Response to Finding No. 935:

Respondent refers to its response to Proposed Finding No. 933.

936. Vegetable glycerine is a kosher and USP product that is used in many personal care items such as soap, shampoo, lotion, processed foods, and toothpaste. (Giniger, Tr. 227).

Response to Finding No. 936:

Respondent refers to its response to Proposed Finding No. 933.

937. Triethanolamine (TEA) is a USP ingredient that is used in milk, skin lotion, and eye gels. (Giniger, Tr. 227-228).

Response to Finding No. 937:

Respondent refers to its response to Proposed Finding No. 933.

938. To Dr. Giniger's knowledge, every teeth bleaching product manufactured in the United States uses only USP or food-grade materials. (Giniger, Tr. 225-226)

Response to Finding No. 938:

Respondent refers to its response to Proposed Finding No. 933. Dr. Giniger's credibility is also very pertinent in assessing this statement. *See* Respondent's Proposed Findings of Fact Nos. 341-362. Further, there is no foundation for this statement, as there was no evidence presented that Dr. Giniger is aware of the formula of every single teeth whitening product on the market (nor would such a statement be plausible, especially given the lack of regulation of the products used by unlicensed non-dentists in the teeth whitening services that they provide).

939. Dr. Haywood could not cite any instance in which any person anywhere suffered an anaphylactic reaction as a result of non-dentist teeth bleaching. (Haywood, Tr. 2729; CX0823 at 024 (Haywood, Dep. at 89)).

Response to Finding No. 939:

Respondent refers to its response to Proposed Finding No. 931.

940. Dr. Haywood also suggested that gluten, an allergen to sufferers of Celiac Disease, banana flavorings, which he stated are biochemically related to latex, and other allergens may be present in bleaching formulations. However, neither Drs. Giniger nor Haywood are aware of any teeth bleaching products that contain gluten or banana flavorings; nor, to their knowledge, has any consumer had an allergic reaction to gluten or banana flavorings as a result of exposure at a lay-operated bleaching facility. (Giniger, Tr. 223-224; Haywood, Tr. 2725-2728).

Response to Finding No. 940:

Respondent refers to its response to Proposed Finding Nos. 931 and 938. Respondent also disputes the portion of this statement that blatantly misstates the record. Dr.

Haywood **did** in fact testify at his deposition that he was aware of teeth bleaching products containing banana flavorings. (Haywood, Dep. at 83, 86-87 (“I know Opalescence by Ultradent made a banana flavoring”)).

941. In fact, based on his experience in formulating and testing the safety and efficacy of teeth bleaching products, Dr. Giniger cannot imagine a use for gluten in a teeth bleaching product. (Giniger, Tr. 222).

Response to Finding No. 941:

Respondent refers to its response to Proposed Finding Nos. 931 and 938.

942. Dr. Haywood also claimed that use of latex gloves could cause an allergic reaction, but dentists and non-dentist providers alike wear gloves when interacting with patient/customers – generally to protect the dental professionals from infections potentially carried by their patients. (Giniger, Tr. 230; Hardesty, Tr. 2781-2782)). In any event, Dr. Haywood could not cite any instance in which any person suffered a latex allergy as a result of non-dentist bleaching. (Finding ¶¶ 939-940).

This statement blatantly mischaracterizes the record. Dr. Haywood did not claim that the use of latex gloves could cause an allergic reaction in connection with citing his concerns about teeth whitening. Dr. Haywood cited concerns that teeth whitening customers with latex allergies could be allergic to banana flavorings. CX0823 (Haywood, Dep. at 83 (“people with a latex allergy can’t deal with bananas because they have the same ingredient that causes an anaphylactic reaction. So you may have a -- something that has some component of banana like banana flavoring in there that can create a reaction in somebody not knowing what’s in there.”)). As noted above, Dr. Haywood testified to the existence of teeth whitening products that contain banana flavoring, despite Dr. Giniger’s testimony to the contrary. (Haywood, Dep. at 83, 86-87 (“I know Opalescence by Ultradent made a

banana flavoring’’)). He also testified that ‘‘Most dentists use nonlatex gloves now because of the latex allergies.’’ (Haywood, Dep. at 85).

943. Testing a patient for specific sensitivity to teeth whitening is outside the practice of dentistry; a patient would need to consult an allergist. (CX0566 at 019 (Hardesty, IHT at 73)).

Response to Finding No. 943:

Respondent has no specific response.

944. Dentists might be able to tell if a patient would have an allergic reaction to teeth whitening, but it would require knowledge of a patient’s previous experience with a similar material. (CX0554 at 008-009 (Allen, Dep. at 25-26)). Dr. Allen does not ask his patients if they have ever had an allergic reaction to a similar material before performing teeth whitening. (CX0554 at 009 (Allen, Dep. at 26)).

Response to Finding No. 944:

This statement blatantly misstates the record because it does not accurately describe Dr. Allen’s testimony. Dr. Allen testified that before performing a teeth whitening procedure he does not ‘‘ask [his] patients if they’ve ever had an allergy to -- **when a bonding procedure had been done.**’’ (CX0554 (Allen, Dep. at 26)). Complaint Counsel improperly mischaracterizes Dr. Allen’s methodology by taking his answer to a very specific question and then transforming his answer into a more general assertion that was never made and has no support in the record.

2. There Is Little or No Risk of Structural Damage

945. Teeth bleaching, whether performed by a dentist, a lay-provider, or the consumer using an OTC product at home, poses no risk of harm to the enamel of teeth. (Giniger, Tr. 355-356).

Response to Finding No. 945:

Dr. Haywood testified that Dr. Giniger’s claims that use of teeth bleaching products does not readily or permanently damage enamel or gingival tissue touches on a hotly contested

point in the profession. There are many dental experts who believe it does cause damage. There are also reports of damage to enamel by inappropriate use of bleaching materials. (Haywood, Tr. 2517). For example, one of the products touted by Dr. Giniger is Simply White, which is a paint-on whitener made by Colgate. (Haywood, Tr. 2414). While reviewing literature on teeth bleaching, Dr. Haywood read an article in the Journal of Esthetic and Restorative Dentistry that evaluated this product. The article stated that Simply White contained phosphoric acid, which can be detrimental to enamel because it reduces enamel microhardness. The product is now no longer on the market. (Haywood, Tr. 2427-2428).

946. Scientific studies of all types confirm that teeth bleaching poses no risk of harm to the enamel of teeth. There are two methods of constructing a study on the effect of teeth whitening on enamel: in vitro and in vivo. In vitro means “outside the body”; these studies typically involve application of peroxide to extracted teeth, or pieces of enamel. In vivo means “inside the body”; these studies apply peroxide to vital teeth inside of a subject’s mouth. (Giniger, Tr. 218-220).

Response to Finding No. 946:

Respondent refers to its response to Proposed Finding No. 945.

947. Dr. Haywood acknowledges that in vivo studies are superior to in vitro studies because they more accurately capture the effects of peroxide inside the oral cavity. (Haywood, Tr. 2657). This is because in vivo studies take into account: (1) that saliva dilutes and buffers the tooth, thereby reducing the acidity within the mouth; (2) surface changes on the tooth from peroxide are reduced by saliva’s ability to remineralize the tooth; and (3) peroxidase, a chemical which breaks down hydrogen peroxide, occurs naturally within the oral cavity, further reducing the effect of peroxide on enamel. (Giniger, Tr. 213, 221, 453; CX0653 at 028-029; Haywood, Tr. 2656-2657).

Response to Finding No. 947:

Respondent has no specific comment.

948. In vitro studies have shown that any surface changes due to peroxide are smaller than normal variations in the enamel and are substantially smaller than the surface changes caused by orange juice and carbonated beverage challenges. (CX403 at 005; Giniger, Tr. 217-221; CX0653 at 028-029; CX0632 at 007-008).

Response to Finding No. 948:

Respondent refers to its response to Proposed Finding No. 945.

949. An article by Dr. M. Cadenaro and others titled, "Effect of Two In-Office Whitening Agents on the Enamel Surface in Vivo: A Morphological and Noncontact Profilometric Study," discusses the results of one of the few in vivo studies of bleaching and enamel, and one of the very few studies to use a profilometric instrument to assess the degree of change in enamel as a result of bleaching. The study found no clinical significant softening or etching of enamel as a result of application of even 38% hydrogen peroxide, and concluded that "this in vivo study supports the hypothesis that the use of in-office bleaching agents is a safe and reliable procedure, inducing no structural damage to the enamel surface, even after prolonged and repeated applications." (Haywood, Tr. 2657-2664).

Response to Finding No. 949:

Although this statement cites Dr. Haywood's deposition transcript for this proposition, it should be noted that the quotation was from the article and not from his testimony; he merely affirmed that he believed that the conclusion of this article was correctly read by Complaint Counsel. Dr. Haywood stated that he did not have any problem with this study, but that it presents a limited picture of the problem with teeth whitening products: "I don't have a concern that you can successfully and safely do in-office bleaching by a dentist if you have the right product and the right technique. That's fundamentally what these articles say. My concern is somebody who not being a dentist, misdiagnosing and then using a product that we don't know anything about because we don't know where it was made or anything about it." (Haywood, Tr. 2666-2667).

950. The value of the profilometric instrument used in the Cadenaro study is aptly described in Dr. Sulieman's article: "Bleaching has no effect on erosion and demineralization of enamel, but the methods of assessment have been debated as microhardness has often been the sole method of measurement. The argument is that measuring only the softened portion of the lesion is unable to quantify the bulk loss of tissue, which would require assessment methods such as profilometry." (Haywood, Tr. 2666).

Response to Finding No. 950:

Respondent refers to its response to Proposed Finding No. 949.

951. These studies confirm what Dr. Haywood himself wrote in 1991: "No published reports have demonstrated any change in hardness of enamel, nor have studies at the University of North Carolina shown any significant concerns . . . Studies which evaluate change in surface must take into account the remineralization potential in the mouth which may negate any potential change." (CX0402 at 005; Haywood, Tr. 2665).

Response to Finding No. 951:

Respondent refers to its response to Proposed Finding No. 949. Further, Dr. Haywood testified that "The issue is not the harm to the enamel," but that people who are not dentists may be misdiagnosing customers/patients and using products they do not know anything about. (Haywood, Tr. 2666-2667).

952. Dr. Haywood claims that non-dentist providers of teeth bleaching products and services and their customers have no way of knowing the pH or other compositional aspects of those products. However, manufacturers of teeth bleaching products are required to supply an MSDS for each product on request of any purchaser; in many instances, they are provided along with the product. The MSDS is specifically intended to disclose to interested persons product composition, product properties of potential significance, including pH, and other safety-related information. (Giniger, Tr. 218; CX0632 at 008).

Response to Finding No. 952:

It is not clear what basis there is in the record for the claim that non-dentist teeth whiteners are subject to any requirements at all. As Respondent noted in its response to Proposed Finding No. 931, Dr. Haywood also points out that another issue with non-dentist teeth bleaching products is that the ingredients of many of the products being put on the market is not known. Haywood, Tr. 2572). For instance, one of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product, stating only that it's percentage of carbamide peroxide is "proprietary" and not disclosing what other ingredients are in the product. (CX108 at 4).

953. Dr. Giniger testified that, based on his experience as a formulator and consultant for the formulation of teeth whitening products, the quality of ingredients used in teeth bleaching products by dentists and non-dentists are comparable. (Giniger, Tr. 218; CX0632 at 008-009).

Response to Finding No. 953:

Respondent refers to its response to Proposed Finding No. 933 and 938 discussing the complete lack of foundation for Dr. Giniger's testimony as to the safety or ingredients of every teeth whitening product on the market.

954. Dr. Giniger also testified that teeth bleaching products used by dentists and non-dentists are typically manufactured in FDA approved labs, often by the same manufacturers, using food-safe ingredients. (Giniger, Tr. 218; CX0632 at 009; Finding ¶¶ 933-987; CX0810 at A, B (non-dentist teeth whitening product); CX0806 at A, B, C, D (dentist teeth whitening product) are manufactured by the same company and contain the same ingredients).

Response to Finding No. 954:

Respondent refers to its response to Proposed Finding No. 933 and 938 discussing (1) the complete lack of foundation for Dr. Giniger's testimony as to the safety or ingredients of every teeth whitening product on the market and (2) the fact that there has been no evidence presented in this proceeding that all non-dentist teeth whiteners use FDA-approved teeth whitening products, nor was there any evidence presented that there is a state or federal regulatory entity that ensures that FDA-approved teeth whitening products are used by non-dentists selling the product to consumers.

955. Most importantly, however, is the evidence of experience; despite millions of non-dentist teeth bleachings over the last twenty years, Dr. Haywood was unable to cite any instance, other than a 1991 report of a single alleged incident, in which non-dentist teeth bleaching, or any other method of teeth bleaching, caused clinically significant adverse effects to the enamel of teeth. (Haywood, Tr. 2666-2668; Giniger, Tr. 218-219; CX0653 at 029; CX0632 at 001, 007-008).

Response to Finding No. 955:

This statement is misleading in a number of ways. For one, “millions of non-dentist teeth bleaching over the last twenty years” actually aggregates the statistics from the over-the-counter teeth whitening products with non-dentist teeth whitening offered at spas and kiosks. (Haywood, Tr. 2527 (“There’s really nothing about non-dentist-provided bleaching in the context of the way it’s used in these slides. Those years are of over-the-counter bleaching.”)). There is no data on non-dentist teeth whitening that would show harm. (Haywood, Tr. 2547-2548). But despite there being no statistical studies, there is still anecdotal evidence of this recent development. *See* Respondent’s Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531 (other consumer harm). Additionally, Complaint Counsel’s expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466). The statement that Dr. Haywood was unable to cite of any “clinically significant adverse effects” is thus misleading in the face of such evidence.

956. Indeed, if teeth bleaching caused harm to the enamel at all, the most likely source of such harm would be dentist provided chair-side bleaching, because the hydrogen peroxide concentrations used there are greatest, and generally require the greatest acidity (i.e., the lowest pH) to prevent premature reactivity of the peroxide. (Giniger, Tr. 172-173; CX0653 at 021; Haywood, Tr. 2652).

Response to Finding No. 956:

Respondent strongly objects to this statement because it cites testimony that Dr. Giniger **voluntarily retracted** on cross-examination. When asked about this earlier statement and informed that Dr. Haywood in his report or deposition testimony “did not refer to the difference between teeth whitening in dentist’s offices and chairside treatments,” Dr. Giniger retracted his earlier testimony “that side effects occur more frequently in

treatments by a dentist than a kiosk” to only indicate that there was a greater likelihood of “irritation” from sensitivity. (Giniger, Tr. 445-447). A full statement of his retraction is as follows:

I’m going to -- I can even redact my comment about Dr. Haywood, if that would please the court, and just say my knowledge of the art and science, and it should make logical sense that the higher concentration of a bleaching agent -- and that’s the part of the bleaching preparation that would cause sensitivity -- the higher the concentration, the greater likelihood there would be for irritation.

(Giniger, Tr. 446-447) (emphasis added).

Further, aside from the fact that there is no basis for this statement in the record, it misleadingly cites Dr. Haywood’s testimony for this assertion when his testimony actually indicated the opposite. After a discussion of the higher acidity of more concentrated teeth whitening solutions, Dr. Haywood admitted that dentists use more concentrated teeth whitening solutions but pointed out that they do so “[a]fter they’ve done isolation of the gingiva to protect it from the higher concentrations,” (Haywood, Tr. 2652), and further stated “That’s why I’m a fan or a supporter of carbamide peroxide, because it elevates the pH in the mouth so that you don’t have any enamel harm.”

(Haywood, Tr. 2653).

957. Teeth bleaching, whether performed by a dentist, a lay-provider, or the consumer using an OTC product at home, poses no risk of harm to the pulp of teeth. (Giniger, Tr. 355). Dr. Haywood conceded as much in a previous publication. (CX0627 at 002 (2009 interview with Dr. Haywood) (Q: “Can bleaching sensitivity cause damage in the long term?” A: “Although penetration of peroxide through the tooth to the pulp can produce sensitivity, the pulp remains healthy and the sensitivity is completely reversible when treatment is terminated. No long-term sequelae remain after the sensitivity has abated.”); CX0402 at 005 (article authored by Dr. Haywood noting studies on application of 35% hydrogen peroxide on teeth “has shown effects which are reversible over time, with no clinical consequence other than immediate but transient sensitivity”)).

Response to Finding No. 957:

Respondent has no specific response.

958. Further, as Dr. Haywood himself wrote in a 1991 article: “[t]he effects on the pulp were extensively evaluated in the previous generation of bleaching with 35% hydrogen peroxide, and a lower concentration of peroxide would not be expected to be as detrimental to the pulp. The effects on pulp have not been evaluated with the weaker peroxide solutions, but the research on 35% hydrogen peroxide has shown effects which are reversible over time, with no clinical consequence other than immediate but transient sensitivity.” (CX0402 at 005).

Response to Finding No. 958:

Respondent has no specific response..

959. It is unsurprising then, that despite millions of non-dentist teeth bleachings, Dr. Haywood was unable to cite any instance in which non-dentist teeth bleaching caused clinically significant adverse effects to the pulp of teeth. (Haywood, Tr. 2696).

Response to Finding No. 959:

As noted previously, the “millions” statistic is misleading because it lumps together statistical data from FDA-approved OTC teeth whitening products with new and unregulated non-dentist teeth whitening services for which there is not yet statistical data.

960. If teeth bleaching caused harm to the pulp at all, the most likely source of such harm would be dentist provided chair-side bleaching, because of the combination of highly concentrated hydrogen peroxide and, often, heat-producing lamps used there. The pulp and its enzymatic processes are not adversely affected unless pulpal temperature is raised by about four degrees. Unlike the lamps used by dentists, non-dentist providers of chairside bleaching use cool LED lamps, which do not emit material heat above the ambient temperature. (Giniger, Tr. 187-189; CX0632 at 011; Haywood 2699-2702).

Response to Finding No. 960:

Respondent strongly objects to this statement because it cites testimony that Dr. Giniger **voluntarily retracted** on cross-examination, as explained Respondent’s response to Proposed Finding No. 956.

Further, although Dr. Haywood did admit on cross that he was concerned about the potential of lights used by dentists, he stated “That’s a concern in all issues with lights,

[which is] why we need it regulated by the profession.” (Haywood, Tr. 2699). Otherwise no support is provided for this statement other than the opinion testimony of Dr. Giniger.

961. Dr. Hardesty never had an experience in connection with his use of the Zoom! System using what he believes is 35% hydrogen peroxide whitening gel in which the enamel of the patient’s tooth was eroded or softened to a degree of clinical significance. (Hardesty, Tr. 2810-2811).

Response to Finding No. 961:

Respondent has no specific response.

962. Dr. Hardesty has never experienced any of his patients having clinically significant erosion of enamel or softening of enamel as a consequence of sending them home with a nightguard vital bleaching kit using 15% carbamide peroxide. (Hardesty, Tr. 2811).

Response to Finding No. 962:

Respondent has no specific response.

3. Risks from Dentist and Non-dentist Teeth Whitening Are Similar and Low

963. Teeth bleaching, whether performed by a dentist, a lay-provider, or the consumer using an OTC product at home, poses no risk of systemic side effects. (Giniger, Tr. 249, 356; CX0653 at 032).

Response to Finding No. 963:

In response to this claim by Dr. Giniger, Dr. Haywood stated “The problem here is we don’t know what are in the ingredients that non-dentist folks are using,” and that the same thing is “true . . . with enamel damage.” (Haywood, Tr. 2546). He also said that “knowing the higher concentrations of peroxide, such as cited with the [Procter & Gamble] data, we don’t have any data on that. The higher the concentration, the greater concern for systemic problems, so that’s why I’m a fan of low concentrations.” (Haywood, Tr. 2547).

964. The American Dental Association agrees with this conclusion, noting that “[t]ooth whitening products have not been associated with reports for (systemic) toxicity or carcinogenicity.” (CX0227 at 005 (ADA Frequently Asked Questions about Teeth Whitening dated July 2010, Question #10)).

Response to Finding No. 964:

First, the text quoted in this document does not “agree” with the previous statement, Proposed Finding No. 963. Just because there are not yet any reports does not mean there is “no risk.” Further, the very next sentence in the ADA FAQ states “Importantly, proceeding with tooth whitening without consulting a dental professional may miss untreated dental diseases: patients with some conditions may not be suitable candidates for teeth whitening.” (CX0227 at 5).

965. There are two considerations in determining whether a material has the potential for systemic toxicity: (1) the amount of exposure; and (2) the chemical conditions of use. (Giniger, Tr. 240; CX0653 at 030).

Response to Finding No. 965:

Respondent has no specific response.

966. The amount of exposure to humans engaged in teeth bleaching is well below any known risk levels for humans. (Giniger, Tr. 240; CX0653 at 030).

Response to Finding No. 966:

Respondent refers to its response to Proposed Finding No. 963.

967. Hydrogen peroxide has been extensively studied for systemic toxicity in experimental animals. Numerous drinking water and gastric gavage studies (pumping peroxide directly into the stomach) using rats and mice as test subjects indicate that, although adverse effects are observed at repeated high exposures (100 mg/kg), no adverse effects occur at doses of less than 36 mg/kg. Very conservatively—that is to say, ignoring the very consequential differences between the methods of administration in these animal studies and the exposure of consumers to hydrogen peroxide having their teeth bleached—these studies would suggest that for a 70 kg person (one weighing 154 lbs), no adverse affects are plausible unless systemic exposure exceeds two grams (2,000 milligrams). (Giniger, Tr. 240; CX0653 at 031).

Response to Finding No. 967:

Respondent has no specific response to this study.

968. Crest Whitestrips has been extensively studied by P&G and independent sources because of its popularity with the public. A recent independent review of the safety profile of Crest Whitestrips concluded that the maximum daily exposure to hydrogen peroxide from use of its retail product is 42 mg, and from use of its professional product—often sold through dental offices—is 49 mg. (CX0400 at 014; Giniger, Tr. 241; CX0653 at 030).

Response to Finding No. 968:

Respondent has no specific response to this study.

969. The exposure potential from dentist or non-dentist provided teeth bleaching is substantially less than Crest Whitestrips. The most popular professional chair-side bleaching preparation would expose a person to only 11.25 mg of hydrogen peroxide (3 applications x 15 mg/application x 25% hydrogen peroxide concentration). The most popular non-dentist provided chair-side bleaching preparation would expose a person to only 4 mg of hydrogen peroxide per application (1 application x 50 mg/application x 8% hydrogen peroxide (of 30% carbamide peroxide)). (Giniger, Tr. 242-243; CX0653 at 030).

Response to Finding No. 969:

Respondent has no specific response to this study.

970. Further, the conditions of use of peroxide in teeth bleaching work against any material systemic exposure. Saliva in the oral cavity dilutes the peroxide in any teeth bleaching product, and the peroxidase enzymes in saliva and elsewhere in the oral cavity harmlessly break it down. For these reasons, there is no risk of significant systemic absorption of peroxide used in teeth bleaching through the tongue, gingiva, or other structures in the oral cavity. (Giniger, Tr. 247-248; CX0653 at 030).

Response to Finding No. 970:

Respondent refers to its response to Proposed Finding No. 963. Dr. Haywood also testified that this description of how carbamide peroxide is broken down by salivary enzymes is not scientifically established. (Haywood, Tr. 2637-2638).

971. Ingredients in teeth bleaching formulations other than peroxide are considered safe inactive ingredients for various OTC drug and cosmetic products. They all have been rigorously evaluated for toxicity, and as present in bleaching gels present no safety

concern, even if accidentally ingested. (CX0653 at 031; CX0806; Giniger, Tr. 203-204, 250; Valentine, Tr. 532).

Response to Finding No. 971:

Respondent refers to its response to Proposed Finding No. 963.

972. The European Commission's Scientific Committees of Consumer Products (SCCP), in a super-abundance of caution, has severely limited the sale of most peroxide-containing teeth bleaching products. (CX0653 at 032).

Response to Finding No. 972:

Respondent disputes this fact, as there is no foundation for Dr. Giniger to testify as to the motives of the European Commission SCCP, or to characterize such motives as stemming from a "super-abundance of caution." Dr. Haywood testified to the fact that the European Commission "made two significant rulings after reviewing all the safety data on bleaching since all this began, and their comments were that bleaching with low concentrations of peroxide is safe . . . but they couldn't support over-the-counter sales, that you needed to have a dental examination and get a prescription for whatever the product you're going to use and get it from a pharmacy, and even with it the maximum allowable concentration they would allow was 6 percent hydrogen peroxide or its equivalent, which would be 17 percent carbamide peroxide." (Haywood, Tr. 2509-2510).

973. However, the SCCP's actions were based on studies of extreme peroxide exposure in non-human subjects. For example, the SCCP cited extensively to a study in which rats or mice are administered hydrogen peroxide in drinking water taken at liberty or through continuous infusion into the stomach by gastric tube, for 20 to 100 weeks. In these studies, adverse effects are observed only at high exposures (100 mg/kg) of hydrogen peroxide. (Giniger, Tr. 251-252; CX0653 at 033).

Response to Finding No. 973:

Respondent refers to its previous response to Proposed Finding No. 972.

974. Following issuance of the SCCP report, others independently reviewed the literature, including studies not available to the SCCP, and found no cause for concern.

Munro *et al.* concluded that available data did not reflect any genotoxic or carcinogenic (cancer causing) risk for either intended or exaggerated use of hydrogen peroxide. (Giniger, Tr. 253-254; CX0653 at 035).

Response to Finding No. 974:

Respondent refers to its previous response to Proposed Finding No. 972.

975. Munro *et al.* separately conducted a dosimetric analysis of exposure to carbamide and hydrogen peroxide in humans engaged in bleaching. They found that the exposure level at the floor of the mouth after teeth bleaching was 100-1000 times less than the lowest level at which toxic effects would be plausible. The floor of the mouth was analyzed because it is the most vulnerable area of the mouth for peroxide absorption. (Giniger, Tr. 253-256; CX0653 at 035).

Response to Finding No. 975:

Respondent refers to its previous response to Proposed Finding No. 972.

976. The FDA was unmoved by the SCCP report and continues to conclude that hydrogen peroxide is safe when used in teeth bleaching. It also continues to consider hydrogen peroxide used in teeth bleaching as a cosmetic, not a drug. (Giniger, Tr. 256; CX0653 at 035-036).

Response to Finding No. 976:

Respondent notes first that there is no evidence in the record to support the assertion that the FDA was “unmoved” other than Dr. Giniger’s assertions, and disputes Dr. Giniger’s characterization of the “feelings” of a federal agency. Respondent presented testimony and other evidence that the ADA House of Delegates adopted a policy stating that the ADA’s official position was to request that the Food and Drug Administration reevaluate bleaching and classify it as a medical procedure to more appropriately reflect what it is. (Haywood, Tr. 2510, 2561; RX144 at 2). The ADA House of Delegates also adopted a policy to request that the Food and Drug Administration classify teeth whitening and bleaching agents so that they could not be available for use by non-dentists. (Haywood, Tr. 2561-2563; RX144 at 2).

977. The most powerful evidence is that of experience; despite millions of non-dentist teeth bleachings, Dr. Haywood was unable to cite any instance in which non-dentist teeth bleaching caused systemic toxic effects. (Giniger, Tr. 239-240).

Response to Finding No. 977:

Respondent refers to its response to Proposed Findings Nos. 955 and 963.

978. Indeed, if teeth bleaching caused systemic toxicity, the most likely source of such harm would be long-term (months- and years-long) dentist provided at-home teeth bleaching. Dr. Haywood recommends such long-term bleaching for remediation of some intrinsic stains, even in children; for use by people with orthodontic appliances, typically adolescents; and for the elderly for caries control for the balance of their lives. Yet, assuming that such bleaching involved use of a 10% carbamide peroxide gel in a single maxillary tray - a tray for the upper teeth - the patient's total peroxide exposure would be more than 200 mg and as much as 1000 mg. This peroxide exposure is far more than the exposure reasonably associated with non-dentist- provided teeth whitening, and comes close to the exposure levels said to be of concern by the EU. (CX0632 at 013-014).

Response to Finding No. 978:

Respondent refers to its response to Proposed Findings No. 963.

979. However, there are no reports of clinical harm even from peroxide exposure of this magnitude (200 mg to 1000 mg), and it is properly considered safe. The same, then, must be said of non-dentist-provided teeth bleaching products and services. (CX0632 at 013-014).

Response to Finding No. 979:

Respondent refers to its response to Proposed Findings No. 963.

980. Non-dentist teeth whitening services are safe for 90% of users. While the remaining 10% may experience some sensitivity, less than 1% would experience a serious side-effect, such as an allergic reaction. Such a reaction could also occur during an in-office dentist teeth whitening. (CX0578 at 050-051 (Parker, Dep. at 191-194).

Response to Finding No. 980:

Respondent disputes this proposed finding of fact as it mischaracterizes Dr. Parker's testimony. Dr. Parker testified that based on his personal experience, perhaps 90 percent of the population would not have any side effects and "some group of the population"

may have potentially some kind of adverse or unwanted outcome. (CX578 (Parker, Dep. at 191-192)). He testified that the adverse or unwanted outcome could include sensitivity. (CX587 (Parker, Dep. at 192)). He did not testify as to a 10 percent segment of the population. (CX587 (Parker, Dep. at 191-194)). His testimony was also that 1 – 2% of the population may experience and adverse or unwanted outcome requiring medical treatment. (CX587 (Parker, Dep. at 192-193)).

981. Board members testified that they are not aware of any evidence compiled by the Board or anyone else on the relative harm caused by dentists practicing teeth whitening versus non-dentists practicing teeth whitening. (CX0555 at 026 (Brown, Dep. at 96); CX0565 at 016 (Hardesty, Dep. at 54-55)). Indeed, many Board members testified that they do not even know whether the products they used contained hydrogen peroxide or carbamide peroxide, or what percentage of peroxide those products contained. Dr. Hardesty testified that he does not review the MSDS sheets for every product that he uses in his office that comes in contact with his patients, including products that go in the patient's mouth. (Hardesty, Tr. 2816; Owens, Tr. 1622-1623; CX0554 (Allen Dep. at 155); CX0556 (Burnham, Dep. at 146)).

Response to Finding No. 981:

Respondent disputes this proposed finding of fact as including mischaracterizations of the testimony by Complaint Counsel. Dr. Hardesty's testimony as cited by Complaint Counsel did not concern the relative harm caused by dentists versus non-dentists; he testified as to his awareness of any information on the percentage of dental bleachings that caused harm to patients and the percentage of nondental bleachings that resulted in harm to patients. (CX565 (Hardesty, Dep. at 54-55)). In response to the later inquiry, Dr. Hardesty also testified that he doubted if any information would even be kept for nondental. (CX565 (Hardesty, Dep. at 55)).

982. Dr. Feingold is not aware of any empirical literature establishing that the practice of teeth whitening by non-dentists leads to a higher incident of adverse outcomes than teeth whitening by dentists. (CX0560 at 065 (Feingold, Dep. at 252-253)).

Response to Finding No. 982:

Respondent disputes this finding of fact. Complaint Counsel has mischaracterized Dr. Feingold testimony. He testified that he was not aware of “any literature in either direction on that subject.” (CX560 (Feingold, Dep. at 252-253)).

983. Dr. Litaker stated that he has never seen a patient with any negative experience from any either dental or non-dental teeth whitening procedure. (CX0576 at 005 (Litaker, Dep. at 13)).

Response to Finding No. 983:

Respondent disputes this finding of fact as a mischaracterization of the record. Dr.

Litaker testified that he did not believe that he had seen such patients – not that he had never seen such patients. (CX576 (Litaker, Dep. at 13)).

984. Dr. Wester testified that “[t]he only side effects I have seen from mall cases would be the sensitivity issue, and I see those in my [teeth whitening] cases.” (Wester, Tr. 1314).

Response to Finding No. 984:

Respondent has no specific response.

985. Dr. Wester testified that transient sensitivity as a reaction to peroxide was common (CX0572 at 033 (Wester, Dep. at 123)). Dr. Wester testified that a dentist would not necessarily know if a patient would experience ordinary sensitivity to the teeth whitening process by just examining the teeth (CX0572 at 033 (Wester, Dep. at 124)).

Response to Finding No. 985:

Respondent disputes this proposed finding of fact. It is an incomplete statement of fact in that Dr. Wester’s testimony in between these two statements was omitted by Complaint Counsel. Dr. Wester testified that transient sentitivity was fairly common; however, certain conditions present in the mouth would “picked up at the front end [by a dentist] to – avoid real bad problems after bleaching.” (CX572 (Wester (Dep. at 123-124)).

986. Dr. Wester testified that he sent his teeth whitening patients home with their bleaching trays and the patients had to put the bleaching solution into the trays before

using them. (Wester, Tr. 1319-1320). Although he gives them instructions, he does not know whether his teeth whitening patients comply with his instructions. (Wester, Tr. 1320-1321, 1345).

Response to Finding No. 986:

Respondent has no specific response.

987. Dr. Hardesty is not generally concerned about the slight acidity of the take-home whitening solution he provides to his patients in connection with nightguard vital bleaching. (Hardesty, Tr. 2811-2812, 2855).

Response to Finding No. 987:

Respondent disputes this proposed finding of fact as a mischaracterization of Dr.

Hardesty's testimony. He testified that although he did not have a general concern, he monitored it "with every patient." (Hardesty, Tr. 2812).

988. Dr. Wester testified that if his patients inserted too much bleaching solution into their teeth whitening trays, they would "just get a mouthful of bubbles." (Wester, Tr. 1366).

Response to Finding No. 988:

Respondent has no specific response.

989. Dr. Morgan stated he believed that based on his education, training, background and experience, he did not believe that non-dentists should provide teeth whitening services in part because he did not know what effects might emerge twenty years from now. He stated that the unknown effects would be the same whether the teeth whitening was performed by a dentist or a non-dentist. (CX0569 at 038 (Morgan, Dep. at 143-145)).

Response to Finding No. 989:

Respondent disputes this potential finding of fact. Complaint Counsel has misrepresented the testimony of Dr. Morgan. In response to the question, "what are the contributing factors to your view that nondentists should not be allowed to provide any teeth-whitening services?", he first responded: "[b]ecause I do think it can be unsafe."

{CX569 (Morgan, Dep. at 144)). He then added the concern about deleterious effects that might emerge later on. (CX569 (Morgan, Dep. at 144)).

990. Any potential risks associated with peroxide in non-dentist teeth whitening products are the same potential risks associated with peroxide in OTC products, including bottles of peroxide available in drug stores. (Nelson, Tr. 808).

Response to Finding No. 990:

Respondent disputes this proposed finding of fact as a mischaracterization of the testimony offered in support of it. Mr. Nelson testified as to possible damage to eyes, skin, and inhalation, he did not testify as to any potential risks associated by peroxide. (Nelson, Tr. 808).

991. Dr. Hardesty does not review the MSDS sheets for every product that he uses in his office that comes in contact with his patients, including products that go in the patient's mouth. (Hardesty, Tr. 2816).

Response to Finding No. 991:

Respondent has no specific response.

4. Masking Pathology Is Not a Legitimate Concern Regarding Nondentist Teeth Whitening

992. Dr. Haywood claims that non-dentist provided teeth bleaching masks pathologies for which the only symptom is discoloration of the affected tooth, delaying diagnosis and treatment, and causing additional harm to consumers. (Haywood, Tr. 2950; CX0823 at 005, 020 (Haywood, Dep. at 10, 70, 72)).

Response to Finding No. 992:

The portion of the transcript cited here does not fully support this statement, as the discussion of Dr. Haywood's claims goes on for several pages and is not limited to page 2950. Otherwise Respondent does not disagree. Respondent also notes that one of Complaint Counsel's teeth whitening industry witnesses, Jim Valentine of WhiteSmile,

admitted under oath that “bleaching can potentially mask pathology.” (Valentine, Tr. 599).

993. Dr. Haywood acknowledges that there is no empirical literature demonstrating masked pathology; it has not been proven. (Haywood, Tr. 2734-2735).

Response to Finding No. 993:

Respondent has no specific comment.

994. There is not a single “case report” identifying any incident of masked pathology. (Giniger, Tr. 301; Haywood, Tr. 2734; CX0632 at 017-018).

Response to Finding No. 994:

Respondent has no specific comment.

995. Dr. Haywood is not aware of any instance of masked pathology. (Haywood, Tr. 2928-2932).

Response to Finding No. 995:

This statement blatantly mischaracterizes Dr. Haywood’s testimony. Dr. Haywood stated that he was not aware of any instance of a masked pathology “that actually was masked by non-dental teeth whitening.” (Haywood, Tr. 2928-2929).

996. Dr. Haywood claims that the absence of reports/awareness of instances of masked pathology is because the pathologies are, after all, masked. (Haywood, Tr. 2735). Dr. Haywood’s *apologia* for the absence of reports/awareness of instances of masked pathologies is inadequate.

Response to Finding No. 996:

The second sentence of this statement is not supported by any evidence in the record. Dr. Haywood was qualified by the Court as an “an expert in the fields of practical and clinical esthetic and restorative dentistry.” (Haywood, Tr. 2391). His concerns are echoed by the ADA, which states that a person who gets teeth whitening without a dental

exam is at risk. (Haywood, Tr. 2472; CX227 at 5 (“proceeding with tooth whitening without consulting a dental professional may miss untreated dental diseases”)).

997. There have been perhaps 100 million non-dentist provided teeth bleachings, including at-home use of OTC teeth bleaching products, over a period of about 20 years. (CX0585 at 009 (50 million uses of Crest Whitestrips alone); Giniger, Tr. 122-123, 214-215, 279, 356). Yet there is not a single reported instance of harm resulting from a masked pathology. (Haywood, Tr. 2734-2735).

Response to Finding No. 997:

Respondent refers to its response to Proposed Finding No. 955 detailing the dubious assumptions made in Dr. Giniger’s claim.

998. Given the public’s long and extensive experience with non-dentist provided teeth bleaching, it is not credible to claim that masked pathology is a noteworthy public health risk and, at the same time, assert that not a single person has connected up and reported a single instance of a late discovery of a pathology and an earlier non-dentist provided teeth bleaching. (CX0632 at 015-017; Giniger, Tr. 319-320).

Response to Finding No. 998:

As detailed in Proposed Finding No. 955, the only extensive experience the public has with non-dentist-provided teeth bleaching is with OTC products that are all FDA-approved. Dr. Haywood’s concerns lie with spa/kiosk-provided non-dentist teeth whitening, which uses stronger concentrations, is not subject to FDA regulation, and poses a number of health and safety risks to its consumers.

999. Nor is it credible to suggest that dentists observing masked pathology could not or would not submit such a case report for publication. Dr. Haywood admitted that such a case report would be important and well received. (Haywood, Tr. 2934).

Response to Finding No. 999:

As Dr. Haywood pointed out, it is not possible for a dentist to point out a masked pathology if it was truly masked. (Haywood, Tr. 2729-2730, 2735).

1000. Yet Dr. Haywood testified that he would continue to assert his masked pathology theory even if there had been 100,000,000 instances of non-dentist provided teeth

bleaching without an adverse report. Furthermore, Dr. Haywood would be unwilling to make a safety finding even if there were 500,000,000 instances of non-dentist provided teeth bleaching without an adverse report. (Haywood, Tr. 2950).

Response to Finding No. 1000:

Respondent has no specific comment.

1001. Dr. Haywood's claim that non-dentist provided teeth bleaching masks pathologies is unsupported by any reliable evidence. His theory never rises above a speculation. (Giniger, Tr. 301; Haywood, Tr. 2734-2735, 2934; CX0632 at 017-018; CX0823 at 035 (Haywood, Dep. at 130)).

Response to Finding No. 1001:

This is not a statement of fact, it is a statement of opinion by Dr. Giniger. Dr. Haywood's testimony is improperly cited here for this proposition.

1002. Dr. Haywood's theory provides no basis for prediction of size or magnitude of masked pathology subject to any known error rate. (Haywood, Tr. 2735; CX0823 at 035 (Haywood, Dep. at 130)).

Response to Finding No. 1002:

This is not a statement of fact, it appears to be the unsupported opinion of Complaint Counsel which is improperly included in Complaint Counsel's Proposed Findings of Fact. Respondent moves herein for the Court to strike and/or disregard this Proposed Finding.

1003. Also, Dr. Haywood acknowledges that his "masking pathology theory," even if it were false, could not be disproved. (Haywood, Tr. 2735; CX0823 at 035 (Haywood Dep. at 130)).

Response to Finding No. 1003:

This statement mischaracterizes the record and Dr. Haywood's testimony. He does not say "even if it were false", but does acknowledge the Catch22 nature of the masking pathology theory.

1004. Dr. Haywood's masked pathology theory lacks general acceptance in the field of dentistry. Neither Dr. Haywood nor any other witness pointed this court to a cadre of "believers." However, Dr. Giniger and numerous other expert commentators – among them Dr. Heymann, Dr. Haywood's co-developer of Nightguard Vital Bleaching – plainly reject Dr. Haywood's theory of masked pathology. (Haywood, Tr. 2735; Giniger, Tr. 356; CX0585 at 001-012).

