

ORIGINAL

**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.)
)
)

**COMPLAINT COUNSEL'S POST TRIAL PROPOSED FINDINGS OF FACT
AND CONCLUSIONS OF LAW**

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RECORD REFERENCES

References to the record are made using the following citation forms and abbreviations:

JX - Joint Exhibit

CX - Complaint Counsel Exhibit

RX - Respondent Exhibit

Tr. - Citations to Trial Testimony

(CX0000 at 000 (XX, Dep. at xx)) - Citations to Deposition Testimony

(CX0000 at 000 (XX, IHT at xx)) - Citations to Investigational Hearing Testimony

Joint Stipulations of Law and Fact - Citation to Joint Stipulations of Law and Fact

State Action Opinion - Citation to the Opinion of the Commission issued February 3, 2011

Response to RFA - Citation to Respondent's Objections and Responses to Complaint Counsel's
First Set of Requests for Admissions

Commission Complaint – Administrative Complaint filed June 17, 2010

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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.
2. The Board’s six dentists members are elected by licensed North Carolina dentists.
3. The six Board dentist members control the Board.
4. The Board has the power to exclude.
5. There are Board members and dentists that offer teeth whitening services in North Carolina.
6. Non-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.
8. The Board’s dentist members and its dentist constituents have a financial interest in prohibiting teeth whitening by non-dentists.
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.
10. The 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.
12. Specifically, the Board has issued more than 40 “Cease and Desist Orders” to non-dentist competitors providing teeth whitening services.
13. The Commission has held that it is undisputed that the letters were intended as and received as orders from the Board.
14. These orders were issued without statutory authority, and in many cases, without any factual investigation.
15. Non-dentists that have been ordered to “Cease and Desist” have exited the market as a

result.

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.
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.
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.
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."
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.
21. The Board's conduct to excluded a new and low cost class of competitors is an inherently suspect restraint of trade.
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.
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.
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.
25. Consumer injury will continue and grow unless the Board's exclusionary conduct is enjoined.
26. There is no cognizable efficiency justification offsetting the consumer harm.
27. Complete exclusion is not justified by any economic argument set forth by the Board.

28. Respondent's claims of health, safety, and other consumer protection problems associated with kiosk/spa teeth whitening providers have little evidentiary support.
29. To the extent there could be any legitimate, cognizable efficiency concerns, less restrictive alternatives are available.
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.

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).
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.

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).
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).
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).
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).

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)).

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

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)).
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).
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)).

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).
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)).

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).

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).
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).
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).
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)).

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)).
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)).
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)).
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)).

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).
58. The dentist members of the Board are elected for three-year terms and can run for re-election, 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).
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)).

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).
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 Efirid (Consumer Member), Joseph S. Burnham, W. Stan Hardesty, and Brad C. Morgan. (CX0085 at 002, Annual Report to the Governor – 2005).
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 Efirid (Consumer Member), Clifford O. Feingold, W. Stan Hardesty, and Ronald K. Owens. (CX0086 at 002, Annual Report to the Governor – 2006).
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 Efirid (Consumer Member), Clifford O. Feingold, C. Wayne Holland, and Ronald K. Owens. (CX0088 at 002, Annual Report to the Governor – 2007).
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 Efirid (Consumer Member), Clifford O. Feingold, C. Wayne Holland, and Brad C. Morgan. (CX0089 at 002, Annual Report to the Governor, 2008).
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 Efirid (Consumer Member), Joseph S. Burnham, Brad C. Morgan, and Millard W. Wester. (CX0091 at 002, Annual Report to the Governor – 2009).
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).

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).
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)).
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).
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).
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).
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).
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).
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)).
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)).
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)).

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).

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).

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)).

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).

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).

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)).
83. The Dental Practice Act sets forth practices that constitute the practice of dentistry. (CX0019 at 007-008, Dental Practice Act § 90-29(b)).
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)).
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)).
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)).
87. Dr. Owens testified that the Board had no authority to discipline non-licensees. (Owens, Tr. 1443, 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)).
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).

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).

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)).
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)).

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)).
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)).
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)).
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)).
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)).
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).

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).
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).
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).
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).

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).
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)).
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)).
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).

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)).
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)).

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)).
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)).
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)).

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).
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)).
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)).
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).
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)).

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)).
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 e-mail and, in some instance, vote by e-mail. (CX0554 at 021 (Allen, Dep. at 74)).
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).

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).

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)).

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)).
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)).
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).
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; CX0109 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)).
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)).
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).

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).
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).
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 (Efird, Dep. at 34-35)).

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).
132. All of the members of the Board are also members of the North Carolina Dental Society. (CX0556 at 044 (Burnham, Dep. at 169)).
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).
134. Board members also consider themselves “liaisons” between the Board and the licensees. (Hardesty, Tr. 2764-2765).
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)).

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)).
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)).
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)).
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)).

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).
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).
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).
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).

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

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).
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 follow-up final cosmetic exam where dentists point out other improvements through esthetic procedures that your "esthetic practice could explode overnight." (CX0381 at 002).
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)).
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)).
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)).
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

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).

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).
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).
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).
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).
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)).
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).

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).
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).

D. Historical Overview of Teeth Whitening

159. Teeth may be whitened in several ways including: (1) bleaching using peroxide-containing 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).
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).

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).
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).
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).
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).

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)).
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)).

2. Modern Teeth Whitening After 1989

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

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 seek 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).

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) non-dentist teeth whitening services in salons, retail stores, and mall kiosks. (CX0392 at 002; CX0053 at 004-005; Osborn, Tr. 650; Valentine, Tr. 515).

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).
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).
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).
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)).

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

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

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).
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).
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)).

3. Over the Counter Teeth Whitening

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).
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).
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).
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)).
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).
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)).

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).
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).
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).
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).
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).

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).

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)).
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).
204. Dentists in North Carolina use Ultradent's Opalescence teeth whitening system. (Tilley, Tr. at 2002-2003); (CX0572 at 009 (Wester, Dep. at 26)).
205. Dentsply is an international dental product distributor based in York, Pennsylvania. Dentsply sells its products to dentists. (CX0597 at 059).
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).
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).
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).
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).
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).

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).
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).
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).
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).
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).
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).

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

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).

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.”).

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).

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).

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 customers teeth. (CX0159 at 001-002; CX0337 at 001; CX0363 at 001).
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).
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 e-mail 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).

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).

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).
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).
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).
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).

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).

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).
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).

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).
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).
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).

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)).

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))).
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)).
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).
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)).

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).
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).
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).
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)).
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, “[I]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)).
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).
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).

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)).
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).
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).
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).

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).

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).

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).
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)).
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)).
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).

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)).
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)).
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)).

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).

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).
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).

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; 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; Joint Stipulations of Law and Fact ¶ 30.).

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)).
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).
273. In contrast to the three consumers who filed complaints with the Board regarding non-dentist 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).

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 Lightning 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.).

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).

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).
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).
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)).
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")).

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).

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).
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).
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)).
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)).
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)).

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 member's 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).
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).

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)

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).

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).
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).
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 hand-delivery by a private investigator (CX0094 at 005), or personal service by a Board investigator (CX0044 at 004-005).

C. 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.

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)).
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)).
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)).
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)).
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)).
299. Dr. 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).
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)).

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)).

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).
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).
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).
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).
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).
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).
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).

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).
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).
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).

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).
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).
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 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 close of the business." (Nelson, Tr. 850).

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).
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).
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).
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)).
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)).
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 non-dentist teeth whitening other than the fact that kiosk teeth whitening would be lawful if a

dentist was supervising. (CX0565 at 056 (Hardesty, Dep. at 215-216); CX0203 at 001-002).

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 non-dentist 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)).
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).
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).
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)).
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”))).
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)).

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)).
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).
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).

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 non-dentist 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).

i. Hull Storey 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).
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).
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).
334. HSG had a successful non-dentist teeth whitening event at its Lake City Mall. (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).

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).

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).
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).
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).
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).
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).

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

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).
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 non-dental teeth whitening kiosk using the WhiteScience system – opened December 7, 2008. (CX0664 at 001; CX0665 at 001-011).
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).
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).

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).

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).
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).

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).
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)).
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).
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)).
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).

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. MERRIAM-WEBSTER’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)).
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 on-site visit to confirm that Weaver no longer offered teeth whitening services)).
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)).
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)).

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).

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)).

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).

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).

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).

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).

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

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).
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)).
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).
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).

3. The 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).
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).

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).

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).
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).
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).

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).
383. In an e-mail dated January 17, 2008, Board counsel Carolin Bakewell informed a non-dentist 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 non-dentist touches the customer’s mouth. (CX0291 at 002-003).
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).
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).
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).

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).

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).
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).
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).
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).
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).
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).
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 e-mail 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).

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).
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).
397. On April 7, 2010, Dr. Owens asked Mr. White who sent requests to the Board in his e-mail 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).
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).
399. The Board refused to meet with members of the cosmetic teeth whitening industry. (Osborn, Tr. 692; Nelson, Tr. 783-784; CX0521 at 001).

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).

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).

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).
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)).
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)).
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).
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)).
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).
408. WhiteScience operates in over 40 states. (Nelson, Tr. 800).
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).
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).

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)).
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).
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).
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).
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).
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).

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)).

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).
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).
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).
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).
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).

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).
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).
425. The cost of non-dentist teeth whitening varies but seemingly ranges between \$75 and \$150. (Kwoka, Tr. 984; CX0654 at 004).
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).

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).
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).
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).
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).

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).
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).
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).
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).
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).
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).
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)).

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).
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).
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).
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)).

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).
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).
444. CX0808 is a box of Crest Whitestrips using 9% hydrogen peroxide. (Giniger, Tr. 204-205).
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).

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).

4. Non-Dentist Teeth Whiteners

447. Non-dentist provided chair-side bleaching, also called non-dentist bleaching or non-dentist 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).
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).
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).
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).
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).
452. CX0811 is an LED light manufactured by Lightnew that could be used in a non-dentist bleaching center. (Giniger, Tr. 186-188).

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).
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).
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).
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).
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).
458. Mr. George Nelson of WhiteScience also demonstrated the use of his company's non-dentist 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).

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)).
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 lay-operated 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).
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).
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).
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).
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).

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).

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).
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).
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).
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).
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).
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).
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).
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).

474. Dentist provided teeth bleaching (\$400-\$800) is typically more expensive than non-dentist 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).
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)).
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)).
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)).
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).
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)).
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).
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)).
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).

483. Teeth whitening is a frequently requested procedure in dentist offices. (CX0555 at 027 (Brown, Dep. at 100)).
484. Consumers want their teeth whitened because “anything cosmetic sells.” (CX0555 at 034 (Brown, Dep. at 129)).
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).
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).
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).
488. Dentists differentiate themselves from non-dentist teeth whiteners in terms of training, privacy, and professional ethics. (CX0595 at 003; CX0185 at 001).
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)).
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)).
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).
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)).
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).
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).

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).
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).
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).
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).
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).
500. The cost of non-dentist teeth whitening varies but seemingly ranges between \$75 and \$150. (Kwoka, Tr. 984; CX0654 at 004).
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).

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.”)).
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).
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)).
505. Dentist and non-dentist teeth whitening products tend to have greater concentrations of hydrogen peroxide than do OTC products. (Giniger, Tr. 204-205).
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).
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)).
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).
509. Consumers that place the highest priority on speed of whitening results could prefer in-office 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)).
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).
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).