Response to Finding No. 1004:

Respondent objects to Complaint Counsel's needlessly dramatic language in this statement. Further, there is no basis in the record for this statement, other than Dr. Giniger's testimony that he disagrees with Dr. Haywood's masking pathology theory. In fact, the only testimony cited by Complaint Counsel that addresses the acceptance of Dr. Haywood's masked pathology theory in the field of dentistry is his own testimony, in which he clearly testifies that his theory has gained general acceptance in the field. (Haywood, Tr. 2736) ("Q. So it is fair to say that your theory of masked pathology has not gained general acceptance in the field of dentistry among experts? A. Incorrect."). Complaint Counsel's cite to the entirety of CX585 is also inappropriate as it does not readily support with any clarity this statement.

1005. Several of the consultants engaged by the American Dental Association to review a draft of the ADA's 2009 position paper on teeth whitening supported the unrestricted sale of Crest Whitestrips. (Haywood, Tr. 2736; CX0585 at 001-012). If Dr. Haywood's theory were correct, unrestricted use of those products would be a significant cause of masked pathology. Their support of unrestricted sale of those products is a clear and strong rejection of Dr. Haywood's theory of masked pathology.

Response to Finding No. 1005:

Dr. Haywood's theory of masked pathology is not concerned with just Crest Whitestrips, it is with the many non-dentist provided teeth whitening products on the market, many of which little is known about their ingredients. *See* Respondent's Response to Proposed Finding No. 931.

1006. Even Board witnesses at trial rejected Dr. Haywood's masked pathology theory. Dr. Wester, for example, testified that he was unconcerned that non-dentist provided teeth bleaching would cause him to miss a diagnosis: "I would think that I would pick up the pathology. Being a trained dentist, I would pick up the pathology." (Wester, Tr. 1397). Among other reasons for his confidence: "I don't know that a bleaching would lighten it [a tooth darkened as a result of abscess] up enough that we couldn't tell that there was a shade difference . . ." (Wester, Tr. 1398).

Response to Finding No. 1006:

This statement blatantly mischaracterizes the record to distort Dr. Wester's testimony. He did not "reject" Dr. Haywood's masked pathology theory, he merely expressed confidence that he himself would be able to catch a diagnosis. Complaint Counsel completely ignores Dr. Wester's follow-up statement, where he states his opinion that masking the pathology of the tooth **would** be an issue with the consumer/patient themselves not being able to recognize something wrong with their tooth. (Wester, Tr. 1398 ("My concern with bleaching during, say, with an abscessed tooth or with some pathology going on would be from an individual that did not recognize the pathology going on prior to bleaching.")).

1007. Dr. Haywood has claimed that acceptance of the masked pathology theory underlay the European Union's restrictions on non-dentist provided teeth bleaching, but that claim too is wholly without support. (Haywood, Tr. 2738-2742 (unable to identify any specific language in SCCP's March 2005 opinion indicating concern that non-dentist provided teeth bleaching might mask pathologies)).

Response to Finding No. 1007:

This statement blatantly mischaracterizes Dr. Haywood's testimony regarding the SCCP's March 2005 opinion, and there is no basis in the record for the assertion that his claim is "wholly without support." This follows a pattern of deception that is prevalent throughout these Proposed Findings of Fact – Complaint Counsel asked Dr. Haywood a specific question that it knew he could not answer in the affirmative, and then goes on in

its Proposed Finding to make a more general statement that is misleading and overbroad. Here, Complaint Counsel demanded that Dr. Haywood point to specific language that “the SCCP was concerned that non-dentist-provided bleaching of single discolored teeth would mask pathology” on just a handful of pages in a 53-page report. Complaint Counsel’s assertion in this statement is patently not valid, however, when the entirety of Dr. Haywood’s testimony is taken into account. Dr. Haywood actually stated that his impression from reading the entire document before was that it supports his theory, and that even when prompted to only review a handful of pages he found support there for his theory: (1) “This appears to be a general statement about their concerns about why you should have a dental exam and the impacts on the pulp and the different things that it does, but it doesn’t make that statement. That’s my summary of what I believe this 53-page document represents”; and also (2) “I think that’s implied in the statement that you have to have a consultation and approval of the consumer’s dentist as we’ve explained what we do in the dental exam to determine the cause of discoloration and to avoid masking pathology. That’s my assessment of this entire document.” (Haywood, Tr. 2740-2741).

1008. Dr. Giniger provided a detailed explanation of why masked pathology is not a risk or consequence. (Giniger, Tr. 299-301, 319, 435-437; CX0632 at 017).

Response to Finding No. 1008:

However, Dr. Giniger also admitted that having a dental examination prior to undergoing non-dentist bleaching could resolve the issue cited by Dr. Haywood of bleaching masking a tooth’s pathology. (Giniger, Tr. 437-440).

1009. Indeed, Dr. Giniger concluded that there may never have been an instance in which nondentist provided teeth bleaching masked pathology, delaying diagnosis and treatment and thereby harming a consumer. (Giniger, Tr. 302, 319-320).

Response to Finding No. 1009:

This is not a fact but mere speculation by Dr. Giniger.

1010. Dr. Haywood agrees with Dr. Giniger's explanation in several important respects. In particular, Dr. Haywood agrees that pathology cannot be masked unless: non-dentist provided teeth bleaching entirely lightens severe discoloration resulting from a trauma or resulting pathology, (Haywood, Tr. 2954; CX0823 at 021 (Haywood, Dep. at 20-24); the consumer has not consulted a dentist while his tooth is discolored, and when he does finally consult a dentist he has none of the many symptoms that would be typical of trauma or resulting pathology, (Haywood, Tr. 2969-2970); and when he does finally consult a dentist, neither his oral history, the condition of his teeth and gums, nor any other circumstance suggest the taking of an x-ray of the affected tooth, which would reveal any pathology requiring treatment. (Haywood, Tr. 2955-2957, 2986).

Response to Finding No. 1010:

The second sentence misstates Dr. Haywood's testimony. He did not say that the discoloration had to be "severe", he just said that if the discoloration is bleached incompletely and there is still a mismatch with the other teeth, then the discoloration is clinically observable. (Haywood, Tr. 2954). Dr. Haywood also did not entirely agree with this statement as Complaint Counsel claims. Elsewhere, he pointed out that diagnosing a tooth could be problematic if a patient has several teeth that are of varying colors. (Haywood, Tr. 2955).

1011. It is extremely unlikely that any person would satisfy each and every condition necessary for the masking of pathology, and all the more unlikely given an appreciation of the additional conditions and explanation provided by Dr. Giniger. (Giniger, Tr. 319).

Response to Finding No. 1011:

This is not a fact, it is the opinion statement of Dr. Giniger and is unsupported by any evidence. Dr. Haywood rebutted this testimony with his description of a cheerleader who fell and injured her teeth. Her teeth darkened over time, but the two crowns that she received after the fall did not. Dr. Haywood has found that such circumstances are more

common than not, but a patient often does not make the connection other than perceiving that they have a dark tooth. (Haywood, Tr. 2467, 2533).

Dr. Giniger's credibility in this regard is also tainted by his clear bias as a member of the teeth whitening industry and his dubious business practices. *See* Respondent's Proposed Findings of Fact Nos. 341-362.

Regardless of Dr. Giniger's biased opinion regarding the likelihood of instances where teeth whitening could mask pathology, Dr. Haywood testified to his conclusion that "bleaching has some risk to the public safety and needs a proper dental exam prior to initiation due to the unknowns of what bleaching does in terms of masking pathology," (Haywood, Tr. 2398), and his concerns are echoed by the American Dental Association. (Haywood, Tr. 2472; CX0227 at 5 (ADA: "Importantly, proceeding with tooth whitening without consulting a dental professional may miss untreated dental diseases: patients with some conditions may not be suitable candidates for teeth whitening.")). Even Dr. Giniger himself acknowledged the possibility when he admitted that having a dental examination prior to undergoing non-dentist bleaching could resolve the issue cited by Dr. Haywood of bleaching masking a tooth's pathology. (Giniger, Tr. 437-440).

1012. The only pathologies that could, even in theory, be masked by non-dentist provided teeth bleaching are abscess of the tooth, internal resorption, and calcific metamorphosis. (*Compare* Haywood, Tr. 2963 (listing pathologies which are candidates for masked pathology) *with* Haywood, Tr. 2958-2959 (caries could not be masked) *and* RX0077 at 007 (noting that external resorption can be identified with physical examination; therefore cannot be masked) *and* Haywood, Tr. 2972-2974 (to be a candidate for masking, an oral cyst or tumor would have to kill the nerve of the tooth causing discoloration, an event Dr. Haywood has not seen in 35 years of practice)).

Response to Finding No. 1012:

This statement blatantly misrepresents Dr. Haywood's testimony. His testimony was not that abscess of the tooth, internal resorption, and calcific metamorphosis are the **only**

pathologies that could in theory be masked by non-dentist provided teeth whitening, he also included tumors and cysts as well. (Haywood, Tr. 2963 (“Q: Now, the diseases that you say are of concern to you in this connection are abscess, internal and external resorption, and calcific metamorphosis; correct? A. And tumors and cysts I believe was on that list.”). Complaint Counsel attempts to rebut his testimony regarding tumors and cysts with his testimony that he “has not seen” this occur in his practice, but this does not mean it is theoretically impossible as Complaint Counsel’s statement is worded.

Further, Complaint Counsel misleadingly provides comparisons to suggest that Dr. Haywood contradicted his own testimony by setting forth statements of pathologies that could be masked with what would appear (based on the summary here) to be contradictory statements made by Dr. Haywood. Complaint Counsel clearly misrepresents his testimony with this technique, displaying either (1) a complete lack of understanding of his masked pathology theory or (2) a knowing misrepresentation of the record. As is evident from reviewing the testimony cited here, Dr. Haywood’s theory of masking pathology takes on more than one dimension: it can mask the pathology of a tooth to either the dentist or to the consumer. (Haywood, Tr. 2958 (Complaint Counsel reading to Dr. Haywood his deposition testimony: “it may or may not match, so it may be slightly darker, but it may not be enough now to drive the consumer or whatever to go have it evaluated because it looks better than it did. So it -- it kind of masks it partially but doesn’t totally eliminate it, but it may mask it from the consumer’s mind or the non-kiosk operator’s mind.”).

1013. Of these, abscess is the most common. However, an abscess incidental to caries could not, even in theory, be masked by non-dentist provided teeth bleaching because caries is readily detectable through routine dental examination irrespective of the coloration of the affected tooth. Caries is not a candidate for a masked pathology because

it leaves a hole that is readily detectable through a physical examination. (Giniger, Tr. 309; Haywood, Tr. 2958-2959; CX823 at 029 (Haywood, Dep. at 107-108) (“Caries would not be masked from the dentist”).

Response to Finding No. 1013:

This statement also blatantly misrepresents Dr. Haywood’s testimony. Respondent refers to its response to Proposed Finding No. 1012.

1014. Internal resorption is not a common pathology. (Haywood, Tr. 2469). Indeed, Dr. Giniger testified that resorption (internal or external), only occurs in two or three percent of people who experience trauma. (Giniger, Tr. 295). Even if this pathology were present, it would ordinarily be detected through an x-ray (as opposed to a dental examination). (Giniger, Tr. 291, 300 (it is “highly unlikely” that a severely discolored tooth is the only symptom of a resorption)). It is therefore highly unlikely that nondentist teeth bleaching would mask an incidence of internal resorption.

Response to Finding No. 1014:

This statement also demonstrates a misunderstanding of Dr. Haywood’s masked pathology theory or an attempt to mischaracterize it through its inclusion with the previous statements. Respondent refers to its response to Proposed Finding No. 1012. Further, Dr. Haywood testified that however common resorption is in the population, it exists and “Because trauma is so common with basketball and soccer and bicycles and skating accidents and stuff, it’s just something you have to evaluate for.” (Haywood, Tr. 2470). He also emphasized the importance of catching internal resorption early through the diagnosis of discoloration: “the first indication typically is the discoloration of the tooth. And . . . if you don’t catch it early, then you wind up losing the tooth because your only treatment is to excise all that material and hope it won’t come back, very similar to cancer surgery.” (Haywood, Tr. 2469).

1015. Dr. Haywood claims that oral cysts and tumors, and external resorption could be masked by non-dentist provided teeth bleaching, (Haywood, Tr. 2963), but this is contrary to the greater weight of evidence.

Response to Finding No. 1015:

This statement also blatantly misrepresents Dr. Haywood's testimony. Respondent refers to its response to Proposed Finding No. 1012. There is no basis in the record for the statement that this is "contrary to the greater weight of evidence", and Complaint Counsel provides no support for this statement.

1016. Dr. Haywood previously had acknowledged that external resorption "may be found clinically when carefully exploring at or beneath the gum tissue . . ." (RX00077 at 007). Accordingly, it cannot be masked by teeth bleaching at all.

Response to Finding No. 1016:

This statement also blatantly misrepresents Dr. Haywood's testimony. Respondent refers to its response to Proposed Finding No. 1012. There is no basis in the record for the statement that this external resorption "cannot be masked by teeth bleaching at all", and Complaint Counsel provides no support for this statement.

1017. Oral cysts and tumors do not present with discoloration. (Giniger, Tr. 300; Haywood Tr. 2974-2976 (discoloration is not listed as a symptom of oral cysts and tumors on the University of California, San Francisco Medical Center Website)).

Response to Finding No. 1017:

This statement blatantly and egregiously mischaracterizes Dr. Haywood's testimony. He did not testify that "oral cysts and tumors do not present with discoloration", he merely stated that he himself has not observed such symptoms. He did, however, state that he had seen a pathologist make a presentation regarding a tumor causing discoloration of the tooth:

Q. Have you ever encountered such a tumor that affects the whole side and therefore somehow causes discoloration of the tooth?

A. I recall seeing presentations by an oral pathologist on that, but personally in my clinical practice I don't see that, haven't seen that."

(Haywood, Tr. 2974) (emphasis added).

Further, Dr. Haywood pointed out that the lone exhibit that Complaint Counsel presented to attempt to impeach this testimony, which was merely one website from the University of California, San Francisco Medical Center, did not specify whether the symptoms that it listed concerned actual teeth or not, or for that matter even soft tissue or hard tissue:

Q. Dr. Haywood, CX 832 purports to include a description of the signs and symptoms of jaw tumors and cysts; correct?

A. It appears to, yes.

Q. And if you look at the symptoms listed on this page, is there anywhere described discoloration of tooth?

A. I don't see anything listed here.

Q. All right. Now --

A. I didn't read this bottom part. I'm sorry.

Q. Please read the entirety of it if you'd like.

A. These are talking about tumors and cysts of soft tissue. I don't believe they're dealing with bone.

Q. Is the jaw a bone?

A. I'm sorry.

Q. Is the jaw a bone?

A. Yes -- well, the jaw is this whole anatomic complex. It includes bone and tissue and teeth.

Q. And this relates to jaw tumors; correct?

A. I don't know whether they're talking about soft tissue or hard tissue here.

(Haywood, Tr. 2975-2976).

1018. Dr. Haywood claimed that if a cyst or tumor impinged on the nerve of the tooth and rendered the tooth non-vital, discoloration could result. (Haywood, Tr. 2972). However, Dr. Haywood has had no idea as to the frequency of such an event. (Haywood, Tr. 2972). Dr. Haywood conceded that in his 35 years of practice, much of it involving populations of people with discolored teeth, he has never seen a cyst or tumor that caused discoloration of a tooth. (Haywood, Tr. 2974; CX0823 at 042 (Haywood, Dep. at 158-159)). If cysts or tumors have any capacity to cause discoloration of teeth, that capacity is so negligible as to be beneath consideration here.

Response to Finding No. 1018:

Respondent notes that the last sentence of this statement is not a fact, but unsupported argument that is improperly included in Proposed Findings of Fact. Respondent moves herein that this final sentence be stricken and/or disregarded, as it is neither evidence nor fact.

1019. As Dr. Giniger explained, a remarkable chain of occurrences would have to occur for non-dentist provided teeth bleaching to mask a pathology. (Giniger Tr, 306-319).

Response to Finding No. 1019:

This statement is essentially a paraphrased restatement of Proposed Finding No. 1011.

Respondent refers to its response to Proposed Finding No. 1011.

1020. All of the pathologies relevant to Dr. Haywood's masked pathology theory are incident to dental trauma. (Giniger, Tr. 306; CX0823 at 043 (Haywood, Dep. at 163) ("[T]rauma is always the big overriding thing for almost every major problem, whether it's trauma from the patient or trauma from external.")). Accordingly, for Dr. Haywood's masked pathology theory to apply, even in theory, a consumer would have to suffer trauma.

Response to Finding No. 1020:

This statement blatantly mischaracterizes Dr. Haywood's testimony by only quoting part of his answer to a question at a deposition, but fails to provide the complete answer that

clearly does not support the statement for which it is cited. His entire answer, indicating that trauma is not the only issue to be analyzed by a dentist in connection with his masked pathology theory, is presented below,

Again, trauma is always the big overriding thing for almost every major problem, whether its trauma from the patient or trauma from external. That – **there's all these other little things**, and that's why we have to teach dental students it is not everything is a nail and I've got a hammer and that's all they've got to do is hit the nail. It's like, okay, there is -- **most of the things cause this, but you've also got to rule out this and this and this and this**. They're not as likely, but it could be -- this could be the one that may be part of a differential diagnosis. The question is did you find something, yes or no.

(CX0823 (Haywood, Dep. at 163-164) (emphasis added). Elsewhere in his deposition, Dr. Haywood provides examples of other non-trauma pathologies: (1) "It could be that you bleached teeth that were -- had fillings or crowns that originally matched the teeth and now that the teeth get white -- no fillings or crowns change color with bleaching, so then you have kind of an esthetic outcome, kind of like a pinto pony"; (2) "You could have lingual -- how do I say this? Fillings on the tongue side of the teeth that are silver that when the teeth whiten they get more transparent and make the tooth actually look dark -- darker than it was beforehand due to the transparency and the show through of the filling on the inside"; and (3) "Some of the older amalgams turn green around the edges of the teeth, and so if the patient has had something that was done long ago when they were a child, they may actually get some greening of the tooth or lack of response to a tooth that's had amalgam in it." (CX0823 (Haywood, Dep. at 71-71).

1021. Moreover, the trauma would have to be relatively severe, causing rupture of blood vessels within the tooth and therefore internal staining and devitalizing (or beginning the process of devitalizing) of the affected tooth (Giniger, Tr. 309-310).

Response to Finding No. 1021:

Respondent refers to its response to Proposed Finding No. 1020 for examples of other non-trauma pathologies related to Dr. Haywood's masked pathology theory. This statement also blatantly misrepresents Dr. Giniger's testimony, who actually testified that trauma would have to be "moderate to severe" to cause discoloration. (Giniger, Tr. 306 ("that dental trauma should -- would have been -- should have had to be either moderate to severe, not just a minor, you know, hit to the teeth like that, would have to be moderate to severe dental trauma").

Further, Dr. Haywood testified to more than one theory of trauma masking pathology, so it is not clear from this statement which pathology Dr. Giniger's testimony refers to. Dr. Haywood did not testify that trauma to a tooth would have to be "severe" in order for discoloration to occur, though he did testify that tooth traumas need to be evaluated because "trauma is so common with [sports activities]." (Haywood, Tr. 2470)

1022. A relatively severe trauma can result from accident, malocclusion, or parafunction. (Haywood, Tr. 2965-2967; CX0823 at 039-040 (Haywood, Dep. at 150-157)).

Response to Finding No. 1022:

Respondent has no specific response.

1023. In addition, for Dr. Haywood's masked pathology theory to apply, even in theory, the relatively severe trauma would have to neither cause the consumer immediately to seek medical or dental care nor produce signs or symptoms of trauma that would be apparent during a subsequent routine dental examination, either of which would alert the dentist to the possibility of pathology. (Giniger, Tr. 308-310).

Response to Finding No. 1023:

Respondent notes its objection to Complaint Counsel's continuing assumption that trauma must be severe, since even its own expert testified that it only needed to be

“moderate” to cause discoloration, as discussed in Respondent’s response to Proposed Finding No. 1021.

1024. In a substantial super-majority of instances of relatively severe trauma resulting from accident, the consumer immediately will seek medical or dental care, (Giniger, Tr. 308-309), and/or have signs or symptoms that would be apparent during a subsequent routine dental examination, such as crazing, chipping, or loosening of the affected tooth. (Giniger Tr. 306-308). Dr. Giniger testified that a recent peer-reviewed study published in the Journal of Dental Traumatology reported that well over 90% of the subject accidental dental trauma victims had such readily notable signs or symptoms of the trauma. (Giniger, Tr. 307-308). In such instances, the pathologies of concern will not be masked.

Response to Finding No. 1024:

This may well be true, but as established in the above responses, Complaint Counsel’s own expert witness testified that instances of less than severe trauma can also alter the discoloration of a tooth, and Respondent’s expert witness, Dr. Haywood, testified that pathologies other than trauma can result in discoloration of a tooth.

1025. Similarly, trauma resulting from malocclusion or parafunction produces readily notable signs and symptoms, such as unusual wear of the teeth. Checking for those signs and symptoms is part of routine dental examination. (CX0823 at 040 (Haywood Dep. at 151-153) (examination will reveal “unusual wear on their teeth - kind of like somebody taking an automobile to the - to the car shop and they see one tire that’s wearing on the side of and say that’s not the way tires are supposed to wear”). If such signs or symptoms are detected, an X-ray would be taken, which would reveal any pathology of concern. (CX0823 at 040-041 (Haywood Dep. at 153-154)).

Response to Finding No. 1025:

Respondent does not disagree, and notes that this underscores the importance of patients having a dental exam prior to undergoing teeth whitening, as dentists will be able to catch pathologies that have been masked to lay people’s discernment.

1026. The likelihood that a consumer would suffer a trauma causing the tooth to devitalize and discolor without also causing the consumer immediately to seek medical or dental care and/or produce signs or symptoms that would be apparent during a subsequent routine dental examination is small. (Giniger, Tr. 307-310).

Response to Finding No. 1026:

This statement is based on the assumption that the trauma is severe, which is not what Dr. Giniger or Dr. Haywood testified is a requirement for tooth discoloration. That assumption is not reflected in the record and the statement is therefore invalid.

1027. In addition, for Dr. Haywood's masked pathology theory to apply, even in theory, the consumer then would have to have his/her teeth bleached by a non-dentist provider, and that non-dentist provided teeth bleaching would have to lighten the affected tooth so that a dentist no longer would be able to discern any difference between that tooth and the others. (Giniger, Tr. 311-312; Haywood, Tr. 2978.) If a remaining difference in coloration were notable by a dentist, any pathology would not be masked. (CX0823 at 021 (Haywood, Dep. at 77)).

Response to Finding No. 1027:

This statement is based on the assumption from the previous Proposed Finding that trauma is required to cause discoloration, which is not what Dr. Haywood testified is a requirement for tooth discoloration. That assumption is not reflected in the record and the statement is therefore invalid.

1028. Based on his experience with thousands of subjects in tests of the effectiveness of non-dentist provided teeth bleaching products, Dr. Giniger concluded that neither non-dentist provided chair-side bleaching nor multi-week use of a non-dentist provided at-home bleaching system could not so thoroughly lighten the affected tooth—especially given the particular resistance to lightening of internal stains such as trauma-related discolorations—that a dentist would not notice its discoloration. (Giniger, Tr. 312-315).

Response to Finding No. 1028:

Dr. Haywood's testimony disagrees with this finding. He concluded that "bleaching has some risk to the public safety and needs a proper dental exam prior to initiation due to the unknowns of what bleaching does in terms of masking pathology." (Haywood, Tr. 2398, 2449, 2472, 2547)

1029. Dr. Haywood himself repeatedly claimed that non-dentist provided teeth bleaching was of limited or no meaningful effect in lightening discolored teeth. This

claim of ineffectiveness is a direct contradiction to his claim that non-dentist provided teeth bleaching masks pathology. (Haywood, Tr. 2978-2979).

Response to Finding No. 1029:

This statement mischaracterizes the cited portion of Dr. Haywood's testimony in a way that distorts its meaning. When asked whether he thought that non-dental teeth whitening is less effective than dentist-teeth whitening, he said "It can be", and that "It all depends on what product and how long they use it as far as what the outcome is going to be.

That's true with the Crest Whitestrips. That's true with non-dentists. That's true with dentists." (Haywood, Tr. 2978). He did not say unequivocally that it was of "limited or no meaningful effect in lightening discolored teeth" as the above statement claims.

Complaint Counsel here attempts to distort Dr. Haywood's testimony so as to enable it to point to a logical fallacy in Dr. Haywood's theory that would be quite obvious if not for the distortion.

1030. With respect to chair-side bleaching, Dr. Haywood testified that consumers may "be excited when they leave a non-dental center due to the dehydration effect of the procedure, but in a matter of days they will have lost the color shift and the financial investment is lost as well." (RX0077 at 016 (Haywood Expert Report); Haywood, Tr. 2978-2979; RX0077 at 004-005, 015 (noting that even dentists providing chair-side bleaching, who use more potent bleaching products than non-dentist providers, require multiple multi-application appointments with customers to resolve all but the least discolorations)).

Response to Finding No. 1030:

Respondent does not dispute this testimony by Dr. Haywood in his report. However, Respondent notes that the context in which the statement is made does not indicate it means anything like "all non-dentist teeth whitening is less effective than dentist teeth whitening", as Complaint Counsel clearly implies. Rather, this statement by Dr.

Haywood is entirely consistent with his testimony that non-dentist teeth whitening "can

be” less effective and that “It all depends on what product and how long they use it as far as what the outcome is going to be. That’s true with the Crest Whitestrips. That’s true with non-dentists. That’s true with dentists.” (Haywood, Tr. 2978).

1031. Also, with respect to non-dentist provided at-home teeth bleaching products and systems, Dr. Haywood testified that even dentists providing at-home bleaching systems are unlikely to be able to lighten the single dark tooth characteristic of trauma or pathology so that it matches the surrounding teeth without using specially designed trays and bleaching regimens of more than six weeks. (Haywood, Tr. 2983-2985).

Response to Finding No. 1031:

Respondent disputes the relevance of this fact given that the record clearly shows that the Board has not sought to regulate OTC or take-home teeth whitening products. Also, this statement blatantly misstates the above-cited portion of Dr. Haywood’s testimony. In fact, the cited testimony does not appear to support this statement at all. Dr. Haywood did not make any statement about “even dentists providing at-home bleaching systems” nor did he comment on the likelihood of any bleaching systems to lighten any tooth, whether single or multiple. (See Haywood, Tr. 2983-2985). Thus the above statement has no support in the cited portion of the record whatsoever.

1032. The likelihood that non-dentist provided teeth bleaching would lighten the affected tooth so that a dentist no longer would be able to discern any difference between that tooth and the others is small, perhaps nonexistent. (Giniger, Tr. 312-314).

Response to Finding No. 1032:

The cited portion of Dr. Giniger’s testimony does not address “likelihood” at all. Dr. Giniger merely testifies that it would be “difficult” to sufficiently bleach a “stain that results from trauma and rupture of blood vessels . . . so completely that a dentist would not note the presence of stain.” (Giniger, Tr. 313). Respondent also finds the wording of

this statement by Dr. Giniger conflicts with his other testimony that teeth

bleaching/whitening is not stain removal.

1033. An additional condition for Dr. Haywood's masked pathology to apply, even in theory, is that the customer would have to overcome his previous reluctance to see a dentist, and finally see one relatively soon after his non-dentist provided teeth bleaching, before color rebound became noticeable – usually within three to six months of bleaching. (Giniger, Tr. 315, 382, 388-389).

Response to Finding No. 1033:

This statement contains the assumption that a patient/customer has a “reluctance” to see a dentist that they must “overcome.”

1034. At the time the consumer did see a dentist, he would have to present with no signs or symptoms of the trauma or pathology – no redness, swelling, purulence, fistula, or pain. Pathology would not be masked in the presence of any such sign or symptom. (Giniger, Tr. 315-316; Haywood, Tr. 2969-2970).

Response to Finding No. 1034:

Respondent has no specific comment.

1035. An abscess ordinarily manifests with a variety of notable symptoms, which may include pain, swelling, discoloration of the gum tissue, discharge of pus between the tooth and gum, foul taste (from the discharge of pus), and the development of a fistula (a hole through the bone and gum tissue). (Giniger, Tr. 281-283). Even if an abscess initially manifested without any signs or symptoms of trauma or abscess other than discoloration of the affected tooth, some of these symptoms would emerge as the pathology progressed and before the occurrence of any incremental harm to the consumer. (Giniger, Tr. 316; CX0823 at 029 (Haywood, Dep. at 108-109) (defining an abscess and explaining that it “creates byproducts of the breakdown of tissue much like a rotting body does . . . ”)).

Response to Finding No. 1035:

Dr. Giniger's testimony that other symptoms of an abscess “would emerge as the pathology progressed and before the occurrence of any incremental harm to the consumer” has been refuted by the testimony of two of Respondent's witnesses. First, Dr. Hardesty testified that, in his experience as a dentist, teeth bleaching could mask the

pathology of an abscess. (Hardesty, Tr. 1306). Further, Dr. Haywood provided an example of a patient that is living proof that Dr. Giniger's statement is incorrect. The patient actually had an abscess that resulted in harm to the patient and of which the only outward symptom was a darkened tooth. While reviewing the slide showing the patients symptoms, Dr. Haywood commented as follows:

This is another example of a patient who was interested in bleaching their teeth because they have two crowns on those two front teeth and the other teeth are slightly darker, significantly darker. And my suggestion to her was that she needed to make an appointment so I can take an x-ray of those teeth and see was there any pathology that needed to be addressed that might be causing those teeth to be dark. So on the next slide we took the x-rays.

[. . .]

And what we found is that the dark tooth to your right of those two front teeth had a big abscess on it. **And she had never had any pain, never had any swelling, never had any mobility, never had any other symptom other than that tooth gradually got dark over a large number of years.** So I sent her to a specialist who does root canals, and it took him almost a year to resolve this issue. **Because that abscess had been there so long, it was damaging the root of the tooth,** so he had to put a special ingredient in there to get that resolved, and then he did one root canal and found out that the other tooth was also abscessed. So two root canals later and a year she's ready to bleach her teeth, but if I had bleached her teeth without an exam and an x-ray, I can make a tooth that's abscessed get lighter, but it's still abscessed, and so that abscess continues to progress with the chance of loss of the tooth.

(Haywood, Tr. 2466-2467; RX141 at 53-54).

1036. Yet another condition for Dr. Haywood's masked pathology theory to be applicable, even in theory, is that the dentist is and remains ignorant of the fact that the consumer previously had a dental trauma, which had been marked by discoloration of the affected tooth. If, of his or her own initiative or in response to questions from the dentist, a consumer indicates that he or she previously had a single darkened or traumatized tooth, pathology would not be masked. (Giniger, Tr. 316-317).

Response to Finding No. 1036:

Respondent refers to its response to Proposed Finding No. 1035.

1037. The taking of an oral history is part of routine dental examination. (Haywood, Tr. 2998; (ADA/FDA guidelines stress the importance of a thorough oral history); Giniger, Tr. 317). Especially given the prevalence of non-dentist provided teeth bleaching, including use of at-home OTC teeth bleaching products, dentists are well-served to ask each patient whether he or she had suffered any prior dental trauma, whether his or her teeth had been bleached at any time subsequent to his or her last dental visit, and whether, prior to such bleaching, any tooth was darker than the surrounding teeth. (Giniger, Tr. 317; Haywood, Tr. 2999-3001; CX0823 at 051 (Haywood, Dep. at 194-195) (it is “good standard practice for a dentist to ask whether you’ve had your teeth bleached since [your] last visit”); Hardesty, Tr. 2868 (Dr. Hardesty asks new patients whether they have had teeth bleaching). The simple expedient of asking the right questions even further reduces the risk of masked pathology. (Haywood, Tr. 3004) (patient history of lightening of single discolored tooth helps dentist determine what tests to undertake and eventual diagnosis.).

Response to Finding No. 1037:

But as Dr. Haywood testified, there are limits to what a dentist can learn from taking an oral history. Sometimes patients that do not recall previous dental work that has been done on them, including one of his patients, a “lady who went to the over-the-counter and did self-administered bleaching not realizing that she had multiple fillings between her front teeth that had been there for a while but matched previously. And so patients just don’t seem to remember or can’t identify where the restorations are, or the restorations are done so well that they’re hidden, which is the idea behind doing them in the first place, so . . . part of the examination is to identify to them all the things that would have to be done to wind up with a better smile.” (Haywood, Tr. 2484-2485).

1038. In Dr. Haywood’s theory of masked pathology, the discoloration of a single tooth is significant only insofar as it might lead a dentist to take an X-ray of that tooth: it is the Xray, not the discoloration, that is the basis for diagnosis of the pathologies of concern. If, for any reason at all, the dentist takes an X-ray of the affected tooth, there can be no masking of pathology: the X-ray provides all information necessary for diagnosis, and treatment can then be rendered. (Giniger, Tr. 302-303, 317-318; Haywood, Tr. 2955-2957, 2986).

Response to Finding No. 1038:

First, this statement ignores the other aspect of Dr. Haywood's masking pathology theory, which is that customers/patients may not notice the tooth and thus be less inclined to go see a dentist, as described in the response to Proposed Finding No. 1012. Second, as Dr. Haywood points out in the testimony cited, this line of reasoning by Complaint Counsel "assum[es] that the dentist for no reason is going to take an x-ray of a front tooth." (Haywood, Tr. 2956).

1039. There are many reasons to take an X-ray, including indicators based on overall dental health and overall dental history. (Giniger, Tr. 318; Haywood, Tr. 2989).

Response to Finding No. 1039:

In the portion of his testimony cited here, Dr. Haywood only stated that there are different reasons to take an X-ray. The rest of the statement is not supported by his testimony. Later during his testimony, Dr. Haywood also explained why he might not take X-rays:

If a patient comes into my office and has no signs or symptoms of any problems that would warrant radiation exposure, and there's no discoloration of teeth, there's no other indication to warrant to do that, I don't routinely take panoramics for both radiation and the cost unless there's some – something that tips the differential diagnosis scale to say it's more in the patient's best interest to have a radiograph than to not.

(Haywood, Tr. 2996).

1040. In deciding on the propriety of taking dental X-rays, the potential utility of the X-rays is balanced against the desire to avoid unnecessary radiation exposure. (CX0823 at 038 (Haywood, Dep. at 145)). However, the radiation exposure from a dental-X-ray is relatively slight: roughly one-thousandth the amount of radiation received from a typical chest X-ray. (Giniger, Tr. 85). It is approximately equal to the radiation exposure from a single day's exposure to the sun. (CX0823 at 039 (Haywood, Dep. at 146-147)). Put another way, an individual will have a greater radiation exposure aboard an airline flight from New York to Los Angeles than from a full series of dental X-rays. (Giniger, Tr. 85).

Response to Finding No. 1040:

Dr. Haywood also noted that the amount of radiation that people receive is cumulative, which also forms part of the cost-benefit and risk-benefit ratio analysis that a dentist performs in deciding whether to take X-rays: "radiation is radiation and it's cumulative, so we have to keep records of every time we take a radiograph of a patient because that's all part of their -- increasing their risk and you have to make sure you justify the benefit for the risk in that." (CX0823 (Haywood, Dep. at 146-147)). Also, as noted above in the response to Proposed Finding No. 1039, another consideration in the cost-benefit ratio is the expense of taking X-rays.

1041. The ADA Council on Scientific Affairs and the U.S. Food and Drug Administration have jointly published guidelines on the selection of patients for radiograph examination. According to the ADA/FDA Guidelines, the reasons for taking an X-ray include, among others: history of pain and trauma; presence of cavities; previous periodontal or endodontic treatment; presence of implants or evaluation for implants; evidence of periodontal disease; large or deep restorations; cavities elsewhere in the mouth; malposed or clinically impacted teeth; mobility of any teeth; fistula; suspected sinus pathology; positive neurological findings in the head and neck; facial asymmetry; unusual tooth morphology; clinical erosion; history of recurrent caries even in the absence of active caries; poor oral hygiene; existing restorations of poor quality; dietary indications like frequent high sucrose content; and poor family dental health. (Haywood, Tr. 2992-2995).

Response to Finding No. 1041:

Respondent has no specific comment.

1042. The ADA/FDA Guidelines also suggest taking posterior bitewing X-rays with a panoramic examination or selected periapical images for all new patients. (Haywood, Tr. 2997). The ADA/FDA guidelines suggest taking a full mouth series of X-rays when the patient has clinical evidence of generalized dental disease or a history of extensive dental treatment. (Haywood, Tr. 2997). The ADA recommends a full mouth series of radiographs even if the patient has a cavity in a single tooth. (Giniger, Tr. 318-319).

Response to Finding No. 1042:

Respondent has no specific comment.

1043. For Dr. Haywood's masked pathology theory to be applicable, each and every one of the conditions identified in Finding ¶¶ 1020, 1021, 1024, 1027, 1033, 1034, 1036, 1038 would have to occur. (Giniger, Tr. 302). Although not susceptible to precise

quantification, the likelihood that any one of these conditions will occur is small, and as to some conditions, "small" may overstate the likelihood. (Giniger, Tr. 319, 435, 437; CX0632 at 017).

Response to Finding No. 1043:

Respondent refers to its responses to Proposed Finding Nos. 1020, 1021, 1024, 1027, 1033, 1034, 1036, and 1038, noting that Respondent has identified a number of fallacious assumptions unsupported assertions, or other fallacies with these Proposed Findings. Further, as noted in Respondent's response to Proposed Finding No. 1032, the cited portion of Dr. Giniger's testimony does not address "likelihood" at all, nor does the word "small" appear anywhere in the cited portions of the record evidence (despite the word having quotation marks around it).

At best, Dr. Giniger states that a dental examination before non-dentist bleaching may "sometimes" resolve the problem of an existing pathology, but he does not make any comment as to likelihood. (Giniger, Tr. 437 ("Q. Isn't it true that a dental examination before non-dentist bleaching would resolve the problem of a pathology, an existing pathology? A. Sometimes and -- sometimes yes, sometimes no. Just because there's been a dental examination, oftentimes people -- examinations are not perfect and oftentimes pathologies are missed."))).

This statement amounts to Complaint Counsel testifying on the record without any support for its alleged facts and providing its own assertions as to probability.

1044. The likelihood that all of these conditions will occur is so vanishingly small as to be of no practical significance. (The likelihood that all of several independent conditions will occur is equal to the arithmetic product of the likelihoods that each separate condition will occur. For example only, if each one of eight conditions has a 10% likelihood of occurring, the likelihood that all of the eight conditions will occur is $10\% \times 10\% \times 10\% \times 10\% \times 10\% \times 10\% \times 10\% \times 10\%$, or one millionth of one percent. If seven of the eight conditions has a 10% likelihood of occurring and one has a five percent likelihood, the likelihood that all of the eight conditions will occur is $10\% \times 10\% \times 10\% \times$

10% x 10% x 10% x 10% x 5% x, or one twenty-millionth of one percent. It is not likely that each of the conditions necessary for Dr. Haywood's theory to be applicable is entirely independent of all of the others, and so the above formula would not precisely describe the likelihood that all of the conditions will occur, but it does dramatize the compounding effect of having to satisfy multiple low probability conditions.) (Giniger, Tr. 319, 435, 437; CX0632 at 017).

Response to Finding No. 1044:

Respondent objects to this Proposed Finding and moves herein to strike it and/or have it be disregarded. These statistics are not discussed anywhere in the citations provided by Complaint Counsel, nor elsewhere in the entire record. This statement amounts to Complaint Counsel testifying on the record without any support for its statements and self-servingly providing its own assertions as to probability.

1045. Finally, assuming for purposes of argument that non-dentist provided teeth bleaching did mask pathology in some number of instances, little, if any, harm to the consumer would result from delayed diagnosis in any such instance. The pathologies in question, if diagnosed early, ultimately would be treated with the affected tooth's root canal or extraction and placement of an implant to replace said tooth; if diagnosis and treatment were delayed due to masking of pathology, the consumer's treatment would be the affected tooth's root canal or extraction and placement of an implant to replace said tooth. No more severe consequence is plausible. (Giniger, Tr. 320, 289-299).

Response to Finding No. 1045:

Respondent objects to Complaint Counsel "assuming for purposes of argument" in its Proposed Findings of Fact. Respondent objects to this Proposed Finding and moves herein to strike it and/or have it be disregarded. This statement amounts to Complaint Counsel testifying on the record without any support for its statements, which is more appropriately done in its Post-Trial Brief.

5. Other Alleged Concerns of the Board Are Not Legitimate Concerns Regarding Non-dentist Teeth Whitening

1046. Dr. Hardesty stated that faulty infection control procedures could make a non-dentist teeth whitening case among the most serious the Board investigates because the

nondentist might spread contagious pathogens like tuberculosis or hepatitis C. (CX0565 at 038 (Hardesty, Dep. at 144-145)).

Response to Finding No. 1046:

Respondent does not disagree.

1047. Board members testified that they are not aware of any of any transmission of tuberculosis, hepatitis, or any other infectious disease being attributed to a business providing non-dentist teeth whitening services. (Hardesty, Tr. 2829; CX0565 at 038 (Hardesty, Dep. at 145); CX0555 at 016 (Brown, Dep. at 55-56) (with respect to taking impressions of teeth); CX0657 at 037 (Holland, Dep. at 139-140); CX0564 at 016 (Hall, Dep. at 55); Wester, Tr. 1405; Owens, Tr. 1664).).

Response to Finding No. 1047:

Respondent has no specific comment.

1048. Board Member Hall stated she is not aware of anyone that has had an infection requiring treatment with antibiotics as a result of teeth whitening. The most serious reaction Ms. Hall has observed with respect to teeth whitening is some mild teeth sensitivity that is not at all severe. Patients with take-home whitening kits were instructed that if they had any problems, to call the office, stop using the tray and solutions, and sensitivity would go away within a day or two of using sensitivity toothpaste. (CX0564 at 016 (Hall, Dep. at 55-56)).

Response to Finding No. 1048:

Respondent has no specific comment.

1049. Dr. Wester testified that he had not personally seen any cases in which a mall teeth whitening customer got peroxide in his or her eye. (Wester, Tr. 1313). He had not heard of irreversible eye damage caused by non-dentist teeth whitening either discussed in the literature, from his patients, or discussed by his dental colleagues. (Wester, Tr. 1314). He had not heard of one of his patients or his colleague's patients needing to flush their eyes with water as a result of using OTC teeth whitening products. (Wester, Tr. 1314-1315).

Response to Finding No. 1049:

Respondent has no specific comment.

1050. Dr. Hardesty has never heard of anyone who has received teeth whitening services from a non-dentist who had a choking episode or went into anaphylactic shock in connection with receiving those services. (Hardesty, Tr. 2818).

Response to Finding No. 1050:

Respondent has no specific comment.

1051. Dr. Allen has never heard of a case where carbamide peroxide was swallowed during teeth whitening and caused a necrotic condition in the throat known as sloughing. (CX0554 at 008 (Allen, Dep. at 23-24)).

Response to Finding No. 1051:

Respondent has no specific comment.

1052. Dr. Owens testified that teeth whitening can cause harm by affecting, damaging or necrosing the nerve of the tooth, harming gingival tissue, damaging oral soft tissue, or tearing the patient's lips or tearing parts of the patient's mouth. (Owens, Tr. 1453-1454). He testified that he could not think of any other ways that teeth whitening can cause harm. (Owens, Tr. 1545).

Response to Finding No. 1052:

The second sentence has is not supported in the portion of the record cited by Complaint Counsel. All that appears on the page cited, page 1545, is a question by Complaint Counsel and an objection by Respondent's Counsel. Thus there is no support for the second statement.

1053. Notwithstanding Dr. Owens' testimony, the bleaching product in a tooth bleaching kit does not penetrate the dentin, pulp, and enamel. The bleaching product essentially leaches the organic material from the enamel and lightens the tooth. (CX0554 at 014 (Allen, Dep. at 47)).

Response to Finding No. 1053:

Complaint Counsel blatantly and egregiously misstates Dr. Allen's testimony from his deposition. He did not say that the bleaching product "does not" penetrate the dentin, pulp, and enamel. He said it "should not", but then went on to describe one page later in his deposition testimony how it possibly could get into the dentin and thereby irritate the pulp: "what can happen -- you know, remember dentin is live tissue. It has extensions into the

enamel, and if you irritate those little dentinal protections you can inflame the pulp of the tooth and that will cause root canal problems.” (CX0554 (Allen, Dep. at 49)).

1054. Dr. Owens’ testimony is contradicted by his own testimony, and by the testimony of another Board member. Dr. Owens testified that he has no knowledge of a nerve of a tooth ever being necrosed as a result of non-dentist teeth whitening. (Owens, Tr. 1648). Dr. Hardesty testified that he never had a patient experience “nerve death,” that is, pulpal necrosis, in connection with teeth bleaching he performed. (Hardesty, Tr. 2812).

Response to Finding No. 1054:

The first sentence is not a statement of fact, it is the unsupported statement of Complaint Counsel. Further, this does not at all “contradict” Dr. Owens’ previous testimony regarding necrosis. There is a manifest difference between saying that necrosis is *possible* and the assertion that one has not personally witnessed it before.

6. Dentist Teeth Whitening Can Cause More Harm Than Non-Dentist Teeth Whitening

1055. The Board has found, through its investigations, that some licensed dentists have caused non-transient harm to patients during treatment. (Response to RFA ¶ 30; Respondent’s Response to Interrogatory ¶ 4 (“With regard to the provision of teeth whitening by licensed dentists, . . . Respondent draws Complaint Counsel’s attention to one case involving a dentist, Dr. Joseph T. Jakubek, file number 09-031, where a patient went to the dentist to have a single tooth whitened and complained that during the procedure the dentist broke the tooth. This complaint also involved crowns and bridge work. Respondent is informed and believes that other files exist regarding non-physical injuries that could result from dishonesty or deception”)).

Response to Finding No. 1055:

This statement underscores the need for regulation of the dental profession by licensing boards such as Respondent.

1056. The Board has identified at least one example of a North Carolina dentist causing nontransient harm to a patient while performing a teeth whitening procedure. (Response to RFA ¶ 30; Respondent’s Response to Interrogatory ¶ 4).

Response to Finding No. 1056:

This statement underscores the need for regulation of the dental profession by licensing boards.

1057. Dr. Martin Giniger stated that side effects related to teeth whitening “may be most frequent and pronounced with dentist provided chair-side bleaching owing to the greater concentration of hydrogen peroxide often used in dental offices” as compared to other forms of teeth bleaching. (CX0653 at 046).

Response to Finding No. 1057:

This is opinion statement made by Dr. Giniger without any evidence in support. It is purely speculative and has no basis in the record. Dr. Haywood also pointed out that the issues with the composition of non-dentist teeth bleaching products is not limited to the concentration of those products; it is that the ingredients of many of the products being put on the market are not known. Haywood, Tr. 2572). For instance, one of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product, stating only that it’s percentage of carbamide peroxide is “proprietary” and not disclosing what other ingredients are in the product. (CX108 at 4).

1058. Dr. Burnham has “absolutely” and “unequivocally” heard of and personally witnessed patients suffering from gingival irritation after receiving a teeth whitening procedure from a dentist. (CX0556 at 031 (Burnham, Dep. at 116)). However, Dr. Burnham has heard of only one case where a customer of a non-dentist teeth whitener suffered from gingival irritation after a teeth whitening procedure. (CX0556 at 031 (Burnham, Dep. at 115-116)).

Response to Finding No. 1058:

This statement completely mischaracterizes Dr. Burnham’s testimony by fabricating portions of the statement that were not made and by omitting critical other points made by Dr. Burnham in his follow-up to the question. First, he never stated that he had “personally witnessed” gingival irritation in a patient after receiving a teeth whitening

procedure from a dentist in the portion of the transcript cited, that fact has been fabricated by Complaint Counsel. Further, he explained that his basis for saying that gingival irritation “absolutely” happens is because “a lot of people are just so sensitive if you get that stuff up on their gum tissue it burns.” (CX0556 (Burnham, Dep. at 116)). Further to this point, he also explained in his deposition that the reason non-dentists using stronger teeth whitening products threatens public health is because “[t]he bleaching materials themselves are capable of producing gingival inflammation and irritation which may or may not be irreparable, but it certainly could be an injury.” (CX0556 (Burnham, Dep. at 114)).

1059. On June 4, 2007, an anonymous Adverse Event Report was received by the United States Food and Drug Administration regarding the Discus Dental Zoom2 Teeth Whitening System. The complainant experienced intense pain in and discoloration of his or her upper gums and teeth. Six days later, the complainant’s gums appeared “pus-like with need for debridement,” and his or her teeth had returned to their pre-whitening color, signaling adverse effects as well as inefficacy. (CX0535 at 001).

Response to Finding No. 1059:

Respondent has no specific comment.

1060. The Zoom! teeth whitening system involves placing a rubber dam about the gums in order to prevent gingival contact with whitening material. After this, the material is placed on the teeth in multiple applications. (CX0578 at 007 (Parker, Dep. at 20-21)).

Response to Finding No. 1060:

Respondent has no specific comment.

1061. Dr. Hardesty had one patient who experienced tooth sensitivity when using the Zoom! system with what he believes was a 35% hydrogen peroxide whitening solution. The sensitivity lasted approximately two weeks. (Hardesty, Tr. 2809). Dr. Hardesty later determined that the sensitivity was root surface hypersensitivity and he testified that it had no connection to the whitening he performed on the patient. (Hardesty, Tr. 2809-2810).

Response to Finding No. 1061:

Respondent has no specific comment.

1062. Dr. Feingold decided against offering in-office teeth whitening using the Zoom! System because of the frequent occurrence of patient sensitivity for a week or two after the procedure is done. (CX0560 at 005 (Feingold, Dep. at 11)).

Response to Finding No. 1062:

Respondent has no specific comment.

1063. Dr. Owens testified that after treating patients with the Zoom! system he has seen sensitivity that lasted for several months to a year. (CX0570 at 024 (Owens, Dep. at 89)).

Response to Finding No. 1063:

Respondent has no specific comment.

1064. Dr. Haywood has observed, including in his writings, that, “[t]he biggest challenge in esthetic dentistry is to maintain the ethics of the dental profession and to place patient care ahead of financial gain.” (Haywood, Tr. at 2626).

Response to Finding No. 1064:

Respondent has no specific comment.

1065. Dr. Haywood has listed a few ethical issues facing dentists, including that some dentists may be recommending expensive teeth bleaching to patients when there are other “more appropriate” options for their patients. (CX0492 at 003).

Response to Finding No. 1065:

Respondent has no specific comment.

1066. Dentists use a higher concentration of peroxide bleaching agents for their in-office procedures than non-dentists use for their chair-side services. (Giniger, Tr. 182, 215; Haywood, Tr. 2652; Hardesty, Tr. 2809).

Response to Finding No. 1066:

Dr. Haywood pointed out in the portion of his testimony cited by Complaint Counsel that dentists using the higher concentrations “isolate[e] the gingiva to protect it from the higher concentrations.” (Haywood, Tr.2652). The portion of Dr. Hardesty’s testimony that is cited here does not even remotely support the statement.

1067. Dentists use teeth whitening products that are higher in strength and efficacy than OTC teeth whitening products or those used for cosmetic teeth whitening. Additionally, UV light activation systems used by dentists are often quite different than those used by nondentists. The powerful light sources, combined with higher concentrations of whitening ingredients, can be potentially more damaging to a client's gums or teeth. (CX0630 at 005).

Response to Finding No. 1067:

As noted above, dentists have the training to conduct such procedures in a safer manner, such as by isolating the gingival. (Haywood, Tr.2652).

1068. Jim Valentine of WhiteSmileUSA stated that the strength of the hydrogen peroxide solution in the WhiteSmile booster gel had always been 12%. (Valentine, Tr. 522). Mr. Valentine stated that WhiteSmile had never marketed a whitening gel with a hydrogen peroxide concentration of over 12%, because with stronger concentrations come a greater risk of side-effects. (Valentine, Tr. 523). Mr. Valentine stated that the strength of the hydrogen peroxide solution in the multiple-use syringe is 10%. (Valentine, Tr. 523).

Response to Finding No. 1068:

Mr. Valentine is but one of many non-dentist teeth whiteners on the market. As Dr. Haywood has pointed out, one of the issues with non-dentist teeth bleaching products is that the ingredients of many of the products being put on the market is **not** known. (Haywood, Tr. 2572). For instance, one of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product: under the Section labeled "Composition", the MSDS sheet states only that it's percentage of carbamide peroxide is "proprietary" and does not disclose what other ingredients are in the product. (CX108 at 4).

1069. Dr. Allen has never heard or read of 7% hydrogen peroxide solution causing any damage beyond transient tooth and gum irritation. (CX0554 at 041 (Allen, Dep. at 157)). Dr. Allen would be less concerned about a 7% hydrogen peroxide solution in the hands of a non-dentist than a higher concentration of peroxide in the hands of a non-dentist. (CX0554 at 041 (Allen, Dep. at 156)).

Response to Finding No. 1069:

This statement mischaracterizes Dr. Allen's testimony. He said that he would "be less concerned with a lower percentage in any situation than [he] would a higher percentage." (CX0554 (Allen, Dep. at 156)). He also said that while he would not be as concerned about a non-dentist using a 7% solution of hydrogen peroxide, he would be more concerned about a non-dentist using a 22% solution. (CX0554 (Allen, Dep. at 156)).

7. Take-home Trays Are Used Longer and Therefore Create a Greater Possibility of Abuse

1070. The Board is not aware of any study showing that dental teeth whitening is safer than teeth whitening provided at a mall or salon. (Response to RFA ¶ 21).

Response to Finding No. 1070:

Respondent has no specific response.

1071. The Board is not aware of any empirical data or studies showing that provision of teeth whitening services by non-dentists is more likely to lead to patient health issues than that provided by dentists. (Response to RFA ¶ 38).

Response to Finding No. 1071:

Respondent has no specific response.

1072. The Board is not aware of any empirical data or studies showing that provision of teeth whitening services by non-dentists is more likely to lead to public safety issues than that provided by dentists. (Response to RFA ¶ 39).

Response to Finding No. 1072:

Respondent has no specific response.

1073. Ms. Friddle testified that she does not recall ever working with the health department with respect to non-dentist teeth whitening. (CX0562 at 018-019 (Friddle, IHT at 69-70)).

Response to Finding No. 1073:

Board Counsel contacted the county or state health department about the sanitation issues in the mall kiosks. (RX50 (Bakewell, Dep. at 317-321)).

1074. Dr. Burnham stated that if there was a risk to the population due to teeth whitening it would be of interest to the North Carolina Division of Oral Health, but that he never discussed teeth whitening with head of the Division of Oral Health. (CX0556 at 044 (Burnham, Dep. at 166-167)).

Response to Finding No. 1074:

Board Counsel contacted the county or state health department about the sanitation issues in the mall kiosks. (RX50 (Bakewell, Dep. at 317-321)).

1075. The American Dental Association reported, in a July 2010 article entitled "Frequently Asked Questions on Tooth Whitening Safety," that "[w]hether tooth whitening is performed under the care and supervision of a dentist, self-applied at home or in a nondental setting, whitening materials are generally well-tolerated when used appropriately and according to directions. Tooth sensitivity is not unusual but it normally is self-limiting and resolves." (CX0227 at 005).

Response to Finding No. 1075:

The same paragraph of that document also states that "Importantly, proceeding with tooth whitening without consulting a dental professional may miss untreated dental disease: patients with some conditions may not be suitable candidates for tooth whitening," thereby echoing Dr. Haywood's concerns regarding the safety issues with non-dentist teeth whiteners. (CX0227 at 005).

1076. Dr. Morgan stated he will tell patients who ask that he does not see any problem with trying OTC teeth whitening products. (CX0569 at 019 (Morgan, Dep. at 68-69)). He stated that he has seen no evidence that Crest Whitestrips are less safe than dentist provided teeth whitening systems. (CX0569 at 019 (Morgan, Dep. at 69)). His patients have not complained to him about problems with Crest Whitestrips, except that some have indicated the Crest Whitestrips were inconvenient or did not work fast enough. (CX0569 at 019 (Morgan, Dep. at 69)).

Response to Finding No. 1076:

Respondent has no specific response.

8. Concerns About Any Lack of Sanitation Related to Non-dentist Teeth Whitening Is Pretextual

PART E

1077. Teeth bleaching, whether performed by a dentist, a lay-provider, or the consumer using an OTC product at home, poses no unusual risks associated with sanitation or infection control breakdowns, and there are no known instances in which any communicable disease has been spread as a result of non-dentist teeth bleaching. (Giniger, Tr. 262-266; CX0653 at 036; Hardesty, Tr. 2829; CX0565 at 038 (Hardesty Dep. at 145) (Dr. Hardesty is not aware of any incident where a non-dentist spread a communicable disease); CX0555 at 016 (Brown, Dep. at 55-56) (Dr. Brown is also not so aware)).

Response to Finding No. 1077:

Dr. Giniger's testimony that teeth bleaching performed by a lay-provider poses no unusual risks has been thoroughly refuted by Dr. Haywood. Respondent's Proposed Findings of Fact Nos. 375-384, 389-400. Also, teeth whitening performed by a lay-provider is illegal in North Carolina. (CX19 at 7 (N.C. Gen. Stat. § 90-29); Respondent's Proposed Findings of Fact Nos. 363-374).

1078. Manufacturers design products for use by non-dentist bleaching facilities that are in prepackaged single-use containers, sterile, and meant to be self-applied by the consumer. (Giniger, Tr. 262-263).

Response to Finding No. 1078:

Respondent notes that despite Dr. Giniger's testimony that lay bleaching facility operators do not touch the mouth of the customer during bleaching procedures, kiosk/spa operators and their employees do not consistently follow these "self-administration" guidelines. *See* Respondent's Proposed Findings of Fact No. 686; (Runsick, Tr. 2109) (testifying that employees placed the mouthpiece for the light into his mouth themselves); RX11 at 6 (teeth whitening spa employee touched investigator's face with her hands during teeth whitening procedure and admitted to having touched poison ivy).

1079. Non-dentist providers adhere to sanitary standards and protocols provided by manufacturers which include procedure about disinfection, gloving, and other measures. (CX0653 at 036).

Response to Finding No. 1079:

Testimony presented at trial indicated that these so-called sanitation measures consists of using Handi-wipes and antibacterial gels and spray and are not universally followed.

(Runsick, Tr. 2108-2109) (Mr. Runsick did not observe any BleachBright employee sanitize the chair before he sat in it and saw BleachBright employees take a mouth piece out of another customer's mouth, detach it from the teeth whitening light, wipe it down with "a Handi-Wipe which you might see at KFC", and place it in Mr. Runsick's mouth for him); (Osborn, Tr. 718-719) (customers using her product do not wash their hands with soap, but are given antibacterial gels to sanitize their hands); RX11 at 5, 6; RX15 at 9; RX27 at 1; RX25 at 15; RX22 at 18, 19; RX8 at 9. These measures are not adequate to ensure proper sanitation, because sanitation is best accomplished through washing hands with soap and water. (Wester, Tr. 1321, 1323-1324, 1406-1407; Owens, Tr. 1457-1459; RX63 (Holland, Dep. at 139); RX65 (Morgan, Dep. at 146)). Proper methods require adequate training in sanitation control measures, such as avoiding cross-contamination and knowing how to use OSHA-approved products such as Pro-Spray. (Hardesty, Tr. 2782-2785; RX63 (Holland, Dep. at 138-139); RX75 (Oyster, Dep. at 32)).

1080. Consumers at lay-operated bleaching facilities typically are directed to self-apply their purchased teeth bleaching products using the information and advice supplied by the product manufacturer and bleaching facility personnel. (CX0653 at 036).

Response to Finding No. 1080:

Respondent refers to its response to Proposed Finding No. 1079.

1081. Moreover, hydrogen peroxide is itself a potent antimicrobial agent and likely helps prevent any possible cross-contamination. (Giniger, Tr. 263; CX0653 at 036-037).

Response to Finding No. 1081:

Dentists concerns as to cross-contamination are not limited to the surface areas that come into contact with the hydrogen peroxide itself, not to mention that the hydrogen peroxide is not in the customer's mouth the entire time that they are in the spa/kiosk area.

1082. There may be periodic breaches of proper sanitation and infection control in lay-operated bleaching facilities, but that will be true in dental offices as well. (Giniger, Tr. 263, 420-423; CX0652 at 037).

Response to Finding No. 1082:

Dentists and their staff have much better training for preventing such breaches of proper sanitation and infection control than non-dentist teeth whitening facilities. *See*

Respondent's Proposed Findings of Fact Nos. 385-388.

1083. It is not customary – and would be impractical – to expel dentists from the practice of dentistry for breaches of sanitation or infection control in a dental environment. (Giniger, Tr. 264).

Response to Finding No. 1083:

Respondent does not disagree with this statement.

1084. The appropriate action for breaches of regulatory sanitation or infection control measures by dentists or non-dentists is re-education. (Giniger, Tr. 264-265; 423-424).

Response to Finding No. 1084:

Respondent has no specific comment.

1085. Breach of proper procedure may warrant action against any breaching facility operator or dentist, but it does not justify exclusion of an entire class of competitors. (Giniger, Tr. 265; CX0653 at 037).

Response to Finding No. 1085:

Because of the FTC's lawsuit, there is no way for any action to be taken by a state regulatory agency against non-dentist teeth whiteners for such breaches.

1086. The Board's concerns about sanitation are not credible as they appear never to have complained of unsanitary practices at a non-dentist operated teeth bleaching facility to state or local health department or to any other responsible official. (CX0653 at 037).

Response to Finding No. 1086:

Respondent disputes this statement. Board Counsel testified that she contacted the county or state health department about the sanitation issues in the mall kiosks. (RX50 (Bakewell, Dep. at 317-321)). The only support Complaint Counsel provides for this statement is the opinion statement of Dr. Giniger, who has no basis for being aware of all of the Board's activities and provides no evidence of his incorrect observation that the Board "appears" to have not contacted a state or local health department regarding unsanitary practices at a non-dentist operated teeth bleaching facility.

1087. Board Investigator Kurdys testified that he was not aware of any sanitation issues arising in any investigation of non-dentist teeth whitening that he has conducted. Mr. Kurdys did not recall case officers raising sanitation issues in non-dentist teeth whitening investigations. (CX0568 at 019 (Kurdys, Dep. at 69)).

Response to Finding No. 1087:

Although Mr. Kurdys did not recall at his deposition that sanitation issues had arisen during a teeth whitening investigation, he was not the only investigator from the Board to investigate such cases. But the Board files indicate that during one investigation of a teeth whitening spa, the spa employee touched the investigator's face with her hands during a teeth whitening procedure and then admitted to having touched poison ivy. (RX11 at 6).

1088. The Board has never conducted a systematic assessment of sanitation and infection control measures taken by non-dentist teeth bleaching establishments. (Hardesty, Tr. 2822).

Response to Finding No. 1088:

Respondent has no specific comment.

1089. Dr. Brown testified that he is not aware of the Board ever approaching any department of health with a complaint about sanitation or any unhealthful conditions at a non-dental teeth whitening business. (CX0555 at 049 (Brown, Dep. at 187)).

Response to Finding No. 1089:

The Board is the state agency charged with enforcing the unlicensed practice of dentistry, including inadequate sanitation measures involved in dental procedures being performed by non-licensees. This is why other public complainants have reported sanitation concerns about non-dentist teeth whiteners to the Board.

1090. Dr. Wester testified that he does not advise his patients to sterilize the syringe containing bleaching solution before applying it to the tray. He does not tell his patients their hands must be sterile before handling the tray. He does not send his patients home with goggles or tell his patients to wear goggles while using the teeth whitening products he sells them. (Wester, Tr. 1366-1367).

Response to Finding No. 1090:

Respondent has no specific comment.

1091. Dentists use gloves, but not sterile gloves. Gloves are used to protect the dental professionals from infections potentially carried by their patients. (Hardesty, Tr. 2781-2782). Dentists and their employees normally only wear sterile gloves when in the course of surgery. (Giniger, Tr. 166).

Response to Finding No. 1091:

In citing this testimony, Complaint Counsel misleadingly provides only a portion of Dr. Hardesty's answer to a question about what infection control measures he uses. Dr. Hardesty also testified that he provides eye protection for his patients to wear, and after each procedure "all the surfaces that may or may not be contaminated are wiped with a material that kills tuberculosis and other potentially infectious material that may have spattered on those areas." (Hardesty, 2782). He and his staff also sterilize their instruments in an autoclave that is tested on a weekly basis. (Hardesty, 2782). Lysol wipes and other disinfectant wipes used by non-dentist teeth whiteners at malls are not sufficient methods for ensuring proper sanitation when interacting with consumers receiving teeth whitening treatments. Proper methods require adequate training in

sanitation control measures, such as avoiding cross-contamination and knowing how to use OSHA-approved products such as Pro-Spray. (Hardesty, Tr. 2782-2785; RX63 (Holland, Dep. at 138-139); RX75 (Oyster, Dep. at 32)).

Also, Complaint Counsel clearly misstates Dr. Giniger's comment that dentists and their employees "only" wear sterile gloves during surgery. In fact, Dr. Giniger testified that dentists and their staff do "Not typically [wear gloves] in the course of dentistry, only typically when we're performing surgery." (Giniger, Tr. 166). Further, this comment is misleading because it overlooks the fact that, unlike teeth whitener kiosk operators (who lack running water), dentists and their staff take proper sanitation measures according to their dental training by washing their hands with soap and water. (Wester, Tr. 1321, 1323-1324, 1406-1407; Owens, Tr. 1457-1459; RX63 (Holland, Dep. at 139); RX65 (Morgan, Dep. at 146)).

1092. Cosmetology Board Rules are generally very stringent. Salons and spas must adhere to sanitation requirements overseen by other state licensing boards, including, for example, cosmetology boards. (Nelson, Tr. 849; CX0827 at 001-006; CX0828 at 001).

Response to Finding No. 1092:

Respondent disputes this fact because Mr. Nelson admitted in his full answer that he had no basis for this testimony. He stated "I don't know what a salon and spa would do, individual salons and spas, other than it's -- other than, I mean, they have -- they have to conform to their -- to their licensing, which is usually cosmetology, which requires strict sanitation." It is not clear what basis Mr. Nelson has for his understanding that spas require "strict sanitation," since there is no evidence in the record establishing any foundation for his knowledge of spa sanitation requirements.

1093. The Board has found, through its investigations, that licensed dentists have engaged in unsanitary practices. (Response to RFA ¶ 32-33).

Response to Finding No. 1093:

This statement underscores the need for regulation of the dental profession by licensing boards such as Respondent. Any licensed dentists who are found to have engaged in unsanitary practices are disciplined by the Board.

1094. Concerns related to running water are unsubstantiated; salons have running water. (Osborn, Tr. 954-955 (describing using water and washing hands in salon); Wester, Tr. 1322 (“I’m sure [salons] do” have running water)).

Response to Finding No. 1094:

This statement on its face does not establish that such concerns are “unsubstantiated”, it merely establishes that one aspect of a sanitation concern cited by the Board in connection with non-dentist teeth whitening operations, i.e., a lack of running water to properly wash employees’ and customers’ hands with soap and water, may not apply with respect to salons. However, there has been clear testimony in this matter that many kiosks with teeth whitening operations do not have running water. (Runsick, Tr. 2108 (no sink with running water at kiosk at which he had teeth whitening procedure); Valentine, Tr. 598 (WhiteSmile mall kiosks do not have running water available for employees to wash their hands); (RX50 (Bakewell, Dep. at 318) (the Board has received reports about non-dentist teeth whiteners operating at mall kiosks where there was no running water)).

There has been **no testimony** regarding teeth whitening kiosks that have had running water.

1095. Kurdys does not know whether the lack of running water at a facility conducting teeth whitening would ever be a problem. Kurdys does not recall sanitation problems existing at any facility conducting teeth whitening. Kurdys did not initially recall any case officer ever raising a lack of running water or sanitation problems as issues at facilities conducting non-dentist teeth whitening. (CX0568 at 019 (Kurdys, Dep. at 68-69)).

Response to Finding No. 1095:

Mr. Kurdys is not a dentist who would necessarily have knowledge of proper sanitation measures. It is misleading for Complaint Counsel to cherry-pick testimony from an investigator about this issue from a witness who would not necessarily have knowledge of such issues in a naked attempt to impute this to the entire Board, as there has been clear testimony from Board members who are licensed dentists of the need for running water at facilities conducting dental procedures.

1096. Kurdys does not know why Dr. Holland raised questions about sanitation and running water at a spa engaging in non-dentist teeth whitening when Kurdys had not observed any problems, concerns, or issues. (CX0250; CX0251; CX0568 at 028-029 (Kurdys, Dep. at 103, 105-107)).

Response to Finding No. 1096:

Respondent refers to its responses to Proposed Finding Nos. 1095 and 1087.

1097. Kiosks often have access to running water. Mr. Gibson, President of Hull Storey Gibson Companies, L.L.C. ("HSG"), testified that if a mall kiosk tenant needs water to operate, the mall can pipe water to the kiosk. Mr. Gibson gave the example of a TCBY frozen yogurt store operating as a kiosk and having water piped to the location. (Gibson, Tr. 639; Valentine, Tr. 598).

Response to Finding No. 1097:

This fact does not establish that kiosks "often" have access to running water. It establishes that teeth whitening operations at mall kiosks may be able to obtain access to running water at HSG malls in order to ameliorate just one of the many concerns cited by dentist Board members and Dr. Haywood about the lack of sanitation measures at kiosks. But there has been no testimony at all that any kiosk operator attempted to do so. For instance, Mr. Nelson testified that WhiteScience did not require its local affiliates operating teeth whitening kiosks at malls to have running water, (Nelson, Tr. 834), and Mr. Valentine testified that none of his WhiteSmile mall kiosks have running water available for employees to wash their hands. (Valentine, Tr. 598).

1098. Running water is not generally needed. Jim Valentine testified that WhiteSmile used Lysol sanitary wipes to wipe its lights, cabinets, and chairs after each customer use because Lysol sanitary wipes kill germs on contact. (Valentine, Tr. 531-532).

Response to Finding No. 1098:

Mr. Valentine is a businessman, and provided no testimony that he has any dental training. His testimony was refuted by dentists who have training in proper sanitation measures, and who stated that Lysol wipes and other disinfectant wipes used by non-dentist teeth whiteners at malls are not sufficient methods for ensuring proper sanitation when interacting with consumers receiving teeth whitening treatments. Proper methods require adequate training in sanitation control measures, such as avoiding cross-contamination and knowing how to use OSHA-approved products such as Pro-Spray. (Hardesty, Tr. 2782-2785; RX63 (Holland, Dep. at 138-139); RX75 (Oyster, Dep. at 32)).

1099. George Nelson testified that WhiteScience's protocol is to clean equipment with a disinfectant pad, and that doing so complies with sanitation rules at malls. (Nelson, Tr. 834-835).

Response to Finding No. 1099:

Mr. Nelson is a businessman, and provided no testimony that he has any dental training. His testimony was refuted by dentists who have training in proper sanitation measures, and who stated that Lysol wipes and other disinfectant wipes used by non-dentist teeth whiteners at malls are not sufficient methods for ensuring proper sanitation when interacting with consumers receiving teeth whitening treatments. Proper methods require adequate training in sanitation control measures, such as avoiding cross-contamination and knowing how to use OSHA-approved products such as Pro-Spray. (Hardesty, Tr. 2782-2785; RX63 (Holland, Dep. at 138-139); RX75 (Oyster, Dep. at 32)).

1100. Dentist office equipment with running water can carry deadly microbes. (CX0508 at 036; Wester, Tr. 1412 (Dr. Wester agrees that there could be "potential fatal issues in

dentist's offices" associated with dental equipment using running water); Owens, Tr. 1671-1672).

Response to Finding No. 1100:

When asked about the article Complaint Counsel presented regarding this issues, Dr. Wester said "Other than this article, which I don't remember reading, I don't think I've heard anything approaching fatal diseases from dental treatments." (Wester, Tr. 1411). The same article also states that "[t]he consensus from the scientific community is that biofilm from dental unit waterlines does not present a significant public health problem." (CX0508 at 036).

1101. Dr. Baumer provides no evidence that there have been sanitation problems with respect to non-dentist teeth whiteners. Even if there had been sanitation issues with non-dentist teeth whiteners it would not provide a justification for their exclusion. Sanitation problems can be remedied through less restrictive alternatives. (Kwoka, Tr. 1087-1088; CX0631 at 011).

Response to Finding No. 1101:

Dr. Baumer is Respondent's economic expert, and it was not incumbent on him to provide such evidence. He did cite the other evidence of such concerns provided by the Board. Evidence in the record of concerns regarding sanitation problems with respect to non-dentist teeth whiteners includes the testimony of Dr. Haywood, the Respondent's dental expert, numerous members of the Board, the admissions of members of the teeth whitening industry, the Board's investigative files, and the testimony of Mr. Runsick, a consumer who was injured by a non-dentist teeth whitening operation. See Respondent's Proposed Findings of Fact Nos. 425-445 (dentist Board member concerns), 471-474 (Runsick testimony), 438-439 and 442-443 (teeth whitening industry representative admissions), 386-387 (Dr. Haywood testimony), 101-237 (Board investigative files).

1102. Dr. Baumer agrees that one anecdote that a non-dentist did not use gloves and put his or her finger in a consumer's mouth is not sufficient to justify banning all non-dentist teeth whitening. (Baumer, Tr. 1958). Dr. Baumer cannot recall more than one incident to support this justification for banning non-dentist teeth whitening. (Baumer, Tr. 1958).

Response to Finding No. 1102:

Respondent refers to its response to Proposed Finding No. 1101.

9. Concerns About Any Lack of Liability Related to Non-Dentist Teeth Whitening Are Pretextual

1103. The market would not tolerate a lack of liability for the safety and efficacy of non-dentist teeth whitening products by the manufacturers and sellers of those products. For example, in an e-mail dated April 28, 2010 from George Nelson of WhiteScience to C.W. Baudot, Mr. Nelson poses the rhetorical question, "do you think the major malls, spas, and cruise ships would tolerate offering [non-dentist teeth whitening] if there were any complaints from the public." (CX0821 at 002)

Response to Finding No. 1103:

Respondent objects to the above statement. It is not a fact, it is the opinion testimony of Complaint Counsel. There is no evidence to support this statement, and the exhibit cited in no way supports this proposed finding.

1104. Dr. Baumer agrees that markets tend to work and that working markets discipline providers of unsafe or ineffective products and services. (Baumer, Tr. 1961).

Response to Finding No. 1104:

Respondent disputes this paraphrase of Dr. Baumer's statement because it misleadingly only provides part of his response. He also said in the same response that "On the other hand, the discipline of the market relies upon people to be injured, and that's precisely the origin of licensing." (Baumer, Tr. 1961-1962). During his direct examination, Dr. Baumer provided a thorough refutation of Dr. Kwoka's theory about market measures providing adequate regulation:

To claim that the market without licensing has legal recourse through contract and tort is an old argument that has not been found persuasive.

In order for tort remedies to make sense, you have to have people hurt basically. That's why we have licensing, is to avoid the method of getting to court by having injured or dead bodies.

As far as contracts, I read some of the summaries of these people who had conducted, you know, provided non-dentist teeth whitening. I don't think they have the financial resources to make good if there was a contract.

So, you know, Dr. Kwoka talks about the market will expose people, providers who are – provide substandard or dangerous products. I disagree with that. I think ultimately it will, but it's a heckuva road to get there to that point. You've got to have people injured basically.

(Baumer, Tr. 1771).

1105. Dr. Baumer agrees that just because a business is unlicensed does not mean that it is not going to satisfy consumer demand in a safe and efficient manner. (Baumer, Tr. 1977-1978). That is because there are market mechanisms to ensure consumer trust, such as business reputation, the Better Business Bureau, and other non-governmental agencies. (Baumer, Tr. 1977).

Response to Finding No. 1105:

Respondent refers to its response to the previous Proposed Finding No. 1104.

1106. Dr. Baumer admitted that mall owners have an interest in maintaining their reputations and are unlikely to bring in businesses, such as teeth whitening kiosks, that are going to have a negative impact on their reputations. (Baumer, Tr. 1929; CX0826 at 056 (Baumer, Dep. at 215-216)).

Response to Finding No. 1106:

Respondent refers to its response to the Proposed Finding No. 1104.

1107. There are protections for consumers of non-licensee teeth whitening. Sellers have reputations, that represent the same kind of investment as licensing, in continuing to provide good, quality service. Further, consumers may seek legal redress for harm or an unsatisfactory experience. (Kwoka, Tr. 1084-1085).

Response to Finding No. 1107:

Respondent refers to its response to the previous Proposed Finding No. 1104.

1108. Jim Valentine testified that in the course of WhiteSmile's roughly three years in operation, providing over 100,000 bleachings in 28 states, no customers sued

WhiteSmile. (Valentine, Tr. 560). Mr. Valentine stated that during this time period, only one customer made a claim. The claim for gum irritation was settled by WhiteSmile's insurance for \$1200. (Valentine, Tr. 560-561).

Response to Finding No. 1108:

WhiteSmile USA also requires that its customers sign a consent form containing a waiver of liability. (Valentine, Tr. 597). This no doubt played a role in discouraging lawsuits by lay consumers.

1109. Mr. Nelson testified that WhiteScience has had no claims made against its liability insurance policy for teeth whitening. (Nelson, Tr. 736). Mr. Nelson testified that he knew of no claims paid out by salons in response to problems relating to teeth whitening with the WhiteScience product. (Nelson, Tr. 737).

Response to Finding No. 1109:

Respondent has no specific comment.

1110. A concern that non-dentist teeth whiteners do not carry sufficient liability insurance does not justify exclusion of non-dentist teeth whiteners. A less restrictive requirement that non-dentists carry a certain level of liability could be imposed without banning the service. (Kwoka, Tr. 1088-1089).

Response to Finding No. 1110:

Respondent has cited other concerns in this proceeding aside from the fact that many teeth whiteners do not carry insurance. Also, the Board is statutorily mandated to enforce the practice of dentistry, including by preventing the unlicensed practice of dentistry. *See* Respondent's Proposed Findings of Fact Nos. 11-49.

1111. Dr. Baumer agrees that if the teeth whitening supplier required the non-dentist teeth whitener to subscribe to a master insurance plan in addition to carrying liability insurance it would make it less likely that a ban of teeth whitening would be justified based on a cost-benefit analysis. (Baumer, Tr. 1938).

Response to Finding No. 1111:

Respondent does not disagree with this statement. But Respondent notes that there is no basis in the record for finding that this hypothetical statement generally reflects the

reality of the non-dentist teeth whitening industry. For instance, WhiteSmileUSA did not require salons using its products to carry general liability insurance. (Valentine, Tr. 606). Further, there was no testimony from Mr. Nelson that WhiteScience “required” salons or kiosks using its product to carry general liability insurance.

1112. Mr. Nelson testified that the salons which carry his product are required to carry their own liability insurance. In addition, the company that carries the WhiteScience insurance policy provides each salon with a rider that covers the salon under the WhiteScience product liability insurance plan. (Nelson, Tr. 736-737).

Response to Finding No. 1112:

This testimony only purports to establish that “salons” carry their own liability insurance as an independently operated business. It does not establish that it was required as part of a master insurance plan. Also, Mr. Nelson provided no testimony that kiosks carry general liability insurance.

1113. Dr. Baumer agreed that the fact that salons offering non-dentists teeth whitening maintain liability insurance could negate some of his objections to salons offering teeth whitening. (Baumer, Tr. 1931).

Response to Finding No. 1113:

This statement misrepresents Dr. Baumer’s testimony by providing an incomplete paraphrase of it. First, Respondent notes that he only testified in the conditional, in response to a hypothetical question. Further, Dr. Baumer noted that this would only address but one of his concerns in a long list: “listed a number of factors that were of concern about non-dentist teeth whitening and one of those factors was the fact that they didn’t have financial backing, they didn’t have insurance, the ways in which dentists do, and then if you tell me, well, that salons are required to be insured, well, that -- that cuts out that particular objection with respect to salons.” (Baumer, Tr. 1931).

1114. Jim Valentine testified that WhiteSmile required its operators to maintain general liability insurance. The WhiteSmile company carries product liability insurance. (Valentine, Tr. 585).

Response to Finding No. 1114:

This statement is overly general and misleading. Mr. Valentine did testify that WhiteSmile required “state owners” to maintain a general liability policy, but explicitly stated that the company did not require salons to carry liability insurance. (Valentine, Tr. 606). The term “state owners” was not ever defined by Mr. Valentine and it is not clear what he meant by his use of that term.

1115. BriteWhite requires its operators to obtain product liability insurance. (Osborn, Tr. 702).

Response to Finding No. 1115:

Ms. Osborn presented no testimony that she required her operators to carry general liability insurance, which typically provides wider coverage than products liability coverage, which generally does not provide coverage for injuries on a business’s premises.

1116. The BriteWhite consent form for teeth whitening in use on April 3, 2006, represented among other things, that the customer was aware that there were a number of possible outcomes from teeth whitening, that a customer affirms that they do not have decayed or loose teeth, and that the customer takes certain steps, such as not drinking coffee for three days after the procedure, to ensure the best possible results. There is no waiver of liability provision in the consent form. (CX0643 at 004).