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).
513. Despite their diverse characteristics, the alternative methods of teeth whitening address the same consumer need – whiter teeth. (Kwoka, Tr. 996, 1171).
514. Many consumers want their teeth whitened and are seeking the “cosmetic” effect of whiter teeth. (CX0555 at 034 (Brown, Dep. at 129)).
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).
516. Dentists differentiate themselves from non-dentist teeth whiteners in terms of training, privacy, and professional ethics. (CX0595 at 003; CX0185 at 001).
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).
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).
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).
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).
521. Fifth, there is substantial cross-elasticity of demand between dentist and non-dentist teeth whitening services. (Kwoka, Tr. 999; RX0078 at 009).

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).
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 non-dentist teeth whitening and dentist teeth whitening could be closer substitutes than dentists teeth whitening and OTC products. (Baumer, Tr. 1925).
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)).
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)).
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)).
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)).
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).
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).
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).
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).

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).
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).
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).
535. In keeping with its interest, “[t]he Board has acted vigorously to prohibit non-dentist teeth whitening in North Carolina.” (CX0654 at 001).
536. The magnitude of the price effect of exclusion depends upon the substitutionality 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)).
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).
538. Dr. Baumer agrees that a reduction in supply of teeth whitening will have an upward impact on price. (Baumer, Tr. 1700).
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).
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 non-dentist 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).

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.”)).
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)).
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)).
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)).

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)).

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)).
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).
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).
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).
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).
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).
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).
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).
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)).

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).
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)).
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)).
558. Dr. Baumer agrees that a reduction in supply of teeth whitening will have an upward impact on price. (Baumer, Tr. 1700).
559. Exclusion of competition will result in competitive consequences, one of which is a price increase. (CX0826 at 045 (Baumer Dep. at 171)).
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)).
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).
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)).
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).
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).

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).
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).
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.")).
568. Consumer surplus can be measured regardless of whether the product is legal or illegal. (Kwoka, Tr. 1188-1189, 1197).

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).
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).
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).

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).
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).
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).
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.")).
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)).
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).
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).

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).
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).
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).
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).
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).
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).

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).
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).
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).
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”)).
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).
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).
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).
592. Dr. Baumer agrees that professional boards, including dental boards, have supported

anticompetitive restrictions in the past. (Baumer, Tr. 1884).

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).
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).
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)).
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).
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).
598. Dr. Baumer agrees that economists can learn from other types of exclusionary conduct to make inferences about new exclusionary conduct. (Baumer, Tr. 1982).
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).
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).

601. Dr. Baumer admits that he may have exaggerated in describing the professions studies as outdated. (Baumer, Tr. 1766).
602. Dr. Baumer “provides no theoretical or empirical basis for disregarding the academic literature” cited by Professor Kwoka. (CX0631 at 013).
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).
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)).
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”)).
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)).
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).
608. Dr. Baumer agreed that professional boards have sometimes operated to enhance income, and sometimes operated strictly in the public interest. (Baumer, Tr. 1848).
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 mall letter to a mall 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).

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).
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).
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).
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)).
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)).
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)).
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).
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)).

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).
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).
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).
621. Certification would be a less restrictive alternative than a ban and result in a reduction in anticompetitive effects. (Kwoka, Tr. 1124).
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).
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).
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).
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)).

626. Dr. Baumer does not believe that all services need to be provided by licensed professionals. (CX0826 at 046 (Baumer, Dep. at 177)).
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 non-dentist 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).

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)).
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).
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).
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).
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).
633. Triad Body Secrets was “forced out of business” after receiving a Cease and Desist Order from the Board. (CX0815 at 001).

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).
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).
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).
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).
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).
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).

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).
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).

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).
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).
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).
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).
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).
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, non-dentist teeth whitening businesses, including the Carolina Place Mall in Pineville, North Carolina. (Wyant, Tr. 874-884, 902-903; CX0629).
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).
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).

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)).
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).
652. Cosmetology Board licensees learned of the Dental Board's stance against non-dentists performing teeth whitening services from the Cosmetology Board. (CX0347; CX0050 at 001; CX0814; Hughes Tr. 940-941).
653. As a direct result of the Board's actions with respect to the Cosmetology Board, non-dentists stopped providing teeth whitening services. (CX0050 at 001; CX0814; Hughes Tr. 941-943).
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).
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).

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).

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).
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).
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).
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).
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).

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).
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).
664. But for the Board's actions, Ms. Osborn would sell the BriteWhite System in North Carolina. (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).

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).
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).
668. Mr. Valentine stated that WhiteSmile was aware of the Board's stance against non-dentist 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).
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).
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).
671. Valentine stated that WhiteSmile did not want to operate in North Carolina because it knew it would have an issue. (Valentine, Tr. 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).
673. Mr. Valentine stated that WhiteSmile eventually entered the North Carolina market in 2009 with Sam's Club road shows. (Valentine, Tr. 567).
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).

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).
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).
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).
678. The Cease and Desist Orders sent by the Board also had the effect of deterring other non-dentists from entering into the teeth whitening business in North Carolina, resulting in the continued denial of consumer choice. (Kwoka, Tr. 1129, 1136-1137).
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).
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).

E. Exclusionary Conduct Results in Harm to Consumers

681. The exclusion of nondentist teeth whitening represents a loss of consumer surplus. (Kwoka, Tr. 1013).
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).

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).
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).
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).
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).
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 non-dentist 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).
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)).

689. Dr. Baumer agrees that a reduction in supply of teeth whitening will have an upward impact on price. (Baumer, Tr. 1700).
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).
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).
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).
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).
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).
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).
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).
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).
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).
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).
700. Exclusionary conduct can be harmful even if the price effect is small. (CX0631 at 014).
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).
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).
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).
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).
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).

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).
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).
708. Economists would expect that a market would reach an equilibrium that included both low and high quality products. (Kwoka, Tr. 1101-1102).
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).
710. Absent an efficiency justification, the Board's conduct in excluding non-dentist teeth whiteners was anticompetitive. (Kwoka, Tr. 1075).

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))).
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).
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).
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).

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).

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, non-dentists, or consumers. (Giniger, Tr. 356, 453-455).
717. Non-dentist provided bleaching does not harm consumers by masking the sole symptom of progressive pathologies. (Giniger, Tr. 356).
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).
719. Teeth bleaching products do not contain notable allergens. (Giniger, Tr. 355).
720. Teeth whitening, whether performed by dentists, non-dentists, or consumers, does not cause material damage to the enamel or pulp. (Giniger, Tr. 355).
721. Teeth whitening, whether provided by dentists, non-dentists, or consumers, does not cause systemic toxicity. (Giniger, Tr. 356).
722. Vital teeth bleaching does not remove stains. (Giniger, Tr. 116-118).
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).
724. The Board's effort to exclude non-dentist providers of teeth bleaching is not warranted by health, aesthetic, or efficacy considerations. (Giniger, Tr. 353-354).
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).
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).

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).
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).
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).
730. The United States Environmental Protection Agency has authorized the application of hydrogen peroxide to foods as a pesticide. (CX0653-025-026).
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).
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).
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).
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, non-transient 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).
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).
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 non-

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)).
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).

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[.]")).
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).
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. (Giniger, Tr. 287-288).
742. Anaphylactic Reaction: A potentially life-threatening allergic reaction where the airways to the lungs are closed. (Giniger, Tr. 355).
743. Avulsion: A condition where the tooth is knocked out of the mouth. (Giniger, Tr. 306).
744. Calcific Metamorphosis: A condition caused by pulpal injury. When calcific

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.

metamorphosis is present in a tooth, cells fill in the pulp with additional dentin, thereby creating a “natural” root canal. (Giniger, Tr. 285-286).

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)
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).
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.
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).
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).
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).
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).
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).
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).

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).
755. Luxation: A condition where the tooth is dislodged in the socket. (Giniger, Tr. 306-307).
756. Malocclusion: A misalignment of the teeth, where “your teeth don’t fit together correctly.” (CX0823 at 041 (Haywood, Dep. at 154)).
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).
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).
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).
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)).
761. Periapical X-Ray: An x-ray of the entire tooth. (Haywood, Tr. 2987)
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).
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).
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).
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).

- 766. Resorption is not a cancer. (Giniger, Tr. 292; Haywood, Tr. 2964).
- 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).
- 768. Root: The portion of the tooth beneath the gum line. (Giniger, Tr. 158-159).
- 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).
- 770. Root canals are performed on teeth that are non-vital or are about to become non-vital. (Giniger, Tr. 287).
- 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).
- 772. Systemic Toxicity: Side effects that would affect the organs or systems of the body. (Giniger, Tr. 239).
- 773. Vital Tooth: A tooth that is alive. (Giniger, Tr. 112-113).

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).
- 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).
- 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).

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).
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).
779. Dr. Giniger attained the degree Ph.D. in Biomedical Science, specializing in Oral Biology in 1993. (Giniger, Tr. 78-79; CX0653 at 051).
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).
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).
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).
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).
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).
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).
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).

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).
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).
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).
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).
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).
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).
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).
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).
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).
796. In formulating his opinions in this litigation, Dr. Giniger used due diligence in

ascertaining relevant facts. (Giniger, Tr. 106-107).

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).
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).
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).

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).
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).
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).
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).
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).
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).
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).
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).

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).
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).
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).
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).
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).
813. Dr. Haywood has no training, expertise, or experience in the formulation of teeth bleaching products. (Haywood, Tr. 2577-2579).
814. Dr. Haywood has no training, expertise or experience in marketing any product to consumers, nor in evaluating consumer satisfaction/preferences. (Haywood, Tr. 2579).
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)).
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).
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).

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).
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)).
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).
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).
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).
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).
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).
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).
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).
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)).
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).
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).
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).
831. In his 2010 article, Dr. Haywood acknowledged concerns as to the safety of such long-term 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.
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).

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).
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).
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).
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).
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).
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).
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).

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)).
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).
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)).
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).
844. Dr. Haywood believes that a non-dentist’s mere offer to provide or assist a consumer in teeth bleaching is irredeemably deceptive by implication, wrong, and that all non-dentist providers are “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).
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)).
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).

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).
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)).
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).
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)).
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).
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).
854. Dr. Haywood did not inquire about the legality of non-dentist teeth whitening in other states. (Haywood, Tr. 2640).

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).
856. Dr. Haywood alleges that he had been so-informed by a representative of P&G itself. (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).
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).
859. But Dr. Haywood acknowledged that not all dentists satisfy the American Dental Association's ethical standards. (Haywood, Tr. 2625).
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).
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).
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).
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).
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).

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 non-dentist 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).
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)).
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).
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).
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 non-dentist 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).

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).
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)
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).
873. MSDS sheets contain relevant information regarding product composition and characteristics, and are readily available on request. (Giniger, Tr. 178; CX0632 at 008)).
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).
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).
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).
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).
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).

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.
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)).
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).
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).
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).
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).
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).

886. Dr. Haywood has claimed that in part the paucity of reports of consumer harm from non-dentist 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)).
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)).
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).
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).

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).
891. Dr. Haywood insists that only empirical studies of non-dentist provided teeth bleaching could establish its safety. (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).
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"))).
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.
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).
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)).
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).

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).
899. Dr. Haywood’s reasoning is deeply flawed. (Giniger, Tr. 257-259; CX0632 at 010; CX0585 at 002-003, 005; CX0497 at 005-006).
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).
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).
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).
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”).
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).
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!”).

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).

B. 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 non-dentist teeth whitening. (Nelson Tr. 771; Osborn Tr. 664-665; CX0554 at 026 (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)).
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)).
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)).
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)).
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).

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).
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 non-dentists.” (Response to RFA ¶ 38).
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).

C. 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).
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)).
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, non-transient 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).
919. There is little to no evidence of any serious harm or non-transient effects caused by non-dentist teeth whitening. (Nelson, Tr. 771; 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)).

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)).
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).
923. The only specific instance that Dr. Allen is aware of non-transient harm due to non-dentist 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)).

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)).
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).
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).
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).

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)).
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).
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).