Response to Finding No. 1116:

While there is no waiver of liability on the form, the form does contain a limitation of liability, which states that the “patient” “agree[s] that the total liability is limited to the amount of the cost for whitening [their] teeth.” (CX0643 at 1-4, 6-20)

10. Any Concern That Non-Dentist Teeth Whitening Operations Are “Fly-by-night” Operations Is Pretextual

1117. Malls are permanent and have reputations to maintain. In explaining how he chooses appropriate candidates for kiosk rental space, Mr. Gibson identified inappropriate uses of mall space by referencing gun sales, sales of gang paraphernalia, eyebrow needle work (or eye threading), or “anything that may . . . bring us more problems than benefits.” (Gibson, Tr. 621-623).

Response to Finding No. 1117:

John Gibson also testified that he would have been willing to lease a kiosk at his malls to a teeth whitening operation if he was assured that it could be done legally, but when he heard that the Board considered it the unlicensed practice of dentistry without a licensed dentist supervising, he was not willing to allow it. (Gibson, Tr. 630-631). A standard provision included in leases with Mr. Gibson’s management company, Hill Story Gibson Companies (“HSG”), is that his tenants be in compliance with the law and carry liability insurance. (Gibson, Tr. 636). Mr. Gibson would not decline a tenant that wanted to lease a kiosk at his mall to provide over-the-counter teeth whitening products. (Gibson, Tr. 633-634).

1118. Mr. Gibson stated that he would have considered teeth whitening an appropriate use for his company’s mall space. HSG would have rented either in-line or specialty (kiosk) space in its North Carolina properties to non-dentist teeth whitening or bleaching services, prior to its receipt of letters from the North Carolina State Board of Dental Examiners addressed to some of its North Carolina malls. (Gibson, Tr. 622-623).

Response to Finding No. 1118:

Respondent refers to its response to Proposed Finding No. 1117.

1119. Sam’s Clubs are permanent and have reputations to maintain. Jim Valentine testified that one of Sam’s Club’s primary considerations in doing business with WhiteSmile was the safety of the WhiteSmile product. (Valentine, Tr. 554).

Response to Finding No. 1119:

Respondent has no specific response.

1120. Dr. Baumer has only anecdotal evidence – based on his wife’s observations – to support his theory that salons are fly-by-night operations that close or turn-over more

frequently than other types of businesses. (Baumer, Tr. 1928). Dr. Baumer has not performed an empirical review to determine whether salons are fly-by-night operations. (Baumer, Tr. 1928).

Response to Finding No. 1120:

This statement misrepresents Dr. Baumer's testimony by clearly misstating multiple aspects of it. He stated that it was his "observation" that kiosks were fly-by-night operations ("I said 'fly-by-night' in referring to the kiosks in malls"), but conceded that this term might be a little strong to describe spas. However, he did maintain that salons have a lot of turnover, which carries a "risk [for] a patient who was a victim of malpractice having no remedy because the vendor was no longer within their jurisdiction." Further, he never limited his anecdotal evidence to his wife's observations, as this statement clearly implies. Complaint Counsel in questioning him during cross-examination did not press him on what other anecdotal evidence he had other than to ask if he had done empirical studies "to determine whether salons close or turn over more frequently than any other type business," to which he stated he had not. (Baumer, Tr. 1928).

1121. Dr. Baumer admits that if evidence showed that salons did not turn over more frequently than other businesses that he would not view them as being fly-by-night. (Baumer, Tr. 1928).

Response to Finding No. 1121:

Respondent does not disagree with this statement.

1122. Dr. Baumer admitted that mall owners have an interest in maintaining their reputations and are unlikely to bring in businesses, such as teeth whitening kiosks, that are going to have a negative impact on their reputations. (Baumer, Tr. 1929; CX0826 at 056 (Baumer, Dep. at 215-216)).

Response to Finding No. 1122:

Respondent does not disagree with this statement.

1123. Dr. Baumer agreed that if Sam's Club allowed non-dentist teeth whitening in its stores it would lessen the risk that consumers using the Sam's Club kiosk would be harmed by a fly-by-night operation. (Baumer, Tr. 1930). The presence of teeth whitening kiosks in places like Sam's Club would militate against a complete ban on non-dentist teeth whitening in North Carolina. (Baumer, Tr. 1930-1931).

Response to Finding No. 1123:

The second sentence is misleading because it omits Dr. Baumer's answer to the previous question, where he stated that "if Sam's Club put its corporate wealth behind this service and that they were holding themselves liable for malpractice or other unethical practices, that would certainly cut in the direction of saying the fly-by-night problem was not as bad in Sam's." (Baumer, Tr. 1930). Further, Complaint Counsel in the final sentence omitted the hypothetical condition that it placed in its question to Dr. Baumer, and also failed to give the entirety of his response stating that this was but one component of his concerns about non-dentist teeth whitening. The question and response as fully set forth in the transcript are as follows:

Q. So that would argue against a complete ban on services if there were some locations where there was less risk of flight or less risk that there would not be a deep pocket at the end of the day in the event of consumer harm; correct?

A. Right. I think we have various components, and that would be one that would militate in that direction, yes.

(Baumer, Tr. 1930-1931).

11. Any Concern That Manufacturers of Non-dentist Teeth Whitening Products Are Unreliable Is Pretextual

1124. Teeth whitening products that contain either carbamide peroxide or hydrogen peroxide are classified as cosmetics by the FDA. (Giniger, Tr. 213, 216, 256; CX0653 at 024, 035-036). Teeth whitening products must comply with FDA requirements for manufacturing controls, quality systems, and labeling for cosmetic products. (CX0532 at 001). In 2009, the ADA petitioned the FDA to change the status of hydrogen peroxide

used in teeth whitening from a cosmetic to a drug, which would require a prescription for Crest Whitestrips and other OTC products. (CX0169 at 001-003; Haywood, Tr. 2510, 2564-2565). The ADA petition is based on faulty science according to numerous sources, and is still pending. (Cf. CX0497 at 001-006 (Dr. Heymann); Haywood, Tr. 2564-2565).

Response to Finding No. 1124:

Respondent disputes this statement of fact to the extent it suggests that teeth whitening is subject to any active regulation by the FDA. As the letter cited above makes clear, because of the current classification of teeth whitening products as a cosmetic, “there is no filing requirement with the FDA.” (CX532 at 1). A recent letter from Robert Eshelman, a member of the OTC Drugs Team at the FDA, indicates that “[v]arious tooth whitening preparations were introduced into the market **without the approval or sanction** of the Food and Drug Administration.” (CX646 at 1) (emphasis added). The letter also states that the FDA is still conducting its review of whether to classify teeth whitening products as cosmetics or “new drugs”, the latter classification of which would be subject filing a New Drug Application and obtaining approval. (CX646 at 1). Because teeth whitening products are currently classified as cosmetics, there is, as noted above in CX532, no filing requirement. Accordingly, compliance with the FDA’s marketing/labeling guidelines is the responsibility of the product’s manufacturer. (CX646 at 1 (“Marketing of such over-the-counter tooth whitening preparation containing carbamide peroxide or hydrogen peroxide as the bleaching ingredient is on the manufacturer’s own responsibility at this time.”)). Accordingly, the only “regulation” to which non-dentist teeth whiteners currently are subject to is essentially self-enforcement guidelines, which arguably at least one in this proceeding has failed to meet. (CX108 at 4 (MSDS sheet states only that its percentage of carbamide peroxide is “proprietary” and does not disclose what other ingredients are in the product)).

Also, Respondent disputes Complaint Counsel's contention that the ADA petition is based on "faulty science" according to "numerous sources." First, Complaint Counsel only provides **one** source for this contention, that of Dr. Heymann (Dr. Haywood did not dispute the ADA petition). Second, Dr. Heymann in his review does not call label the ADA petition "faulty science." He merely states his opinion that some of the claims in the petition are "exaggerated" and that he disagrees with others. (CX0497 at 1). In fact, the very first sentence of the report states that "Overall, I believe this report is well organized and is an accurate assessment of the state of the art with regards to vital tooth bleaching." (CX0497 at 1). Further, he praises Dr. Haywood in his review, calling Dr. Haywood "the **pre-eminent expert** in this field" and states that "In summary, I believe overall this report is an excellent treatise on the state of the art of vital bleaching" and that the ADA "has done well to solicit the input of Dr. Haywood." (CX0497 at 6) (emphasis added).

Additionally, Dr. Heymann echoes Dr. Haywood's concerns about the importance of a dental exam: "I agree with Dr. Haywood's emphasis on the importance of a dental examination coupled with most bleaching treatments, and consider this to be ideal." (CX0497 at 4).

1125. WhiteSmile obtains in teeth whitening products from Da Vinci Systems. Da Vinci Systems sells to both the dental and non-dental community. (Valentine, Tr. 520).

Response to Finding No. 1125:

Respondent has no specific comment.

1126. CX0810 (non-dentist take home product) and CX0806 (dentist take-home product) are both manufactured by Whiter Image and contain the same ingredients. (*Compare CX0810 with CX0806; Giniger, Tr. 203-204*).

Response to Finding No. 1126:

Respondent has no specific comment.

1127. Manufacturers of teeth whitening products are required to supply a MSDS for each product, at the request of any purchaser; in many instances, they are provided along with the product. The MSDS is specifically intended to disclose, to interested persons, product composition, product properties of potential significance, including pH, and other safety-related information. (Giniger, Tr. 218; CX632 at 008).

Response to Finding No. 1127:

One of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product: under the Section labeled "Composition", the MSDS sheet states only that its percentage of carbamide peroxide is "proprietary" and does not disclose what other ingredients are in the product. (CX108 at 4).

1128. Dr. Giniger testified that based on his experience as a formulator and consultant for the formulation of teeth whitening products, the quality of ingredients used in teeth bleaching products by dentists and non-dentists are comparable. (Giniger, Tr. 218; CX632 at 008, 009).

Response to Finding No. 1128:

Respondent disputes this testimony by Dr. Giniger. Dr. Haywood points out that one of the issues with non-dentist teeth bleaching products is that the ingredients of many of the products being put on the market is **not** known. Haywood, Tr. 2572). As noted above, one of the Material Safety Data Sheets provided by Complaint Counsel in this matter **does not disclose** the precise ingredients used in that particular White Science teeth whitening product: under the Section labeled "Composition", the MSDS sheet states only that its percentage of carbamide peroxide is "proprietary" and does not disclose what other ingredients are in the product. (CX108 at 4).

1129. Dr. Giniger also testified that teeth bleaching products used by dentists and non-dentists are typically manufactured in FDA approved labs, often by the same manufacturers, using food-safe ingredients. (Giniger Tr. 218; CX632 at 009; *compare*

CX0810 (nondentist teeth whitening product) *with* CX0806 (dentist teeth whitening product) (both products are manufactured by the same company - Whiter Image - and contain the same ingredients)).

Response to Finding No. 1129:

Respondent has no specific comment.

12. Any Concerns Related to the Collection and Sale of Medical Information (HIPAA) Are Unfounded

1130. Dr. Baumer admits that his sole basis for contending that non-dentists could be collecting dental information and, because they are not bound by HIPAA, may be tempted to sell that information comes from Respondent's Counsel and Respondent's briefs. (Baumer, Tr. 1721, 1951-1952, 1955). Dr. Baumer admits that he has no evidence of non-dentist providers of teeth whitening selling medical information. (Baumer, Tr. 1956).

Response to Finding No. 1130:

Respondent has no specific comment.

1131. Dr. Baumer claims that non-dentist teeth whiteners ask for medical information or medical-type information from a prospective client, and that this information is not subject to the same confidentiality protections as in the medical profession. Dr. Baumer cites no evidence that non-dentist teeth whiteners have improperly disclosed confidential medical information. Even if this were true, information gathering is not inherent to the teeth whitening service and could be solved through state statutes or regulations requiring confidentiality of such information. (Kwoka, Tr. 1058-1059).

Response to Finding No. 1131:

Dr. Kwoka's testimony that "information gathering is not inherent to the teeth whitening service" is contradicted by the testimony of the Ms. Osborn, the President of the teeth whitening industry's trade group that issues the practice guidelines for the industry (the Council for Cosmetic Teeth Whitening). She testified that she formerly required that her local affiliates provide a consent form to customers purchasing teeth whitening services, but she has reconfigured the form as an "information form" about her teeth whitening products. The current information form requests personally identifying information

regarding her customers. This information is kept on file in an unlocked cabinet at her office in Alabama. (Osborn, Tr. 665, 702-703, 708-709).

1132. Without any foundation, Board witnesses wildly asserted their concern for "HIPAA" (Health Information Portability and Accountability Act) privacy violations, alleging that the non-dentist teeth whitening operators were collecting medical information and selling it on the open market. The record is devoid of any evidence that this has occurred, and in fact, witnesses testified that no such information is gathered, let alone sold. (Nelson, Tr. 824; Valentine, Tr. 594; Wyant, Tr. 912-913 ("My understanding of HIPAA is that it relates to healthcare records and documents. We did not have anything to do with healthcare records and documents.")).

Response to Finding No. 1132:

Respondent objects to the inaccurate and needlessly dramatic language in this statement (e.g., "wildly asserted"). Board members did not lack "foundation" for this statement.

Because of their experience as Board members in regulating unlicensed non-dentist teeth whiteners, they testified as to their concerns that the teeth whiteners would not be subject to HIPAA and may be tempted to sell such information on the open market.

G. The Only Board Witness Who Testified About Purported Harm Due to Non-Dentist Teeth Whitening Was Not Harmed by Non-Dentist Teeth Whitening

1133. On April 11, 2008, Mr. Brian K. Runsick filed a notarized complaint with the Board. In the complaint, Mr. Runsick related his experience undergoing and following non-dental teeth whitening on February 17, 2008 at a BleachBright kiosk in Crabtree Valley Mall. Joe Willet owned this teeth whitening establishment. Immediately following the procedure, Mr. Runsick was satisfied with his experience. (CX0055 at 001-004).

Response to Finding No. 1133:

Respondent has no specific response.

1134. In Mr. Brian Runsick's April 11, 2008 complaint to the Board, he stated that his gums began to hurt on February 21, 2008, four days after undergoing non-dental teeth whitening. He boarded a cruise ship on February 23, 2008 and did not seek medical attention until February 26, 2008. During this time Mr. Runsick self-treated his conditions of gum bleeding, deterioration, and pain by brushing thrice per day, rinsing

with mouthwash, and taking 800 mg of Motrin. The cruise ship doctor made an appointment for him on February 27, 2008 with a dentist in Mexico the next day. The dentist applied a gel to facilitate healing, but Mr. Runsick's condition only worsened over the next day. At this time, February 28, 2008, he started a course of Zythromax and "was 80% better" in 24 hours. Nine days following completion of his Zythromax course while in Myrtle Beach, South Carolina, Mr. Runsick's symptoms returned so he visited an urgent care facility and was prescribed a second Zythromax course. Following this course, Mr. Runsick's symptoms subsided except what he referred to as "permanent damage to my gums on my lower teeth." (CX0055 at 001-004).

Response to Finding No. 1134:

Respondent has no specific response.

1135. Dr. Tilley conducted a physical examination of Mr. Runsick's mouth, took intraoral photographs, may have taken X-rays, and may have made an impression of his teeth and gums. (CX0580 at 022 (Tilley, Dep. at 78-79)).

Response to Finding No. 1135:

Respondent has no specific response.

1136. Upon examination Dr. Tilley found that Mr. Runsick's maxillary and mandibular teeth and gum tissue were in generally good condition. (Tilley, Tr. 2076-2077).

Response to Finding No. 1136:

Respondent has no specific response.

1137. Upon examination Dr. Tilley found that Mr. Runsick's gums were within normal ranges, notwithstanding an incomplete filling of his interdental space. (Tilley, Tr. 2078-2079).

Response to Finding No. 1137:

Respondent has no specific response.

1138. Dr. Tilley had no baseline information about Mr. Runsick's gums and their height prior to his having his teeth bleached. (Tilley, Tr. 2079).

Response to Finding No. 1138:

Respondent has no specific response.

1139. Dr. Tilley found that Runsick had a healthy mouth with tartar present. The gum tissue was pink, stippled, and firm. Runsick was concerned about tissue height, but Dr.

Tilley was not concerned as the gum tissue height was within the limits of normal. (CX0580 at 023 (Tilley, Dep. at 82-85)).

Response to Finding No. 1139:

Respondent has no specific response.

1140. Dr. Tilley testified that it was not clinically significant if Runsick's gums between three of his lower teeth had deteriorated approximately 1/8 inch; the main significance was cosmetic. Dr. Tilley thought any lost tissue in the interdental space would substantially regenerate, filling in about 90% of the space. (CX0580 at 030-031 (Tilley, Dep. at 113-115)).

Response to Finding No. 1140:

Respondent has no specific response.

1141. The lack of a complete filling of the interdental space between Runsick's number 23 and 24 teeth could be the result of a congenital condition, or the result of an infection either prior to or secondary to an abscess. (CX0580 at 035 (Tilley, Dep. at 130-131)).

Response to Finding No. 1141:

Respondent disputes this proposed finding of fact as a mischaracterization of Dr. Tilley's testimony. Dr. Tilley testified at the hearing that there was no evidence of a periodontal or periapical abscess. (Tilley, Tr. at 2022, 2040).

1142. Infections, abscesses, and periodontal disease can cause gums to bleed. (Tilley, Tr. 2087-88).

Response to Finding No. 1142:

Respondent has no specific response.

1143. Mr. Runsick had supragingival tartar between all mandibular incisors, suggesting a prior absence of good dental care. Tartar on teeth leads to periodontitis which can then lead to periodontal disease. Removing the supragingival tartar will improve the health of the tissue. (CX0580 at 035 (Tilley, Dep. at 131-133)).

Response to Finding No. 1143:

Respondent disputes this proposed finding of fact as a containing an assumption and as a misrepresentation of Dr. Tilley's complete testimony. Dr. Tilley testified that he

included the information about the tartar in his observations to the Board because removal of the tartar prior to whitening was part of the standard of care that would have been followed in his office prior to teeth whitening. (Tilley, Tr. at 2081).

1144. Mr. Runsick gargled regularly with Listerine, which is 26% alcohol and can increase sensitivity. Aggressive brushing of the teeth and gums can possibly exacerbate any dental condition. (Tilley, Tr. 2083-2084).

Response to Finding No. 1144:

Respondent disputes this proposed finding of fact as a mischaracterization of the entire record. Dr. Tilley testified in particular in regard to someone who suffered a chemical burn to their gingival, brushing their teeth three times a day would most likely not significantly aggravate their condition. (RX73 (Tilley, Dep. at 117)).

1145. Dr. Tilley is not aware of any literature indicating that commercially available teethwhitening products can result in destruction of blood vessels. (CX0580 at 028 (Tilley, Dep. at 102)). Dr. Tilley does not recall hearing, nor is he aware of any report, of a chemical burn incident so severe that tissue was sloughed, but with days passing between the incident and the sloughing. (CX0580 at 032 (Tilley, Dep. at 118)).

Response to Finding No. 1145:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Dr. Tilley's testimony was that he was not aware of any literature regarding the destruction of blood vessels by commercially-available teeth-whitening products, but he testified that that it was something that dentists were aware of occurring (CX580 (Tilley, Dep. at 102)). Also, Dr Tilley testified that it was possible for a severe chemical burn to cause the skin to slough off four days later although he doesn't know whether he has ever heard of such an incident. (CX580 (Tilley, Dep. at 118)).

1146. During his non-dental teeth whitening procedure (while the tray was in his mouth and the light was on), Mr. Runsick did not experience any discomfort. (CX0579 at 015-016 (Runsick, Dep. at 53-54)).

Response to Finding No. 1146:

Respondent has no specific response.

1147. Upon completion of his non-dental teeth whitening procedure, Mr. Runsick's teeth were three to four shades lighter. "I was pretty happy at this point. I don't recall anything other than that and paying the bill." (CX0579 at 016 (Runsick, Dep. at 55)).

Response to Finding No. 1147:

Respondent has no specific response.

1148. Although Mr. Runsick made reference to possible permanent damage in his deposition while referring to documents from 2008, he proceeded to admit that his "gums are back to almost normal," and that he has had no lasting effects. (CX0579 at 019 (Runsick, Dep. at 66)). He testified that any gum loss he experienced was not permanent; "most of it is back and not noticeable to the eye." (Runsick, Tr. 2135-2136).

Response to Finding No. 1148:

Respondent disputes this proposed finding of fact as it contains an assumption. Mr.

Runsick's testimony at his deposition and the hearing related to his condition at that point in time. Further, Mr. Runsick's did not testify that his gum loss was not permanent; he testified that Dr. Tilley told him that it was hard to tell if the gum loss would be permanent. (Runsick, Tr. at 2135-2136).

1149. Dr. Giniger also assessed a complaint filed with the Board by Mr. Runsick, and concluded that Mr. Runsick's claimed injuries could not have been caused by chemical burn from non-dentist teeth bleaching. (Giniger, Tr. 274-276, 337-338; CX0653 at 045).

Response to Finding No. 1149:

Respondent disputes this proposed finding of fact as a statement of opinion rather than fact.

1150. Mr. Runsick reported that four days elapsed between his non-dentist provided teeth bleaching and the first appearance of any adverse symptoms. Dr. Giniger explained that there is no plausible mechanism by which a chemical burn from exposure to a bleaching agent could produce no discernible symptoms for more than three days, only becoming symptomatic on the fourth. (Giniger, Tr. 270-274).

Response to Finding No. 1150:

Respondent disputes this proposed finding of fact as a statement of opinion rather than fact.

1151. Other explanations for Mr. Runsick's claimed symptoms are, however, plausible. For example, Dr. Tilley, who had been engaged by the Board some time later to examine and report on Mr. Runsick's condition, found his teeth and gum tissue to be stippled and in "generally good condition." But Dr. Tilley observed that tartar build-up and that the tissue between two of Mr. Runsick's teeth "did not completely fill the interdental space (which is the triangular tissue that descends between two teeth)." (CX0327 at 001). Those latter findings are consistent with periodontal disease. (Giniger, Tr. 273-276; CX0653 at 045).

Response to Finding No. 1151:

Respondent disputes this proposed finding of fact as a statement of opinion and not fact in regards to Dr. Giniger's observations.

1152. Given Dr. Tilley's observations and Mr. Runsick's descriptions, the more likely cause is that Mr. Runsick suffered from a periodontal abscess that occurred within a few days of his teeth bleaching. Indeed, Mr. Runsick may have worsened his condition in his effort to remedy it with constant teeth brushing and other attempted therapies. (Giniger, Tr. 273-276; 492; Tilley, Tr. 2084; CX0653 at 045).

Response to Finding No. 1152:

Respondent disputes this proposed finding of fact as a statement of opinion rather than of fact.

1153. Dr. Tilley testified that there are "other conditions that can cause the gum tissue to bleed other than hydrogen peroxide" including holding an aspirin against the cheek or gums and periodontal disease. (Tilley, Tr. 2093-2094).

Response to Finding No. 1153:

Respondent has no specific response.

1154. In sum, Mr. Runsick's questionable claim, and the lack of similar complaints, shows that anecdotal claims of harm are of little value when assessing the harm from a procedure without generally accepted follow-up procedures. Even more importantly, such anecdotes cannot be a substitute for reliable clinical or empirical evidence about a product's safety and efficacy. (Giniger, Tr. 278-279).

Response to Finding No. 1154:

Respondent disputes this proposed finding of fact as a statement of opinion, not fact.

Further, in regards to anecdotal claims, Mr. Runsick's condition was treated by a dentist in Mexico and evaluated by a dentist at the request of the Board. (CX327 at 1; CX55 at 3).

1155. Mr. Runsick received a document disclosing information before electing to undergo nondental teeth whitening. (Runsick, Tr. 2140).

Response to Finding No. 1155:

Respondent disputes this proposed finding of fact as containing an assumption as to the contents of the information provided to Mr. Runsick prior to the teeth whitening procedure. Mr. Runsick testified that he could not recall the contents of the document. (Runsick, Tr. at 2140-2141).

1156. No one at the non-dental teeth whitening kiosk told to Mr. Runsick that he or she was a dentist, dental hygienist, or a dental assistant. (CX0579 at 016-017 (Runsick, Dep. at 57-58)).

Response to Finding No. 1156:

Respondent disputes this proposed finding of fact as containing an assumption an incomplete statement of fact. Mr. Runsick testified that he believed he was paying for a service from someone who was "medically trained," and the appearance of the kiosks facility (dental chairs) and personnel (dressed in scrubs) conveyed that impression. (Runsick, Tr. at 2145-2146).

1157. Mr. Runsick's signature was required on a form before he was allowed to undergo his non-dental teeth whitening procedure. Regarding the form, he "might have read a few details of it, but I can't recall exactly if I read it or how much of it I read." (CX0579 at 016 (Runsick, Dep. at 56-57)).

Response to Finding No. 1157:

Respondent has no specific response.

1158. In approximately April 2008, Dr. Alec Parker, executive director of the North Carolina Dental Society ("NCDS"), received two calls from Mr. Runsick regarding issues with a non-dental teeth whitening procedure Mr. Runsick had undergone. (CX0578 at 051-052 (Parker, Dep. at 197-198)).

Response to Finding No. 1158:

Respondent has no specific response except to object to the characterization of this proposed finding of fact as supportive of showing that Mr. Runsick was not harmed by his teeth whitening experience.

1159. During Dr. Parker's first conversation with Mr. Runsick, Mr. Runsick explained his experience undergoing a non-dental teeth whitening procedure and, several days later, enduring oral pain and sensitivity to such a degree that it compromised his ability to enjoy the vacation he had taken. He then expressed his desire to tell the public about his experience. Finally, he requested assistance from the NCDS. Dr. Parker explained that the issue was not under the purview of the NCDS, but that regulatory bodies may be interested, including the Board. (CX0578 at 052-053, 055 (Parker, Dep. at 199-203, 211)).

Response to Finding No. 1159:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Dr. Parker testified that Mr. Runsick described his condition as follows: his mouth was burned, the tissue sloughed, and he was in a great deal of pain. (CX578 (Parker, Dep. at 200)). Further, in support of this proposed finding of fact, Complaint Counsel did not cite to any designated testimony regarding communication with regulatory bodies other than the Board. (CX578 (Parker, Dep. at 199-203)).

1160. The NCDS maintains an annual public relations budget of approximately \$300,000, which is managed by Mr. Mike Hoyt of Hoyt & Hamilton. Mr. Hoyt reports directly to Dr. Parker. (CX0578 at 029, 030 (Parker, Dep. at 109, 111)).

Response to Finding No. 1160:

Respondent has no specific response except to object to the characterization of this proposed finding of fact as supportive of showing that Mr. Runsick was not harmed by his teeth whitening experience.

1161. On April 14, 2008, Dr. Parker introduced Mr. Runsick to Mr. Hoyt and informed him that Mr. Hoyt might be able to provide some media contacts. (CX0166 at 001; CX0578 at 054 (Parker, Dep. at 206-208)).

Response to Finding No. 1161:

Respondent disputes this proposed finding of fact as containing an assumption and as to the use of "introduced" as an undefined term.

1162. Prior to introducing Mr. Runsick to Mr. Hoyt on April 14, 2008, Dr. Parker told Mr. Hoyt about Mr. Runsick, and that Mr. Runsick wanted to tell the public his story in their service. (CX0578 at 056 (Parker, Dep. at 215-216)).

Response to Finding No. 1162:

Respondent disputes this proposed find of fact based of the ambiguous and undefined phrase "in their service." Respondent also objects to the characterization of this proposed finding of fact as supportive of showing that Mr. Runsick was not harmed by his teeth whitening experience.

1163. Mr. Runsick spoke with Channel 5 News on approximately May 21, 2008, at which time he reportedly said that after his teeth were bleached, "[e]verything was fine until about five days later when, while on a cruise, his gums became sore." (Runsick, Tr. 2166-2167; CX0117). Yet Mr. Runsick testified at trial that pain and swelling began within two to three days after bleaching, and that the pain may have preceded the swelling. (Runsick, Tr. 2150). Mr. Runsick later testified that he may have had minor pain on or before the second day after the bleaching, and pain may have become excessive five days after the bleaching. (Runsick, Tr. 2166-2167). Mr. Runsick then testified that the reporter may have been correct, and he did not have any pain until five days after the bleaching. (Runsick, Tr. 2168). During his testimony Mr. Runsick finally agreed with his complaint to the Board that he presented no symptoms whatsoever until February 21, 2008, four days after he underwent non-dental teeth whitening. (Runsick, Tr. 2171-2172; CX0055).

Response to Finding No. 1163:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. The citations to Mr. Runsick's testimony in this proposed finding of fact all relate to one line of questioning about a Channel 5 News report about his experience. (Runsick, Tr. 2166-2167, 2150, 2166-2167, 2168, 2171-2172). This entire line of questioning is based on a misrepresentation made during the hearing, and in the first sentence of this proposed finding of fact, that the statement attributed to Mr. Runsick is a direct quotation of what he said to the reporter. An examination of the exhibit offered in support of this proposed finding of fact plainly shows that while other statements by Mr. Runsick are contained within quotation marks, the statement regarding the onset of his pain five days later is not. (CX117 at 1). Further, Mr. Runsick's notarized complaint to the Board averred that his gums began to hurt four days after the teeth whitening procedure was performed. (CX55 at 3).

1164. Dr. Parker was interviewed by Monica Laliberte in connection with Mr. Runsick's story. This is likely the name Mr. Runsick intended rather than Monica Lewinsky. (Runsick, Tr. 2165). Dr. Parker conveyed reservations regarding general health and safety similar to those he expressed in a March 15, 2008 News & Observer article. He also expressed that non-dentist teeth whitening provisions ought to be regulated. (CX0163 at 001-002; CX0578 at 054-055 (Parker, Dep. at 209-210)).

Response to Finding No. 1164:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. Respondent does not dispute that Mr. Runsick and Dr. Parker testified regarding an interview with Ms. Laliberte. However, Dr. Parker's testimony cited by Complaint Counsel in support of this proposed finding of fact was directed to the actual interview that he did with Ms. Laliberte – he did not characterize it as being similar to the News and Observer interview cited as an exhibit to this proposed finding of fact. (CX578 (Parker, Dep. at 209-210); (CX163 at 1-2).

H. Other Allegations of Consumer Harm Raise Questions of Credibility and Causation

1. Patient X

1165. On February 20, 2008, Dr. Michael Hasson submitted a practitioner complaint form to the Board against Port City Tanning. The complaint regarded a patient (hereafter "Patient X" to protect sensitive health information) who had recently visited Port City Tanning. The patient presented with mucosal ulcers and, potentially, permanent nerve damage. (CX0476 at 001-003).

Response to Finding No. 1165:

Respondent has no specific response.

1166. Dr. Hasson examined Patient X for the first and only time on February 19, 2008. Prior to this, Dr. Hasson had never seen Patient X or had any contact with her. (CX0575 at 012 (Hasson, Dep. at 40-41)).

Response to Finding No. 1166:

Respondent has no specific response.

1167. Dr. Hasson had never seen any dental records of Patient X. (CX0575 at 016 (Hasson, Dep. at 56-57)).

Response to Finding No. 1167:

Respondent has no specific response.

1168. Patient X claimed that she underwent a non-dental teeth whitening procedure at a tanning salon two days prior to visiting Dr. Hasson, and that she had soreness in her mouth with ulcers. (CX0575 at 015 (Hasson, Dep. at 53)).

Response to Finding No. 1168:

Respondent has no specific response.

1169. Dr. Hasson does not know what type light, whitening gel, or chemical agent was used at the tanning salon for Patient X's non-dental teeth whitening procedure. (CX0575 at 018, 023 (Hasson, Dep. at 62-63, 85)).

Response to Finding No. 1169:

Respondent disputes this proposed finding of fact as containing an assumption. Dr. Hasson testified that gathering such information was not what he “was tasked to do;” rather, his job was to treat the patient instead of investigating what was done at the salon. (RX71 (Hasson, Dep. at 64). One of the Board’s investigators testified that he conducted an investigation of this tanning salon to find out what their procedures were for bleaching. (RX21 (Kurdys, Dep. at 59)).

1170. During his February 19, 2008 examination of Patient X, Dr. Hasson determined that she had bone loss, including about 50% bone loss around her wisdom teeth, which is serious and indicative of infection. (CX0575 at 015-016 (Hasson, Dep. at 53-54)).

Response to Finding No. 1170:

Respondent disputes this proposed finding of fact as creating an assumption and as a mischaracterization of the record. Dr. Hasson also testified that Patient X did not have an infection in the area where the ulcers were present. (RX71 (Hasson, Dep. at 70)). He testified that she had ulceration, she had inflammation – “you can have inflammation without infection.” (CX71 (Hasson, Dep. at 70)).

1171. During his February 19, 2008 examination of Patient X, Dr. Hasson found she also had missing teeth, teeth out of position, teeth which had root canals, and teeth which had crowns. (CX0575 at 015-016 (Hasson, Dep. at 53-54)). Teeth out of position can make them “impossible to clean adequately” and can lead to contact fractures of the teeth. (CX0575 at 020 (Hasson, Dep. at 72-73)).

Response to Finding No. 1171:

Respondent notes that dentists have testified in this proceeding that some of these conditions would be contraindications to proceeding with teeth whitening – if the person had consulted a dentist first. (RX62 (Hardesty, IHT at 13-17); RX66 (Owens, Dep. at 113-115); RX73 (Tilley, Dep. at 20-22)).

1172. During his February 19, 2008 examination of Patient X, Dr. Hasson found she had teeth that were moving more than they should, which is associated with bone loss, not teeth whitening. (CX0575 at 019 (Hasson, Dep. at 68)).

Response to Finding No. 1172:

Respondent has no specific response.

1173. During his February 19, 2008 examination of Patient X, Dr. Hasson found her gums presenting inflammation and bleeding when probed, indicative of chronic infection not caused by teeth whitening. (CX0575 at 019 (Hasson, Dep. at 66-69)). Inflammation can be caused by infection or blunt trauma. (CX0575 at 020 (Hasson, Dep. at 70)).

Response to Finding No. 1173:

Respondent disputes this proposed finding of fact as creating an assumption and as a mischaracterization of the record. Dr. Hasson specifically did not attribute the bleeding that he observed upon probing to the bleaching two days earlier. (RX71 (Hasson, Dep. at 69)). Dr. Hasson also testified that Patient X did not have an infection in the area where the ulcers were present. (RX71 (Hasson, Dep. at 70)). He testified that she had ulceration, she had inflammation – “you can have inflammation without infection.” (CX71 (Hasson, Dep. at 70)).

1174. Dr. Hasson stated that ulcers can be caused by autoimmune reactions, viruses, or chemical or thermal reactions. (CX0575 at 017 (Hasson, Dep. at 60)). Dr. Hasson's patient records indicate Patient X used tobacco, but Dr. Hasson does not know whether she smoked tobacco or chewed it. (CX0575 at 021 (Hasson, Dep. at 76)). Any tobacco use by Patient X would increase the inflammatory state in her mouth, thereby retarding the healing of any oral injury. (CX0575 at 017 (Hasson, Dep. at 61)).

Response to Finding No. 1174:

Respondent disputes this proposed finding of fact as containing an assumption as to the of tobacco use of Patient X retarding the healing process for the ulcers in her mouth. Dr. Hasson testified that his patient reported to him that she visited the tanning salon two days prior to her appointment with him. (RX71 (Hasson, Dep. at 60)).

1175. In review of his February 19, 2008 examination of Patient X, Dr. Hasson found Patient X presenting the following dental conditions: bone loss, missing teeth, teeth moving more than ordinary, teeth out of position, inflammation, bleeding when probed, ulcers, soreness, and evidence of root canals and crowns. Many of these indicated infection, and Patient X's noted tobacco use would only exacerbate her inflammation and ostensible infection. (CX0476 at 002, 004; CX0575 at 015-016, 018-021, 023 (Hasson, Dep. at 53-54, 62-63, 66-69, 72-73, 76, 85)).

Response to Finding No. 1175:

Respondent has no specific response.

1176. Dr. Hasson referred Patient X to a general dentist, Dr. Plasky, "who could actually speak with a higher level of expertise regarding her long term care." (CX0575 at 024; (Hasson, Dep. at 87)). Dr. Plasky had greater experience with teeth whitening, including more extensive training on the procedure in dental school. (CX0575 at 024 (Hasson, Dep. at 88-89)).

Response to Finding No. 1176:

Respondent disputes this proposed finding of fact as a misrepresentation of Dr. Hasson's testimony. In the testimony cited by Complaint Counsel in support of this proposed finding of fact, Dr. Hasson did not testify that Dr. Plasky had greater experience with teeth whitening; he testified that she would have had greater experience in teeth whitening in dental school since she was a relatively recent graduate esthetic dentistry is a bigger part of the curriculum now than when he graduated from dental school 40 years ago. (CX575 (Hasson, Dept. at 88)).

1177. There have been four complaints made by patients against Dr. Hasson at the North Carolina State Board of Dental Examiners during the last five years. Only one had been resolved at the time of his deposition, and three were still pending. Dr. Hasson claimed he could not remember what the resolved case was about, and he refused to answer questions about the three cases that were still pending and the delay in resolution of the three pending cases. (CX0575 at 028-030 (Hasson, Dep. at 102-111)).

Response to Finding No. 1177:

Respondent objects to this proposed finding of fact as it contains an assumption and a mischaracterization of the record. Dr. Hasson did not refuse to answer questions about

pending cases; his attorney put an end to Complaint Counsel's line of questioning with the statement, "[w]e won't talk about things that are pending." (CX575 (Hasson, Dep. at 104).

2. Patient Y

1178. On July 10, 2008, a gentleman (hereafter "Mr. Y" to protect sensitive health information-Mr. Y's wife complained to the Board regarding non-dentist teeth whitening) sent an email to Carolin Bakewell describing a condition on his wife's (hereafter "Mrs. Y" to protect sensitive health information) lip that appeared after having her teeth whitened at Lite Brite in Greenville, North Carolina. A dentist could not connect the problem from which Mrs. Y was suffering to its cause, whatever it may be. (CX0517 at 001). Mrs. Y filed an earlier complaint with the Board on June 3, 2008. (CX0462 at 001, 003).

Response to Finding No. 1178:

Respondent disputes this proposed finding of fact as incomplete and as a mischaracterization and misrepresentation of the record. Mr. Y described the "condition" as a "burn or reaction to the inner part of her lip – not the gum line." (CX517 at 1). Mrs. Y contact the company and was told that this was a normal reaction. (CX517 at 1). Mr. Y stated that the dentist that his wife consulted would not give her a direct explanation of the cause – not that he could not. (CX517 at 1). Finally, Mrs. Y had not filed an earlier complaint with the Board on June 3, 2008; that complaint was filed by a different consumer, Ms. Z, who reported an injury (blisters inside her upper and lower lips) received from a teeth whitening session at the same mall kiosk in Colonial Mall. (CX462 at 3; RX1-2).

1179. In his July 10, 2008 e-mail to Ms. Bakewell, Mr. Y asked her for information about licensing and guidelines for non-dental teeth whitening providers. Ms. Bakewell responded that "[t]he N.C. State Board of Dental Examiners does not license whitening salons or spas, as our authority is generally limited to the conduct of dentists and hygienists. . . ." She added, "I cannot offer you an opinion regarding whether the business your wife dealt with is engaged in the unauthorized practice of dentistry." (CX0517 at 001).

Response to Finding No. 1179:

Respondent disputes this proposed finding of fact as incomplete and as containing an assumption that Ms. Bakewell did not offer any assistance to Mr. Y. Ms. Bakewell also suggested that Mr. Y could contact an attorney if he wished to pursue a legal claim against the business; she also suggested that he could complaint to the Consumer Protection Division of the North Carolina Attorney General's Office. (CX517 at 1).

1180. In her August 12, 2010 "Open Investigative Files Memorandum" to Dr. Owens, Ms. Friddle describes a complaint received June 3, 2008 from a consumer, Mrs. Y, wife of Mr. Y, who claimed injury resultant from non-dental teeth whitening provision at Lite Brite, a kiosk in Colonial Mall in Greenville, North Carolina. In response to Mrs. Y's complaint the Board sent a Cease and Desist Order July 17, 2008. (CX0462 at 001, 003). Mr. Y later complained about the same business. (CX0517 at 001).

Response to Finding No. 1180:

Respondent disputes this proposed finding of fact as incomplete and as blatantly misrepresenting the record. Ms. Friddle's memorandum actually referred to a complaint from Ms. Z, an entirely different consumer from Mrs. Y, who reported an injury received from a teeth whitening session at the same mall kiosk in Colonial Mall. (CX462 at 3; RX1-2). Ms. Z reported her injury to the Board on June 3, 2008. (RX17 at 2). Mr. Y reported his wife's experience at the same kiosk on July 10, 2008. (RX17 at 1). The cease and desist letter of July 17, 2008 was actually sent following the Board's receipt of both complaints. (CX462 at 3; RX17 at 1-2).

I. The Board Has No Evidence of Consumer Protection Problems Associated with Non-dentist Teeth Whitening in North Carolina

1181. Without any foundation, the Board has claimed that non-dentist teeth whiteners deceive customers into believing that the teeth whitening is being performed by a dentist or other health care professional. The Board admits that it has no basis for this allegation. (Response to RFA 29).

Response to Finding No. 1181:

Respondent objects to Complaint Counsel's mischaracterization of Respondent's Response to RFA 29. Respondent admitted that it was not aware of any complaint by a consumer of non-dental teeth whitening services to the State Board or to another consumer protection agency in North Carolina, in which the complainant alleged that he or she believed or was led to believe that the services were being provided by a dentist. However, Respondent did not admit that there is no basis for its statement that non-dentist teeth whiteners may give the illusion that they are dentists who possess the knowledge of a dental professional about teeth whitening. Indeed, Respondent's expert witness—Dr. Haywood—testified that he formed an opinion, based on his observations and his conversations, that non-dentists who perform teeth whitening are presenting themselves as health care professionals. (Haywood, Tr. 2403, 2473-74, 2646-47.)

1182. Such deception is extremely unlikely. The operators typically provide disclosure material to their customers which state both that the operator is not a dentist, that the operator is not making any diagnosis, and that the customer should see a dentist if he/she has any dental concerns before undergoing whitening. (CX0643 at 001; Giniger, Tr. 360; Valentine, Tr. 545-546).

Response to Finding No. 1182:

This is an opinion, and not a statement of fact. Furthermore, Complaint Counsel blatantly misrepresents CX0643—the consent form for BriteWhite teeth whitening—which: (1) does not provide that the operator is not a dentist; (2) does not provide that the operator is not making any diagnosis; and (3) does not provide that the customer should see a dentist if he or she has dental concerns before undergoing whitening. Respondent objects to Complaint Counsel's reliance on Giniger, Tr. 360 and Valentine, Tr. 545-46 in support of this Proposed Finding of Fact because it is hearsay. Respondent objects to the

mischaracterization of Giniger, Tr. 360, who only indicates that consumers are asked a short series of unknown questions to determine if they should proceed with teeth whitening. Respondent objects to the mischaracterization of Valentine, Tr. 545-46, who indicates that consumers were told that the operators were not dental professionals but did not indicate whether consumers were told that the operator is not making any diagnosis or whether the consumer should see a dentist before undergoing treatment.

1183. Dr. Giniger testified persuasively that there is no evidence that consumers of non-dentist teeth bleaching establishments mistakenly believe that the operators are dentists. Dr. Giniger also testified persuasively that common sense suggests that consumers who enter a non-dentist teeth whitening establishment at a mall or cruise ship understand that they are not being treated by a dentist. (Giniger, Tr. 348).

Response to Finding No. 1183:

This is an opinion, and not a statement of fact. Respondent objects to the mischaracterization of Giniger, Tr. 348. He did not testify that there is no evidence of consumer confusion; he testified that he is not aware of customer confusion.

Furthermore, Giniger did not testify that "common sense suggests" that consumers are not confused; he testified, "I think that people generally know" that they are not being treated by dentists in teeth whitening kiosks in malls or cruise ships, without giving any basis for this opinion.

1184. In contrast, Dr. Haywood raises "concerns" about consumer confusion, but admits that he has not studied the issue and can provide no evidence to that effect. (Haywood, Tr. 2745).

Response to Finding No. 1184:

Respondent incorporates by reference its responses to Finding No. 1181-83. Respondent objects to the mischaracterization of Haywood, Tr. 2745, which only indicates that Dr.

Haywood has not studied whether consumers are confused or deceived by what they see in non-dental teeth-bleaching establishments.

1185. There is substantial evidence that non-dentist providers of teeth bleaching products work carefully to avoid consumer confusion. For example, literature provided to consumers by operators of non-dentist teeth whitening facilities clearly state that the operators are not dentists. Furthermore, manufacturers of non-dentist bleaching materials provide literature and training instructing retailers not to pass themselves off as dentists. (Giniger, Tr. 348-352; CX0632 at 022; CX0637 at 001,006-012).

Response to Finding No. 1185:

This is an opinion, and not a statement of fact. Respondent objects to Complaint

Counsel's reliance on CX0632 in support of this Proposed Finding of Fact because it is hearsay.

1186. Manufacturers of non-dentist teeth bleaching products also provide directions to retail businesses to avoid consumer confusion. For example, BleachBright Corporation directs retail businesses that purchase the BleachBright system and products to: (1) never try to pass yourself off as a dentist; (2) never offer advice or opinions to customers about their oral health; (3) cosmetic teeth whitening should only be purchased by clients with healthy teeth and gums; (4) any abnormal condition raised by a client should be immediately referred to a dentist for further evaluation; (5) if potential customer has any questions about the effects of these products on their teeth or existing dental work, they should be referred to their dentist to have their questions answered or concerns addressed; and (6) if in doubt, send the consumer to a dentist. (CX0637 at 001, 006; Giniger, Tr. 350-352; CX0632 at 023).

Response to Finding No. 1186:

Respondent has no specific comment.

1187. Cosmetologists and estheticians - anyone that touched skin - have historically been trained to wear white lab coats. Ms. Osborn testified that wearing a white lab coat "definitely does not indicate that you have a title." (Osborn, Tr. 710-711).

Response to Finding No. 1187:

Respondent objects to the mischaracterization of Osborn, Tr. 710-11, in which Osborn testified that she has "no idea" if employees working in spas and for her affiliates wear white lab coats. Furthermore, Osborn testified that, where she went to school, she was

taught to wear white; she said nothing about being taught to wear a white lab coat.

Osborn testified that "wearing a specific color does not definitely indicate that you have a title;" she said nothing about whether wearing a white lab coat indicates the existence of a particular title.

1188. The Board is not aware of any complaint by a consumer that he or she was misled into thinking that the non-dentist performing the teeth whitening was in fact a dentist. (Response to RFA 29; CX0566 at 029 (Hardesty, IHT at 112); White, Tr. 2307-2308).

Response to Finding No. 1188:

Respondent has no specific comment.

1189. The Board is not aware of any complaint by a consumer of non-dentist teeth whitening services that he or she believed that the services were being provided by a dentist. (Response to RFA 29).

Response to Finding No. 1189:

Respondent has no specific comment.

1190. Dr. Baumer admits that he does not have any evidence that non-dentist dress in medical garb in a way that deceives customers other than from Respondent's Counsel and Respondent's pleadings. (Baumer, Tr. 1935). Dr. Baumer also addressed the issue because Professor Kwoka discussed the issue in his report in response to Respondent's pleadings. (Baumer, Tr. 1934-1936).

Response to Finding No. 1190:

Respondent has no specific comment.

1191. Dr. Baumer provides no evidence in his report that consumers have been confused into believing that non-dentists teeth whiteners are medical professionals. (Kwoka, Tr. 1086).

Response to Finding No. 1191:

Respondent has no specific comment.

1192. Dr. Baumer was unaware that there have been no complaints to the Board that any customers have been misled by non-dentist teeth whiteners appearing to be dentists. (Baumer, Tr. 1951).

Response to Finding No. 1192:

Respondent has no specific comment.

1193. Dr. Baumer admits that if it were not true that non-dentists wore medical apparel in a way that confused consumers he would have less of an economic reason to conclude that the Board's conduct was justified. (Baumer, Tr. 1935-1936).

Response to Finding No. 1193:

Respondent objects to the mischaracterization of Baumer, Tr. 1935-36. Dr. Baumer testified that, in reaching his conclusions, he considered certain justifications raised by the State Board to which Dr. Kwoka responded in his report, including the justification that consumers may mistakenly believe non-dentist teeth whitening providers are dentists because of their medical garb. Dr. Baumer testified that, if there were no truth to this justification, he would take that factor off of his list of reasons for concluding that the conduct was justified.

1194. Even if there were consumer confusion about whether non-dentists were medical professionals it would not provide a sensible economic justification for excluding nondentist teeth whiteners. This would be a textbook situation where a less restrictive alternative should be implemented so that the product can remain on the market. For example, a less restrictive alternative would require non-dentist teeth whiteners to prominently post a disclosure that they are not medical professionals. (Kwoka, Tr. 1086-1087; CX0631 at 011).

Response to Finding No. 1194:

This is an opinion, and not a statement of fact. Respondent objects to Complaint Counsel's reliance on CX0631 at 011 in support of this Proposed Finding of Fact because it is hearsay.

1195. Dr. Hardesty has never seen a complaint by a consumer that he or she was misled into thinking that the non-dentist performing the teeth whitening was in fact a dentist. (CX0566 at 029 (Hardesty, IHT at 112)).

Response to Finding No. 1195:

Respondent objects to the mischaracterization of CX0566 at 029. In response to being asked whether he recalled seeing a complaint from somebody that claimed they were misled into thinking that a non-licensed person that was performing teeth whitening were actually dental professionals, Dr. Hardesty testified, "I don't recall at this point."

1196. The Board is not aware of any complaint by a consumer of non-dentist teeth whitening services that he or she believed that the services were being provided by a dentist. (Response to RFA 29).

Response to Finding No. 1196

Respondent disputes this proposed finding of fact as a mischaracterization of Respondent's response to the Request for Admission cited by Complaint Counsel as support for this proposed finding of fact. Respondent's full response was that it was not aware of any such reports; "however, this does not mean that the impression was not projected by non-dentist providers of teeth whitening services that they were a member of the health care profession, but not specifically a dentist." (Respondent's Objections and Responses to Complaint Counsel's First Set of Requests for Admission, ¶ 29). Further, Mr. Runsick testified that he believed he was paying for a service from someone who was "medically trained," and the appearance of the kiosks facility (dental chairs) and personnel (dressed in scrubs) conveyed that impression. (Runsick, Tr. at 2145-2146).

IX. The Board's Unsubstantiated Claims of Consumer Harm Do Not Justify Exclusion Based on Any Economic Theory

1197. "Exclusion is not justified by any economic argument set forth by the Board." (CX0822 at 002).

Response to Finding No. 1197:

This is not a fact, it is an opinion stated by Dr. Kwoka. Respondent disputes this statement, which is a quotation from Dr. Kwoka's Report. Dr. Baumer refuted this

statement, pointing out that the statement makes no sense if one considers the economic component of the clear potential for injuries to consumers from non-dentist teeth whitening: "When you measure costs and benefits, you can measure value of life and the value of injury and you can set that against consumer surplus or consumer welfare, and those trade-offs are made on a regular basis." (Baumer, Tr. 1708). Further, Dr. Baumer noted other non-economic justifications for exclusion, such as the enforcement of an existing statute: "if you're simply enforcing a state statute that you're being charged to enforce, I don't think that that is a bad act, an anticompetitive act." (Baumer, Tr. 1699).

1198. Economists allow for the possibility that exclusion has a justification and examine the basis for it; "there can be circumstances in which unrestricted firm behavior can harm consumers, and in such cases remedial intervention may be appropriate." (Kwoka, Tr. 1107-1108; CX0654 at 010).

Response to Finding No. 1198:

This is not a fact, it is an opinion stated by Dr. Kwoka. Respondent disputes this statement through the testimony of Dr. Baumer, who pointed out that Kwoka's assessment of consumer harm is fixated on price:

Well, in reading Dr. Kwoka's report, it seemed like there was a fixation on price. Economics is concerned about price, but it's mainly concerned about choice. And I believe that there is a health dimension to the dental markets for non-dentist teeth whitening, and that is part of my analysis, so I would say I'm a two-handed economist. On the one hand I look at the economics; on the other hand I look at the nonprice economic aspects as well as kind of health and public policy.

(Baumer, Tr. 1695-1696).

1199. There are situations where complete exclusion of a product is appropriate economic policy, such as where the product is "irremediably dangerous." (Kwoka, Tr. 1056; CX0631 at 008).

Response to Finding No. 1199:

This is not a fact, it is an opinion stated by Dr. Kwoka. Respondent does not dispute that complete exclusion of a product may be appropriate if it is “irremediably dangerous.”

1200. Exclusion of non-dentist teeth whitening might be appropriate where (1) there is convincing evidence of significant health or safety problems, (2) the health and safety problems are inherent in the excluded service, not ancillary, and (3) there are no less restrictive alternatives to outright exclusion of the product. Non-dentist teeth whitening does not meet this standard. (Kwoka, Tr. 1056-1057).

Response to Finding No. 1200:

This is not a fact, it is an opinion stated by Dr. Kwoka. Contrary to the above statement, Dr. Kwoka admitted that you can have a justifiable **limited** exclusionary model. (Kwoka, Tr. 1108). The Board has presented convincing evidence that exclusion of certain unlicensed dental teeth whiteners on a case-by-case basis is justified based on health and safety considerations, including the testimony of an expert in the fields of practical and clinical esthetic and restorative dentistry, the testimony of Mr. Runsick, an actual consumer, the testimony of a dentist that evaluated Mr. Runsick’s injury that was caused by teeth whitening, the testimony of licensed dentists regarding the health and safety issues involved with kiosk/spa teeth whitening, and the documentary evidence of other consumers injured by kiosk/spa teeth whitening. *See* Respondent’s Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531 (other consumer harm). Additionally, Complaint Counsel’s expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466). The Board’s investigation of non-dentist teeth whiteners was conducted on a case-by-case basis. *See* Respondent’s Proposed Findings of Fact Nos. 100-244. Further, the Board has acted pursuant to a statute that the Board was charged with enforcing. “[I]f you’re simply

enforcing a state statute that you're being charged to enforce, I don't think that that is a bad act, an anticompetitive act." (Baumer, Tr. 1699).

1201. Exclusion is the last possible resort even where a product has inherent health or safety problems and there are no significantly less restrictive alternatives to exclusion. Many products have potential harms and are tolerated in a world full of risk (Kwoka, Tr. 1061-1062). Dr. Baumer is not in favor of banning all products or services that pose a risk to customers. (CX0826 at 029 (Baumer, Dep. at 108)).

Response to Finding No. 1201:

Respondent refers to its response to Proposed Finding No.1200.

1202. Professor Kwoka analyzed the Board's justifications from an economic perspective. (Kwoka, Tr. 1107-1109, 1127-1128, 1226-1227).

Response to Finding No. 1202:

Dr. Kwoka's characterization of his analysis is a statement of opinion, not fact. He also admitted that his analysis did not assume that evidence of health and safety issues was present, either in the form of expert testimony or literature. (Kwoka, Tr. 1139-1140, 1141-1143). Dr. Baumer found that Dr. Kwoka failed to account for significant health considerations in his discussion. (Baumer, Tr. 1817). Further, the Board notes that Dr. Kwoka is not a dentist, but purported to testify as to the existence (or non-existence) of reliable evidence of serious and systematic harm (from teeth whitening). (Kwoka, Tr. 1223). Also, although Dr. Kwoka was not tendered as an expert in law, he concluded that cease and desist letters issued by the Board were "in contravention of North Carolina state law." (Kwoka, Tr. 1216-1217).

1203. The Board's economic efficiency justification for exclusion was that health and safety benefits required Board intervention. Professor Kwoka disputes this, stating that he "did not find convincing evidence of health and safety concerns." (Kwoka, Tr. 1066-1067; CX0631 at 010).

Response to Finding No. 1203:

Respondent refers to its response to Proposed Finding No. 1202.

1204. Even if a product carried small risks, that would not justify banning the product because it is not possible to live without exposure to products or services that have a small degree of possible risk. (Kwoka, Tr. 1084; CX0826 at 050 (Baumer, Dep. at 190) (“all products have risk”)).

Response to Finding No. 1204:

This is not a fact, it is the opinion statement of Dr. Kwoka. And while Dr. Baumer did agree that all products have some degree of risk, however slight, he pointed out that the Board has demonstrated a great deal of consumer harm that is both actual and theoretical. (Baumer, Tr. 1769). *See also* Respondent’s Response to Proposed Finding No. 1200.

1205. Several objections to non-dentist teeth whitening raised by Dr. Baumer are textbook examples problems [sic] that, even if supported by evidence, are not inherent to non-dentist teeth whitening itself, and can easily be remedied by less restrictive alternatives. As an example, Dr. Kwoka discusses Dr. Baumer’s concern with non-dentist teeth whiteners insisting that customers sign liability waivers. Dr. Kwoka testified that in addition to there being no evidence that non-dentists require their customers to sign liability waivers, banning the waivers would be a less restrictive alternative to banning the service, and would address the concern. (Kwoka, Tr. 1057-1059).

Response to Finding No. 1205:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, this statement falls outside of Dr. Kwoka’s expertise because he purports to evaluate the existence (or non-existence) of reliable evidence of serious and systematic harm (from teeth whitening). Dr. Kwoka was accepted by the court as an expert in the fields of “industrial economics and the economics of professional regulation.” (Kwoka, Tr. 976). Thus this testimony falls outside his expertise.

1206. Dr. Baumer claims that non-dentist teeth whiteners insist on waivers of liability from their customers. Even if this is true, and Dr. Baumer cites no evidence in support, a waiver is ancillary to the whitening service and could be prohibited by the Board or other state agency, or be found unenforceable by a court, without banning non-dentist teeth whitening entirely. (Kwoka, Tr. 1057-1058).

Response to Finding No. 1206:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, Complaint Counsel has provided no citation for its contention as to how Dr. Baumer made this claim.

Respondent, however, has provided evidence that non-dentist teeth whiteners insisted on waivers of liability from their customers. *See Respondent's Proposed Findings of Fact Nos. 631 (WhiteSmile USA requires that customers at its local affiliates sign a consent form containing a waiver of liability).*

1207. Dr. Baumer claims that non-dentist teeth whiteners ask for medical information or medical-type information from a prospective client, and that this information is not subject to the same confidentiality protections as in the medical profession. Dr. Baumer cites no evidence that non-dentist teeth whiteners have improperly disclosed confidential medical information. And the evidence suggests that non-dentist teeth whiteners do not even request confidential medical information. Even if this were true, information gathering is not inherent to the teeth whitening service and could be solved through state statutes or regulations requiring confidentiality of such information. (Kwoka, Tr. 1058-1059; Nelson, Tr. 824; Valentine, Tr. 594).

Response to Finding No. 1207:

Respondent notes that this statement is a nearly word-for-word duplicate of Proposed Finding No. 1131. As Respondent noted before, Dr. Kwoka's testimony that "information gathering is not inherent to the teeth whitening service" is contradicted by the testimony of the Ms. Osborn, the President of the teeth whitening industry's trade group that issues the practice guidelines for the industry (the Council for Cosmetic Teeth Whitening). She testified that she formerly required that her local affiliates provide a consent form to customers purchasing teeth whitening services, but she has reconfigured the form as an "information form" about her teeth whitening products. The current information form requests personally identifying information regarding her customers.

This information is kept on file in an unlocked cabinet at her office in Alabama. (Osborn, Tr. 665, 702-703, 708-709).

1208. It is important to use available less restrictive alternatives to exclusion because it preserves the beneficial part of the product desired by consumers. This maximizes consumer benefit while reducing or eliminating possible adverse impacts. When compared to a complete ban on a product, less restrictive alternatives enhance consumer welfare and should be adopted. (Kwoka, Tr. 1059-1060, 1088, 1239-1240).

Response to Finding No. 1208:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, Dr. Baumer pointed out that it is not clear that less restrictive alternatives were available to the Board, as it acted according to the statute with which it was charged with enforcing, and it does not have the power to alter that statute. (Baumer, Tr. 1708-1709).

1209. Dr. Baumer agrees that, in general, where intervention is appropriate less restrictive alternatives should be used. (Baumer, Tr. 1771).

Response to Finding No. 1209:

This statement is misleading because it provides only part of Dr. Baumer's response to a question, and even excises the rest of his sentence. Dr. Baumer made the point that less restrictive alternatives may not be adequate to prevent people from getting hurt by dangerous or substandard products, but "in general, where intervention is appropriate, yes, we want less restrictive measures, but we don't want sacrifice health along the way." (Baumer, Tr. 1771).

1210. Even if the Board does not have the authority to impose or enforce less restrictive alternatives, there are other agencies in North Carolina that the Board could ask or require to enforce appropriate less restrictive alternatives, with respect to, for example, sanitation issues. (Kwoka, Tr. 1149-1150, 1223-1225, 1238).

Response to Finding No. 1210:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, it is apparent that this testimony lies outside of his field of expertise in the fields of “industrial economics and the economics of professional regulation”, because he merely speculates as to the existence of another agency or whether it would even be possible for the Board its enforcement responsibilities to defer to that agency. (Kwoka, Tr. 1149-1150). In fact, Dr. Kwoka admits that he has not even made an attempt to determine if there is such an agency: “I have not investigated who does so in the state of North Carolina . . . I assume that there's a state board that oversees health -- excuse me -- sanitation requirements in different types of establishments . . . I don't know the details . . . For all I know, the state dental board has some prerogatives in this respect, too, but as I've stated, I've not studied that question.” (Kwoka, Tr. 1223).

1211. The Board has made use of less restrictive alternatives to exclusion, most significantly to address complaints against dentists. It would not be economically sensible to ban the entire practice of dentistry in response to complaints about specific dentists. (Kwoka, Tr. 1059-1061). By contrast, when the Board received complaints about non-dentist teeth whiteners, its response was to prohibit the practice. (Kwoka, 1233-1234).

Response to Finding No. 1211:

Respondent disputes this statement, as it is the opinion testimony of Dr. Kwoka and no evidence is provided to support the statement that the Board used less restrictive alternatives to address complaints against dentists. In fact, Dr. Kwoka admits that he has no evidence, only an assumption: “the board had any number of complaints against dentists each year, and they presumably took whatever action they deemed appropriate in those cases to examine them, to resolve them.” (Kwoka, Tr. 1060-1061). Also, this statement and Dr. Kwoka's testimony once again fails to consider that the Board is acting pursuant to its statutory mandate to regulate the practice of dentistry.

1212. There is no evidence of risk to life or any other significant harm from non-dentist teeth whitening services. (Kwoka, Tr. 1062-1064). "Speculation about what 'can' happen and what can be 'imagined' are not substitutes for evidence." (CX0631 at 010).

Response to Finding No. 1212:

Respondent refers to its response to Proposed Finding No. 1202 for a list of the numerous sources recounting evidence of the significant risk of harm from non-dentist teeth whitening.

1213. Dr. Baumer admitted that he was "unprofessional" and "needlessly dramatic" in describing non-dentist teeth whitening as life-threatening in his report. (Baumer, Tr. 1768; CX0631 at 010). Dr. Baumer admitted that he has no evidence that anyone has died from non-dentist teeth whitening. (Baumer, Tr. 1768-1769).

Response to Finding No. 1213:

Complaint Counsel only provides part of Dr. Baumer's answer to the question that elicited the above statement. Dr. Baumer was very candid and forthcoming in his assessment of issues with teeth whitening, but he also maintained that his conclusion remained the same. He stated that while he has not seen evidence that anyone has died as a result of teeth whitening, that does not mean it is not possible: "if these non-dentists transmit infection because they are unaware of things that a dentist would know, infections could lead to a death So I'm going to criticize myself and say that this is a little overly dramatic, but it still could happen, and it's more likely to happen with a non-dentist than with a dentist." (Baumer, Tr. 1769).

1214. Dr. Baumer admitted that he has no medical or advanced science training and that he did not perform a quantitative risk analysis for the health issues in this case. (Baumer, Tr. 1818-1819).

Response to Finding No. 1214:

Dr. Kwoka also did not perform a quantitative analysis of the price effects of exclusion, asserting that such evidence was not required. (Kwoka, Tr. 1190).

1215. It is not appropriate from an economic perspective to fail to examine the underlying consequences of a board's actions purely out of deference to the board's judgment regarding health and safety issues. It has historically been the case that boards have routinely expressed public interest purposes for restrictions, but that the restrictions have nonetheless been found to be unduly restrictive and anticompetitive. (Kwoka, Tr. 1075-1076; Baumer, Tr. 1916-1917 (prudent to maintain a "healthy skepticism" of restrictions imposed by professional boards)).

Response to Finding No. 1215:

This statement is not a fact, it is an opinion statement by Dr. Kwoka. Respondent disputes this statement as it does not tend to establish any issue of consequence in this proceeding, and further it misleadingly suggests that Dr. Baumer has given "deference" to the Board's actions. In fact, Dr. Baumer has looked at the evidence of health and safety issues and has found that the potential for harm from teeth whitening is significant. (Baumer, Tr. 1767-1768).

1216. Dr. Baumer states that as a result of the professions studies economists look very carefully for evidence of anticompetitive behavior when there is licensing taking place. (Baumer, Tr. 1896-1897).

Response to Finding No. 1216:

This is accurate, though Dr. Baumer pointed out that "over time much of the anticompetitive conduct that the boards have undertaken in the '70s and the '80s has been eliminated." (Baumer, Tr. 1898).

1217. The record does not disclose convincing evidence of health and safety concerns from non-dentist teeth whitening that justify banning the service. (Kwoka, Tr. 1066-1067, 1212). There is no convincing evidence within Dr. Baumer's report that non-dentist teeth whitening results in harm to the health and safety of consumers. (Kwoka, Tr. 1068; CX0631 at 010-011).

Response to Finding No. 1217:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, this statement falls outside of Dr. Kwoka's expertise because he purports to evaluate the existence (or non-

existence) of reliable evidence of health and safety concerns from non-dentist teeth whitening. Dr. Kwoka was accepted by the court as an expert in the fields of “industrial economics and the economics of professional regulation.” (Kwoka, Tr. 976). Thus this testimony falls outside his expertise.

1218. There have been a total of four complaints, covering three instances of teeth whitening, filed by consumers to the Board from 2004 to 2010. (Kwoka, Tr. 1077). If non-dentist teeth whitening was systematically harmful there should have been considerably more complaints from consumers to the Board. (Kwoka, Tr. 1078).

Response to Finding No. 1218:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, this statement falls outside of Dr. Kwoka’s expertise because he purports to evaluate the existence (or non-existence) of reliable evidence of health and safety concerns from non-dentist teeth whitening. Dr. Kwoka was accepted by the court as an expert in the fields of “industrial economics and the economics of professional regulation.” (Kwoka, Tr. 976). Thus this testimony falls outside his expertise.

1219. Most complaints to the Board regarding non-dentist teeth whitening were submitted by competitors of non-dentist teeth whitening – licensed dentists. (Kwoka, Tr. 1078-1079).

Response to Finding No. 1219:

Respondent has no specific response.

1220. The articles referenced by Dr. Baumer in his report as evidence of consumer harm are not the type of medical studies that economist weigh most seriously as a basis for concluding that there are significant health and safety concerns from non-dentist teeth whitening. Most of the articles referenced by Dr. Baumer are newspaper articles. (Kwoka, Tr. 1139-1140).

Response to Finding No. 1220:

This is not a fact, it is an opinion statement made by Dr. Kwoka. Dr. Baumer noted that some of these articles are “full-fledged academic articles” and some are newspaper or

magazine articles. (Baumer, Tr. 1821). He found that if you put such search terms as “teeth whitening” and “dangers” in an internet search engine it results in several pages of articles that assert that there are significant dangers. (Baumer, Tr. 1821-1822). Dr. Haywood noted that despite this lack of scientific data regarding the dangers of teeth whitening, there is anecdotal evidence of harm from teeth whitening. (Haywood, Tr. 2520-2521). Dr. Haywood also found that while anecdotal evidence may not be as reliable as a scientific article, sometimes that is all that is available. In fact, some estimates indicate that 80 percent of the practice of dentistry is non-evidence-based because it is what people have learned from doing it through the years, so it is very difficult to come up with evidence for every aspect of dentistry. (Haywood, Tr. 2519-2520).

1221. Dr. Baumer admits that some of the articles he relied upon in his report to come to the conclusion that there were significant health and safety concerns from non-dentist teeth whitening were not academic or governmental sources. (Baumer, Tr. 1956-1957). Dr. Baumer agrees that exclusive reliance on such sources is not his standard practice informing expert opinions. (Baumer, Tr. 1957).

Response to Finding No. 1221:

Respondent refers to its response to Proposed Finding No. 1220. Also, the second sentence misleadingly provides only a portion of Dr. Baumer’s response. His entire response to a question asking whether he normally relied on such sources was “Well, exclusive reliance upon it, no. Some notice of the plethora of articles, yes. I think it’s called anecdotal type of evidence.” (Baumer, Tr. 1957).

1222. It is economically significant that Dr. Giniger stated in his report that millions of applications of non-dentist teeth whitening have been made without resulting harm. (Kwoka Tr. 1081). It is significant that there is a long history of use of non-dentist teeth whitening in North Carolina and the United States. When available, economists look to this type of evidence for indications of systematic and significant harm, and are not

limited to exploring theoretical possibilities of what may happen from a particular practice. (Kwoka, Tr. 1082-1083).

Response to Finding No. 1222:

This is not a fact, it is an opinion statement by Dr. Kwoka, who is relying on the opinion statement of Dr. Giniger, who is citing a misleading statistic that lumps together non-dentist teeth whitening with over-the-counter teeth whitening products. *See*

Respondent's Proposed Finding of Fact No. 402. Similarly, the "long history of use" of non-dentist teeth whitening in North Carolina primarily refers to over-the-counter products.

1223. Dr. Baumer agrees that if there was a health problem with non-dentist teeth whitening he would expect to see it systematically reported over the years through consumer complaints and through the need for dentists to perform remedial work to repair the damage. (Baumer, Tr. 1967).

Response to Finding No. 1223:

Dr. Baumer said he would expect that these problems would be manifested "in part" by some kind of complaints by customers. He did not necessarily state that these complaints would be consumer complaints to the Board. The complaints by non-dentist teeth whitening customers could have been provided elsewhere, perhaps to reporters writing the newspaper articles that Dr. Kwoka appears to so readily discount. This may explain why there are so many newspaper articles discussing the dangers of teeth whitening.

1224. Dr. Baumer admits that he is not aware of any empirical data indicating a systemic public health problem with non-dentist teeth whitening. (Baumer, Tr. 1962, 1967-1968; CX0826 at 043 (Baumer, Dep. at 162)). If such empirical data existed Dr. Baumer would have made use of it. (Baumer, Tr. 1962). Dr. Baumer requested all relevant information from Respondent's Counsel, and none of it showed a systemized collection of data showing harm from non-dentist teeth whitening. (Baumer, Tr. 1968).

Response to Finding No. 1224:

Respondent refers to its response to the previous Proposed Finding No. 1223.

1225. Dr. Baumer admits that he does not know whether any of the “double-blind studies” that he states contradict Dr. Giniger’s report and testimony actually involved teeth whitening. (CX0826 at 028 (Baumer, Dep. at 103-105)).

Response to Finding No. 1225:

On a follow-up question regarding how the absence of such double-blind studies would impact his opinion on the case, Dr. Baumer stated “[t]he fact that there isn't such a study, if there isn't one, does not discount the possibility that anecdotal evidence is convincing given the magnitude and given the fact that other authorities with the same responsibilities such as the EU have made pretty much the same decision.” (CX0826 (Baumer, Dep. at 105)).

1226. After ten years of experience with non-dentist teeth whitening there appears to be no evidence of significant and nontransient harmful effects to consumers, and no empirical studies supporting theoretical concerns regarding non-dentist teeth whitening. (Kwoka, Tr. 1138, 1221).

Response to Finding No. 1226:

This statement is not a fact, it is the opinion of Dr. Kwoka. Further, this statement falls outside of Dr. Kwoka’s expertise because he purports to evaluate the existence (or non-existence) of reliable evidence of health and safety concerns from non-dentist teeth whitening. Dr. Kwoka was accepted by the court as an expert in the fields of “industrial economics and the economics of professional regulation.” (Kwoka, Tr. 976). Thus this testimony falls outside his expertise.

1227. Despite a total absence of any reliable evidence or data, Dr. Baumer’s main disagreement with Professor Kwoka is Dr. Baumer’s belief that there are significant health and safety risks in conjunction with the provision of non-dentist teeth whitening services. (Baumer, Tr. 1829; CX0826 at 044-045 (Baumer, Dep. at 169-170) (agreeing that “the recurring theme” of his argument is “whether or not the non-dentist teeth whitening is safe”)).

Response to Finding No. 1227:

Respondent disputes the first clause of the first sentence of this statement, because there is no basis in the record for the statement and no support is provided. As noted in Respondent's response to Proposed Finding No.1200, there is considerable evidence in the record of actual harm to consumers and sound theoretical bases for further potential harm from non-dentist teeth whitening.

1228. Dr. Baumer performed a "thought analysis" by assuming that non-dentist teeth whitening could result serious [sic] harm to consumers – such as one in ten customers suffering from oral cancer in ten years – in support of his assertion that exclusion of non-dentist teeth whiteners is justified. (Baumer, Tr. 1708, 1776, 1819-1820).

Response to Finding No. 1228:

Dr. Baumer's point in making this statement was not to merely assert a justification for exclusion, but to put it in terms of an economic argument, in response to Dr. Kwoka's statement that the Board set forth no "economic argument" to justify exclusion. He made the hypothetical statement of assuming one in ten customers is suffering from oral cancer in ten years in order to show a numerical basis for quantifying the potential harm of teeth whitening. "When you measure costs and benefits, you can measure value of life and the value of injury and you can set that against consumer surplus or consumer welfare, and those trade-offs are made on a regular basis." (Baumer, Tr. 1708).

1229. Dr. Baumer has admitted that he does not have any actual evidence that non-dentist teeth whitening causes cancer. (Baumer, Tr. 1820).

Response to Finding No. 1229:

This statement blatantly misstates Dr. Baumer's testimony. In fact, Dr. Baumer **explicitly denied** a question by Complaint Counsel that he did not have any evidence supporting his view. (Baumer, Tr. 1820 ("Q: You don't have any evidence; correct? You said you don't have enough evidence. You don't have any evidence; correct? A: No. I don't agree with

that.”). Asked to explain his evidence, Dr. Baumer testified that he conducted research on the internet and easily found articles discussing concerns about non-dentist teeth whiteners. (Baumer, Tr. 1821). Dr. Baumer noted that there were numerous articles, more than 30 total, in “page after page” of results, that these included “full-fledged academic articles” and as well as newspaper or magazine articles, and that he had noted the titles of the articles describing the dangers of non-dentist teeth whitening and had read several of them. (Baumer, Tr. 1821-1822, 1827). He also described how some studies he read showed how giving heavy doses of materials as innocuous as Coke could give cancer to a higher percentage of rats over a period of six months. So while he admits that his “1 in 10” hypothetical figure was far-fetched, he did not think that it’s farfetched to exclude the possibility of a higher rate of cancer based on exposure to an untested product, we just do not have the data at this point. (Baumer, Tr. 1821).

1230. Dr. Baumer admits that he does not have any reason to think that his assumption that non-dentists teeth whitening causes oral cancer in one in ten customers is valid. Dr. Baumer assumed “extreme” and “farfetched” facts in order to make a point. (Baumer, Tr. 1820, 1938-1939).

Response to Finding No. 1230:

Respondent has no specific comment.

1231. Dr. Baumer stated that his research regarding cancer risks of non-dentists teeth whitening consisted of typing various search terms in an internet browser. (Baumer, Tr. 1821-1822).

Response to Finding No. 1231:

This statement misleadingly suggests and clearly implies that Dr. Baumer’s research consisted merely of “typing various search terms” into his internet browser. This statement does not accurately reflect Dr. Baumer’s testimony. As noted in Respondent’s response to Proposed Finding No. 1229 above, Dr. Baumer’s research found “page after

page” of articles describing the dangers of teeth whitening, these articles included “full-fledged academic articles” as well as newspaper or magazine articles, and Dr. Baumer read several of them. (Baumer, Tr. 1821-1822, 1827).

Further, the context of the cross-examination at this point indicates that Dr. Baumer’s research was not just confined to the cancer risks of non-dentist teeth whitening, but the risks of non-dentist teeth whitening in general. (Baumer, Tr. 1820-1828)

1232. Dr. Baumer agrees that if states other than North Carolina permitted non-dentist teeth whitening it would have an impact on his conclusion that the Board restrictions on nondentist teeth whitening are justified by health and safety concerns, and that he would be more concerned about the Board decision to exclude. (Baumer, Tr. 1919-1920, 1923).

Response to Finding No. 1232:

Respondent objects to this statement. Complaint Counsel blatantly misstates Dr. Baumer’s testimony because it provides Dr. Baumer’s agreement to the question Complaint Counsel asked without providing the qualifying explanation that formed part of his answer. Dr. Baumer agreed with this statement, but only “to the extent that another state doesn’t see a health problem, that has an impact. That would cut in the direction of causing me to be more concerned about the North Carolina decision.” (Baumer, Tr. 1920).

1233. Dr. Baumer admits that he does not recall asking Respondent’s Counsel for information relating to how states other than North Carolina treated non-dentist teeth whitening. (Baumer, Tr. 1923).

Response to Finding No. 1233:

Respondent objects to this statement. Complaint Counsel blatantly misstates Dr. Baumer’s testimony because it provides Dr. Baumer’s agreement to the question Complaint Counsel asked without providing the qualifying explanation that formed part of his answer. This statement clearly implies that Dr. Baumer did not have or rely on

outside information regarding how other states treat non-dentist teeth whitening as part of his analysis. In his answer, after stating that he does not recall asking for such information, Dr. Baumer clearly states that he did still rely on such information: "I don't recall asking. I was given information that at least some states viewed it as illegal and, you know, moved to take action against these non-dentist teeth whiteners." (Baumer, Tr. 1923).

1234. Dr. Baumer admits that at the time he wrote his report he had not read the articles he cited as evidence of health problems with non-dentists teeth whitening, other than their titles. (Baumer, Tr. 1827-1829). These articles were contained in Respondent's statement of facts. (Baumer, Tr. 1829).

Response to Finding No. 1234:

Respondent strongly objects to this statement because it blatantly misrepresents Dr. Baumer's testimony. He stated: "My recollection is that at the time I wrote the report I had not read the underlying articles, **but I could have read one or two.** There were about 30 of them. By the time of the deposition I believe I had read a few more." (Baumer, Tr. 1828 (emphasis added)).

1235. Dr. Baumer admits that at the time he wrote his report he had not read the expert reports of either Dr. Giniger or Dr. Haywood. (Baumer, Tr. 1827-1828). Dr. Baumer admits that he formed the opinions in his report without having read the report of either industry expert. (Baumer, Tr. 1828-1829).

Response to Finding No. 1235:

Respondent disputes this statement because it misleadingly provides only part of Dr. Baumer's answer to this line of questions. Although Dr. Baumer stated that he had not read both expert reports when he wrote his report, he had been informed of the conclusion of Dr. Haywood, the Board's expert: "I was certainly informed by counsel that a leading expert in the field, Dr. Haywood, would provide a comprehensive report as

to the dangers of teeth whitening.” (Baumer, Tr. 1829). Further, Dr. Baumer stated that he reserved the right to revise his report based on Dr. Haywood’s conclusions if he later found anything that disagreed with his findings, that he had read the reports of both dental experts by the time of his deposition, and that he “did certainly ask about the health aspects, and from what I’ve seen since then, there’s no reason to revise my report.” (Baumer, Tr. 1828, 1830).

1236. Dr. Baumer admits at the time he wrote his report he had no basis for his conclusions or assumptions relating to the health effects of non-dentist teeth whitening other than from conversations with Respondent’s Counsel and from reading titles and abstracts of articles cited in Respondent’s statement of facts. (Baumer, Tr. 1830; CX0826 at 022-023 (Baumer, Dep. at 79-82)).

Response to Finding No. 1236:

This statement misstates Dr. Baumer’s testimony. Respondent refers to its response to Proposed Findings Nos. 1229, 1234, and 1235.

1237. Dr. Baumer was not aware that there is an oral hygiene section of the North Carolina Department of Health. (Baumer, Tr. 1944).

Response to Finding No. 1237:

Respondent has no specific comment.

1238. Dr. Baumer admits that he would have liked a more “leisurely pace” for his investigation into health aspects of non-dentist teeth whitening. (Baumer, Tr. 1830).

Response to Finding No. 1238:

Respondent notes that Dr. Baumer was providing an explanation here as to why, at the time he wrote his report, he had only relied upon reading a few articles on the dangers of non-dentist teeth whitening, his conversation with Respondent’s counsel, and the conclusions of Dr. Haywood. He further noted that he received his assignment eight days before his report was due and, as a department head at North Carolina State University,

was simultaneously beset by administrative responsibilities during this time. (Baumer, Tr. 1830). He noted in his report that he reserved the right to revise any findings, and subsequently reviewed both experts' reports and conducted further research on the dangers of teeth whitening before his deposition and did not find a need to revise anything. (Baumer, Tr. 1828, 1830).

1239. Dr. Baumer admits that he did not engage in "due diligence" in writing his report. (Baumer, Tr. 1835-1836; CX0826 at 023 (Baumer, Dep. at 82)).

Response to Finding No. 1239:

Respondent refers to its response to Proposed Finding No. 1238.