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 is not aware of any consumer having an anaphylactic reaction from non-dentist teeth whitening).
932. Hydrogen peroxide is a naturally occurring product of cellular metabolism, and therefore peroxide allergy is extremely rare. (Giniger, Tr. 224).
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).
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).
935. Carbomer is commonly used in gelled foods, gelled cosmetic, and toothpaste. (Giniger, Tr. 226).
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).
937. Triethanolamine (TEA) is a USP ingredient that is used in milk, skin lotion, and eye gels. (Giniger, Tr. 227-228).
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)

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)).
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).
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).
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).
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)).
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)).

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).
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).

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).
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).
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 clinically 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).
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).
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).
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).

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).
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).
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).
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).
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"))).
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).

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).
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 chair-side 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).
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).
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).

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).
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)).
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).
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).
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 effects are plausible unless systemic exposure exceeds two grams (2,000 milligrams). (Giniger, Tr. 240; CX0653 at 031).

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).
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).
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).
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).
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).
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).

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).
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).
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).
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)
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).
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).
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).

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)).
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)).
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)).
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).
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)).
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).
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).
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).
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)).

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).
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).

4. Masking Pathology Is Not a Legitimate Concern Regarding Non-dentist 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)).
993. Dr. Haywood acknowledges that there is no empirical literature demonstrating masked pathology; it has not been proven. (Haywood, Tr. 2734-2735).
994. There is not a single "case report" identifying any incident of masked pathology. (Giniger, Tr. 301; Haywood, Tr. 2734; CX0632 at 017-018).
995. Dr. Haywood is not aware of any instance of masked pathology. (Haywood, Tr. 2928-2932).
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.
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).
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).
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).

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).
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)).
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)).
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)).
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).
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.
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).
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)).

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).
1009. Indeed, Dr. Giniger concluded that there may never have been an instance in which non-dentist provided teeth bleaching masked pathology, delaying diagnosis and treatment and thereby harming a consumer. (Giniger, Tr. 302, 319-320).
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).
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).
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)).
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")).
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 non-dentist teeth bleaching would mask an incidence of internal resorption.

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.
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.
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)).
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.
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).
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.
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).
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)).
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).

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.
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)).
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).
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)).
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).
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).

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)).
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).
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).
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).
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).
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 . . .”)).
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).

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.).
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 X-ray, 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).
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).
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).
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).

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).
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).
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 $10\% \times 10\% \times 10\% \times 10\% \times 10\% \times 10\% \times 10\% \times 5\%$, 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).
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).

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 non-dentist might spread contagious pathogens like tuberculosis or hepatitis C. (CX0565 at 038 (Hardesty, Dep. at 144-145)).
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).).
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)).
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).
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).
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)).
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).

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)).
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).

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")).
1056. The Board has identified at least one example of a North Carolina dentist causing non-transient harm to a patient while performing a teeth whitening procedure. (Response to RFA ¶ 30; Respondent's Response to Interrogatory ¶ 4).
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).
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)).
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).

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)).
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).
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)).
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)).
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).
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).
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).
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 non-dentists. 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).
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).

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)).

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).
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).
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).
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)).
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)).
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 non-dental 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).
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)).

8. Concerns About Any Lack of Sanitation Related to Non-dentist Teeth Whitening Is Pretextual

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)).
1078. Manufacturers design products for use by non-dentist bleaching facilities that are in pre-packaged single-use containers, sterile, and meant to be self-applied by the consumer. (Giniger, Tr. 262-263).
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).
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).
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).
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).
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).
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).
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).
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 a state or local health department or to any other responsible official. (CX0653 at 037).

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)).
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).
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)).
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).
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).
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).
1093. The Board has found, through its investigations, that licensed dentists have engaged in unsanitary practices. (Response to RFA ¶ 32-33).
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)).
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)).
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)).

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).
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).
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).
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).
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).
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).

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)
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).

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).
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)).
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).
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).
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).
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).
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).
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).
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).

1114. Jim Valentine testified that WhiteSmile required its operators to maintain general liability insurance. The WhiteSmile company carries product liability insurance. (Valentine, Tr. 585).
1115. BriteWhite requires its operators to obtain product liability insurance. (Osborn, Tr. 702).
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).

**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).
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).
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).
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).
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).

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)).
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).

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).
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).
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).
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).
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).
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 (non-dentist teeth whitening product) *with* CX0806 (dentist teeth whitening product) (both products are manufactured by the same company - Whiter Image - and contain the same ingredients)).

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).
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).
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.")).

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).
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).

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)).
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).
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).
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).
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)).
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)).
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)).
1142. Infections, abscesses, and periodontal disease can cause gums to bleed. (Tilley, Tr. 2087-88).
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)).

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).
1145. Dr. Tilley is not aware of any literature indicating that commercially available teeth-whitening 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)).
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)).
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)).
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).
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).
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).
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).

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).
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).
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).
1155. Mr. Runsick received a document disclosing information before electing to undergo non-dental teeth whitening. (Runsick, Tr. 2140).
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)).
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)).
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)).
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)).
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)).

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)).
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)).
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).
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)).

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).
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)).

1167. Dr. Hasson had never seen any dental records of Patient X. (CX0575 at 016 (Hasson, Dep. at 56-57)).
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)).
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)).
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)).
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)).
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)).
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)).
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)).
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)).

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)).
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)).

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 e-mail 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).
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).
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).

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).

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).
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).
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).
1185. There is substantial evidence that non-dentist providers of teeth beaching 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).
1186. Manufacturers of non-dentist teeth bleaching products also provide directions to retail businesses to avoid consumer confusion. For example, BleachBright Corporation directs retails 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).
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).
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).
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).

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).
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).
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).
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).
1194. Even if there were consumer confusion about whether non-dentists were medical professionals it would not provide a sensible economic justification for excluding non-dentist 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).
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)).
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).

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).
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).

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).
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).
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)).
1202. Professor Kwoka analyzed the Board’s justifications from an economic perspective. (Kwoka, Tr. 1107-1109, 1127-1128, 1226-1227).
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).
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”)).
1205. Several objections to non-dentist teeth whitening raised by Dr. Baumer are textbook examples problems 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).
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).

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).
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).
1209. Dr. Baumer agrees that, in general, where intervention is appropriate less restrictive alternatives should be used. (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).
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).
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).
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).
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).

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)).
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).
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).
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).
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).
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).
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 in forming expert opinions. (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).

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).
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).
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)).
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).
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"))).
1228. Dr. Baumer performed a "thought analysis" by assuming that non-dentist teeth whitening could result serious 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).
1229. Dr. Baumer has admitted that he does not have any actual evidence that non-dentist teeth whitening causes cancer. (Baumer, Tr. 1820).
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).
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).

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 non-dentist 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).
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).
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).
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).
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)).
1237. Dr. Baumer was not aware that there is an oral hygiene section of the North Carolina Department of Health. (Baumer, Tr. 1944).
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).
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)).
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).

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).
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).
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).
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).
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).

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).

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)).
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).
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 dentist 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)).

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).

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).
1252. Dr. Baumer agrees that, in general, where intervention is appropriate less restrictive alternatives should be used. (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).
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).
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).
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”).
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)).
1258. Even if there were consumer confusion about whether non-dentists were medical professionals it would not provide a sensible economic justification for excluding non-dentist 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).

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).
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).
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).
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)).

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:

John Gibson

1264. Mr. Gibson is a partner and Chief Operating 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).

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).

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).

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).

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).

1269. Mrs. Hughes operates her business as SheShe Skin, currently located within the Hair Republic Salon in Dunn, North Carolina. (Hughes, Tr. 932-933).

George Nelson

1270. Mr. Nelson is the President of WhiteScience, a teeth whitening manufacturing company located in Alpharetta, Georgia. (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).

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).

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).

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).

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 USA 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).

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).

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).

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)).

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)).

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).
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).
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 e-mail from Terry Friddle to complaining dentist thanking him and stating that the Board will “let you know what we find out”).
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)).

1284. Dr. Hardesty earned \$47,279 from teeth whitening from 2005 to 2010. (CX0378 at 012).
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).
- 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).
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).
- 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).
- 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).

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).
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 2009-2010, Dr. Owens served as Immediate Past President. (Owens, Tr. 1439-1440).
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).
1290. Dr. Owens earned \$77,333 from teeth whitening from 2005 to 2010. (CX0467 at 001).

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).
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).
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).
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).
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.")).
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).
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).
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)).
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)).

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).
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, 2171-2172; CX0055 at 001-004).

Dr. Larry Tilley

1302. Dr. Larry Tilley is a licensee of the Board and practices general dentistry in Raleigh, North Carolina. (Tilley, Tr. 1997).
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).

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).
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.

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; CX0574 at 004 (White, IHT at 11)).

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)).
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)).
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).
1310. Mr. White testified that Board members do not discuss the details of investigations with members of the public. (White, Tr. 2222).
- a. On April 24, 2008, Bobby White forwarded to Christine Bennet, Assistant Producer of *5 On Your Side*, a 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).
 - 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 001-004).
 - 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 operations. . . ." (CX0117 at 001).
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).
- 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)).

- 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).

1312. Mr. White testified that the primary reason for the Board to investigated complaints is to protect the public.

- 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).

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).
- 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).
- 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).
- 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).
- 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).
- 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).

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).
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).
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).
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).
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).

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).
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).
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).
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).

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).
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).
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).

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)).
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)).
1333. Dr. Baumer has not authored an article in one of the "top" economics journals. (CX0826 at 012 (Baumer, Dep. at 41)).
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).

- (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).
- (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)).
- (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).
- (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)).
- (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).
- (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).
- (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)).
- (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).

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).
 - (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).
 - (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).
 - (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).
 - (e) 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. 1934-1936).
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 non-dentist teeth whiteners collect and sell medical information comes from Respondent's Counsel and Respondent's briefs. (Baumer, Tr. 1721, 1951-1952, 1955).
 - (b) Dr. Baumer admits that he has no evidence of non-dentist providers of teeth whitening selling medical information. (Baumer, Tr. 1956).
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).
 - (b) Dr. Baumer admits that the one anecdote he recalls 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).
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).
 - (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).
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).
- (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).
 - (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).
 - (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).

- (d) 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)).
- b. 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.
- 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. Balmer'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")).
 - 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)).
 - 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).
 - 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)).

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.

1. Dr. Baumer admits 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 non-dentist 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 non-dentist teeth whitening. (Baumer, Tr. 1923-1924).

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, non-dentist teeth whitening. (Baumer, Tr. 1944).

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).

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)).

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)).

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).

b. Dr. Baumer agrees with Professor Kwoka that an "exclusion model" is the proper

theoretical framework. (Baumer, Tr. 1839-1840).

- 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)).
- 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).
- 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.]")))).
- 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).
- 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).
- 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).
- 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).

- 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)).
- 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).
- 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).
- 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).
- 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).
- 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.”)).
- 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).
- q. Dr. Baumer agrees that, in general, where intervention is appropriate less restrictive alternatives should be used. (Baumer, Tr. 1771).

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).
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).
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).
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).
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).
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).
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).
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).
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).
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).
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).

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)).
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)).
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)).

Carolin 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 Carolin Bakewell, PLLC. (CX0581 at 005 (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)).
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)).
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)).

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)).

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)).
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

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)).
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)).
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)).

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)).
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)).

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)).
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)).
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)).
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)).

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)).
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)).

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)).
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. at15)).

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)).
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)).

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)).
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)).

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)).
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).

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)).
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)).

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)).
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)).

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)).
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)).
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)).

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)).

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)).

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)).

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)).

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)).

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 extra-legal “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 non-dentist 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 non-dentist 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 non-dentist 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 Propertties, 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"))).

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).