1240. Dr. Baumer admits that he wrote his report and formed his opinions without evidence on many points. For example, his report states that non-dentist teeth whiteners may pose a lethal threat to their customers, yet Dr. Baumer admits that he has no evidence that anyone has ever died of teeth whitening and further states that he was "unprofessional" and "needlessly dramatic" in describing non-dentist teeth whitening as life-threatening. (RX0078 at 013; Baumer, Tr. 1768-1769). Further, Dr. Baumer claimed repeatedly in his report that non-dentist teeth whitening posed a health threat to consumers as a justification for the Board's actions, and yet Dr. Baumer admitted that at the time he wrote his report and came to his conclusion he had not read either of the industry expert reports, had only read the titles of a collection of non-empirically based articles cited in a pleading document, and otherwise only spoken with Board counsel. (Baumer, Tr. 1827- 1829, 1830; CX0826 at 022-023 (Baumer, Dep. at 79-82)). In addition, Dr. Baumer admitted he had no evidence, other than Board counsel's statements and pleadings, for his assertions that non-dentist teeth whiteners may be selling medical information collected from their customers or his assertion that non-dentist teeth whiteners dress in medical garb in a way that deceives customers into thinking they are medical professionals. (Baumer, Tr. 1935, 1956).

Response to Finding No. 1240:

Respondent objects to this statement as duplicative because it merely re-phrases many of the previous 30 or so Proposed Findings and presents them again. In fact, each of these sentences is a word-for-word duplicate or a nearly word-for-word duplicate of previous Proposed Findings. Respondent refers to its responses to those previous Proposed

Findings and moves herein for this Proposed Finding to be disregarded as needlessly duplicative.

X. Less Restrictive Alternatives to the Exclusion of Non-Dentist Teeth Whiteners Are Available and Would Be Effective to Remedy Any Potential, Legitimate Problems Associated with Non-Dentist Teeth Whitening

A. The ADA Identifies Viable Less Restrictive Alternatives

1241. An ADA document states that an outright ban on non-dentist teeth whitening “could be portrayed as dentists protecting [their] ‘turf’ against cheaper alternative whitening services and could be used to cast dentistry as being more concerned with lucrative cosmetic services than with access to care issues.” (CX0487 at 008).

Response to Finding No. 1241:

This document is an internal memorandum from an unknown person in the ADA whose identify has not been disclosed to Respondent. It is not clear what foundation there is for its admission for the truth of the contents asserted here. Accordingly, this document is hearsay and should be disregarded. Further, Respondent notes that, until the ADA House of Delegates actually adopts a proposed resolution, any such memorandum is not the official policy of the ADA and therefore carries no weight within the organization.

1242. The ADA suggests that a dental board could require non-dentist teeth whitening providers to provide a fact sheet or other form of notice and disclosure that indicates teeth whitening providers are not dentists or health care professionals, and are not qualified to provide services, instruction, or assistance on matters related to oral health and safety. These fact sheets could identify risk factors, describe potential side effects, and encourage consumers to consult a dentist prior to teeth whitening. (CX0487 at 008-009).

Response to Finding No. 1242:

This document is hearsay and should be disregarded, as described in Respondent’s response to Proposed Finding No. 1241. This statement is not appropriately regarded as a recommendation of the ADA because there is no evidence that it has been adopted by the ADA House of Delegates.

1243. The ADA suggests that a dental board could require businesses that offer teeth whitening products or services to have customers complete a screening application form drafted by the dental board prior to the sale of any product. If a customer checked any risk factor, then the non-dentist could be prohibited from offering teeth whitening to the customer. (CX0487 at 010).

Response to Finding No. 1243:

This document is hearsay and should be disregarded, as described in Respondent's response to Proposed Finding No. 1241. This statement is not appropriately regarded as a recommendation of the ADA because there is no evidence that it has been adopted by the ADA House of Delegates.

1244. The ADA does not recommend that a dental board could offer or require training for employees and operators of non-dentist teeth whitening establishments because this "could provide such businesses with additional credibility." (CX0487 at 010).

Response to Finding No. 1244:

This document is hearsay and should be disregarded, as described in Respondent's response to Proposed Finding No. 1241. This statement is not appropriately regarded as a recommendation of the ADA because there is no evidence that it has been adopted by the ADA House of Delegates.

1245. The ADA does not recommend that a dental board could offer and issue permits for teeth whitening businesses because this "could provide such businesses with additional credibility." (CX0487 at 010).

Response to Finding No. 1245:

This document is hearsay and should be disregarded, as described in Respondent's response to Proposed Finding No. 1241. This statement is not appropriately regarded as a recommendation of the ADA because there is no evidence that it has been adopted by the ADA House of Delegates.

B. Other States Allow Non-Dentist Teeth Whitening Using Less Restrictive Alternatives to Ensure Safety

1246. Non-dentist teeth whitening is permitted in such states as Florida, California, New York, Illinois, Ohio, Indiana, Wisconsin, Tennessee, and Texas. (Nelson, Tr. 769; CX0419 at 001; CX0649 at 001; CX0488 at 049; Osborn, Tr. 668-669; CX0651 at 003; CX0650 at 004).

Response to Finding No. 1246:

Respondent notes in rebuttal that other states have followed the same line of conduct as the North Carolina State Board of Dental Examiners in terms of restricting non-dentist teeth whitening, including Alabama, where the Supreme Court of Alabama held that non-dentist teeth whitening was the illegal practice of dentistry. (Baumer, Tr. 1917). Further, what is most important is that the evidence clearly establishes that the Board has acted pursuant to its statutory authority under the North Carolina Dental Practice Act as dictated by the North Carolina General Assembly. *See* Respondent's Proposed Findings of Fact Nos. 11-74. Respondent also notes that much of the support for this statement is not evidence, but merely lay opinion testimony.

1247. Mr. White testified that he was aware that some states draw the line between practicing and not practicing dentistry, with respect to teeth whitening, at whether or not a provider of teeth whitening services touched the customer's mouth. (CX0573 at 015 (White, Dep. at 51)).

Response to Finding No. 1247:

This statement is irrelevant. What is most important is that the evidence clearly establishes that the Board has acted pursuant to its statutory authority under the North Carolina Dental Practice Act as dictated by the North Carolina General Assembly. *See* Respondent's Proposed Findings of Fact Nos. 11-74. Further, the Board's investigation of non-dentist teeth whiteners has been conducted on a case-by-case basis. *See* Respondent's Proposed Findings of Fact Nos. 100-244.

1248. The Ohio State Dental Board adopted a policy stating that, “[s]imply providing a customer with the materials to make a tray and demonstrating how to apply materials to their teeth for bleaching purposes is not the practice of dentistry, unless and until someone other than the consumer places their hands in the consumer’s mouth, and/or positions the activation light or similar device on behalf of the consumer.” (CX0487 at 003).

Response to Finding No. 1248:

Respondent refers to its response to Proposed Finding No. 1247.

1249. In deciding that non-dentists could perform teeth whitening, the Wisconsin Department of Regulation and Licensing General Counsel and the Department of Justice explained:

Teeth bleaching is markedly different from prophylactic teeth cleaning. It involves the application of a commonly available substance, hydrogen peroxide, to change nothing more than the color of the outer layer of the tooth enamel. This process produces no changes in the texture or structure of the teeth. Whitening is primarily a cosmetic exercise with no significant health implications.

Besides, it is now common for people who are not dentists to whiten their own teeth. Numerous products for that purpose are readily available without a prescription. These products are classified as cosmetics by the Food and Drug Administration. It would be unreasonable to conclude that all these people were guilty of the crime of practicing dentistry without a license by treating or caring for their teeth with a cosmetic for the purpose of whitening them.

There are undoubtedly some who will operate unscrupulous or incompetent commercial ventures which purport to whiten teeth. Those who are harmed by these ventures are not without a remedy even though the operators may not be prosecuted for practicing dentistry without a license. Like other consumers who have been harmed by the provision of inadequate or improper services, they may complain to the Office of Consumer Protection for redress.

(CX0651 at 003); *see also* CX0650 at 004 (Tennessee AG rejecting Tennessee Board’s position: “In the absence of specific, supporting statutory authority, we do not believe that a Court would uphold an attempt to regulate and characterize – as the practice of dentistry – the application of over-the-counter teeth whitening formulations and the performance of activities incident to such application”); CX0288 at 001 (FDA told Idaho that non-dentist teeth whitening is lawful)).

Response to Finding No. 1249:

Respondent refers to its response to Proposed Finding No. 1247.

1250. In California, “[t]he board which operates under the state Department of Consumer Affairs, found that businesses were not violating state law, because the bleaching agent is far less than prescription strength and the lights customers sit under are similar to a flashlight bulb. Also, operators do not touch the client's mouths” (CX0488 at 049).

Response to Finding No. 1250:

Respondent refers to its response to Proposed Finding No. 1247.

C. Drs. Kwoka and Baumer Testified That There Are Less Restrictive Alternatives

1251. It is important to use available less restrictive alternatives to exclusion in response to a concern, because it preserves the beneficial part of the product desired by consumers. This maximizes consumer benefit while reducing or eliminating possible adverse impacts. When compared to a complete ban on a product, less restrictive alternatives enhance consumer welfare and should be adopted. (Kwoka, Tr. 1060, 1088, 1239-1240).

Response to Finding No. 1251:

This statement is a nearly word-for-word duplicate of Proposed Finding No. 1208. This statement is not a fact, it is the opinion of Dr. Kwoka. Further, Dr. Baumer pointed out that it is not clear that less restrictive alternatives were available to the Board, as it acted according to the statute with which it was charged with enforcing, and it does not have the power to alter that statute. (Baumer, Tr. 1708-1709).

1252. Dr. Baumer agrees that, in general, where intervention is appropriate less restrictive alternatives should be used. (Baumer, Tr. 1771).

Response to Finding No. 1252:

This statement is an exact word-for-word duplicate of Proposed Finding No. 1209. This statement is misleading because it provides only part of Dr. Baumer’s response to a question, and even excises the rest of his sentence. Dr. Baumer made the point that less restrictive alternatives may not be adequate to prevent people from getting hurt by dangerous or substandard products, but “in general, where intervention is appropriate,

yes, we want less restrictive measures, but we don't want sacrifice health along the way.”

(Baumer, Tr. 1771).

1253. Certification would be a less restrictive alternative than a ban and result in a reduction in anticompetitive effects. (Kwoka, Tr. 1124).

Response to Finding No. 1253:

This is not a fact, it is the opinion statement of Dr. Kwoka.

1254. State agencies, private organizations, trade associations, or other professional bodies may offer certifications of a minimal quality standard that can be relied upon by consumers. Certification does not require prohibition of non-certified products and services, and some consumers may prefer a low-cost provider above a certified provider. (Kwoka, Tr. 1125).

Response to Finding No. 1254:

This is not a fact, it is the opinion statement of Dr. Kwoka.

1255. The certification model is not the abolition of intervention in the market, but it offers a less restrictive alternative to prohibition of products that consumers desire. (Kwoka, Tr. 1125-1126).

Response to Finding No. 1255:

This is not a fact, it is the opinion statement of Dr. Kwoka.

1256. The potential of small risks associated with non-dentist teeth whitening would not justify banning the service because it is not possible to live without exposure to products or services that have a small degree of possible risk. (Kwoka, Tr. 1084; CX0826 at 050 (Baumer, Dep. at 190) (“all products have risk”).

Response to Finding No. 1256:

This is not a fact, it is the opinion statement of Dr. Kwoka. Respondent objects to the citation to Dr. Baumer's statement here as it clearly does not support this proposition in any way and is a blatant misrepresentation of the record. Although Dr. Baumer stated in his deposition that “all products have risk”, this was a foundational statement that Complaint Counsel has excised from Dr. Baumer's answer without providing any of his

follow-up explanation. In fact, when the full statement is read, Dr. Baumer clearly **directly contradicts** this statement by Dr. Kwoka. When Dr. Baumer's entire answer is taken into account, his point is clearly that although he accept that all products have risk and he is not calling for licensing all of these products, he thinks that the need for licensing is "particularly particularly acute in the medical-type industries." (CX0826 at (Baumer, Dep. at 190).

1257. Even if the Board does not have the authority to impose or enforce less restrictive alternatives, there are other agencies in North Carolina that the Board could ask to enforce appropriate less restrictive alternatives, such as with sanitation issues. (CX0555 at 049 (Brown, Dep. at 187); (CX0556 at 028, 044 (Burnham, Dep. at 102-103, 166-167)).

Response to Finding No. 1257:

This statement is an exact word-for-word duplicate of Proposed Finding No. 1210 and a blatant misrepresentation of the record. The testimony cited by Complaint Counsel here clearly does not support this statement (the previous duplicate statement cited Dr. Kwoka's report without any other evidence). Dr. Burnham testified that the Board will work with a local district attorney to enforce the unlicensed practice of dentistry. (CX0556 (Burnham, Dep. at 102-103)). This is not a "less restrictive alternative", nor even an alternative at all. It is precisely what Board members have testified that the Board has done when necessary to enforce the Dental Practice Act. (CX19 at 20-21; White, Tr. 2206 (Pursuant to N.C. Gen. Stat. §§ 90-40 and 90-40.1, the North Carolina General Assembly has given the State Board the authority to petition a North Carolina court, either on its own or with the assistance of a District Attorney, to stop violations of the Dental Practice Act). The other two citations merely reference whether the those two members of the Board have had conversations with the North Carolina Department of

Health, and do not in any way establish that the NCDOH has the authority to enforce “less restrictive alternatives.” (CX0555 (Brown, Dep. at 187); (CX0556 (Burnham, Dep. 166-167)).

1258. Even if there were consumer confusion about whether non-dentists were medical professionals it would not provide a sensible economic justification for excluding nondentist teeth whiteners. This would be a textbook situation where a less restrictive alternative should be implemented so that the product can remain on the market. For example, a less restrictive alternative would require non-dentist teeth whiteners to prominently post a disclosure that they are not medical professionals. (Kwoka, Tr. 1086-1087; CX0631 at 011).

Response to Finding No. 1258:

This statement is a word-for-word duplicate of Proposed Finding No. 1194. Further, this is an opinion, and not a statement of fact. Respondent objects to Complaint Counsel’s reliance on CX0631 at 011 in support of this Proposed Finding of Fact because it is hearsay.

1259. Dr. Baumer provides no evidence that there have been sanitation problems with respect to non-dentist teeth whiteners. Even if there had been sanitation issues with non-dentist teeth whiteners it would not provide a justification for their exclusion. Sanitation problems can be remedied through less restrictive alternatives. (Kwoka, Tr. 1087-1088; CX0631 at 011).

Response to Finding No. 1259:

This statement is a word-for-word duplicate of Proposed Finding No. 1101. Dr. Baumer is Respondent’s economic expert, and it was not incumbent on him to provide such evidence. He did cite the other evidence of such concerns provided by the Board. Evidence in the record of concerns regarding sanitation problems with respect to non-dentist teeth whiteners includes the testimony of Dr. Haywood, the Respondent’s dental expert, numerous members of the Board, the admissions of members of the teeth whitening industry, the Board’s investigative files, and the testimony of Mr. Runsick, a

consumer who was injured by a non-dentist teeth whitening operation. *See* Respondent's Proposed Findings of Fact Nos. 425-445 (dentist Board member concerns), 471-474 (Runsick testimony), 438-439 and 442-443 (teeth whitening industry representative admissions), 386-387 (Dr. Haywood testimony), 101-237 (Board investigative files).

1260. Dr. Baumer agrees that one anecdote that a non-dentist did not use gloves and put his or her finger in a consumer's mouth is not sufficient to justify banning all non-dentist teeth whitening. (Baumer, Tr. 1958). Dr. Baumer cannot recall more than one incident to support this justification for banning non-dentist teeth whitening. (Baumer, Tr. 1958).

Response to Finding No. 1260:

This statement is a word-for-word duplicate of Proposed Finding No. 1102. Respondent refers to its response to Proposed Finding No. 1259 for its objection to this statement.

1261. A concern that non-dentist teeth whiteners do not carry sufficient liability insurance does not justify exclusion of non-dentist teeth whiteners. A less restrictive requirement that non-dentists carry a certain level of liability could be imposed without banning the service. (Kwoka, Tr. 1088-1089).

Response to Finding No. 1261:

This statement is a word-for-word duplicate of Proposed Finding No. 1110. Further, Respondent has cited other concerns in this proceeding aside from the fact that many teeth whiteners do not carry insurance. Also, the Board is statutorily mandated to enforce the practice of dentistry, including by preventing the unlicensed practice of dentistry. *See* Respondent's Proposed Findings of Fact Nos. 11-49.

1262. Dr. Baumer admits that the only basis he had for asserting that non-dentist teeth whiteners require their customers to sign waivers comes from Respondent's Counsel and from Respondent's legal briefs. (Baumer, Tr. 1932-1933). Dr. Baumer agreed that if non-dentists teeth whiteners did not require releases of liability that it could lead him to reconsider his opinion about the Board's decision to ban teeth whitening. (Baumer, Tr. 1933-1934). Dr. Baumer admits that simply because consumers are required to sign releases of liability does not mean that the product associated should be banned. (CX0826 at 025 (Baumer, Dep. at 92)).

Response to Finding No. 1262:

There is nothing improper with the fact that Respondent has provided summaries of its evidence in the form of pleadings to its expert. Further, Complaint Counsel's contention is irrelevant because Respondent has established this fact through the admission of a member of the non-dentist teeth whitening industry that the practice of requiring customers to sign liability waivers is widespread. (Valentine, Tr. 597, 519 (admitting that he requires customers to sign liability waivers and also providing testimony that he has local affiliates in numerous states)).

XI. Witnesses

A. Lay Witnesses Who Testified at Trial

1. Complaint Counsel's Witnesses

1263. Each of the following witnesses called by Complaint Counsel was reliable and credible:

Response to Finding No. 1263:

Respondent disputes this proposed statement of fact as an opinion, not fact.

John Gibson

1264. Mr. Gibson is a partner and Chief Operation Officer ("COO") of Hull Storey Gibson Companies, L.L.C., also known as HSG. Mr. Gibson oversees the operations of HSG, a retail property management company that owns and operates 11.5 million square feet of retail space in seven states, including the management of five enclosed malls in North Carolina. Mr. Gibson became the COO of HSG in 1999. (Gibson, Tr. 613-615).

Response to Finding No. 1264:

Respondent has no specific response.

1265. Mr. Gibson is an attorney; he graduated from law school in 1976 and served in the United States military as a JAG Officer for four years. He thereafter practiced securities and real estate law for approximately fifteen years in Augusta, Georgia. (Gibson, Tr. 614-615).

Response to Finding No. 1265:

Respondent has no specific response.

Margie Hughes

1266. Mrs. Hughes is a licensed esthetician, broadcasts a radio show (Sunshine for Shut-Ins), and assists her husband with his job as a church minister. Mrs. Hughes, a resident of Dunn, North Carolina, has lived there or in the surrounding area most of her life. (Hughes, Tr. 928).

Response to Finding No. 1266:

Respondent has no specific response.

1267. Since 2005, Mrs. Hughes has been licensed as an esthetician by the North Carolina Board of Cosmetic Art Examiners. Mrs. Hughes performs facials, at times using such modalities as a micro current machine and LED light therapy. As an esthetician she also performs other skin care treatments, including waxing. (Hughes, Tr. 928-931).

Response to Finding No. 1267:

Respondent has no specific response.

1268. Mrs. Hughes's training as an esthetician has included a 600-hour course at Central Carolina Community College in Sanford, North Carolina, and continuing education courses of at least eight hours per year. (Hughes, Tr. 930-931).

Response to Finding No. 1268:

Respondent has no specific response.

1269. Mrs. Hughes operates her business as SheShe Skin, currently located within the Hair Republic Salon in Dunn, North Carolina. (Hughes, Tr. 932-933).

Response to Finding No. 1269:

Respondent has no specific response.

George Nelson

1270. Mr. Nelson is the President of WhiteScience, a teeth whitening manufacturing company located in Alpharetta, Georgia. (Nelson, Tr. 721-722).

Response to Finding No. 1270:

Respondent disputes this proposed finding of fact. Mr. Nelson testified that

WhiteScience is a teeth whitening manufacturing and marketing business. (Nelson, Tr. 721-722).

1271. WhiteScience manufactures and sells a teeth whitening system called SpaWhite. SpaWhite is principally marketed to spas, salons, fitness centers, trade shows, and mall locations. WhiteScience also sells a teeth whitening product to dentists called Artiste. WhiteScience sells its products in over 40 states. (Nelson Tr. 725-726, 729, 800)

Response to Finding No. 1271:

Respondent has no specific response.

Joyce Osborn

1272. Ms. Osborn is the president and founder of BEKS, Inc., which manufactures and distributes the BriteWhite Teeth Whitening System ("BriteWhite System") BEKS, located in Jasper, Alabama, has been in operation since 2004. (Osborn, Tr. 646-647).

Response to Finding No. 1272:

Respondent has no specific response.

1273. Ms. Osborn is the President of the Council for Cosmetic Teeth Whitening ("CCTW"), created in 2007 and incorporated in 2008. CCTW is a trade association that promotes the cosmetic teeth whitening industry, and provides a self-administered teeth whitening protocol for use by manufacturers and distributors of non-dentist teeth whitening systems. (Osborn, Tr. 675, 687).

Response to Finding No. 1273:

Respondent disputes this proposed finding of fact. Ms. Osborn testified that the Council for Cosmetic Teeth Whitening is a trade organization that "support[s] the self-administered teeth-whitening protocol." (Osborn, Tr. 675). Ms. Osborn also testified that the CCTW is "devoted to the professional development of the cosmetic teeth-whitening industry in the United States." (Osborn, Tr. 687).

1274. Ms. Osborn has been in the beauty industry for more than 30 years, and has operated a beauty salon and spa for more than 26 years. (Osborn, Tr. 647).

Response to Finding No. 1274:

Respondent disputes this proposed finding of fact. Ms. Osborn testified that she has been a businesswoman for the past 30 years – not in the beauty industry for more than 30 years. (Osborn, Tr. 647).

James Valentine

1275. Mr. Valentine is a co-founder of WhiteSmile USA, a manufacturer and marketer of teeth whitening products, founded in 2007. By 2008, WhiteSmile USE earned revenues of \$10 million, had 125 to 130 employees, and operated in more than 60 Sam's Club stores across the United States. In its first three years of operation, WhiteSmile oversaw more than 100,000 in-store bleachings. (Valentine, Tr. 515, 546-548).

Response to Finding No. 1275:

Respondent has not specific response.

1276. Mr. Valentine delayed and later limited WhiteSmile USA's entry into North Carolina due to the Board's opposition to non-dentist teeth whitening, causing substantial losses. (Valentine, Tr. 574-575, 578).

Response to Finding No. 1276:

Respondent disputes this proposed finding of fact. Mr. Valentine testified that Sam's made the decision not to let WhiteSmile USA go into its stores in North Carolina until 2009. (Valentine, Tr. 574).

Brian Wyant

1277. Mr. Wyant is an entrepreneur who has owned and operated several businesses. His work has included being a general contractor for home improvements, engaging in real estate development, selling products online, and operating a teeth-whitening business. Prior to moving to Charlotte, Mr. Wyant owned an insurance brokerage business in Michigan. Mr. Wyant currently lives in Charlotte, North Carolina, and has lived in the state of North Carolina for about 27 years. (Wyant, Tr. 860, 892). Mr Wyant opened a WhiteScience kiosk after asking questions about the business over the phone and traveling to the company's headquarters in Atlanta for training on the protocol relating to teeth whitening, product information, and issues relating to documentation, utilizing a consent form, and procedures for safety and cleanliness. (Wyant, Tr. 864-866). Mr. Wyant's kiosk lease was not renewed after he was told that the Board had sent a letter

to the mall where he was located stating that the business was the illegal practice of dentistry. (Wyant, Tr. 876-884; CX0629 at 001-003).

Response to Finding No. 1277:

Respondent has no specific response.

2. Respondent's Witnesses

Dr. Willis Stanton Hardesty, Jr.

1278. Dr. Hardesty is a licensed dentist in Raleigh, North Carolina. He served two terms on the Board, from August 2004 through July 2010. His first term was from August 2004 to July 2007; his second term was from August 2007 to July 2010. (Hardesty, Tr. 2759, 2761-2762; CX0565 at 007 (Hardesty, Dep. at 20-21)).

Response to Finding No. 1278:

Respondent has no specific response.

1279. Dr. Hardesty held the following positions on the Board: Secretary-Treasurer from August 2006 to July 2007; President from August 2007 to July 2008; and Immediate Past President from August 2008 to July 2009. (Hardesty, Tr. 2790-2793; CX0565 at 007-008 (Hardesty, Dep. at 20-23)).

Response to Finding No. 1279:

Respondent has no specific response.

1280. Dr. Hardesty was a member of both the Academy of General Dentistry, the North Carolina Academy of General Dentistry and the American Academy of Cosmetic Dentistry. Dr. Hardesty held "every office beginning with a delegate through presidency and on to the past presidency" at the North Carolina Academy of General Dentistry, and was a delegate to the House of Delegates of the Academy of General Dentistry. The North Carolina Academy of General Dentistry has, as one of its purposes the furthering of interest of dentists in the dental profession, including financial interests. (Hardesty, Tr. 2798-2800).

Response to Finding No. 1280:

Respondent disputes this proposed finding of fact as containing an assumption.

According to Dr. Hardesty's testimony, he assumed that financial interests were part of the N.C. Academy of General Dentistry's purposes. (Hardesty, Tr. 27799-2800).

1281. There was a multi-year overlap between Dr. Hardesty's service in officer positions at the North Carolina Academy of General Dentistry and a delegate to the House of Delegates of the Academy of General Dentistry and Dr. Hardesty's service on the Board. (Hardesty, Tr. 2800).

Response to Finding No. 1281:

Respondent disputes this proposed finding of fact as containing an assumption about Dr.

Hardesty's ethical performance of his duties as a member of the State Board.

1282. Dr. Hardesty testified that even if the complainant in a matter was a dentist, the case would not be discussed with that dentist other than notification that there was resolution or closure of the investigation instigated by that dentist's complaint to the Board. (Hardesty, Tr. 2768). However, documents show that teeth whitening investigations were discussed on multiple occasions with dentist-complainants. (CX0365 at 002 (complainant dentist thanking Dr. Hardesty for sending a Board investigator to the allegedly problematic non-dentist teeth whitening kiosk and expressing hope that the Board will issue an injunction); CX0292 at 001 (January 2007 e-mail from Terry Friddle to complaining dentist thanking him and stating "[i]t appears from reviewing this website that the procedure being utilized could be considered the practice of dentistry. As such, the Board will conduct an investigation."); CX0282 at 001 (January 2007 e-mail from Terry Friddle to complaining dentist thanking him and assuring him that the Board "will look into this matter and notify you of our findings."); CX0460 at 001 (October 2009 email from Terry Friddle to complaining dentist thanking him and stating that the Board will "let you know what we find out").

Response to Finding No. 1282:

Respondent disputes this proposed finding of fact as a mischaracterization of the record and as an incomplete statement of fact. The testimony cited by Complaint Counsel in support of this proposed finding of fact is an incomplete recounting of Dr. Hardesty's response to Complaint Counsel's series of questions as to whether there would be any discussions with dentist complainants about investigations that have been or are being conducted (emphasis added). (Hardesty, Tr. 2768). Dr. Hardesty also testified that "there would be no discussion of the case specifics." (Hardesty, Tr. 2768).

Each of the documents cited by Complaint Counsel in support of this proposed finding of fact occurred at the time initial contact with the Board was made by the complainant.

(CX365 at 2; CX292 at 1; CX282 at 1; CX460 as 1-2). An examination of each of the documents cited by Complaint Counsel in support of this proposed finding of facts shows that there was no discussion about the case specifics. (CX365 at 2 (complaint dentist provides further details on the teeth whitening kiosk after initial phone call to report the kiosk to the Board); CX292 at 1 (Ms. Friddle requests information about the name and address of the salon from the complainant so investigative file can be opened); CX282 at 1 (cursory email from Ms. Friddle prior to the opening of the investigative file); CX460 at 1-2 (another cursory email exchange between Ms. Friddle and a complainant, in which she requests further information about the owner/operator of the file).

1283. Dr. Hardesty testified without credibility that the Board has indicated that it would not "regulate as teeth whitening" a situation where "a consumer goes to a mall kiosk or a spa or a salon and they are handed a teeth-whitening kit which the consumer uses the contents of the kit themselves with supervision but no touching by the customer representative." (Hardesty, Tr. 2795). Yet Dr. Hardesty previously testified that this exact conduct would constitute the practice of dentistry if the consumer applied the whitening material in a chair provided by the kiosk. (CX0566 at 034 (Hardesty, IHT at 133); Hardesty, Tr. 2849-2850 (kiosk enters the "grey area" if the operator does not touch the customer but reads the instructions of the teeth-whitening product and wears a white coat)). Terry Friddle also testified that it was always the policy of the Board that providing a whitening tray to someone for them to insert in their own mouth would be considered the practice of dentistry. (CX0562 at 010 (Friddle, IHT at 36).

Response to Finding of Fact No. 1283:

Respondent disputes this proposed finding of fact as containing an opinion – not fact.

Respondent also disputes this proposed finding of fact as a mischaracterization of the testimony. Dr. Hardesty's testimony pertained to the handing of a "teeth whitening kit" to a consumer. (Hardesty, Tr. 2795). The handing of a "kit" to someone carries the implication that the "kit" is contained in some sort of packaging that the person will open, read the instructions themselves, prepare the contents for use themselves, and then self-administer the contents of the kit. Ms. Friddle's testimony pertained to providing a "teeth

whitening tray” to someone. (CX562 (Friddle, IHT at 36). The use of the phrase “teeth whitening tray” carries with it the implication that the person handing the tray to someone has prepared the materials in the tray.

1284. Dr. Hardesty earned \$47,279 from teeth whitening from 2005 to 2010. (CX0378 at 012).

Response to Finding of Fact No. 1284:

Respondent strongly objects to the inclusion of Dr. Hardesty’ revenue information in a publicly-filed document since he provided it to the Commission in response to a *subpoena duces tecum* (CX378), which specifically stated “[a]ll information submitted pursuant to this subpoena is subject to the confidentiality provisions of Section 21(f) of the Federal Trade Commission Act, 15 U.S.C. § 57b-2(f), and Rule 4.10 of the Federal Trade Commission.” The subpoena was also accompanied by the protective order issued by Judge Chappell in this matter. (For example, see CX616 at CQA-FTC-15 through CQA-FTC-18 (Complaint Counsel failed to number the individual pages of this exhibit)).

1285. Dr. Hardesty testified that the spread of infectious disease, including HIV, hepatitis, and tuberculosis, is a concern associated with non-dentist teeth whitening that uses a curing light because of the potential of cross-contamination. (Hardesty, Tr. 2783-2784).

Response to Finding of Fact No. 1285:

Respondent has no specific response.

- a. Hardesty testified that he had never heard of any transmission of tuberculosis, hepatitis, or any other infectious disease being attributed to a business providing non-dentist teeth whitening services. (Hardesty, Tr. 2829).

Response to Finding of Fact No. 1285(a):

Respondent has no specific response.

1286. Dr. Hardesty testified that only way a dentist can find out if the Board has taken any action pertaining to an investigation is if the case is finalized as a consent order and then the dentist can look on the Board's web site. (Hardesty, Tr. 2768-2769).

Response to Finding of Fact No. 1286:

Respondent disputes this proposed finding of fact as a mischaracterization of Dr.

Hardesty's testimony and as containing an assumption. Dr. Hardesty's response was framed in terms of "other dentists" being able to look at the Board's website. (Hardesty, Tr. 2768-2769). The only actions placed on the Board's website are disciplinary actions involving licensees. (<http://www.ncdentalboard.org/disciplinary.htm>).

- a. On January 24, 2007, Ms. Friddle replied to Dr. Link's January 12, 2007 complaint e-mail by informing him that Enhanced Light Technology would be investigated. She also asked the name and address of the salon where Dr. Link learned of the company for purposes of the investigation. (CX0372 at 001-002).

Response to Finding of Fact No. 1286(a):

Respondent disputes this proposed finding of fact as containing an assumption. Dr.

Hardesty also testified that the details of an investigation would remain confidential.

(Hardesty, Tr. 2767). Enquiring of a complainant the basic information regarding the name and address of a business so an investigation could be opened are hardly details, and at this point, the case file had not even been opened. (CX372 at 1-2).

- b. On January 23, 2008, Ms. Friddle forwarded to Dr. Kyle Taylor, a dentist with an office in Charlotte, North Carolina, a copy of the letter the Board sent to General Growth Properties on November 21, 2007, asking the mall owners to refrain from renting space to providers of non-dentist teeth whitening. (CX0102 at 001-003).

Response to Finding of Fact No. 1286(b):

Respondent disputes this proposed finding of fact. There is no evidence in the record of Dr. Taylor reporting a teeth whitening kiosk in Carolina Place Mall to the Board. (Entire record). Further, there is no evidence that the mall letters were not part of any particular investigation. (Entire record).

Dr. Ronald Owens

1287. Dr. Ronald K. Owens is a general dentist who has been licensed in the state of North Carolina since 1996. His dental practice is currently located in Winston-Salem, North Carolina. (Owens, Tr. 1434-1435).

Response to Finding No. 1287:

Respondent has no specific response.

1288. Dr. Owens has been a member of the State Board of Dental Examiners since August 2005. He is the current President of the Board until his term expires on July 31, 2011. From August 2007 to July 2008, Dr. Owens served as Secretary-Treasurer of the Board; in 2008-2009, Dr. Owens served as President of the Board; in 2009-1010, Dr. Owens served as Immediate Past President. (Owens, Tr. 1439-1440).

Response to Finding No. 1288:

Respondent has no specific response.

1289. Dr. Owens indicated that he filed a Statement of Economic Interest ("SEI") with the North Carolina Ethics Commission as required by the North Carolina Ethics Act. Dr. Owens testified that after he filed the SEI, he received a letter from the North Carolina Ethics Commission indicating "being a dentist on the Board ... was a possible conflict of interest." (Owens, Tr. 1437-1438).

Response to Finding No. 1289:

Respondent has no specific response.

1290. Dr. Owens earned \$77,333 from teeth whitening from 2005 to 2010. (CX0467 at 001).

Response to Finding No. 1290:

Respondent strongly objects to the inclusion of Dr. Owens' revenue information in a publicly-filed document since he provided it to the Commission in response to a *subpoena duces tecum* (CX467), which specifically stated "[a]ll information submitted pursuant to this subpoena is subject to the confidentiality provisions of Section 21(f) of the Federal Trade Commission Act, 15 U.S.C. § 57b-2(f), and Rule 4.10 of the Federal Trade Commission." The subpoena was also accompanied by the protective order issued

by Judge Chappell in this matter. (For example, see CX616 at CQA-FTC-15 through CQA-FTC-18 (Complaint Counsel failed to number the individual pages of this exhibit)). Further, Respondent disputes this proposed finding of fact as a mischaracterization of the record. Dr. Owens testified that the revenues that he reported in response to the subpoena were revenues that were earned by both himself and his partner; they were not solely his revenues. (Owens, Tr. at 1589-1590).

1291. Dr. Owens testified that he earned revenue from teeth whitening during the period of time when he assigned teeth whitening cases to himself. (Owens, Tr. 1579).

Response to Finding No. 1291:

Respondent has no specific response.

1292. Dr. Owens testified that he has handled approximately eighteen teeth whitening cases as Case Officer and that most of the Board's teeth whitening cases have been assigned to him. He further testified that he became the primary Board member handling teeth whitening cases as a result of assignments he made during his term as Secretary-Treasurer. (Owens, Tr. 1445-1446, 1605).

Response to Finding No. 1292:

Respondent disputes this proposed finding of fact as containing an assumption as to Dr. Owens' motives and as an incomplete statement of fact. Dr. Owens also testified that he kept a lot of cases of all types as secretary-treasurer; it wasn't necessarily just teeth whitening. (Owens, Tr. 1605).

1293. Dr. Owens testified that he never disclosed to anyone on the Board how much money he made from teeth whitening before receiving a subpoena from the Federal Trade Commission. (Owens, Tr. 1579-1580).

Response to Finding No. 1293:

Respondent disputes this proposed finding of fact as containing an assumption as to Dr. Owens' motives and as an incomplete statement of fact. Dr. Owens also testified that the

Board members had no knowledge of how much money he made from “any other things that deal with dentistry.” (Owens, Tr. 1580).

1294. Although Dr. Owens offers teeth whitening services to his patients, Dr. Owens has not recused himself as a case officer for teeth whitening cases. (Owens, Tr. 1451, 1445).

Response to Finding No. 1294:

Respondent disputes this proposed finding of fact as the testimony cited by Complaint Counsel in support of this proposed finding of fact do not mention recusal. (Owens, Tr. 1445, 1451).

1295. Dr. Owens was not a credible witness. He was evasive and did not provide yes or no answers when asked questions that called for them during cross examination. At one point, Judge Chappell stated, "Dr. Owens, I think you need to be more focused. I think you need to pay attention closely, and when a question calls for a yes or no answer, I'd like a yes or no answer. Is that understood? (Owens, Tr. 1600-1601; Owens, Tr. 1648 ("JUDGE CHAPPELL: You're not being asked whether it's happened or not. You're being asked if you have knowledge of it. You know that -- you know whether you have knowledge or not, so you can answer that yes or no. THE WITNESS: Then no.")).

Response to Finding No. 1295:

Respondent disputes this proposed statement of fact as an opinion – not a fact. Further, this proposed finding of fact has omitted Judge Chappell’s admonition to Complaint Counsel that occurred prior to his remarks directed to Dr. Owens – “I’m here, too, and I hear what’s going on. And what I see is, I’m hearing questions that aren’t properly focused.” (Owens, Tr. 1600). Also, directly prior to the second instance cited above by Complaint Counsel, Dr. Owens appealed to Judge Chappell for assistance as to how to respond to a question by Complaint Counsel where a yes or no answer was solicited. Dr. Owens said, “I don’t know, Your Honor.” (Owens, Tr. 1648).

1296. Dr. Owens testified that he was the case officer for the case involving SheShe Studio Spa. Dr. Owens testified that he investigated by personally contacting the salon and asking what teeth whitening product they used and if it was administered by the

customer. Dr. Owens testified that "the response was that the customer places the impression tray into the mouth and that the salon did everything else and said it's just like at the dentist." (Owens, Tr. 1456-1457).

Response to Finding No. 1296:

Respondent disputes this proposed finding of fact as containing an assumption about Dr. Owens' credibility. Dr. Owens' recollection about the basic facts of his investigation was correct; however, the salon's name was different than the salon name that he recalled. (Owens, Tr. 1456-1457; RX28 at 1-2).

1297. SheShe Studio Spa is owned and operated by Ms. Margie Hughes, a witness presented by Complaint Counsel. The Board's records and trial exhibits indicate that Dr. Hardesty was the case officer handling SheShe Studio Spa case, not Dr. Owens. (RX00024 at 001). The Board's "Notice and Order to Cease and Desist" sent to SheShe Studio Spa was dated February 23, 2007. (CX0096 at 001).

Response to Finding No. 1297:

Respondent has no specific response.

1298. When asked whether he had taken into account biases, such as if the complainant might be financially impacted by a teeth whitening kiosk, when determining witness credibility, Dr. Owens provided an evasive answer stating, "I'm not sure that - I'm not sure that I have specifically taken that into consideration." (CX0571 at 023-24 (Owens, IHT at 89-90)).

Response to Finding No. 1298:

Respondent disputes this proposed finding of fact as containing an assumption as to the character of Dr. Owens' response.

1299. Dr. Owens was also evasive when asked about his teeth whitening fees. He stated that he had both decreased and increased his teeth whitening fees over a period of five years. When asked why the decrease took place, Dr. Owens stated, "Just trying to get - we basically were - wanted to have it available for more of our patients." (CX0571 at 008 (Owens, IHT at 29)).

Respondent to Finding No. 1299:

Respondent disputes this proposed finding of fact as containing an assumption as to the character of Dr. Owens' response. The testimony designated by Complaint Counsel shows that Dr. Owens was forthcoming by testifying that his initial fee was decreased, then when everything started getting more expensive, it was increased a bit. (CX571 (Owens, IHT at 29)). He also testified that during the majority of that time, the fee remained the same. (CX571 (Owens, IHT at 29)).

Brian Runsick

1300. Mr. Brian Runsick is a consumer who claimed an injury as a result of his teeth bleaching at the BleachBright facility at Crabtree Valley Mall in February 2008. (Runsick, Tr. 2105-2106).

Response to Finding No. 1300:

Respondent has no specific response.

1301. Mr. Runsick submitted a complaint to the Board in April 2008 and claimed that he did not experience pain until four days after bleaching. Yet at trial, Mr. Runsick claimed he began experiencing pain just two or three days after bleaching. On cross examination, he testified that perhaps he did not have any pain until five days after the bleaching. He later recanted his previous testimony and stood by the facts in his initial complaint; that he did not have any symptoms until four days after the bleaching. (Runsick, Tr. 2167-2168, 2171-2171; CX 0055 at 001-004).

Response to Finding No. 1301:

Respondent disputes this proposed finding of fact as a mischaracterization of the record. The citations to Mr. Runsick's testimony in this proposed finding of fact all relate to one line of questioning about a Channel 5 News report about his experience. (Runsick, Tr. 2166-2167, 2150, 2166-2167, 2168, 2171-2172). This entire line of questioning is based on a misrepresentation made during the hearing, and in the first sentence of this proposed finding of fact, that the statement attributed to Mr. Runsick is a direct quotation of what he said to the reporter. An examination of the exhibit offered in support of this proposed

finding of fact plainly shows that while other statements by Mr. Runsick are contained within quotation marks, the statement regarding the onset of his pain five days later is not. (CX117 at 1). Further, Mr. Runsick's notarized complaint to the Board averred that his gums began to hurt four days after the teeth whitening procedure was performed. (CX55 at 3).

Dr. Larry Tilley

1302. Dr. Larry Tilley is a licensee of the Board and practices general dentistry in Raleigh, North Carolina. (Tilley, Tr. 1997).

Response to Finding No. 1302:

Respondent has no specific response.

1303. Dr. Tilley has worked as a paid consultant for the Board for about twenty years. Dr. Tilley evaluates complaints, examines complainants, and reports back to the Board. Dr. Tilley acts as a consultant for the Board two or three times a year, on issues such as dentures, decay, crowns, and general dental procedures. Dr. Tilley has consulted for the Board on only one teeth whitening complaint. (Tilley, Tr. 2004-2007).

Response to Finding No. 1303:

Respondent disputes this proposed finding of fact as containing an assumption as to Dr. Tilley's compensation. Dr. Tilley testified that the Board paid him standard patient rates and would also pay for the exam and any records. (Tilley, Tr. 2007).

Dr. Millard "Buddy" Wester III

1304. Dr. Millard "Buddy" W. Wester III is a general dentist practicing in Henderson, North Carolina. He became licensed to practice dentistry in North Carolina in August 1980. (Wester, Tr. 1276-1277).

Response to Finding No. 1304:

Respondent has no specific response.

1305. Dr. Wester has been a member of the Board since 2008, and became Secretary-Treasurer in August 2010. (Wester, Tr. 1276, 1278, 1281, 1315-1316). His first term will expire in July 2011.

Response to Finding No. 1305:

Respondent has no specific response.

Bobby White

1306. Mr. Bobby White is the Chief Operating Officer of the Board; he has had this position since February 2004. He is a licensed attorney in North Carolina. (White, Tr. 2189-2189; CX 0574 at 004 (White, IHT at 11)).

Response to Finding No. 1306:

Respondent has no specific response.

1307. Mr. White testified that he is predominantly responsible for the daily operations of the Board. His duties include human resources, payroll, insurance, contract negotiations, and advising the Board with regard to disciplinary and legal matters. As part of his duties, he has been designated as the media contact for the Board, and the Board's representative with the North Carolina legislature. (White, Tr. 2190, 2256; CX0574 at 004, 020 (White IHT at 11-12, 77)).

Response to Finding No 1307:

Respondent has no specific response.

1308. Mr. White testified that part of his duties include serving as liaison with the North Carolina Dental Society. (White, Tr. 2256-2257; CX0574 at 004 (White, IHT at 11-12)).

Response to Finding No. 1308:

Respondent disputes this proposed finding of fact as a mischaracterization of the record.

In response to Complaint Counsel's question as to whether he was the "liaison or point person" for the Board's interactions with the Dental Society, Mr. White answered, "yes." (White, Tr. at 2256-2257).

1309. Mr. White testified that as part of his duties, he regularly meets with counterparts from other licensing boards in North Carolina. Mr. White testified that as a result of those meetings, he has become familiar with how other occupational licensing boards operate. (White, Tr. 2190-2191).

Response to Finding No. 1309:

Respondent has no specific response.

1310. Mr. White testified that Board members do not discuss the details of investigations with members of the public. (White, Tr. 2222).

Response to Finding No. 1310:

Respondent has no specific response.

- a. On April 24, 2008, Bobby White forwarded to Christine Bennett, Assistant Producer of 5 On Your Side, copy of a Cease and Desist Order the Board sent BleachBright on February 20, 2008 and a copy of the Board's complaint against Signature Spa. (CX0103 at 001-002, 011-013, 017-018).

Response to Finding No. 1310 a.:

Respondent disputes this proposed finding of fact as containing an assumption about the actions of Board members. Mr. White is not a Board member, he is a member of Board staff. (White, Tr. 2188).

- b. On April 24, 2008, Bobby White forwarded a copy of the Board's complaint against Carmel Day Spa, filed on January 17, 2008, to Christine Bennett. (CX0405 at 001-0004).

Response to Finding No. 1310 b.:

Respondent disputes this proposed finding of fact as containing an assumption about the actions of Board members. Mr. White is not a Board member, he is a member of Board staff. (White, Tr. 2188).

- c. On May 21, 2008, WRAL.com posted an article entitled "Teeth whitening kiosks at the mall are not regulated." (CX0117 at 001). The article states, "Board leaders told WRAL that the way they see it BleachBright and similar businesses practice dentistry without a license... The [B]oard filed lawsuits against two similar businesses and sent a 'cease and desist' letter telling BleachBright to stop operation..." (CX0117 at 001).

Response to Finding No. 1310 c:

Respondent disputes this proposed finding of fact as containing an assumption and as an incomplete statement of fact. The news article does not state that Board members were in

contact with WRAL; it specifically referred to “Board leaders,” which could be applicable to Board staff. (CX117 at 1).

1311. When asked about the legal effect of Cease and Desist Orders at trial, Mr. White stated that “we intend them as warnings. Folks that are noticed if we believe he [sic] violated the Dental Practice Act and you should – whatever actions that are outlined in this letter that you’re doing, if you’re doing them they violate the act, you should stop.” (White, Tr. 2229).

Response to Finding No. 1311:

Respondent has no specific response.

- a. At his deposition, Mr. White testified “the Board is ordering them either to stop whatever that activity is or to demonstrate why what they’re doing is not a violation of the Act.” (CX0573 at 007 (White Dep. at 19-20)).

Response to Finding No. 1311 a.:

Respondent disputes this finding of fact as an incomplete statement of fact. Mr. White’s complete answer to Complaint Counsel’s question was that the cease and desist letter was patterned after “a number of letters that [state that] the Board has [a] belief that the person receiving the letter has violated the Dental Practice Act.” (CX573 (White, Dep. at 19)). The Board is not ordering them to stop that activity; the Board is instead requesting that they “either stop whatever activity is or to demonstrate why what they’re doing is not a violation of the Act.” (CX573 (White, Dep. at 19-20)).

- b. Mr. White also testified that “[m]y memory is that there was legal counsel for the board prior to my coming to the board had cease and desist letter[s] in kind of a form letter that was used. This was one that I modified I think basically from that letter, so there’s been a kind of chain of Cease and Desist Orders that have gone through modification processes through the years, to my knowledge.” (White, Tr. 2349).

Response to Finding No. 1311 b.:

Respondent has no specific response.

1312. Mr. White testified that the primary reason for the Board to investigate complaints is to protect the public.

Response to Finding No. 1312:

This is an unsupported proposed finding of fact; Respondent, therefore does not have a response.

- a. Mr. White testified that when the Board is faced with something that presents an imminent and immediate health danger, the Board does not send a Cease and Desist Order, but goes directly to court to get an injunction or tries to get the interest of the appropriate assistant district attorney. (White, Tr. 2345-2346).

Response to Finding No. 1312 a.:

Respondent disputes this proposed finding of fact as containing an assumption. There is no requirement in the Dental Practice Act that harm or injury must occur before a complaint is received and accepted by the Board. (CX19 at 1-26).

B. Expert Witnesses Who Testified at Trial

1. Complaint Counsel's Witnesses

Dr. Martin Giniger

1313. Dr. Giniger was qualified without objection as an expert in the prevention, diagnosis, and treatment of diseases and conditions that affect the oral cavity; the history and practice of teeth whitening; and the formulation, safety, efficacy, and consumer acceptance of teeth bleaching, and other oral care, products and services. (Giniger, Tr. 104-105).

Response to Finding No. 1313:

Dr. Giniger was offered and accepted as an expert in the field of "prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products." (Giniger, Tr. 104). He was not offered or accepted as an expert in consumer acceptance of teeth bleaching.

1314. Dr. Giniger has been a licensed dentist since 1984; he also obtained a master's degree in the field of Oral Medicine and a Ph.D. in Biomedical Science, specializing in Oral Biology. (Giniger, Tr. 78-79).

Response to Finding No. 1314:

This proposed Finding is almost identical to proposed Findings Nos. 777 and 778. The Response to those proposed findings is incorporated herein by reference.

1315. Dr. Giniger has taught courses at prestigious dental schools on the topics of operative dentistry, including the history and practice of teeth whitening, oral diagnosis and treatment planning, and oral epidemiology. (Giniger, Tr. 80-83, 92-94; CX0653 at 001-002).

Response to Finding No. 1315:

This proposed Finding is almost identical to proposed Finding No. 781. The Response to that proposed finding is incorporated herein by reference.

1316. Dr. Giniger has a distinguished record as a scientific researcher on a variety of topics, including both basic and applied science, and has an extensive publication record in prestigious peer reviewed journals. (CX0653 at 002, 056-059; Giniger, Tr. 88).

Response to Finding No. 1316:

This proposed Finding is almost identical to proposed Finding No. 785. The Response to that proposed finding is incorporated herein by reference.

1317. Dr. Giniger was instrumental in the development of oral care methods/products for which fourteen patents have been issued, numerous of which relate specifically to teeth bleaching. (Giniger, Tr. 94-95; CX0653 at 055).

Response to Finding No. 1317:

This proposed Finding is almost identical to proposed Findings Nos. 785 and 786. The Response to each proposed finding is incorporated herein by reference.

1318. Dr. Giniger has also worked and consulted for numerous oral care companies, developing and/or testing the safety and effectiveness of a variety of oral care products including teeth bleaching products. (Giniger, Tr. 96-98; CX0653 at 002).

Response to Finding No. 1318:

This proposed Finding is almost identical to proposed Finding No. 789. The Response to that proposed finding is incorporated herein by reference.

1319. Dr. Giniger was instrumental in the development of, among other products, Colgate's Whitening Toothpastes and Systems, Discus' NiteWhite with ACP at-home teeth bleaching product, and Discus' Zoom2 teeth bleaching system for in-office use. Aggregate sales of these products have exceeded \$10 billion. (Giniger, Tr. 94-95; CX0653 at 002-003).

Response to Finding No. 1319:

This proposed Finding is almost identical to proposed Finding No. 791. The Response to that proposed finding is incorporated herein by reference.

1320. In his employments and consultancies, Dr. Giniger also has been involved in the assessment of consumer satisfaction and preference with respect to teeth bleaching methods/formulations. (Giniger, Tr. 126).

Response to Finding No. 1320:

This proposed Finding is almost identical to proposed Finding No. 793. The Response to that proposed finding is incorporated herein by reference.

1321. Dr. Giniger recently founded and is Chief Scientific Officer of Power Swabs Corp, which manufactures and sells to dentists a detergent-containing formulation applied to the teeth before bleaching to increase whitening effectiveness while reducing bleaching-related gingival sensitivity. (Giniger, Tr. 103-104).

Response to Finding No. 1321:

This proposed Finding is almost identical to proposed Finding No. 795. The Response to that proposed finding is incorporated herein by reference.

1322. Dr. Giniger reviewed the documents produced by the Board and by third parties, the depositions taken, various pleadings of both Complaint Counsel and the Board, and the Expert Report of Dr. Haywood. (Giniger, Tr. 106-107).

Response to Finding No. 1322:

This proposed Finding is almost identical to proposed Finding No. 797. The Response to that proposed finding is incorporated herein by reference.

1323. In addition, Dr. Giniger conducted an extensive review of the relevant scientific literature, including the materials referred to in Dr. Haywood's Report, and also drew on his extensive knowledge and expertise in the field of oral care and teeth bleaching. (Giniger, Tr. 106-107).

Response to Finding No. 1323:

This proposed Finding is almost identical to proposed Finding No. 798. The Response to that proposed finding is incorporated herein by reference.

Dr. John Kwoka

1324. Dr. John Kwoka is the Neal Finnegan Distinguished Professor of Economics at Northeastern University, where he teaches in the economics department. (Kwoka, Tr. 969-970).

Response to Finding No. 1324:

Respondent has no specific response.

1325. Professor Kwoka has a bachelor's degree in economics from Brown University and a Ph.D. in economics from the University of Pennsylvania. (Kwoka, Tr. 971).

Response to Finding No. 1325:

Respondent has no specific response.

1326. He has taught at Northeastern University for ten years; prior to that, he taught for twenty years on the economics faculty at the George Washington University. Professor Kwoka has also taught at the University of North Carolina, and has had visiting faculty positions in the economics departments at Northwestern University and at Harvard University. (Kwoka, Tr. 971-972).

Response to Finding No. 1326:

Respondent has no specific response.

1327. In his position at Northeastern University, Professor Kwoka is primarily responsible for the Ph.D. courses in industrial organization economics. He developed the Ph.D. curriculum and each year teaches one of the core courses in industrial organization, covering the economics of antitrust and regulatory policy. He also is responsible for writing and grading comprehensive exams, the qualifying exams for Ph.D. students, and advising Ph.D. students on their dissertations. (Kwoka, Tr. 972).

Response to Finding No. 1327:

Respondent has no specific response.

1328. Professor Kwoka worked for six years in the Bureau of Economics at the Federal Trade Commission, and one year each in the Antitrust Division of the Department of Justice and as a Special Assistant to the Director of the Common Carrier Bureau of the Federal Communications Commission. (Kwoka, Tr. 972-973).

Response to Finding No. 1328:

Respondent has no specific response.

1329. Professor Kwoka has published two books and over 70 scholarly articles, all in the areas of industrial organization, antitrust economics, and regulatory economics. (Kwoka, Tr. 974-975).

Response to Finding No. 1329:

Respondent has no specific response.

1330. Professor Kwoka has been president of the Industrial Organization Society, Vice President of the Southern Economics Association, and general Editor of the Review of Industrial Organizations. (Kwoka, Tr. 973).

Response to Finding No. 1330:

Respondent has no specific response.

2. Respondent's Witnesses

Dr. David Baumer

1331. Dr. David Baumer was not hired for his knowledge of the law. (CX0826 at 004 (Baumer, Dep. at 6)).

Response to Finding No. 1331:

Complaint Counsel has not designated any of Dr. Baumer's deposition.

1332. The last time Dr. Baumer wrote on the issue of antitrust was in 2004, for a textbook. The last time Dr. Baumer published an article in the area of antitrust was in the mid 1980s. (CX0826 at 004 (Baumer, Dep. at 7-9)).

Response to Finding No. 1332:

Complaint Counsel has not designated any of Dr. Baumer's deposition.

1333. Dr. Baumer has not authored an article in one of the "top" economics journals. (CX0826 at 012 (Baumer, Dep. at 41)).

Response to Finding No. 1333:

Complaint Counsel has not designated any of Dr. Baumer's deposition. Furthermore, Dr.

Baumer testified that he co-authored an article, which was published in the American Journal of Agricultural Economics, a top journal in its field.

1334. As discussed at length in the findings below, Dr. Baumer admitted that (a) he had no basis for certain assumptions underlying his opinions, (b) his expert report was not written with "due diligence" and he changed critical opinions after he was engaged to write the report and (c) the presence of other facts that he did not learn during the abbreviated time he had to prepare his report would militate against justifying the Board's exclusion of non-dentist teeth whiteners.

a. Dr. Baumer admits that each of the following facts that the Court finds contrary to his assumptions would lead him to reconsider his opinion that the Board's conduct was economically efficient.

1. Undermined Claim/Assumption: Non-dentist teeth whitening results, or is likely to result, in physical injury to consumers.
 - (a) Dr. Baumer admits that he does not have any actual evidence that non-dentist teeth whitening causes cancer. (Baumer, Tr. 1820).

Response to Finding No. 1334 (a)(1)(a):

Respondent has no specific response.

- (b) Dr. Baumer admits that he does not have any reason to think that his assumption that non-dentists teeth whitening causes oral cancer in one in ten customers is valid. Dr. Baumer assumed "extreme" and "farfetched" facts in order to make a point. (Baumer, Tr. 1820, 1938-1939). Dr. Baumer stated that his research regarding cancer risks of non-dentists teeth whitening consisted of typing various search terms in an internet browser. (Baumer, Tr. 1821-1822).

Response to Finding No. 1334 (a)(1)(b):

Respondent objects to the mischaracterization of Baumer, Tr. 1820-22, 1938-39. Dr. Baumer did not testify that he made extreme or farfetched assumptions to make a point. Dr. Baumer testified that he researched various newspaper articles and magazine articles on the internet, which provided information on the dangers of teeth whitening by non-licensed providers.

- (c) Dr. Baumer admits that he does not know whether any of the "double-blind studies" that he states contradict Dr. Giniger's report and testimony actually involved teeth whitening. (CX0826 at 028 (Baumer, Dep. at 103-104)).

Response to Finding No. 1334 (a)(1)(c):

Complaint Counsel has not designated any of Dr. Baumer's deposition. Furthermore, Respondent objects to the mischaracterization of the evidence. Dr. Baumer testified that he did not know how many of the studies at issue involved or related to nondentist teeth whitening.

- (d) Dr. Baumer admits that he was "unprofessional" and "needlessly dramatic" in describing non-dentist teeth

whitening as life threatening in his report. (Baumer, Tr. 1768; CX0631 at 010).

Response to Finding No. 1334 (a)(1)(d):

Respondent objects to the mischaracterization of the evidence. CX0631, the rebuttal report of Dr. Kwoka, is hearsay and cannot be attributed as evidence of an admission by Dr. Baumer. Although Dr. Baumer admitted his choice of language was “a little overly dramatic,” he did not admit that his conclusions on potential harm were wrong.

- (e) Dr. Baumer agrees that if there were health problems, he would expect to observe, but did not, systematic reporting by consumers of health problems requiring dentists to perform remedial work to repair the damage (Baumer, Tr. 1962, 1967-1968; CX0826 (Baumer, Dep. 162)).

Response to Finding No. 1334 (a)(1)(e):

Complaint Counsel has not designated any of Dr. Baumer’s deposition. Dr. Baumer merely admitted that he was unaware “of any empirical data.”

- (f) Dr. Baumer admits that some of the articles he relied upon in his report to come to the conclusion that there were significant health and safety concerns from non-dentist teeth whitening, were not academic or governmental sources. Dr. Baumer agrees that exclusive reliance on such sources is not his standard practice in forming expert opinions. (Baumer, Tr. 1956-1957).

Response to Finding No. 1334 (a)(1)(f):

Dr. Baumer admitted to using websites; he testified that he would not use them for “exclusive reliance” on such sites.

- (g) Dr. Baumer admits that he did not read the articles cited in his expert report as evidence of health problems, other than

the title and abstract in one the Board's pleadings. (Baumer, Tr. 1827-1829).

Response to Finding No. 1334 (a)(1)(g):

Dr. Baumer testified that he “cannot answer yes or no...there were about 30 of them...but by the time of his deposition I had read a few more.” (Baumer, Tr. 1827).

- (h) Dr. Baumer admits that at the time he wrote his report he had no basis for his conclusions or assumptions relating to the health effects of non-dentist teeth whitening other than from conversations with Respondent counsel and from reading titles and abstracts of articles cited in Respondent's statement of facts. (Baumer, Tr. 1830; CX0826 at 022-023 (Baumer, Dep. at 79-82)).

Response to Finding No. 1334 (a)(1)(h):

Complaint Counsel has not designated any of Dr. Baumer's deposition. Dr. Baumer testified “...but I put in my report that I reserve the right to revise the report if I get any contrary information, ...and, from what I have seen since then, there's no reason to revise my report.” (Baumer, Tr. 1830).

- (i) Dr. Baumer admits that at the time he wrote his report he had not read the expert reports of either Dr. Giniger or Dr. Haywood. Dr. Baumer admits that he formed the opinions in his report without having read the report of either industry expert. (Baumer, Tr. 1827-1829).

Response to Finding No. 1334 (a)(1)(i):

Dr. Baumer testified that he had not read Dr. Haywood's report or Dr. Giniger's report before writing his report. “I'd read both reports by the time of the deposition.” (Baumer, Tr. 1828). Dr. Baumer testified “...but I put in my report that I reserve the right to revise the report if I get any contrary information, ...and, from what I have seen since then, there's no reason to revise my report.” (Baumer, Tr. 1830).

2. Undermined Claim/Assumption: Non-dentist teeth whiteners deceive consumers.

- (a) Dr. Baumer admits that if it were not true that non-dentists wore medical apparel in a way that confused consumers he would have less of an economic reason to conclude that the Board's conduct was justified. (Baumer, Tr. 1936).

Response to Finding No. 1334 (a)(2)(a):

The page citation is incorrect. This proposed finding grossly mischaracterizes Dr. Baumer's testimony. He testified that he had addressed it because Dr. Kwoka did, and because it had been addressed by Respondent's counsel and pleadings. (Baumer, Tr. 1934-1935).

- (b) Dr. Baumer admits that it was wrong to take the view that "where there's smoke, there's fire," simply because Professor Kwoka assumed arguendo that the deception had occurred. (CX0826 at 017 (Baumer, Dep. at 58-59).

Response to Finding No. 1334 (a)(2)(b):

Complaint Counsel has not designated any of Dr. Baumer's deposition.

- (c) Dr. Baumer admits that the only main source for his belief that non-dentist teeth whiteners wear medical garb to deceive consumers was assertions to that effect in the Board's pleadings. (Baumer, Tr. 1934-1936).

Response to Finding No. 1334 (a)(2)(c):

This proposed finding grossly mischaracterizes Dr. Baumer's testimony. He testified that he had addressed it because Dr. Kwoka did, and because it had been addressed by Respondent's counsel and pleadings. (Baumer, Tr. 1934-1935).

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- (d) Dr. Baumer admits that he was unaware that there have been no complaints to the Board that any customers have been misled by non-dentist teeth whiteners appearing to be dentists. (Baumer, Tr. 1951).

Response to Finding No. 1334 (a)(2)(d):

Respondent has no specific response.

- (e) Dr. Baumer admits that he does not have any evidence that nondentist dress in medical garb in a way that deceives customers other than from Respondent's Counsel and Respondent's pleadings. (Baumer, Tr. 1934-1936).

Response to Finding No. 1334 (a)(2)(e):

This proposed finding grossly mischaracterizes Dr. Baumer's testimony. He testified that he had addressed it because Dr. Kwoka did, and because it had been addressed by Respondent's counsel and pleadings. (Baumer, Tr. 1934-1935).

- 3. Undermined Claim/Assumption: Non-dentist teeth whiteners harm consumers by collecting and selling medical information.

- (a) Dr. Baumer admits that his sole basis for contending that nondentist teeth whiteners collect and sell medical information comes from Respondent's Counsel and Respondent's briefs. (Baumer, Tr. 1721, 1951-1952, 1955).

Response to Finding No. 1334 (a)(3)(a):

This proposed finding mischaracterizes Dr. Baumer's testimony. He testified that non-dentists were not covered by HIPPA and "might be tempted to sell that information." (Baumer, Tr. 1720). He also testified that "...it's my understanding that their procedure ...involves questioning patients about their dental history, cavities, abscesses, and reasons for discolored teeth, recent root canals, and so forth, and that they write this information down and make use of it." (Baumer, Tr. 1951).

- (b) Dr. Baumer admits that he has no evidence of non-dentist providers of teeth whitening selling medical information. (Baumer, Tr. 1956).

Response to Finding No. 1334 (a)(3)(b):

Respondent has no specific response.

- 4. Undermined Claim/Assumption: Non-dentist teeth whiteners operate in unsanitary conditions, particularly when compared to dentists.
 - (a) Dr. Baumer was unaware that salon teeth whiteners often have protocols that protect against sanitation issues, and admitted that there would be less reason for a ban if it were true. (Baumer, Tr.1960-1961).

Response to Finding No. 1334 (a)(4)(a):

This proposed finding mischaracterizes Dr. Baumer's testimony. He testified that "...I read it here somewhere, so I was – this is not a complete surprise." (Baumer, Tr. 1960).

- (b) Dr. Baumer admits that the one anecdote he recalls that a nondentist did not use gloves and put his or her finger in a consumer's mouth is not sufficient to justify banning all non-dentist teeth whitening. (Baumer, Tr. 1958).

Response to Finding No. 1334 (a)(4)(b):

Respondent has no specific response.

- 5. Undermined Claim/Assumption: Non-dentist teeth whiteners require their customers to sign waivers and therefore consumers are harmed.
 - (a) Dr. Baumer admits that if non-dentists teeth whiteners did not require releases of liability that it could lead him to reconsider his opinion about the Board's decision to ban teeth whitening. (Baumer, Tr. 1933-1934).

Response to Finding No. 1334 (a)(5)(a):

Respondent has no specific response.

(b) Dr. Baumer admits that the only basis he had for asserting that non-dentist teeth whiteners require their customers to sign waivers comes from Respondent's Counsel and from Respondent's legal briefs. (Baumer, Tr. 1932, 1933).

Response to Finding No. 1334 (a)(5)(b):

Respondent has no specific response.

6. Dr. Baumer admits that the fact that salons offering non-dentists teeth whitening maintain liability insurance could negate some of his objections to salons offering teeth whitening. (Baumer, Tr. 1931).

Response to Finding No. 1334 (a)(6):

Dr. Baumer testified that if they had liability insurance "...that cuts out that particular objection to salons." (Baumer, Tr. 1931).

(a) Dr. Baumer admits that the fact that teeth whitening suppliers require the non-dentist teeth whitener to subscribe to a master insurance plan in addition to carrying liability insurance makes it less likely that a ban of teeth whitening would be justified based on a cost-benefit analysis. (Baumer, Tr. 1938).

Response to Finding No. 1334 (a)(6)(a):

Dr. Baumer testified that such insurance would "...cut in the direction of protecting consumers." (Baumer, Tr. 1938). Not all non-dental teeth whiteners provide such insurance. CX0643.

(b) Dr. Baumer has only anecdotal evidence - based on his wife's observations - to support his theory that salons are fly-by-night operations that close or turn-over more frequently than other types

of businesses. Dr. Baumer has not performed an empirical review to determine whether salons are fly-by-night operations. Dr. Baumer admits that if evidence showed that salons did not turn over more frequently than other businesses that he would not view them as being fly-by-night. (Baumer, Tr. 1828).

Response to Finding No. 1334 (a)(6)(b):

Dr. Baumer testified that such insurance would "...cut in the direction of protecting consumers." (Baumer, Tr. 1938). Not all non-dental teeth whiteners provide such insurance. CX0643.

(c) Dr. Baumer agreed that if Sam's Club allowed non-dentist teeth whitening in its stores it would lessen the risk that consumers using the Sam's Club kiosk would be harmed by a fly-by-night operation. (Baumer, Tr. 1930). The presence of teeth whitening kiosks in places like Sam's Club would militate against a complete ban on non-dentist teeth whitening in North Carolina. (Baumer, Tr. 1930-1931).

Response to Finding No. 1334 (a)(6)(c):

Dr. Baumer did not agree that such a scenario would lessen the risk of harm. Dr. Baumer testified that, if Sam's Club put its corporate wealth behind the non-dentist teeth whitening kiosks, they could hold themselves liable for malpractice and other unethical practices. However, the same amount of risk to the consumer would exist.

(c) Dr. Baumer admits that simply because consumers are required to sign releases of liability does not mean that the product associated should be banned. (CX0826 at 025 (Baumer, Dep. at 92)).

Response to Finding No. 1334 (a)(6)(d):

Complaint Counsel has not designated any of Dr. Baumer's deposition. Furthermore, Respondent objects to the mischaracterization of evidence, as Dr. Baumer testified that

sometimes, but not always, a product should be banned if someone must sign a waiver to use it.

- c. There are credibility and reliability issues with Dr. Baumer's Expert Report because it was written without "due diligence" and because Dr. Baumer admitted that he considered the empirical studies to be valid until after he was engaged to write his Expert Report.
- d.

Response to Finding No. 1334 (b)

This is a statement of opinion, and not a statement of fact. Respondent objects to the extent that no evidence supports this proposed finding.

1. Dr. Baumer admits that he did not engage in "due diligence" in writing his report because of lack of time. (Baumer, Tr. 1835-1836; CX0826 at 023 (Baumer, Dep. at 82)). Dr. Baumer admitted that he had not read the expert reports of Drs. Haywood or Giniger prior to formulating his opinion and writing his report. Baumer, Tr. 1828-1829; CX0826 at 022-023 (Baumer, Dep. at 79-82). In addition, Dr. Baumer's report read like a unfinished draft. (RX0078 at 002 n.4 ("I am hoping that there are reforms of the State Board that I can point out").

Response to Finding No. 1334 (b)(1)

This is a statement of opinion and not a statement of fact. Respondent objects to the mischaracterization of evidence. Dr. Baumer testified that, in his report he reserved the right to revise if he received contrary information. Dr. Baumer testified that, after he finished his report, there was no reason to revise, based on subsequent information he received. Baumer, Tr. 1830. Respondent objects to the reliance on RX0078 at hearsay and not a statement attributed to Dr. Baumer.

2. Dr. Baumer admitted that it is not his standard practice as an economic expert to offer his opinion by simply relying on the counsel that retained him and without having done his own research. (Baumer, Tr. 1838). Professor Baumer essentially relied on two

sources: internet searches and discussions with or pleadings written by Respondent's Counsel. (Baumer, Tr. 1821-1822, 1827-1830, 1837, 1868, 1932-1936, 1951-1952, 1955-1956; RX0078 at 006; CX0826 at 003, 006, 022-023 (Baumer, Dep. at 5,17, 79-82)). Dr. Baumer worked almost solely with Mr. Carlton, counsel for the Board, in writing his expert report. (CX0826 at 006 (Baumer, Dep. at 17)).

Response to Finding No. 1334 (b)(2):

Complaint Counsel did not designate any part of Dr. Baumer's Deposition. Respondent objects to the mischaracterization of the evidence. Dr. Baumer read a number of articles in connection with his expert report that were cited by Dr. Kwoka.

3. Dr. Baumer only came to his opinion that the healthcare professions studies were too old to be valid during the process of writing his paid expert report for the Board. (Baumer, Tr. 1908-1909). Despite relying on studies he now believes are outdated, Dr. Baumer stands by his 2007 study and has no intention of retracting or correcting the article. (Baumer, Tr. 1910).

Response to Finding No. 1334 (b)(3):

Respondent objects to the mischaracterization of the evidence. Dr. Baumer testified that policy prescriptions set forth in his 2007 article are still valid and do not need to be retracted.

4. Dr. Baumer admitted that he could characterize the amount of time he had to write his expert report as "adequate" only if he was able to "reserve the right to revise the report." (CX0826 at 010 (Baumer, Dep. at 32)).

Response to Finding No. 1334 (b)(4):

Complaint Counsel did not designate any part of Dr. Baumer's Deposition. Furthermore, Complaint Counsel mischaracterizes the evidence. Dr. Baumer testified that he reserved the right to revise the report because he wanted to confirm that Dr. Kwoka accurately cited the economics articles. Dr. Baumer testified that he subsequently reviewed the articles, and found no reason to revise his report. Baumer, Dep. at 32-33.

c. Dr. Baumer admits that the presence of certain facts previously unknown by him would lead him to reconsider his opinion that the Board's conduct was economically efficient.

Response to Finding No. 1334(c):

Respondent objects to the extent that Complaint Counsel cites no evidence for this proposed finding.

1. Dr. Baumer admits that if states other than North Carolina permitted nondentist teeth whitening it would have an impact on his conclusion that the Board restrictions on nondentist teeth whitening are justified by health and safety concerns, and that he would be more concerned about the Board decision to exclude. (Baumer, Tr. 1919-1920, 1923). Dr. Baumer admits that he does not recall asking Respondent's Counsel for information relating to how states other than North Carolina treated nondentist teeth whitening. (Baumer, Tr. 1923-1924).

Response to Finding No. 1334(c)(1):

Respondent objects to the mischaracterization of evidence. Dr. Baumer testified that, if there's a split among the states, it would impact his decision as an economist about the wisdom of prohibiting non-dentist teeth whitening.

2. Dr. Baumer admits that he was not aware that there is an oral hygiene section of the North Carolina Department of Health which could regulate, rather than ban, nondentist teeth whitening. (Baumer, Tr. 1944).

Response to Finding No. 1334(c)(2)

Respondent objects to the mischaracterization of evidence. There is no testimony that the oral hygiene section of the NC Department of Health could regulate non-dentist teeth whitening.

3. Dr. Baumer admits that the fact that North Carolina does not allow dental hygienists to perform teeth whitening outside of the supervision of a dentist is a factor supporting the conclusion that dentists were following their own self-interests through exclusion rather than protecting consumer welfare. (Baumer, Tr. 1969).

Response to Finding No. 1334(c)(3):

Respondent objects to the mischaracterization of evidence. There is no evidence that the State Board was involved in any decision regarding dental hygienists' provision of teeth whitening services without dentist supervision. Furthermore, there is no evidence that Dr. Baumer is aware of any decision by the State Board or North Carolina regarding dental hygienists' provision of teeth whitening services without dentist supervisions. Dr. Baumer reached no conclusion that such an alleged factor indicates dentists' self-interest.

4. Dr. Baumer agreed that if the Board did not follow statutory requirements and procedures in acting against the unlicensed practice of dentistry that it "would be a factor that would suggest they're not being completely objective." (CX0826 at 047 (Baumer, Dep. at 179)).

Response to Finding No. 1334(c)(4):

Complaint Counsel did not designate any of Dr. Baumer's deposition.

5. Dr. Baumer admitted that he was not aware of other state regulatory models where Department of Health oversight over state licensing boards provides a disinterested decision-maker for new regulations or rules, but stated "that's an interesting variation" and "removing conflicts of interest . . . other things being equal is a good thing." (CX0826 at 038 (Baumer, Dep. at 142, 144)).

Response to Finding No. 1334(c)(5):

Complaint Counsel did not designate any of Dr. Baumer's deposition. Respondent objects as there is no evidence of the existence of such Department of Health oversight.

1335. Despite his vociferous critique of Professor Kwoka's expert report, Dr. Baumer now expresses full agreement with many of Professor Kwoka's conclusions and admits to errors in his interpretation of that report.

a. Dr. Baumer admits that he misinterpreted Professor Kwoka to be using a cartel model to analyze the Board's conduct, and apologized for exaggerating Professor Kwoka's views on the cartel issue. (Baumer, Tr. 1799, 1808, 1839).

Response to Finding No. 1335(a):

Respondent has no specific response.

b. Dr. Baumer agrees with Professor Kwoka that an "exclusion model" is the proper theoretical framework. (Baumer, Tr. 1839-1840).

Response to Finding No. 1335 (b):

Respondent has no specific response.

c. Dr. Baumer admitted that (1) he criticized Professor Kwoka's as dogmatically opposed to licensing boards based on the "gestalt" of Professor Kwoka's Expert Report; (2) he shared some of the views for which he criticized Professor Kwoka; (3) he viewed Professor Kwoka's citation to a standard Industrial Organization text book as indicative that Professor Kwoka was trying to analyze the conduct of the Board as cartel behavior, and (4) he viewed Professor Kwoka's membership on the editorial board of a mainstream industrial organization journal as indicative of an attempt to analyze the Board conduct as cartel behavior. (Baumer, Tr. 1871-1878, 1885-1886, 1895-1896; CX0826 at 014 (Baumer, Dep. at 48)).

Response to Finding No. 1335 (c):

Complaint Counsel has not designated any of Dr. Baumer's deposition. When asked, Dr. Baumer agree with the statement that: "...Professor Kwoka is engaged in a broad based challenged to regulating professionals and would seek to abolish licensing boards."

(Baumer, Tr. 1876).

d. Dr. Baumer admits that he should not have claimed that Professor Kwoka argued that dentists are "solely" motivated by profit maximization. (Baumer, Tr. 1765).

Response to Finding No. 1335 (d):

Dr. Baumer's also testified that: "...on the other hand, I would say time and time again Dr. Kwoka basically says dentist boards rule in ways so as to profit their constituents, namely dentists. (Baumer, Tr. 1765). He clearly disagrees that dentists are boards are governed exclusively by profit maximization.

e. Dr. Baumer agrees with Professor Kwoka's exclusion analysis, characterizing it as "Economics 101." (Baumer, Tr. 1726-1727, 1763; see also CX0826 at 033 (Baumer, Dep. at 122-123 ("Yes, there's no doubt that, you know, if you reduce products, other things

being equal, that there's a loss in consumer welfare or consumer surplus.")); CX0826 at 045 (Baumer, Dep. at 171 ("[Y]es exclusions will result in competitive consequences and one of which is a price increase, I mean, I don't disagree with him [Dr. Kwoka]."))).

Response to Finding No. 1335 (e):

Complaint Counsel has not designated any of Dr. Baumer's deposition. Dr. Baumer testified that he disagreed with Dr. Kwoka's statement that it's not controversial among economists. "I don't see any evidence of economists calling for deregulation of professionally regulated markets." (Baumer, Tr. 1726).

f. Dr. Baumer agreed with Professor Kwoka that state regulatory boards can be used to exclude competition and augment the incomes of licensed practitioners. (Baumer, Tr. 1763; RX0078 at 008-010). Dr. Baumer agrees that professional boards, including dental boards, have supported anticompetitive restrictions in the past. (Baumer, Tr. 1884).

Response to Finding No. 1335 (f):

Respondent has no specific response.

g. Dr. Baumer agreed with Professor Kwoka that the professions studies showed that in many cases the health and safety justifications proffered by the boards turned out to be false. (Baumer, Tr. 1852-1853).

Response to Finding No. 1335 (g):

Dr. Baumer also testified that there are "pretenses" and "honest concerns about health and safety." (Baumer, Tr. 1854).

h. Dr. Baumer agrees with Professor Kwoka that economists can learn from other types of exclusionary conduct to make inferences about new exclusionary conduct. (Baumer, Tr. 1982).

Response to Finding No. 1335 (h):

Respondent has no specific response.

i. Dr. Baumer admits that he may have exaggerated in describing the professions studies as outdated. (Baumer, Tr. 1766). Dr. Baumer admits that the Kleiner and Kudrle article relied upon by Professor Kwoka is not subject to the same criticism he levels against the other professions studies - that they are too old to be relevant. (Baumer, Tr. 1971-1972). Indeed, Dr. Baumer agrees that he does not have any reason to criticize the Kleiner and Kudrle study. (Baumer, Tr. 1971).

Dr. Baumer admits that the study found that individuals from states with more restrictive dental practice provisions had greater untreated dental problems than individuals from states with less restrictive provisions. (Baumer, Tr. 1971).

Response to Finding No. 1335 (i):

Dr. Baumer testified that "...basically, Dr. Kwoka is relying on – I think “outdated” is an appropriate adjective.” (Baumer, Tr. 1766).

j. Dr. Baumer agrees that not all of the anticompetitive conduct undertaken by the healthcare professional boards in the 1970s and 1980s has been eliminated, and that there is "absolutely" "continuing potential for abuse by state boards," and that "it certainly does occur." (Baumer, Tr. 1898, 1901; CX0826 at 012, 035, 055 (Baumer, Dep. at 39, 136, 211-212)).

Response to Finding No. 1335 (j):

Dr. Baumer also agreed with the statement that: "...much of the anticompetitive conduct that the boards have undertaken in the '70's and the '80's has been eliminated." (Baumer, Tr. 1898).

k. Dr. Baumer agrees that it is well recognized that medical professional board members engaged in conduct that harmed consumers despite their oaths to protect the public health. (Baumer, Tr. 1915).

Response to Finding No. 1335 (k):

Respondent has no specific response.

l. Dr. Baumer agrees with Professor Kwoka about the nature of the relevant market, including that there is substantial cross-elasticity - or substitution - between dentist and non-dentist teeth whitening services. (Baumer, Tr. 1844-1845).

Response to Finding No. 1335 (l):

Respondent has no specific response.

m. Dr. Baumer agrees that one innovative aspect of non-dentist teeth whitening is the ability for consumers to receive a quick teeth whitening in a convenient mall location, on the same day that they desire the whitening, with same-day results. (Baumer, Tr. 1973).

Response to Finding No. 1335 (m):

Respondent has no specific response.

n. Dr. Baumer admits that in order to implement a study that measured the costs and benefits of banning teeth whitening an economist would need access to published data on the subject, which to his knowledge did not exist. (Baumer, Tr. 1978-1979). Dr. Baumer believes that collecting such data and performing the economic study would require "Herculean assumptions that would be virtually unverifiable." (CX0826 at 043 (Baumer, Dep. at 165)). Dr. Baumer did not attempt to undertake such a study. (Baumer, Tr. 1980). Dr. Baumer does not believe that the absence of data allowing such an economic study requires antitrust law to ignore potentially anticompetitive conduct. (Baumer, Tr. 1980).