XIII. Conclusions of Law

1. The Federal Trade Commission ("FTC" or "Commission") has jurisdiction of the subject matter of this proceeding, and over the Respondent, North Carolina State Board of Dental Examiners ("Board"). (State Action Opinion, *In re North Carolina Board of Dental Examiners*, No. 9343 (February 3, 2011)).
2. The Commission has jurisdiction over the subject matter of this proceeding pursuant to Section 5 of the FTC Act, 15 U.S.C. § 45. (State Action Opinion, *In re North Carolina Board of Dental Examiners*, No. 9343 (February 3, 2011)).
3. The Board is an agency of the State of North Carolina that is charged with regulating the practice of dentistry in North Carolina in the interest of the public health, safety, and welfare of the citizens of North Carolina. (N.C. Gen. Stat. § 90-22(b) (CX0019 at 001)).
4. 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 Boulevard, Suite 105, Morrisville, North Carolina 27560. (N.C. Gen. Stat. § 90-22(b) (CX0019 at 001); 21 N.C.A.C. 16A.0103(a)).
5. The Board is composed of eight members: six licensed North Carolina dentists elected by a vote of all licensed dentists in North Carolina; one licensed North Carolina dental hygienist elected by a vote of all licensed dental hygienists in North Carolina; and one

public member appointed by the Governor of North Carolina. (N.C. Gen. Stat. § 90-22(b) (CX0019 at 001)).

6. At all relevant times herein, the Board has been a “person” with the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45. (State Action Opinion, *In re North Carolina Board of Dental Examiners*, No. 9343 (February 3, 2011); *South Carolina Bd. of Dentistry*, 138 F.T.C. 229 (2008); *Massachusetts Bd. of Registration in Optometry*, 138 F.T.C. 549 (1988)).
7. The provision of teeth whitening goods or services in North Carolina by dentists and non-dentists is in or affecting commerce as “commerce” is defined in the FTC Act. (*Summit Health, Ltd. v. Pinhas*, 500 U.S. 322 (1991); *McLain v. Real Estate Board*, 444 U.S. 232 (1980)).
8. The Board is a combination of competitors with respect to its efforts to eliminate teeth whitening goods and services provided in North Carolina by non-dentists. (*American Needle, Inc. v. NFL*, 130 S. Ct. 2201 (2010); *Massachusetts Bd. of Registration in Optometry*, 138 F.T.C. 549 (1988)).
9. Complaint Counsel has established a prima facie case that the Board’s conduct unreasonably restrained trade in teeth whitening goods and services in North Carolina in each of three separate ways: (i) the inherently suspect nature of the restraint has been shown; (ii) the anticompetitive nature of the restraint has been shown together with evidence of the Board’s market power; and (iii) the showing of actual anticompetitive effects. (*Fashion Originators’ Guild v. FTC*, 312 U.S. 457 (1941); *Associated Press v. United States*, 326 U.S. 1 (1945); *E.I. du Pont de Nemours & Co.*, 351 U.S. 377 (1956); *Radiant Burners, Inc. v. Peoples Gas Light & Coke Co.*, 364 U.S. 656 (1961); *Silver v. N.Y. Stock Exchange*, 373 U.S. 341 (1963); *Northwest Wholesale Stationers, Inc. v. Pacific Wholesale Stationers, Inc.*, 472 U.S. 284 (1985); *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447 (1986); *Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492 (1988); *Realcomp II, Ltd. v. FTC*, No. 09-4596, 2011 U.S. App. LEXIS 6878 (6th Cir. Apr. 6, 2011); *In re Polygram Holding, Inc.*, 136 F.T.C. 310 (2003); *United States v. Realty Multi-List, Inc.*, 629 F.2d 1351 (5th Cir. 1980)).
10. In response to Complaint Counsel’s prima facie case, the Board has not shown that its conduct is reasonably necessary to achieve any cognizable, plausible and valid efficiency justifications for the Board’s elimination of non-dentist teeth whitening. (*Fashion Originators’ Guild v. FTC*, 312 U.S. 457 (1941); *Keifer-Stewart Co. v. Joseph E. Seagram & Sons, Inc.*, 340 U.S. 211 (1951); *Nat’l Soc. of Prof. Engineers v. United States*, 435 U.S. 679 (1978); *Broadcast Music, Inc. v. CBS, Inc.*, 441 U.S. 1 (1979); *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447 (1986); *In re Polygram Holding, Inc.*, 136 F.T.C. 310 (2003); 7 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1505, at 370 (3d ed. 2003)).
11. The Board’s conduct constituting the violation was not actively supervised by the State

of North Carolina itself. (State Action Opinion, *In re North Carolina Board of Dental Examiners*, No. 9343 (February 3, 2011)).

12. The Tenth Amendment to the Constitution of the United States does not excuse the Board's violation. *Mercy-Peninsula Ambulance, Inc. v. County of San Mateo*, 592 F. Supp. 956 (N.D. Cal. 1984); *Springs Ambulance Service, Inc. v. City of Rancho Mirage*, No. CV82-5917CBM, 1983 WL 1878 (C.D. Cal. Sept. 27, 1983), *rev'd on other grounds*, 745 F.2d 1270 (9th Cir. 1983); *Omni Outdoor Advertising, Inc. v. Columbia Outdoor Advertising, Inc.*, 566 F. Supp. 1444 (D.S.C. 1983)).
13. The Order entered herein is necessary and appropriate to remedy and prevent the recurrence of the violation of law found to exist. (*FTC v. National Lead Co.*, 352 U.S. 419 (1957); *FTC v. Ruberoid Co.*, 343 U.S. 470 (1952); *Jacob Siegal & Co. v. FTC*, 327 U.S. 608 (1946); *In re Polygram Holding, Inc.*, 136 F.T.C. 310 (2003)).

Respectfully submitted,

s/ Richard B. Dagen
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Dated: April 22, 2011

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2011, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580

I also certify that I delivered via electronic mail and hand delivery a copy of the foregoing document to:

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I further certify that I delivered via electronic mail a copy of the foregoing document to:

Noel Allen
Allen & Pinnix, P.A.
333 Fayetteville Street
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*Counsel for Respondent
North Carolina State Board of Dental Examiners*

CERTIFICATE FOR ELECTRONIC FILING

I 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 the adjudicator.