Response to Finding No. 1335 (n):

Complaint Counsel has not designated any of Dr. Baumer's deposition. He actually testified that calculating the costs and benefits of banning teeth whitening was a relatively simply endeavor. "Conceptually, it is not difficult." (Baumer, Tr. 1978).

o. Dr. Baumer agreed that whether certain activity is legal or illegal is independent from the question of economic impact. (Baumer, Tr. 1711 ("The fact that [the product] is illegal doesn't mean there isn't cross-price elasticity.")).

Response to Finding No. 1335 (o):

Respondent has no specific response.

p. Dr. Baumer agrees that just because a business is unlicensed does not mean that it is not going to satisfy consumer demand in a safe and efficient manner - there are market mechanisms to ensure consumer trust, such as business reputation, the Better Business Bureau, and other non-governmental agencies. (Baumer, Tr. 1977-1978).

Response to Finding No. 1335 (p):

Respondent has no specific response.

q. Dr. Baumer agrees that, in general, where intervention is appropriate less restrictive alternatives should be used. (Baumer, Tr. 1771).

Response to Finding No. 1335 (q):

Dr. Baumer did not make this statement on the page cited.

Dr. Van Benjamin Haywood

1336. Dr. Van B. Haywood was retained by the Board to present his opinions regarding the safety of non-dentist provided teeth bleaching. (Haywood, Tr. 2398-2400).

Response to Finding No. 1336:

Dr. Haywood was tendered to the Court and accepted as an expert in the fields of practical and clinical esthetic and restorative dentistry. (Haywood, Tr. 2391).

1337. Dr. Haywood has no specialized training in oral diagnosis, and has had no experience in the formulation of teeth bleaching products. (Haywood, Tr. 2576-2579).

Response to Finding No. 1337:

In addition to his training as a dentist, Dr. Haywood was a tenured professor at the UNC Dental School for two years and has been a tenured professor at at the Medical College of Georgia for more than 10 years. (Haywood, Tr. 2387-2388).

1338. In formulating his opinion in this matter, Dr. Haywood did not request or review any documents of the Board or any third parties; he also did not seek information from participants in the industry on any information relating to the safety or effectiveness of non-dentist provided teeth bleaching. (Haywood, Tr. 2645-2648).

Response to Finding No. 1338:

Respondent has no specific response.

1339. Dr. Haywood is unquestionably knowledgeable about Nightguard Vital Bleaching by dentists, of which he was a co-developer in 1989. (Haywood, Tr. 2579-2580).

Response to Finding No.1339:

This statement is a word-for-word duplicate of Proposed Finding No. 801. Respondent has no response, but does question why the practice of Nightguard Vital Bleaching is capitalized as if it were a proprietary product or process.

1340. However, Dr. Haywood appears to lack objectivity regarding his promotion of Nightguard Vital Bleaching by dentists and he has profound resistance toward other means and practitioners of teeth bleaching. (See generally Haywood, Tr. 2619-2627).

Response to Finding No. 1340:

This statement is a word-for-word duplicate of Proposed Finding No. 802. Further, Nightguard vital bleaching is a dental technique, not a proprietary product or process. Respondent notes and objects to Complaint Counsel's attempt to insinuate otherwise through the use of capitalization. Further, Dr. Haywood is recognized as the "preeminent expert in [the] field" of teeth whitening by his peers. (CX497 at 6). In order to preserve his independence and objectivity, Dr. Haywood independently performs grant-sponsored research on teeth whitening products with no strings attached. (Haywood, Tr. 2392-2393). Dr. Haywood does not actively promote teeth whitening products. (Haywood, Tr. 2393). Dr. Haywood has never been granted a financial stake or interest in any of the products about which he has consulted or published. (Haywood, Tr. 2407). Dr. Haywood has never been a salaried employee, owner, stockholder, or member of management of any of the firms that have retained him as a consultant. (Haywood, Tr. 2408). Dr. Haywood testified that for "some" non-dentists doing teeth whitening, they were "in it for the money and willing to harm consumers for a dollar." (Haywood, Tr. 2621-2622).

1341. Dr. Haywood is a career academic, whose professional esteem is intimately bound up with the establishment and expansion of Nightguard Vital Bleaching by dentists as the preeminent form of vital teeth bleaching. (Haywood, Tr. 2580).

Response to Finding No. 1341:

This statement is a word-for-word duplicate of Proposed Finding No. 804. Dr. Haywood was in private practice for seven years. (Haywood, Tr. 2387). He currently practices dentistry in addition to his academic responsibilities. (Haywood, Tr. 2384-2385). Dr. Van B. Haywood is an academician who performs independent research in his fields of expertise. (Haywood, Tr. 2392). He also independently performs grant-sponsored research on teeth whitening products with no strings attached. (Haywood, Tr. 2392-2393). Dr. Haywood has never been granted a financial stake or interest in any of the products about which he has consulted or published. (Haywood, Tr. 2407).

1342. Dr. Haywood views the question of whether non-dentists may provide teeth bleaching services or assistance as a wedge issue in dentist control of areas traditionally within the ambit solely of dentists. (Haywood, Tr. 2632).

Response to Finding No. 1342:

This statement is a word-for-word duplicate of Proposed Finding No. 838. Respondent disputes Complaint Counsel's use of an undefined term to misrepresent Dr. Haywood's views. Dr. Haywood testified that "My view is that this is a battle over licensure and the federal government controlling the licensure and defining dentistry different from what the profession has always defined itself as." (Haywood, Tr. 2632).

1343. Indeed, Dr. Haywood believes that a non-dentist's mere offer to provide or assist a consumer in teeth bleaching is by definition deceptive and wrong, and that all non-dentist providers are "charlatans and quacks." (Haywood, Tr. 2748).

Response to Finding No. 1343:

This statement is a word-for-word duplicate of Proposed Finding No. 843. Further, Dr. Haywood did not testify that non-dentist's actions were "deceptive by implication [and] wrong." Dr. Haywood did testify that they confuse and deceive their customers.

(Haywood, Tr. 2645). Dr. Haywood also testified that non-dentists who provide teeth whitening are engaging in the practice of dentistry. (Haywood, Tr. 2459-2460, 2539, 2573). He did testify that in his opinion, they were "charlatans and quacks." (Haywood, Tr. 2748).

1344. Dr. Haywood cannot identify any evidence demonstrating that consumers have been harmed by non-dentist provided teeth bleaching (other than transient sensitivity caused by dentist and non-dentist teeth bleaching). (Haywood, Tr. 2713-2714).

Response to Finding No. 1344:

This statement is incorrect, Dr. Haywood testified that there is anecdotal evidence of harm from teeth whitening. (Haywood, Tr. 2520-2521). Further, the Board in this proceeding has provided numerous examples of health and safety issues, including the testimony of an expert in the fields of practical and clinical esthetic and restorative dentistry, the testimony of Mr. Runsick, an actual consumer, the testimony of a dentist that evaluated Mr. Runsick's injury that was caused by teeth whitening, the testimony of licensed dentists regarding the health and safety issues involved with kiosk/spa teeth whitening, and the documentary evidence of other consumers injured by kiosk/spa teeth whitening. *See* Respondent's Proposed Findings of Fact Nos. 376-424 (Haywood testimony); Nos. 460-494, 512 (Runsick testimony); Nos. 495-511 (Dr. Tilley testimony); Nos. 425-458 (dentist testimony); Nos. 513-531 (other consumer harm). Additionally, Complaint Counsel's expert witness on teeth whitening admitted that there was anecdotal evidence of harm to consumers. (Giniger, Tr. 461-466).

1345. Yet Dr. Haywood has repeatedly analogized customers of lay-operated teeth bleaching facilities to suicides, and the estimated more than 100 million users of OTC Crest Whitestrips and other OTC products to assisted suicides. (Haywood, Tr. 2643-2644).

Response to Finding No. 1345:

This statement is a word-for-word duplicate of Proposed Finding No. 850. The statement also mischaracterizes Dr. Haywood's use of an analogy. Dr. Haywood testified, "You understand by analogy, I don't mean that really happens." (Haywood, Tr. 2645). On direct exam and in his expert report, Dr. Haywood testified, "...when asked what's the difference between mall bleaching and over-the-counter product differences, my comment was that that's the difference between suicide and assisted suicide." (Haywood, Tr. 2458).

1346. Dr. Haywood insists that only clinical studies can establish the safety of non-dentist teeth bleaching, but also insists that it impossible to conduct such studies. (Haywood, Tr. 2729-2730).

Response to Finding No. 1346:

Respondent has no specific comment.

C. Witnesses Who Testified by Deposition and/or Investigational Hearing

Dr. Stanley L. Allen, Jr.

1347. Dr. Allen served two terms on the Board, from August 2001 through July 2007. Dr. Allen became Secretary-Treasurer of the Board in August 2004; President of the Board in August 2005; and immediate Past Preside in August 2006. (CX0554 at 004 (Allen, Dep. at 7-8)).

Response to Finding No. 1347:

Respondent has no specific response.

1348. Dr. Allen has been a member of the American Dental Association for his entire dental career. He is also a member of the American Academy of Implant Dentistry, the American Academy of General Dentistry, the American Dental Society of Anesthesiology, and the Old North State Dental Society. (CX0554 at 005 (Allen, Dep. at 13)).

Response to Finding No. 1348:

Respondent has no specific response.

1349. Dr. Allen has been a member of the North Carolina Dental Society, which is part of the American Dental Association, since he arrived in North Carolina. Dr. Allen served as Secretary-Treasurer, Vice President, and President of the Third District of the North Carolina Dental Society. (CX0554 at 005-006 (Allen, Dep. at 13-14)).

Response to Finding No. 1349:

Respondent has no specific response.

Carolyn Bakewell

1350. From September 2006 through December 2010, Ms. Bakewell was in-house counsel for the Dental Board. Since January 2011, Ms. Bakewell has been outside counsel to the Dental Board, practicing as Carolyn Bakewell, PLLC. (CX0581 at 005 (Bakewell, Dep. at 10)).

Response to Finding No. 1350:

Respondent disputes Finding No. 1350. Ms. Bakewell's period of employment with the Dental Board began in September 2006. She did not testify as to when that employment ended. Also, Ms. Bakewell testified that she began her own law firm, Carolyn Bakewell, PLLC, in January 2010 – not January 2011. (CX581 (Bakewell, Dep. at 10)).

Dr. Benjamin W. Brown

1351. Dr. Brown has been in practice since 1967 and has a specialty in endodontics. (CX0555 at 003-004 (Brown, Dep. at 7-8)).

Response to Finding No. 1351:

Respondent has no specific response.

1352. Dr. Brown served for two terms on the Board and was President from 2005 to 2006; he has also held the position of Board Secretary/Treasurer twice. Dr. Brown was also the chair of the sedation and general anesthesia committee for the Board. (CX0555 at 004-005 (Brown, Dep. at 9-12)).

Response to Finding No. 1352:

Respondent has no specific response.

1353. Dr. Brown is a member of the North Carolina Dental Society, the American Dental Association, the American Association of Endodontists the American Dental Society of Anesthesiology and the Raleigh-Wake County Dental Society. He was a member of the board of trustees, the Vice President and Legislative Chairman and Speaker of the House of Delegates of the North Carolina Dental Society. (CX0555 at 005-006 (Brown, Dep. at 13-14)).

Response to Finding No. 1353:

Respondent has no specific response.

Dr. Joseph S. Burnham, Jr.

1354. Dr. Burnham is a general dentist who has been in practice for 42 years. (CX0556 at 004-005 (Burnham, Dep. at 9-10)).

Response to Finding No. 1354:

Respondent does not dispute that Dr. Burnham has been in practice for 42 years;

however, Complaint Counsel has cited testimony that was not designated in its

Deposition Designations regarding Dr. Burnham's status as a general dentist. (CX556

(Burnham, Dep. at 9-10)).

1355. Dr. Burnham was first elected to the Board in 2003 and served a three-year term. Dr. Burnham ran for a second term on the Board in 2006, was reelected, and served another three-year term. Dr. Burnham served as Secretary-Treasurer on the Board from 2005 to 2006; President from 2007 to 2007; and Immediate Past President from 2008-2009. (CX0556 at 007, 009 (Burnham, Dep. at 20-21, 28)).

Response to Finding No. 1355:

Respondent partially disputes this finding of fact in that Dr. Burnham testified that he served as President from 2006 to 2007, not from 2007 to 2007 as stated by Complaint Counsel, and Immediate Past President from 2007 – 2008, not 2008 – 2009 as stated by Complaint Counsel. (CX556 (Burnham, Dep. at 21)). In addition, Complaint Counsel

has cited testimony that was not designated in its Deposition Designations regarding Dr. Burnham's status as a general dentist. (CX556 (Burnham, Dep. at 28)).

1356. Dr. Burnham never held a position as an officer for the North Carolina Dental Society, but while he was a member of the Board he would give reports to Second District Dental Society's executive meetings as an ex-officio member about what the Board was doing. (CX0556 at 005 (Burnham, Dep. at 12)). Dr. Burnham believes it was common practice for Board members to be ex-officio members of their local Dental Society executive meetings. (CX0556 at 005 (Burnham, Dep. at 13)). Dr. Burnham has occasionally sat as a delegate in the house of representatives at the North Carolina Dental Society. (CX0556 at 005 (Burnham, Dep. at 12)). William Linebaugh Dempsey IV

Response to Finding No. 1356:

Respondent does not dispute the first and last sentences of this proposed finding of fact.

However, Complaint Counsel has cited testimony that was not designated in its Deposition Designations in support of the second sentence regarding Dr. Burnham's service as an ex-officio member of the local Dental Society.

1357. William Linebaugh Dempsey has been employed as an Investigator with the Board since June 2003. (CX0557 at 004 (Dempsey, Dep. at 8); CX0558 at 003 (Dempsey, IHT at 7)).

Response to Finding No. 1357:

Respondent has no specific response.

1358. Mr. Dempsey stated that when a complaint comes into the Board office, it gets assigned to a Board member to act as Case Officer. The Case Officer directs that investigation. The Case Officer reviews the complaint and directs the investigators to conduct interviews or gather additional information. (CX0557 at 005 (Dempsey, Dep. at 10-11)). Mr. Dempsey stated that it is possible that the Case Officer may direct one of the two Board case managers, Ms. Friddle or Ms. Goode, to follow up on an administrative task, such as writing a letter. Mr. Dempsey stated that those tasks may be all the investigation that is necessary. (CX0558 at 004-005 (Dempsey, IHT at 10-11)).

Response to Finding No. 1358:

Respondent disputes the last sentence of this proposed finding. Mr. Dempsey did not testify that “those tasks may be all the investigation that is necessary.” Otherwise,

Respondent does not dispute this proposed finding of fact.

1359. Mr. Dempsey stated that when he investigates a teeth whitening complaint, he might go to the address and observe the kiosk or salon. He often takes pictures and may write notes on topics including, if they had chairs set up, if providers were wearing lab coats, or if LED were lights set up. (CX0557 at 009 (Dempsey, Dep. at 28-29)).

Response to Finding No. 1359:

Respondent has no specific response.

Zannie Poplin Efird

1360. Zannie Poplin Efird testified that she served as the lone Consumer Representative on the Board from August 2003 until August 2009, serving two terms. (CX0559 at 004 (Efird, Dep. at 7)).

Response to Finding No. 1360:

Respondent has no specific response.

1361. Ms. Efird testified that she was a voting member of the Board. However, she did not vote on disciplinary matters involving dentists and hygienists. She stated that she did not participate in any votes on teeth whitening matters. (CX0559 at 006 (Efird, Dep. at 16)).

Response to Finding No. 1361:

Respondent has no specific response.

1362. Ms. Efird testified that she did not participate in any Board matters relating to the unlicensed practice of dentistry while she served on the Board. (CX0559 at 008 (Efird, Dep. at 23)).

Response to Finding No. 1362:

Respondent has no specific response.

1363. Ms. Efird also stated that she believed it would have been within her responsibility as the Consumer Member on the Board to ask questions relating to financial conflicts of interest. However, Ms. Efird testified that in her role as the

Consumer Member of the Board, she did not examine whether the Board members had conflicts of interest regarding matters that could harm consumers. (CX0559 at 008-009 (Efird, Dep. at 25, 27)).

Response to Finding No. 1363:

Respondent disputes this proposed finding. Ms. Efird was asked a hypothetical question, confirmed as such by Complaint Counsel, as to whether she would have viewed it as a financial conflict if a Board member who made a significant amount of money from teeth whitening participated in a vote related to teeth whitening. No part of the question was directed at her responsibility to ask questions related to financial conflicts of interest. (CX559, Efird, Dep. at 27)). Furthermore, the assumption in this question is that Ms. Efird would have been aware of a fellow dentist Board member's earnings from teeth whitening, or any other service that the dentist Board member provides to his patients. Board member did not discuss the amount of teeth whitening services that they performed among themselves. (RX51 (Brown, Dep. at 104)) In regards to any examination by Ms. Efird about conflicts of interest on the part of Board members that would harm consumers, Ms. Efird testified that the Board members were very professional and that she had not "noticed anything of that sort or recognized it as such." (CX550, Efird, Dep. at 25)).

1364. Ms. Efird stated that while on the Board, she knew the Board sent Cease and Desist Orders to some non-dentist teeth whitening providers. However, she stated that she was not consulted about the Cease and Desist Orders before they were sent by the Board. When asked "[w]ould you have expected to have been consulted before they were sent out in your role as consumer member," Ms. Efird replied, "[p]robably not. I - I wouldn't have thought to have objected." (CX0559 at 017 (Efird, Dep. at 58)).

Response to Finding No. 1364:

Respondent disputes this finding of fact. Board members do not discuss with each other anything pertaining to cease and desist letters. (Hardesty, Tr. 2773). The responsibility for running a case, including sending out a cease and desist letters, rests with the case officer. (Wester, Tr. 1281; Owens, Tr. 1440-1441, 1441-1442; White, Tr. 2202-2203; Hardesty, Tr. 2765-2767; RX50 (Bakewell, Dep. at 236); RX56 (Feingold, Dep. at 151); RX57 (Friddle, Dep. at 66); RX58 (Friddle, IHT at 45, 81-82); RX59 (Goode, IHT at 57-58); RX64 (Kurdys, Dep. at 14, 55-56); RX65 (Morgan, Dep. at 122-123)).

1365. Ms. Efird testified that though a series of Cease and Desist Orders were issued to providers of BleachBright teeth whitening services in January 2009 (CX0042 at 001-041), despite the fact that her name was on the letterhead used, she did not see the letters, did not know the letters had been sent, and was not aware of any specifics about them. (CX0559 at 018 (Efird, Dep. at 64-66)).

Response to Finding No. 1365:

Respondent disputes this proposed finding of fact as incomplete as a statement of fact and containing an assumption. Other members of the have testified repeatedly that they do not have knowledge of a case assigned to a case officer; only that case officer and the investigative panel know the details of the case. (Wester, Tr. 1282; Owens, Tr. 1442; Hardesty, Tr. 2767-2768; RX49 (Allen, Dep. at 39); RX51 (Brown, Dep. at 116, 160-161); RX58 (Friddle, IHT at 35-36); RX60 (Hall, Dep. at 61); RX63 (Holland, Dep. at 199); RX65 (Morgan, Dep. at 122-123)).

Dr. Clifford Feingold

1366. Dr. Feingold is a general dentist who has been in practice for 34 years. Dr. Feingold became a Board member in August 2005 and served through August 2008. (CX0560 at 004-005 (Feingold, Dep. at 9, 12)).

Response to Finding No. 1366:

Respondent has no specific response.

1367. Dr. Feingold only served one term on the Board, from August 1995 through July 1998. Dr. Feingold did not hold any officerships while he was on the Board. Dr. Feingold was in charge of dentist examinations for one year while serving on the Board. (CX0560 at 005 (Feingold, Dep. at 12-13)).

Response to Finding No. 1367:

Respondent has no specific response.

Terry W. Friddle

1368. Ms. Friddle is the Deputy Operations Officer for the Board and has worked for the Board for 29 years. As Deputy Operations Officer she is "second in command" at the Board. She also oversees the investigative process, and makes preparations for the Board's meetings. (CX0561 at 004 (Friddle, Dep. at 8-10); CX0562 at 006 (Friddle, IHT at 18)).

Response to Finding No. 1368:

Respondent has no specific response.

1369. Ms. Friddle reports to both the Board's COO Bobby White and the individual Board members. She meets with case officers in her role in investigations, and tried to meet with them at least once per month to discuss their assigned cases. (CX0561 at 006 (Friddle, Dep. at 15)).

Response to Finding No. 1369:

Respondent has no specific response.

Casie S. Goode

1370. Ms. Goode is the Assistant Director of Investigations for the Board, a position she has had since approximately 2004. She began working for the Board in June 2002 as an executive assistant. As Assistant Director of Investigations, Goode assists the director of investigations, Terry Friddle, to oversee investigations. Goode sets up files, drafts correspondence, makes copies, and communicates with case officers. (CX0563 at 003-004 (Goode, IHT at 9-10)).

Response to Finding No. 1370:

Respondent has no specific response.

1371. Ms. Goode and Terry Friddle both work with three of the six Board members in their roles as case officers. Ms. Goode forwards responses on their cases as she receives them, and forwards any draft of a letter requested for review and changes. If one of the Board members requests that a Cease and Desist Order be sent, Ms. Goode knows to send a standard Cease and Desist Order without further clarification. (CX0563 at 004, 027-028 (Goode, IHT at 10-11, 105-107)).

Response to Finding No. 1371:

Respondent has no specific response.

Neplus S. Hall

1372. Neplus S. Hall did not participate in any investigations involving the unlicensed practice of dentistry. By statute, the dental hygienist and the consumer Board members cannot participate or vote in any matters of the Board which involve the issuance, renewal, or revocation of a license to practice dentistry. (CX0564 at 005 (Hall, Dep. at 12-13)).

Response to Finding No. 1372:

Respondent disputes this proposed finding of fact. In support thereof, Complaint Counsel has cited testimony that was not designated in its Deposition Designations. The testimony designated and cited by Complaint Counsel deals solely with Ms. Hall's participation in matters involving dentist licensees of the Board.

1373. Ms. Hall was not involved in any manner with the Board's investigations of teeth whitening. Ms. Hall did not participate in any discussions relating to teeth whitening while on the Board. At a general meeting it was mentioned that the Board would be investigating complaints about teeth whitening, but any discussion did not proceed further in Hall's presence. (CX0564 at 006 (Hall, Dep. at 15-16)).

Response to Finding No. 1373:

Respondent does not dispute this proposed finding.

Dr. Michael L. Hasson

1374. Dr. Hasson is an oral surgeon. His private practice has been in Wilmington, North Carolina since 1997 and is limited to oral surgery. As a specialist in oral surgery in North Carolina he can only do oral surgery. "I can't put a filling in. I can do all the things that

are under the purview of my specialty, which is, shortly put, surgery." Taking out teeth and putting in implants is principally what he does. (CX0575 at 003, 012 (Hasson, Dep. at 2, 7, 41)).

Response to Finding No. 1374:

Respondent disputes this proposed finding in part. The last sentence of Complaint Counsel's proposed finding is testimony that was not designated by Complaint Counsel in its Deposition Designations. Otherwise, Respondent does not dispute this proposed finding.

1375. Despite not performing teeth whitening in his practice, and having very limited knowledge of teeth whitening, Dr. Hasson filed a complaint on behalf of a patient with the Board, asserting claims against a non-dentist teeth whitener. (CX0575 at 025-026 (Hasson, Dep. at 91-94); CX0477 at 001-005).

Response to Finding No. 1375:

Respondent disputes this proposed finding of fact. Nothing in the testimony of Dr. Hasson cited by Complaint Counsel makes a reference to his not performing teeth whitening or having a very limited knowledge of teeth whitening. Otherwise, it is not disputed that Dr. Hasson filed a complaint with the Board on behalf of the patient.

Dr. William M. Litaker, Jr.

1376. Dr. Litaker has practiced dentistry for 25 years. He is a member of the North Carolina Dental Society, and acts as an NCDS delegate to the American Dental Association and also is a member of the NCDS legislative committee. (CX0576 at 004-005 (Litaker, Dep. at 7,11)).

Response to Finding No. 1376:

Respondent has no specific response.

1377. Dr. Litaker was a trustee of the NCDS from 1999-2005. Additionally, from 2006-2009, in successive one-year terms, he was Secretary/Treasurer, President-elect, President, and Past President of the NCDS. (CX0576 at 004 (Litaker, Dep. at 7)).

Response to Finding No. 1377:

Respondent has no specific response.

Dr. Bradley C. Morgan

1378. Dr. Morgan has had a general dentistry practice in Canton, North Carolina since December, 1981. Dr. Morgan is currently serving on the Board. (CX0569 at 004-005 (Morgan, Dep. at 9-10)).

Response to Finding No. 1378:

Respondent has no specific response.

1379. Dr. Morgan also has been a member of the American Dental Association since he started practicing dentistry, as well as the North Carolina Dental Society. He has served as an alternate delegate to the ADA more than once. Dr. Morgan stated he has "held all the offices" in the First District of the North Carolina Dental Society but he "can't remember them all." He has served as a trustee to the North Carolina Dental Society, one of the two trustees from the First District. Dr. Morgan believes he served on the legislation committee and the dental education committee. (CX0569 at 006-007 (Morgan, Dep. at 16-19, 21)).

Response to Finding No. 1379:

Respondent disputes this proposed finding in part. Dr. Morgan testified that he has held all of the offices in the First District of the Dental Society, but his testimony in regard to "can't remember them all" was in reference to Dental Society committees. (CX569 (Morgan, Dep. at 19)). Otherwise, Respondent does not dispute this proposed finding.

Dr. Gary D. Oyster

1380. Dr. Oyster has practiced general dentistry for 37 years. Dr. Oyster's practice is located in Raleigh, North Carolina. (CX0577 at 004, 027 (Oyster, Dep. at 7-8, 99)).

Response to Finding No. 1380:

Respondent has no specific response.

1381. Dr. Oyster is the chairman of the legislative committee of the North Carolina Dental Society, as he has been since approximately 1996. Dr. Oyster has held numerous additional positions for the NCDS, including: Vice President of the NCDS from approximately 2004-2005; NCDS Political Action Committee (hereafter "PAC") treasurer from 1978-1994; NCDS PAC chairman from 1994-1996; and, program

chairman for the NCDS annual session in 2009. Dr. Oyster remains a member of the PAC. (CX0577 at 004-005, 007 (Oyster, Dep. at 8, 10-12, 20-21)).

Response to Finding No. 1381:

Respondent has no specific response.

1382. As chairman of the NCDS legislative committee, Dr. Oyster works with the committee to construct an agenda. This agenda is for presentation to the NCDS board of trustees and enlists the political priorities of the NCDS. (CX0577 at 005-006 (Oyster, Dep. at 13-15)).

Response to Finding No. 1382:

Respondent has no specific response.

Dr. M. Alec Parker

1383. Parker practiced general dentistry from 1979-2007. Dr. Parker ceased his dental practice in 2007 and became an employee of the North Carolina Dental Society. He initially acted in an associative or assistive position to the NCDS executive director until January 2008, when he became executive director. Dr. Parker remains the executive director of the NCDS. (CX0578 at 004-005 (Parker, Dep. at 9-13)).

Response to Finding No. 1383:

Respondent has no specific response.

XII. Remedy

A. An Order Will Not Impair The Board's Ability to Carry Out Its Statutory Obligations

1384. Bobby White testified that he does not believe that the Board's ability to enforce the Dental Practice Act would be impacted if the letters that the Board sent out to non-dentist teeth whitening businesses stated that it was a notice that Board believes that the recipient violated the law and may take the recipient to court. (CX0573 at 010 (White, Dep. at 30)).

Response to Finding No. 1384:

Respondent disputes this proposed finding of fact in that its placement within Complaint Counsel's outline format mischaracterizes the content of this section of Complaint Counsel's proposed findings of fact. Respondent does not dispute that Mr. White

testified in his deposition that he did not think that the Board's ability to enforce the Dental Practice Act would be impacted if the letters that the Board sent out to non-dentist teeth whitening businesses stated that it was a notice that the Board believes that the recipient violated the law and may take the recipient to court. (CX573 (White, Dep. at 30)). Mr. White testified at trial that "[w]e can change the letter." (White, Tr. 2240). Respondent disputes Complaint Counsel's characterization of this testimony as being applicable to the entirety of the proposed relief in this proceeding. (Dagen, Tr. 43).

1385. Bobby White testified that he does not believe that the Board's ability to enforce the Dental Practice Act would be impacted if the letters that the Board sent out to non-dentist teeth whitening businesses stated that the Board believes that the recipient violated the law and may take the recipient to court to get an injunction or other relief, instead of stating "you are hereby ordered to cease and desist." (CX0573 at 010 (White, Dep. at 30)).

Response to Finding No. 1385:

Respondent disputes this proposed finding of fact in that its placement within Complaint Counsel's outline format is deceptive. Respondent does not dispute that Mr. White testified in his deposition that he did not think that the Board's ability to enforce the Dental Practice Act would be impacted if the letters that the Board sent out to non-dentist teeth whitening businesses stated that the Board believes that the recipient violated the law and may take the recipient to court to get an injunction or other relief, instead of stating "you are hereby ordered to cease and desist." (CX573 (White, Dep. at 30)). Mr. White testified at trial that "[w]e can change the letter." (White, Tr. 2240). Respondent disputes Complaint Counsel's characterization of this testimony as being applicable to the entirety of the proposed relief in this proceeding. (Dagen, Tr. 43).

1386. For example, in October 2000, a letter sent to Ortho Depot regarding alleged unauthorized practice of dentistry had no heading stating "Cease and Desist," nor did the body of the letter state "You are hereby ordered to cease and desist." Instead, the Board

stated "This is to advise you that the North Carolina State Board of Dental Examiners is considering initiating a civil suit to enjoin you from the unlawful practice of dentistry." (CX0136 at 001 (October 3, 2000); CX0139 at 001 (December 10, 2001); CX0138 at 001 (February 12, 2002)).

Response to Finding No. 1386:

Respondent has no specific response.

1387. A December 2001 letter simply notified the recipient that "[i]t has come to the attention of the North Carolina State Board of Dental Examiners that you may be setting up a dental practice in conjunction with the Dowd Central YMCA. This is to advise you that the Board is conducting an inquiry based on this knowledge." This letter neither had a heading stating "Cease and Desist," nor did the body of the letter state "You are hereby ordered to cease and desist." (CX0139 at 001 (December 10, 2001)). When the Board did not receive a response to its letter, a follow-up letter is similarly void of any "cease and desist" language, and simply reiterates the request for the recipient to respond. (CX0138 at 001 (February 12, 2002)).

Response to Finding No. 1387:

Respondent has no specific response.

B. There Is a Significant Risk That the Unlawful Conduct Will Recur

1388. The lengths to which the Board went to eliminate non-dentist teeth whitening from North Carolina without creating an opportunity for judicial oversight of its conduct demonstrate the ease with which the Board could again engage, virtually undetected, in such extralegal "enforcement" activity in the future. Those means included, at least, the following:

- a. Avoiding the use of the Board's subpoena power to investigate instances of nondentist teeth whitening (CX0019 at 006, Dental Practice Act § 90-27);
- b. Avoiding the use of pre-filing, court discovery powers to investigate instances of non-dentist teeth whitening (CX0019 at 020-21, Dental Practice Act § 90-40.1(d));
- c. Sending at least 40 Cease and Desist Orders to non-dentist teeth whiteners (Joint Stipulations of Law and Fact 30) that did not include notice of an opportunity to obtain a declaratory ruling from the Board (Compare Board's Opening Stmt., Tr.67 ("... since we have the model Administrative Procedure Act in North Carolina, they could have filed an

action for a declaratory ruling . . .") with CX0042 at 001-002 (January 19, 2009, Cease and Desist Order to James & Linda Holder));

- d. Sending at least 40 Cease and Desist Orders to non-dentist teeth whiteners ((Joint Strip. 30) that did not include notice of an opportunity to file a contested case before the Board (Compare Board's Opening Stmt., Tr. 67 (" . . . since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the Board. . . .") with CX0042 at 001-002 (January 19, 2009, Cease and Desist Order to James & Linda Holder) with Board Rule 21 N.C.A.C. 16N .501 ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, it shall give such person notice of his right to a hearing by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing."));

- e. Sending a Cease and Desist Order to a manufacturer of products used by nondentist teeth whiteners (CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolina Bakewell to WhiteScience, Roswell, Georgia) that did not include notice of an opportunity to obtain a declaratory ruling from the Board (Compare Board's Opening Stmt., Tr. 67 (" . . . since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling") with CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolina Bakewell to WhiteScience, Roswell, Georgia));

- f. Sending a Cease and Desist Order to a manufacturer of products used by nondentist teeth whiteners (CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolina Bakewell to WhiteScience, Roswell, Georgia) that did not include notice of an opportunity to file a contested case before the Board (Compare Board's Opening Stmt., Tr.67 (" . . . since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the Board. . . .") with CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolina Bakewell to WhiteScience, Roswell, Georgia) with Board Rule 21 N.C.A.C. 16N .501 ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, it shall give such person notice of his right to a hearing by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing"));

- g. Sending at least eleven letters to third parties, including out-of-state property management companies, indicating that "North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry" (Joint Stipulations of Law and Fact ¶ 31) that did not include notice of an opportunity to obtain a declaratory ruling from the Board (Compare Board's Opening Stmt., Tr. 67 ("... since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling . . .") with CX0060 at 001-002 (November 21, 2007, letter from Carolin Bakewell to General Growth Properties, Chicago, Illinois));

- h. Sending at least eleven letters to third parties, including out-of-state property management companies, indicating that "North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry" (Joint Stipulations of Law and Fact ¶ 31) that did not include notice of an opportunity to file a contested case before the Board (Compare Board's Opening Stmt., Tr. 67 ("... since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the Board. . .") with CX0060 at 001-002 (November 21, 2007, letter from Carolin Bakewell to General Growth Properties, Chicago, Illinois) with Board Rule 21 N.C.A.C. 16N .501 ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, it shall give such person notice of his right to a hearing by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing"));

- i. Sending a letter to a manufacturer of products used by non-dentist teeth whiteners advising that the users of the manufacturer's product are committing a misdemeanor under N.C. Gen. Stat. § 90-40 (CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina) that did not include notice of an opportunity to obtain a declaratory ruling from the Board (Compare Board's Opening Stmt., Tr. 67 ("... since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling . . .") with CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina)); and

- j. Sending a letter to a manufacturer of products used by non-dentist teeth whiteners advising that the users of the manufacturer's product are

committing a misdemeanor under N.C. Gen. Stat. § 90-40 (CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina) that did not include notice of an opportunity to file a contested case before the Board (Compare Board's Opening Stmt., Tr. 67 ("... since we have the model Administrative Procedure Act in North Carolina, they could have filed ... a contested case before the Board. ...") with CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina) with Board Rule 21 N.C.A.C. 16N .501 ("When the Board acts .. in a manner which will affect the rights ... of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, it shall give such person notice of his right to a hearing by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing"))).

Response to Finding No. 1388:

Respondent objects generally to Finding No. 1388 because it is a statement of opinion and a legal assertion, not a statement of fact. Complaint Counsel mischaracterizes the record, ignoring evidence of Respondant's efforts to initiate legal proceedings against non-licensed teeth whitening providers on various occasions. Specifically, Respondent objects to the subparts of Finding No. 1388 as follows:

Response to Finding No. 1388(a):

This is a statement of opinion and a legal assertion, not a statement of fact.
Complaint Complaint cites no evidence in support of this legal assertion.

Response to Finding No. 1388(b):

This is a statement of opinion and a legal assertion, not a statement of fact.
Complaint Complaint cites no evidence in support of this legal assertion.

Response to Finding No. 1388(c):

This is a statement of opinion and a legal assertion, not a statement of fact.
Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew

of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86; Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0042, as the State Board specifically requested a response from the letter recipients in connection with the investigation; thus, the letter recipients were given an opportunity to respond to the State Board's letter, however they best saw fit. Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(d):

This is a statement of opinion and a legal assertion, not a statement of fact. Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86; Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0042, as the State Board specifically requested a response from the letter recipients in connection with the investigation; thus, the letter recipients were given an opportunity to respond to the State Board's letter, however they best saw fit. Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(e):

This is a statement of opinion and a legal assertion, not a statement of fact. Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86;

Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0100, as the State Board specifically indicated to White Science that it would seek relief in State court if violations continued; in fact, Mr. Nelson of White Science testified that he understood the State Board's determination could be challenged through legal action. (Nelson, Tr. 776.) Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(f):

This is a statement of opinion and a legal assertion, not a statement of fact. Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86; Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0100, as the State Board specifically indicated to White Science that it would seek relief in State court if violations continued; in fact, Mr. Nelson of White Science testified that he understood the State Board's determination could be challenged through legal action. (Nelson, Tr. 776.) Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(g):

This is a statement of opinion and a legal assertion, not a statement of fact. Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew

of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86; Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0260 [which Complaint Counsel mistakenly refers to as CX0060]. In CX0260, the State Board did not indicate that it was considering any recourse against General Growth Properties, or any other property management company. In fact, State Board members testified that they have no intention of taking any action against mall owners. (RX50 (Bakewell Dep. At 264.) Therefore, whether or not these letter recipients knew about the legal procedures to challenge determinations by the State Board is irrelevant. Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(h):

This is a statement of opinion and a legal assertion, not a statement of fact. Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86; Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0260 [which Complaint Counsel mistakenly refers to as CX0060]. In CX0260, the State Board did not indicate that it was considering any recourse against General Growth Properties, or any other property management company. In fact, State Board members testified that they have no intention of taking any action against mall owners. (RX50 (Bakewell Dep. At 264.) Therefore, whether or not these letter recipients knew about the legal

procedures to challenge determinations by the State Board is irrelevant.

Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(i):

This is a statement of opinion and a legal assertion, not a statement of fact.

Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86; Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0371. In CX0371, the State Board provided, "Individuals who use your products to provide teeth whitening services to the public *may* be engaging in the unauthorized practice of dentistry, which is a misdemeanor" (emphasis added). Furthermore, in CX0371, the State Board did not indicate that it was considering any recourse against manufacturers of products used by non-dentist teeth whiteners. Therefore, whether or not the letter recipient knew about the legal procedures to challenge determinations by the State Board is irrelevant. Respondent objects to Complaint Counsel's reliance of Respondent's Opening Statement as evidence to support this proposed finding.

Response to Finding No. 1388(j):

This is a statement of opinion and a legal assertion, not a statement of fact.

Complaint Complaint ignores a substantial volume of evidence indicating that cease and desist letter recipients and those allegedly affected by the letters knew of their rights to challenge the letters through legal action. (Valentine, Tr. 585-86;

Nelson, Tr. 776; Obsorn, Tr. 693-94; Wyant, Tr. 921.) Moreover, Complaint Counsel misrepresents CX0371. In CX0371, the State Board provided, “Individuals who use your products to provide teeth whitening services to the public *may* be engaging in the unauthorized practice of dentistry, which is a misdemeanor” (emphasis added). Furthermore, in CX0371, the State Board did not indicate that it was considering any recourse against manufacturers of products used by non-dentist teeth whiteners. Therefore, whether or not the letter recipient knew about the legal procedures to challenge determinations by the State Board is irrelevant. Respondent objects to Complaint Counsel’s reliance of Respondent’s Opening Statement as evidence to support this proposed finding.

1389. In addition to the operations that have been shut down, prospective operators continue to be turned away from malls. (Gibson, Tr. 624, 627-628, 632-633).

Response to Finding No. 1389:

Complaint Counsel misrepresents CX0255, as the mall operator indicated she based her decision on “feedback from several Developers letting [her] know that this use is illegal in several states and that their operators have been shut down in their malls.” Complaint Counsel disregards CX0647, providing that: (1) in 2009, the mall called Streets of Southpoint still had a teeth-whitening tenant; (2) in 2009, Carolina Place mall still had a teeth-whitening tenant.

This the 5th day of May, 2011.

Respectfully submitted,

ALLEN AND PINNIX, P.A.

/s/ Noel L. Allen

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CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2011, I electronically filed the foregoing with the Federal Trade Commission using the FTC E-file system, which will send notification of such filing to the following:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-113
Washington, D.C. 20580

I hereby certify that the undersigned has this date served copies of the foregoing upon all parties to this cause by electronic mail as follows:

William L. Lanning
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I also certify that an electronic copy of the document was served and two spiral bound copies of the document will be delivered to:

The Honorable D. Michael Chappell
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This the 5th day of May, 2011.

/s/ M. Jackson Nichols
M. Jackson Nichols

CERTIFICATION FOR ELECTRONIC FILING

I further certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and by the adjudicator.

/s/ M. Jackson Nichols
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