April 22, 2011

By: s/ Richard B. Dagen
Richard B. Dagen



EXHIBIT INDEX

**State Board of Dental Examiners
Docket No. 9343**

**Complaint Counsel's
Final Exhibit List**

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0001	Complaint Counsel's Final Proposed Exhibit List	12/7/2010	JX0001 Tr. 56:18-23		N
CX0002 - CX0018	Intentionally Not Used				N
CX0019	N.C. General Statutes, Chapter 90, Article 2, Dentistry		JX0001 Tr. 56:18-23	Tr. 1298:15; 1300:03; 2203:22; 2204:12,16; 2206:22; 2794:04	N
CX0020	N.C. General Statutes, Chapter 90, Article 2, Dentistry (prior to 2009 change to 90-36(e))		JX0001 Tr. 56:18-23		N
CX0021	Letter to Zannie Efrid from Michael F. Easley re: Appointment to NC Board	8/20/2003	JX0001 Tr. 56:18-23		N
CX0022	Letter to Neplus Hall from Terry Friddle re: Nomination for Re-Election	5/16/2005	JX0001 Tr. 56:18-23		N
CX0023	Letter to Stanley Allen from David Cashwell re: Nomination for Election	4/30/2001	JX0001 Tr. 56:18-23		N
CX0024	Faxed Petition for Re-Election in Support of Dr. Stanley Allen	3/17/2004	JX0001 Tr. 56:18-23		N
CX0025	Letter to Dr. Benjamin Brown from Terry Friddle re: Welcome Back to the NC Dental Board w/Attach: Education/Training of New Board Members	6/26/2003	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0026	E-mail to Wester, Bakewell, Friddle et al. from Bobby White re: Training Update for the Ethics Commission	6/25/2008	JX0001 Tr. 56:18-23		N
CX0027	Fax report to Michelle from Kelly Reaves re: Petition for Dr. Millard Wester w/Attach: Signed Petition	5/19/2008	JX0001 Tr. 56:18-23		N
CX0028	Letter to Dr. Millard "Buddy" Wester from Bobby White & Terry Friddle re: Welcome to the NC Dental Board w/Attach: Education/Training of New Board Members	6/25/2008	JX0001 Tr. 56:18-23	Tr. 1324:10; 1333:07,08; 1478:13; 1479:01; 1487:24; 1492:17; 2836:04,05,12,14; 2838:18	N
CX0029	Letter to Rochelle Hunsucker from Terry Friddle re: Meeting with Sean Kurdys	6/23/2006	JX0001 Tr. 56:18-23		N
CX0030	Brighter Image Teeth Whitening advertisement	4/10/0000	JX0001 Tr. 56:18-23		N
CX0031	Letter to Neplus Hall from David Cashwell re: Board Nomination Letter w/Attach: Reater and Hall's Signed Petitions	3/15/2002	JX0001 Tr. 56:18-23		N
CX0032	Email Terry Friddle from Bendob@aol.com re: Great White Case #03-184	7/15/2004	JX0001 Tr. 56:18-23		N
CX0033	Fax to Dr. Benjamin Brown from Terry Friddle re: Richard Yeager DDS Complaint	9/29/2003	JX0001 Tr. 56:18-23		N
CX0034	Log 04-187 of Correspondence re: Edie's Salon Panache	10/8/2004	JX0001 Tr. 56:18-23		N
CX0035	Fax to NCBoard from Kelly Kreeb, DDS re: Edie's Salon Panache Offering TW services	10/15/2004	JX0001 Tr. 56:18-23		N
CX0036	Fax to Dr. Stanley Allen from Terry Friddle re: Caryn Massari, DDS re: Edie's Salon Complaint	10/7/2004	JX0001 Tr. 56:18-23		N
CX0037	Letter to NCBoard from Gale Barnett re: Serenity Day Spa	4/12/2006	JX0001 Tr. 56:18-23	Tr. 1372:20	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0038	Letter to Serenity Day Spa from Terry Friddle re: Taking dental impressions	1/11/2006	JX0001 Tr. 56:18-23		N
CX0039	Serenity Day Spa Advertising Flyer	N/A	JX0001 Tr. 56:18-23		N
CX0040	Letter to Clerk of Superior Court, Davidson County from Terry Friddle re: Judgement in 04 CR 062182 (Brandi Temple)	2/1/2005	JX0001 Tr. 56:18-23	Tr. 2325:21,22	N
CX0041	E-mail to White, Friddle, Holland et al. from Holland re: Hollywood Smiles w/Attach: Advertisements	8/10/2004	JX0001 Tr. 56:18-23	Tr. 2293:19; 2303:10, 13; 2309:04; 2311:06; 2326:19; 2327:06,10	N
CX0042	Collection of letters sent on same day to multiple BleachBright locations from NCBoard re: Notice and Order to Cease and Desist	1/19/2009	JX0001 Tr. 56:18-23	Tr. 1357:23,24; 1507:17; 1609:09	N
CX0043	Fax to Carolyn Bakewell from Jerry Butler DDS re: BleachBright	10/27/2008	JX0001 Tr. 56:18-23	Tr. 1357:22	N
CX0044	E-mail to Friddle, Dempsey, Smith et al. from Burnham re: Star Bright Whitening Systems at Cutting Crib	5/15/2006	JX0001 Tr. 56:18-23	Tr. 2349:16,24; 2367:25	N
CX0045	Fax to Dr. Joseph Burnham from Terry Friddle re: Star Bright Whitening Systems, Inc.	5/12/2006	JX0001 Tr. 56:18-23		N
CX0046	E-mail to Bakewell from Bradshaw re: NCDB v. Signature Spas	4/3/2008	JX0001 Tr. 56:18-23		N
CX0047	NC Board v. Signature Spas: 1st Interrogatories to Defendants	12/15/2006	JX0001 Tr. 56:18-23		N
CX0048	NC Board v. Signature Spas: 1st Interrogatories to Defendants	12/15/2006	JX0001 Tr. 56:18-23		N
CX0049	E-mail to Bridges from Bakewell re: BriteWhite Teeth Whitening System	12/5/2006	JX0001 Tr. 56:18-23		N
CX0050	Letter to Terry Friddle from Pamela Weaver re: Cease and Desist Letter to Nicole's Hair	3/27/2007	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0051	Letter to Joyce Osborn from Carolin Bakewell re: BriteWhite Teeth Whitening System training manual	11/22/2006	JX0001 Tr. 56:18-23		N
CX0052	Email to PA State Dentistry from Bakewell re: BriteWhite	11/21/2006	JX0001 Tr. 56:18-23		N
CX0053	Frequently Asked Questions re: Professional Teeth Whitening	N/A	JX0001 Tr. 56:18-23		N
CX0054	Fax to Dr. Stan Hardesty from Terry Friddle re: Dr. Reese Complaint Form - Signature Spas	9/11/2006	JX0001 Tr. 56:18-23	Tr. 2790:16	N
CX0055	NCDB Complaint Form of Brian Runsick: re: BleachBright	4/11/2008	JX0001 Tr. 56:18-23	Tr. 2074:24,25; 2075:08; 2120:06,11; 2121:08; 2172:25	N
CX0056	Minutes from NC Dental Board Meeting: Morrisville, NC February 9, 2007	2/9/2007	JX0001 Tr. 56:18-23		N
CX0057	North Carolina Board of Dental Examiners v. Signature Spas of Hickory - Findings of Fact	11/22/2006	JX0001 Tr. 56:18-23		N
CX0058	Notice and Order to Cease and Desist to Tom Jones Drug from Casie Goode	2/18/2009	JX0001 Tr. 56:18-23		N
CX0059	Notice and Order to Cease and Desist to Port City Tanning from Casie Goode	10/7/2008	JX0001 Tr. 56:18-23		N
CX0060	ADA: Whitening Issue Heats Up in Other States; ADA Urges Constituents to Act	3/4/2009	JX0001 Tr. 56:18-23		N
CX0061	Letter to Bryson's Jewelers from Terry Friddle re: Cease and Desist Letter	6/6/2006	JX0001 Tr. 56:18-23		N
CX0062	Letter to Jewelry Place from Terry Friddle re: Cease and Desist Letter	6/6/2006	JX0001 Tr. 56:18-23		N
CX0063	Letter to New York Jewelry from Terry Friddle re: Cease and Desist Letter	11/14/2005	JX0001 Tr. 56:18-23		N
CX0064	Webpage: The Wealthy Dentist.com	N/A	JX0001 Tr. 56:18-23		N
CX0065	Notice and Order to Cease and Desist to Patrice Barragan (Sunsational Tan) from Carolin Bakewell	7/3/2007	JX0001 Tr. 56:18-23		N
CX0066	Letter to Algis Augustine from Carolin Bakewell re: White Science	12/27/2007	JX0001 Tr. 56:18-23	Tr. 781:23	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0067	Email to Van Essen from Carolin Bakewell re: Teeth whitening Memo w/Attach: Board of Cosmetology Notice	2/7/2007	JX0001 Tr. 56:18-23	Tr. 941:21; 942:01,02	N
CX0068	Notice and Order to Cease and Desist to Joe Willett (BleachBright- Crabtree Valley Mall) from Casie Goode	2/20/2008	JX0001 Tr. 56:18-23		N
CX0069	Notice and Order to Cease and Desist to Sherry Johnson (Body Mind and Spirit) from Terry Friddle	3/29/2007	JX0001 Tr. 56:18-23	Tr. 2872:22	N
CX0070	E-mail to Friddle from Holland re: Body, Mind & Spirit Day Spa Log #06-217	3/22/2007	JX0001 Tr. 56:18-23	Tr. 2320:01; 2324:19; 2856:15, 16, 17; 2857:22	N
CX0071	E-mail to Friddle from Holland: re: Case Assignment 06-217	10/23/2006	JX0001 Tr. 56:18-23		N
CX0072	Letter to Pam Pearson from Carolin Bakewell re: Consent Order with Carmel Day Spa w/Attach: Unsigned Consent Order	2/28/2008	JX0001 Tr. 56:18-23		N
CX0073	Letter to Judge Martha Curran from Carolin Bakewell re: Summons & Complaint of Carmel Day Spa w/Attach: Summons & Complaint	1/17/2008	JX0001 Tr. 56:18-23		N
CX0074	Notice and Order to Cease and Desist to Dotson, Nelson and York (Celebrity Smiles) from Terry Friddle	11/21/2007	JX0001 Tr. 56:18-23		N
CX0075	Letter to Champagne Taste from Carolin Bakewell re: Acknowledgement of Receipt of Order	3/27/2007	JX0001 Tr. 56:18-23		N
CX0076	Letter to Champagne Taste from Terry Friddle re: No Response to Cease & Desist Order	3/22/2007	JX0001 Tr. 56:18-23		N
CX0077	Notice and Order to Cease and Desist to Champagne Taste from Carolin Bakewell	2/8/2007	JX0001 Tr. 56:18-23		N
CX0078	Webpage: LashLady.com/services	1/19/2007	JX0001 Tr. 56:18-23		N
CX0079	Notice and Order to Cease and Desist to Tim Williams (Movie Star Smile) from Casie Goode	1/17/2008	JX0001 Tr. 56:18-23		N
CX0080	E-mail to Friddle, Dempsey and White from Dr. Brown re: Case 04-090	11/7/2005	JX0001 Tr. 56:18-23	Tr. 2333:04; 2347:16; 2363:21; 2364:16; 2367:21	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0081	North Carolina State Board of Dental Examiners 2002 Annual Report for Governor Michael F. Easley	2002	JX0001 Tr. 56:18-23		N
CX0082	North Carolina State Board of Dental Examiners 2003 Annual Report for Governor Michael F. Easley	2003	JX0001 Tr. 56:18-23		N
CX0083	North Carolina State Board of Dental Examiners 2004 Annual Report for Governor Michael F. Easley	2004	JX0001 Tr. 56:18-23		N
CX0084	Letter to Governor Easley from Stanley Allen re 2005 Annual Report of the North Carolina State Board of Dental Examiners	4/5/2006	JX0001 Tr. 56:18-23		N
CX0085	N.C. State Board of Dental Examiners 2005 Annual Report for Governor Michael F. Easley	2005	JX0001 Tr. 56:18-23		N
CX0086	N.C. State Board of Dental Examiners 2006 Annual Report for Governor Michael F. Easley	2006	JX0001 Tr. 56:18-23		N
CX0087	Letter to Governor Easley from W. Stan Hardesty re: 2007 Annual Report of the N.C. State Board of Dental Examiners	2/15/2008	JX0001 Tr. 56:18-23		N
CX0088	N.C. State Board of Dental Examiners 2007 Annual Report for Governor Michael F. Easley	2007	JX0001 Tr. 56:18-23		N
CX0089	N.C. State Board of Dental Examiners 2008 Annual Report for Governor Beverly Purdue	2008	JX0001 Tr. 56:18-23	Tr. 174:15,17	N
CX0090	Letter to Governor Purdue from C. Wayne Holland re: 2009 Annual Report of the N.C. State Board of Dental Examiners	2/15/2010	JX0001 Tr. 56:18-23		N
CX0091	N.C. State Board of Dental Examiners 2009 Annual Report for Governor Beverly Purdue	2009	JX0001 Tr. 56:18-23		N
CX0092	E-mail to Treman from Goode re: www.shinewhite.net/retailers.php	3/4/2008	JX0001 Tr. 56:18-23		N
CX0093	E-mail to Goode and Bakewell from Owens. re: Port City Tanning	2/28/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0094	Letter to Terry Friddle from Joe Bracey re: Sean Powers - Order to Cease & Desist w/Attach	12/18/2007	JX0001 Tr. 56:18-23		N
CX0095	Letter to Sheriff B.J. Bames from Casie Goode re: Cease & Desist Order for Shawn Powers w/Attach: Cease & Desist Order	10/18/2007	JX0001 Tr. 56:18-23		N
CX0096	Notice and Order to Cease & Desist from to Margie Hughes (SheShe Studio Spa) from Terry Friddle	2/23/2007	JX0001 Tr. 56:18-23	Tr. 937:17,23; 943:12; 962:20; 1653:03	N
CX0097	Notice and Order to Cease & Desist from to Patrice Barragan (Sunsational Tan) from Terry Friddle	9/4/2007	JX0001 Tr. 56:18-23	Tr. 45:15; 46:14,17; 47:19	N
CX0098	Letter to Algis Augustine from Carolin Bakewell re: Communication with NC Dental Board	4/18/2008	JX0001 Tr. 56:18-23		N
CX0099	Letter to Carolin Bakewell from Algis Augustine re: White Science Out File No. N-147-1	1/24/2008	JX0001 Tr. 56:18-23	Tr. 784:20; 840:22; 841:19,21	N
CX0100	Notice to Cease and Desist to White Science from Bakewell	12/4/2007	JX0001 Tr. 56:18-23	Tr. 779:22; 1514:05; 1518:06; 1538:23; 1548:20; 1603:21	N
CX0101	Letter to Frank Recker from Carolin Bakewell re: Response to Recker's April 26 Letter	5/9/2007	JX0001 Tr. 56:18-23		N
CX0102	Letter to Dr. Kyle Taylor from Carolin Bakewell re: Status of Whitening Kiosks in the Carolina Place Mall	1/23/2008	JX0001 Tr. 56:18-23	Tr. 2276:24	N
CX0103	E-mail to Bennett and Bakewell from White re: NC Dental Board v. Signature Spas Motion for TRO & Complaint for Declaratory Judgment & Injunctive Relief	4/24/2008	JX0001 Tr. 56:18-23		N
CX0104	Letter to Betsy Kilts from Carolin Bakewell re: Response to Tooth Whitening Inquiry	3/13/2007	JX0001 Tr. 56:18-23	Tr. 1311:22; 1312:01	N
CX0105	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC	2/9/2007	JX0001 Tr. 56:18-23		N
CX0106	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC 8/10-11/2007 & 2/7-8/2008	8/10/2007	JX0001 Tr. 56:18-23	Tr. 2792:24; 2793:17; 2829:24,25; 2830:04; 2831:07	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0107	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC 2/7-8/2008	2/7/2008	JX0001 Tr. 56:18-23		N
CX0108	E-mail to Bakewell from Recker re: Your Letter dated May 9, 2007	7/24/2007	JX0001 Tr. 56:18-23	Tr. 534:15,16,17,22; 535:07,11,17; 536:11,17; 537:04; 540:06, 24,25; 541:01,03; 542:18; 549:24; 550:02; 551:03; 565:18; 768:15,18; 769:18; 770:09,14; 806:17; 852:21; 853:03; 918:21; 1459:13,16	N
CX0109	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC 3/14-15/2008	3/14/2008	JX0001 Tr. 56:18-23	Tr. 2867:01,03	N
CX0110	Letter to White Science from Carolin Bakewell re: Selling Teeth Whitening Services to non-dental professionals	2/13/2007	JX0001 Tr. 56:18-23	Tr. 774:09; 811:08	N
CX0111	E-mail to Dr. Holland from Terry Friddle re: Log 09-047 Please Assign Case w/Attach: Complaint Form from Dr. Stephen Smith	2/18/2009	JX0001 Tr. 56:18-23		N
CX0112	Notice and Order to Cease and Desist to Jason & Sharon Rabon (Sunsational Tan) from Terry Friddle	3/26/2009	JX0001 Tr. 56:18-23		N
CX0113	Notice and Order to Cease and Desist to James & Linda Holder (BleachBright/ Holders House of Flowers) from Casie Goode	1/19/2009	JX0001 Tr. 56:18-23		N
CX0114	Webpage: TeethWhiteningReviews.com; (Zoom Teeth Whitening System)	00/00/0000	JX0001 Tr. 56:18-23		N
CX0115	Webpage: TeethWhiteningReviews.com (Zoom 2 Teeth Whitening System)	00/00/0000	JX0001 Tr. 56:18-23		N
CX0116	Webpage: TeethWhiteningReviews.com (BriteSmile Teeth Whitening System)	00/00/0000	JX0001 Tr. 56:18-23		N
CX0117	WRAL Article: Teeth Whitening Kiosks at the Mall are Not Regulated	5/21/2008	JX0001 Tr. 56:18-23	Tr. 2164:24,25; 2165:05; 2166:06; 2169:04; 2170:04; 2173:06	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0118	Fax to Dr. Tilley from April Gumaer re: Patent Brian Runnick	4/16/2008	JX0001 Tr. 56:18-23	Tr. 2009:20; 2010:05; 2023:06; 2075:15,16; 2086:15,24,25	N
CX0119	Letter to Carolin Bakewell from Algis Augustine re: Triad Body Secrets & Fantasticians	10/9/2008	JX0001 Tr. 56:18-23		N
CX0120	Notice and Order to Cease & Desist to Fantasticians from Casie Goode	9/24/2008	JX0001 Tr. 56:18-23		N
CX0121	E-mail to Dr. Holland from Terry Friddle re: Log 08-206 Please Assign Case	9/23/2008	JX0001 Tr. 56:18-23		N
CX0122	Notice and Order to Cease & Desist to Florida White Smile from Casie Goode	10/7/2008	JX0001 Tr. 56:18-23		N
CX0123	Notice and Order to Cease & Desist to Joe Willett (iBriteExpress) from Casie Goode	9/24/2008	JX0001 Tr. 56:18-23		N
CX0124	E-mail to Dr. Holland from Casie Goode re: Moviestar Smile vs. Board 07-223	10/7/2008	JX0001 Tr. 56:18-23		N
CX0125	Letter to Whom it may Concern from Jon Toney re: Notice and Order to Cease & Desist to Port City Tanning	10/17/2008	JX0001 Tr. 56:18-23		N
CX0126	Letter to Daniel Christian from Carolin Bakewell re: Reponse to Settlement Offer in NCSDBE vs. Signature Spa	7/22/2008	JX0001 Tr. 56:18-23		N
CX0127	E-mail to Bradshaw from Bakewell re: Signature Spa Consent Order	7/21/2008	JX0001 Tr. 56:18-23		N
CX0128	E-mail to Dr. Holland from Terry Friddle re: Log 09-049 Please Assign Case	2/18/2009	JX0001 Tr. 56:18-23		N
CX0129	E-mail to Dr. Holland from Dr. Morgan re: wral 5 on your side	5/22/2008	JX0001 Tr. 56:18-23		N
CX0130	Open Investigative Files to Dr. Holland from Terry Friddle	3/11/2009	JX0001 Tr. 56:18-23		N
CX0131	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC 12/12-13/2008	12/12/2008	JX0001 Tr. 56:18-23		N
CX0132	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC 10/3-4/2008	10/3/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0133	Closed Session Minutes from NC Dental Board Meeting in Morrisville, NC 4/4-5/2008	4/4/2008	JX0001 Tr. 56:18-23		N
CX0134	Letter to Dr. Ronald Owens from Stacey Phipps re: Evaluation of Statement of Economic Interest Filed by Dr. Charles Wayne Holland	7/22/2009	JX0001 Tr. 56:18-23		N
CX0135	Annual Report to the Governor - 2000	0/0/2000	JX0001 Tr. 56:18-23		N
CX0136	Letter to Ortho Depot from Friddle re: Unlawful Practice of Dentistry	10/3/2000	JX0001 Tr. 56:18-23		N
CX0137	E-mail to Walle from Holland re: Ortho Depot	9/12/2000	JX0001 Tr. 56:18-23		N
CX0138	Letter to Barry Hughie (DOWD Central YMCA) from Terry Friddle re: No Response to Cease & Desist Order	2/12/2002	JX0001 Tr. 56:18-23		N
CX0139	Letter to Barry Hughie (DOWD Central YMCA) from Friddle re: Setting up a Dental Practice	12/10/2001	JX0001 Tr. 56:18-23		N
CX0140	E-mail to Morgan, bcm2912@triad.rr.com, White et al. from Holland re: Brunson Jewelry	8/5/2004	JX0001 Tr. 56:18-23	Tr. 2328:02	N
CX0141	E-mail to bcm2912@triad.rr.com, White, Brown et al. from Morgan re: Brunson Jewelry	8/5/2004	JX0001 Tr. 56:18-23	Tr. 2417:18	N
CX0142	E-mail to Morgan, White, Brown et al. from bcm2912@triad.rr.com re: Brunson Jewelry	8/5/2004	JX0001 Tr. 56:18-23		N
CX0143	E-mail to Morgan, White, Brown et al. from Holland re: Brunson Jewelry	8/5/2004	JX0001 Tr. 56:18-23		N
CX0144	Letter to Roy Cooper from Terry Friddle re: Bleaching Kits Purchased over the Internet	6/10/2003	JX0001 Tr. 56:18-23		N
CX0145	Letter to Claudelle Julien from Casie Smith re: Copy of signed affidavit	3/3/2003	JX0001 Tr. 56:18-23		N
CX0146	E-mail to Hyer from Friddle re: Chase Jewelry	12/9/2002	JX0001 Tr. 56:18-23		N
CX0147	E-mail to Holland and Friddle from Hyer re: Chase Jewelry Store Investigation	11/22/2002	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0148	E-mail to Holland and Friddle from Hyer re: 2nd Follow Up on Chase Jewelry Store Case	10/21/2002	JX0001 Tr. 56:18-23		N
CX0149	E-mail to Holland from Friddle re: Report on Chase Jewelry Gold Teeth	9/6/2002	JX0001 Tr. 56:18-23		N
CX0150	E-mail to Dempsey, Friddle, White et al. from Burnham re: Case 06-041	3/23/2006	JX0001 Tr. 56:18-23		N
CX0151	Letter to Armand Swain from Terry Friddle re: Agree to End Investigation due to discontinued practice	7/11/2007	JX0001 Tr. 56:18-23		N
CX0152	E-mail to Friddle from Holland re: Spanish call lead Notice of Apparent Violation and Demand to Cease & Desist to Serenity Total Body Care/Bleach Bright from Casie Goode	6/1/2009	JX0001 Tr. 56:18-23		N
CX0153	Letter to Judge Sandie Cannon from Carolin Bakewell re: NC State Board of Dental Examiners vs. Mercedes Villanueva w/Attach: Summons & Complaint	9/22/2009	JX0001 Tr. 56:18-23		N
CX0154	Notice of Apparent Violation and Demand to Cease & Desist to Heather Wiecek (Buena Vista Smiles) from Casie Goode	2/19/2010	JX0001 Tr. 56:18-23		N
CX0155	Notice and Apparent Violation and Demand to Cease & Desist to Suaave D's-BleachBright from Casie Goode	12/14/2009	JX0001 Tr. 56:18-23		N
CX0156	E-mail to Feingold from Dempsey re: 07-146 (Carmel Day Spa)	12/22/2009	JX0001 Tr. 56:18-23		N
CX0157	The News & Observer: State lets Whitening Kiosks Be	12/17/2007	JX0001 Tr. 56:18-23		N
CX0158	Order and Judgment re: NCBDE vs. Rodriguez Brunson, Brunson Jewelry	3/19/2010	JX0001 Tr. 56:18-23	Tr. 568:01,02,07; 571:13,15 Tr. 2331:13; 2362:24,25; 2371:16	N
CX0159	Open Investigative Files to Dr. Hardesty from Terry Friddle	3/31/2005	JX0001 Tr. 56:18-23		N
CX0160	Template of Cease & Desist Order	3/11/2009	JX0001 Tr. 56:18-23		N
CX0161		N/A	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0162	Letter to Board from Tonya Norwood (Modern Enhancement Salon) re: Cease & Desist Order response	2/9/2009	JX0001 Tr. 56:18-23	Tr. 39:17	N
CX0163	The News & Observer: Teeth Whitening a Gray Legal Area	3/15/2008	JX0001 Tr. 56:18-23	Tr. 2293:09	N
CX0164	Constitution of the North Carolina Dental Society	05/00/2008	JX0001 Tr. 56:18-23		N
CX0165	E-mail to Parker from White re: Florida White Smile	5/21/2008	JX0001 Tr. 56:18-23		N
CX0166	E-mail to Parker from Runswick re: Whitening kiosks	4/14/2008	JX0001 Tr. 56:18-23	Tr. 2162:03, 14; 2164:19; 2175:05; 2177:07	N
CX0167	N.C. Dental Society Meeting Minutes, Cary, NC	3/6/2009	JX0001 Tr. 56:18-23		N
CX0168	E-mail to Parker from White re: SB-164 w/Attach: Senate Bill 164 History	2/17/2009	JX0001 Tr. 56:18-23	Tr. 2343:15	N
CX0169	E-mail to Hall from Hall re: ADA Association Petitions FDA to Classify, Regulate Tooth Whitening Products w/Attach: Article re ADA seeks FDA classification of whitening agents	11/23/2009	JX0001 Tr. 56:18-23		N
CX0170	E-mail to Parker from Hoyt re: An article from www.newsobserver.com w/Attach: Article re Teeth are NC's Business	7/4/2010	JX0001 Tr. 56:18-23		N
CX0171	E-mail to Allen, McMahan, Edie et al. from O'Doherty re: ADA, Tooth Whitening Conference Call w/Attach: Kimberly Spa Cease & Desist.pdf	7/2/2008	JX0001 Tr. 56:18-23		N
CX0172	The Friday Letter - a Publication of the North Carolina Dental Society, April 2008	4/00/2008	JX0001 Tr. 56:18-23		N
CX0173	E-mail to Parker from West re: FTC Complaint ADA News Today (for publication)	6/19/2010	JX0001 Tr. 56:18-23		N
CX0174	E-mail to ASCDE, Cuffie, Dziwik et al. from Bush re: Teeth Whitening Procedures	3/11/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0175	2007 NCDS Councils & Committees	00/00/2007	JX0001 Tr. 56:18-23		N
CX0176	NCDS Board of Trustees Meeting Agenda	5/14/2008	JX0001 Tr. 56:18-23		N
CX0177	NCDS Board of Trustees Meeting Agenda	7/25/2008	JX0001 Tr. 56:18-23		N
CX0178	NCDS Legislative Contacts	N/A	JX0001 Tr. 56:18-23		N
CX0179	Fax to White from Parker re: Information from Nebraska	8/15/2008	JX0001 Tr. 56:18-23		N
CX0180	WRAL Article: Teeth Whitening Kiosks at the Mall are Not Regulated (NCDS Copy)	5/21/2008	JX0001 Tr. 56:18-23		N
CX0181	NCDB Complaint Form of Brian Runswick re: BleachBright (NCDS Copy)	4/11/2008	JX0001 Tr. 56:18-23		N
CX0182	Fax to Alec Parker from William Litaker re: Requested Documents (NCDS report, President's message, and President's report) (NCDS Copy)	8/9/2010	JX0001 Tr. 56:18-23		N
CX0183	American Dental Association: HOD Adopts Whitening Resolution Amid Safety Concerns for Patients	12/9/2008	JX0001 Tr. 56:18-23		N
CX0184	Dental Bleaching Services by Non-Dentists Summary by State of Legal Information; ADA Division of Legal Affairs (Current as of July 2008)	07/00/2008	JX0001 Tr. 56:18-23	Tr. 1924:02	N
CX0185	American Dental Association: Talking Points; Whitening at a Salon or Mall Kiosk by Unlicensed Individuals	01/00/2010	JX0001 Tr. 56:18-23		N
CX0186	Subpoena Duces Tecum to North Carolina Dental Society	7/21/2010	JX0001 Tr. 56:18-23		N
CX0187	Subpoena Ad Testificandum to Dr. Alec Parker	9/20/2010	JX0001 Tr. 56:18-23		N
CX0188	Subpoena Ad Testificandum to Dr. William Litaker	9/20/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0189	Subpoena Ad Testificandum to Dr. Gary Oyster	9/20/2010	JX0001 Tr. 56:18-23		N
CX0190	Respondent's Preliminary Witness List	8/30/2010	JX0001 Tr. 56:18-23		N
CX0191	North Carolina Dental Society Legislative Committee webpage	9/22/2010	JX0001 Tr. 56:18-23		N
CX0192	Adendum to Investigative Memo to Clifford Feingold & Carolin Bakewell from Line Dempsey re: Carmel Day Spa & Salon (Case 07-146)	12/17/2007	JX0001 Tr. 56:18-23		N
CX0193	North Carolina Dental Political Action Committee Constitution (Revised 10/30/09)	10/30/2009	JX0001 Tr. 56:18-23		N
CX0194	Constitution of the North Carolina Dental Society [Revised May 2010]	5/00/2010	JX0001 Tr. 56:18-23		N
CX0195	2010 NCDS Councils & Committees	00/00/2010	JX0001 Tr. 56:18-23		N
CX0196	E-mail to Friddle & Dempsey from Feingold re: Case Assignment 07-146	8/15/2007	JX0001 Tr. 56:18-23		N
CX0197	Fax to Ronald Owens from Terry Friddle re: Please Assign Case 07-146	8/14/2007	JX0001 Tr. 56:18-23		N
CX0198	Fax to NC Dental Board from Dr. Davis re: Movie Star Smile ad in Hickory Daily Record	2/6/2008	JX0001 Tr. 56:18-23		N
CX0199	E-mail to Goode from Friddle re: Movie Star Smiles (07-223)	1/17/2008	JX0001 Tr. 56:18-23		N
CX0200	E-mail to Dempsey, Friddle, Smith et al. from Feingold re: Movie Star Smiles (07-223)	1/16/2008	JX0001 Tr. 56:18-23		N
CX0201	E-mail to Feingold & Dempsey from Friddle re: Case Assignment 07-223	1/4/2008	JX0001 Tr. 56:18-23		N
CX0202	White Science teeth whitening advertisement	00/00/2006	JX0001 Tr. 56:18-23		N
CX0203	Letter to Blue Ridge Mall from Carolin Bakewell re: Unlawful Teeth Whitening Kiosks	11/21/2007	JX0001 Tr. 56:18-23	Tr. 626:13, 15, 21; 627:06, 09, 10; 628:03, 09, 24; 629:02, 11; 632:01, 05, 11; 633:04; 2863:19, 20	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0204	Letter to CBL & Associates Properties from Carolin Bakewell re: Unlawful Teeth Whitening Kiosks	11/21/2007	JX0001 Tr. 56:18-23		N
CX0205	Letter to Colonial Mayberry Mall Office from Carolin Bakewell re: Unlawful Teeth Whitening Kiosks	11/21/2007	JX0001 Tr. 56:18-23		N
CX0206	Minutes from NC Dental Board Meeting in Morrisville, NC 8/10-11/2007	8/10/2007	JX0001 Tr. 56:18-23	Tr. 564:23,24; 565:21	N
CX0207	E-mail to Feingold from Bakewell re: Carmel Spa CO	2/28/2008	JX0001 Tr. 56:18-23		N
CX0208	E-mail to Bakewell, Hardesty, Owens et al. from Feingold re: Carmel Spa Complaint	12/29/2007	JX0001 Tr. 56:18-23		N
CX0209	E-mail to Hardesty, Owens, Burnham et al. from Bakewell re: 20080714_152954_3184_8773dd706314 w/Attach	7/14/2008	JX0001 Tr. 56:18-23	Tr. 2341:18	N
CX0210	E-mail to White, Feingold, Burnham et al. from Owens re: Signature Spa Case	7/14/2008	JX0001 Tr. 56:18-23		N
CX0211	E-mail to White, Burnham, Owens et al. from Feingold re: Signature Spa Case	7/14/2008	JX0001 Tr. 56:18-23		N
CX0212	E-mail to Owens, Burnham, White et al. from Bakewell re: Signature Spas	5/28/2008	JX0001 Tr. 56:18-23	Tr. 2341:11; 2365:23	N
CX0213	E-mail to Bakewell and White from Feingold re: Signature Spas	5/28/2008	JX0001 Tr. 56:18-23		N
CX0214	E-mail to Bakewell, Burnham, Owens et al. from Hardesty re: Signature Spas	5/27/2008	JX0001 Tr. 56:18-23	Tr. 2340:01	N
CX0215	E-mail to Bakewell and Smith from Feingold re: NC Dental Board v. Signature Spa	5/19/2008	JX0001 Tr. 56:18-23		N
CX0216	E-mail to Bakewell, Friddle, Smith et al. from Feingold re: NC Dental Board v. Signature Spa	5/19/2008	JX0001 Tr. 56:18-23		N
CX0217	E-mail to Hardesty, Burnham, Owens et al. from Holland re: TV (Good Morning America Consumer Alert)	5/21/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0218	The Dental Forum: NC State Board of Dental Examiners; Spring 2007; Editor: Clifford Feingold	00/00/2007	JX0001 Tr. 56:18-23		N
CX0219	Letter to Clifford Feingold from NC Dental Board re: Welcome Letter & Training Information	7/8/2005	JX0001 Tr. 56:18-23		N
CX0220	List of Clifford Feingold's Candidacy Supporters	1/00/2005	JX0001 Tr. 56:18-23		N
CX0221	E-mail to Dempsey, Friddle, Smith et al. from Feingold re: Case 07-048 Central Jewelry	8/7/2007	JX0001 Tr. 56:18-23		N
CX0222	E-mail to Feingold, Friddle, Smith et al. from Dempsey re: Case 07-048 Central Jewelry	8/6/2007	JX0001 Tr. 56:18-23		N
CX0223	E-mail to Dempsey, Friddle, Smith et al. from Feingold re: Case 07-048	6/22/2007	JX0001 Tr. 56:18-23		N
CX0224	Investigative Memo to Feingold & Bakewell from Dempsey re: Central Jewelry (Mr. Dale Lynn; Case 07-048)	6/22/2007	JX0001 Tr. 56:18-23		N
CX0225	E-mail to Bakewell, White & Friddle from Feingold re: Carmel Day Spa	6/4/2008	JX0001 Tr. 56:18-23		N
CX0226	E-mail to Bakewell, Goode & Friddle from Feingold re: Carmel Day Spa	3/2/2008	JX0001 Tr. 56:18-23		N
CX0227	E-mail to Zentz from Zentz re: Memo from Dr. Mike Rethman, CSA Tooth Whitening Guidance w/Attach: ADA Frequently Asked Questions on Tooth Whitening Safety	7/16/2010	JX0001 Tr. 56:18-23	Tr. 2631:01,04,07,08	N
CX0228	Investigative Memo to Burnham & Stanford from Kurdys re: One West Salon - Mount Holly (Case 06-008)	4/10/2006	JX0001 Tr. 56:18-23		N
CX0229	E-mail to Kurdys, Smith, Friddle et al. from Burnham re: One West	4/10/2006	JX0001 Tr. 56:18-23		N
CX0230	E-mail to Bakewell from Burnham re: Signature Spas of Hickory	3/17/2008	JX0001 Tr. 56:18-23		N
CX0231	E-mail to Burnham, Friddle, White et al. from Bakewell re: NCSBDE v. Signature Spas	2/13/2008	JX0001 Tr. 56:18-23	Tr. 42:12	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0232	Investigative Memo to Burnham and Stanford from Dempsey re: Star Bright Whitening Systems Inc.- Sanford (Case 06-)	5/15/2006	JX0001 Tr. 56:18-23	Tr. 1984:15,16,18,21	N
CX0233	DentalProductsReport.com: Federal Whitening Controls?	1/20/2010	JX0001 Tr. 56:18-23		N
CX0234	Memo to Members of the Board from Terry Friddle re: Closed Investigative Files (One West Salon)	5/8/2006	JX0001 Tr. 56:18-23		N
CX0235	Memo to Members of the Board from Terry Friddle re: Closed Investigative Files (Cut Crib)	11/13/2006	JX0001 Tr. 56:18-23		N
CX0236	E-mail to Burnham, Owens, Hardesty et al. from White re: Chemical Bleaching w/Attach: Teeth Whitening Memo	3/17/2008	JX0001 Tr. 56:18-23		N
CX0237	E-mail to White, Owens, Hardesty et al. from Burnham re: Teeth Whitening	3/17/2008	JX0001 Tr. 56:18-23		N
CX0238	E-mail to Friddle from Owens re: Case Assignment 08-083	5/1/2008	JX0001 Tr. 56:18-23		N
CX0239	E-mail to White, Feingold, Owens et al. from Burnham re: Signature Spa Case	7/14/2008	JX0001 Tr. 56:18-23		N
CX0240	Resolution No. 80 Submitted by Eighth Trustee District; Reference Committee: Dental Benefits, Practice, Science and Health	09/00/2009	JX0001 Tr. 56:18-23		N
CX0241	Letter to Governor Easley from Joseph Burnham re: 2006 Annual Report of Activities	2/15/2007	JX0001 Tr. 56:18-23		N
CX0242	Letter to Joseph Burnham from NC Dental Board re: Welcome Letter & Training Information	6/26/2003	JX0001 Tr. 56:18-23		N
CX0243	E-mail to Friddle from Burnham re: Mr. Grillz	2/27/2006	JX0001 Tr. 56:18-23		N
CX0244	Webpage: TeethWhiteningReviews.com (Sapphire In-Office Teeth Whitening System)	N/A	JX0001 Tr. 56:18-23		N
CX0245	E-mail to Kurdys from Bishop re: Teeth Whitening at Southpoint Mall	3/17/2008	JX0001 Tr. 56:18-23		N
CX0246	E-mail to Owens, Kurdys, Friddle et al. from Dempsey re: Whitening @ Southpoint Mall	11/21/2007	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0247	Investigative Memo to Owens & Bakewell from Kurdys re: Mr. Shawn Powers (Savage Tan) - High Point (Case 07-148)	8/30/2007	JX0001 Tr. 56:18-23		N
CX0248	Investigative Memo to Hardesty & Bakewell from Kurdys re: Sunsational Tan- Elizabeth City (Case 07-120)	1/25/2008	JX0001 Tr. 56:18-23		N
CX0249	Investigative Memo to Owens & Bakewell from Kurdys re: Bailey's Lightening Whitening - Greensboro (Case 08-133)	8/13/2008	JX0001 Tr. 56:18-23		N
CX0250	E-mail to Kurdys, Friddle, Goode et al. from Holland re: Inspire Spa	2/3/2009	JX0001 Tr. 56:18-23		N
CX0251	Investigative Memo to Holland & Bakewell from Kurdys re: Inspire Skin & Body (Felicia Brown; Case 08-214)	2/3/2009	JX0001 Tr. 56:18-23	Tr. 1984:17	N
CX0252	E-mail to Dempsey, Kurdys & Friddle from Goode re: Southern Pines	5/20/2008	JX0001 Tr. 56:18-23		N
CX0253	FTC's Proposed Consent Order	7/6/2010	JX0001 Tr. 56:18-23		N
CX0254	E-mail to White from Bakewell re: Teeth Whitening	11/27/2007	JX0001 Tr. 56:18-23		N
CX0255	E-mail to White from Bakewell re: Teeth Whitening	3/24/2008	JX0001 Tr. 56:18-23		N
CX0256	Fax to Frank Recker from Terry Friddle re: Celebrity Smiles Cease & Desist Letter	11/20/2007	JX0001 Tr. 56:18-23		N
CX0257	Letter to Algis Augustine from Carolin Bakewell re: Joe Willett/BleachBright	3/10/2008	JX0001 Tr. 56:18-23		N
CX0258	Investigative Memo to Hardesty & Bakewell from Dempsey re: Spa White/White Science (07-020)	1/17/2008	JX0001 Tr. 56:18-23		N
CX0259	Letter to Cleveland Mall Office from Carolin Bakewell re: Unauthorized Tooth Whitening Kiosk	11/21/2007	JX0001 Tr. 56:18-23	Tr. 626:23; 627:06	N
CX0260	Letter to General Growth Properties from Carolin Bakewell re: Unauthorized Tooth Whitening Kiosk	11/21/2007	JX0001 Tr. 56:18-23	Tr. 878:04,06,07	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0261	Letter to Hendon Properties from Carolin Bakewell re: Unauthorized Tooth Whitening Kiosk	11/21/2007	JX0001 Tr. 56:18-23		N
CX0262	Letter to University Mall Office from Carolin Bakewell re: Unauthorized Tooth Whitening Kiosk	11/21/2007	JX0001 Tr. 56:18-23		N
CX0263	Letter to Westfield Eastridge Mall Office from Carolin Bakewell re: Unauthorized Tooth Whitening Kiosk	11/21/2007	JX0001 Tr. 56:18-23		N
CX0264	NCBDE Board Meeting Agenda; Morrisville, North Carolina 8/10-11/2007	8/10/2007	JX0001 Tr. 56:18-23		N
CX0265	E-mail to BCFamilyDentistry, White & Friddle from Bakewell re: Salon Ads Submitted by Dr. Mathew	9/8/2008	JX0001 Tr. 56:18-23		N
CX0266	E-mail to Haynes & White from Bakewell re: Two Lawsuits Against Kiosks in NC	3/24/2009	JX0001 Tr. 56:18-23		N
CX0267	E-mail to Bakewell from White re: Teeth Whitening Business Proposed Answer	3/23/2009	JX0001 Tr. 56:18-23		N
CX0268	E-mail to Mantel, White & Friddle from Bakewell re: Bleaching	1/23/2009	JX0001 Tr. 56:18-23		N
CX0269	E-mail to Friddle from Bakewell re: Spa Whitening	1/22/2009	JX0001 Tr. 56:18-23		N
CX0270	Chart of Carolin Bakewell's Cases	3/11/2009	JX0001 Tr. 56:18-23		N
CX0271	E-mail to Wright from Bakewell re: Pro White	2/12/2010	JX0001 Tr. 56:18-23		N
CX0272	Cease & Desist Letter to Inspire Skin & Body from Casie Goode	4/3/2009	JX0001 Tr. 56:18-23		N
CX0273	Subpoena Duces Tecum to North Carolina Board of Dental Examiners	2/24/2009	JX0001 Tr. 56:18-23		N
CX0274	NCBDE Board Meeting Agenda in Morrisville, NC 2/9-10/2007	2/9/2007	JX0001 Tr. 56:18-23		N
CX0275	NCBDE Board Meeting Agenda in Morrisville, NC 3/14-15/2008	3/14/2008	JX0001 Tr. 56:18-23		N
CX0276	List of Complainant & Distributor Information	00/00/0000	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0277	E-mail to Bakewell from Friddle re: Complaint Form Attached & Sworn Statement **for Carolyn Bakewell**	4/14/2008	JX0001 Tr. 56:18-23		N
CX0278	Letter to NC Dental Board from Nicole LeCann re: Bleach Bright in Crabtree Valley Mall	2/27/2008	JX0001 Tr. 56:18-23	Tr. 2317:18,21	N
CX0279	Notice and Order to Cease & Desist to Shohreh Rafie (Carnel Day Spa & Salon)	10/1/2007	JX0001 Tr. 56:18-23		N
CX0280	E-mail to Friddle from Bakewell re: Whitening Spa	11/19/2007	JX0001 Tr. 56:18-23		N
CX0281	E-mail to Friddle, Bakewell & White from Hardesty re: Concern about Unlicensed Person Bleaching Teeth	1/20/2007	JX0001 Tr. 56:18-23		N
CX0282	E-mail to Weinstein & Smith from Hardesty re: Concern about Unlicensed Person Bleaching Teeth	1/19/2007	JX0001 Tr. 56:18-23	Tr. 2273:08	N
CX0283	E-mail to Friddle & White from Hardesty re: Case Assignment 06-198	9/12/2006	JX0001 Tr. 56:18-23		N
CX0284	Investigative Memo to Stanley Allen & Denise Stafford from Terry Friddle re: Edie's Salon Panache (Case #04-187)	10/7/2004	JX0001 Tr. 56:18-23		N
CX0285	E-mail to Friddle, Bakewell & White from Hardesty re: Teeth Whitening (Shawn Powers)	8/14/2007	JX0001 Tr. 56:18-23		N
CX0286	Investigative Memo to Terry Friddle from Andrea Smythe re: Serenity Day Spa	1/11/2006	JX0001 Tr. 56:18-23		N
CX0287	Investigative Memo to Terry Friddle from Andrea Smythe re: Signature Spas of Hickory	9/18/2006	JX0001 Tr. 56:18-23		N
CX0288	E-mail to Bakewell from Friddle re: Question on Malpractice Insurance	1/2/2008	JX0001 Tr. 56:18-23		N
CX0289	E-mail to Bakewell from Friddle re: Question on Malpractice Insurance	1/2/2008	JX0001 Tr. 56:18-23		N
CX0290	E-mail to White & Bakewell from Friddle re: Forwarded Image from MX-7001N w/Attach: Indoor Tanning	3/18/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0291	E-mail to White & Friddle from Bakewell re: Teeth Whitening	1/17/2008	JX0001 Tr. 56:18-23		N
CX0292	E-mail to Link from Friddle re: Salon Bleaching	1/24/2007	JX0001 Tr. 56:18-23	Tr. 2272:02	N
CX0293	E-mail to Friddle, Bakewell & White from Hardesty re: Salon Bleaching	1/20/2007	JX0001 Tr. 56:18-23	Tr. 2323:02	N
CX0294	E-mail to Bakewell from Owens re: Case Assignments Log #09-047 & 09-048	3/3/2009	JX0001 Tr. 56:18-23		N
CX0295	E-mail to Friddle, White, Bakewell et al. from Owens re: Complaint Form Attached Sworn Statement **for Carolyn Bakewell**	4/14/2008	JX0001 Tr. 56:18-23		N
CX0296	E-mail to Friddle, White & Bakewell from Holland re: Case Assignment 08-214	9/30/2008	JX0001 Tr. 56:18-23		N
CX0297	E-mail to Friddle, White & Bakewell from Holland re: Case Assignment 08-214	12/1/2008	JX0001 Tr. 56:18-23		N
CX0298	E-mail to Bakewell from Owens re: Florida Smiles	3/3/2009	JX0001 Tr. 56:18-23		N
CX0299	E-mail to Friddle, White & Bakewell from Owens re: Case Assignments Log #09-047 & 09-048	2/19/2009	JX0001 Tr. 56:18-23		N
CX0300	E-mail to Dempsey from Friddle re: Case Assignments Log #09-047 & 09-048	2/19/2009	JX0001 Tr. 56:18-23		N
CX0301	E-mail to Friddle from Howell re: Tooth Whitening/Scope of Practice	4/24/2008	JX0001 Tr. 56:18-23		N
CX0302	E-mail to Harris from Friddle re: Tennessee bans Teeth-Whitening Kiosks at the Mall	1/21/2009	JX0001 Tr. 56:18-23		N
CX0303	Open Investigative Files to Owens from Friddle (March 11, 2009)	3/11/2009	JX0001 Tr. 56:18-23		N
CX0304	E-mail to Friddle from Hyman re: Lightning Whitening	6/17/2008	JX0001 Tr. 56:18-23		N
CX0305	E-mail to Sara Allen from Friddle re: NC Board's 2004 Schedule	5/14/2004	JX0001 Tr. 56:18-23		N
CX0306	Letter to Parses Bangle from Terry Friddle re: Cease & Desist	6/6/2006	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0307	E-mail to Friddle from Smythe re: Undercover Work w/Attach: Memo re Tom Jones Express Smile	3/22/2010	JX0001 Tr. 56:18-23		N
CX0308	Memo to Terry Friddle from Andrea Smythe re: Tom Jones Express Smile w/Attach: Tom Jones Express Smile Information	3/19/2010	JX0001 Tr. 56:18-23		N
CX0309	Letter to Terry Friddle from Mike Hodges re: Tom Jones Drug	3/2/2009	JX0001 Tr. 56:18-23		N
CX0310	Letter to Terry Friddle from Kathleen Longbrake re: Whitening Kiosk in Mebane, NC	7/23/2009	JX0001 Tr. 56:18-23		N
CX0311	E-mail to Friddle from Owens re: Case Assignment 09-269	12/10/2009	JX0001 Tr. 56:18-23		N
CX0312	E-mail to Friddle from Owens re: Case Assignment 09-272	12/18/2009	JX0001 Tr. 56:18-23		N
CX0313	E-mail to Friddle & White from Owens re: Teeth Whitening by Tanning Salon	4/6/2010	JX0001 Tr. 56:18-23		N
CX0314	E-mail to Friddle from Nash re: From Ross W. Nash, DDS, Charlotte	3/10/2010	JX0001 Tr. 56:18-23		N
CX0315	Open Investigative Files to Owens from Friddle (September 16, 2009)	9/16/2009	JX0001 Tr. 56:18-23		N
CX0316	Open Investigative Files to Hardesty from Friddle (November 2, 2009)	11/2/2009	JX0001 Tr. 56:18-23		N
CX0317	Open Investigative Files to Owens from Friddle (April 15, 2010)	4/15/2010	JX0001 Tr. 56:18-23		N
CX0318	Open Investigative Files to Holland from Friddle (June 15, 2010)	6/15/2010	JX0001 Tr. 56:18-23		N
CX0319	Open Investigative Files to Owens from Friddle (June 15, 2010)	6/15/2010	JX0001 Tr. 56:18-23		N
CX0320	Open Investigative Files to Morgan from Friddle (August 12, 2010)	8/12/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0321	Open Investigative Files to Owens from Friddle (August 12, 2010)	8/12/2010	JX0001 Tr. 56:18-23	Tr. 1446:23; 1447:10; 1448:25; 1580:21; 1581:23; 1606:25; 1607:09; 2225:11; 2230:20; 2231:04	N
CX0322	E-mail to Friddle & White from Owens re: Case Assignment 10-061	4/6/2010	JX0001 Tr. 56:18-23		N
CX0323	Letter to Boone Mall Management from Carolin Bakewell re: Illegal Tooth Whitening Kiosks	11/21/2007	JX0001 Tr. 56:18-23		N
CX0324	Letter to Northgate Mall Office from Carolin Bakewell re: Illegal Tooth Whitening Kiosks	11/21/2007	JX0001 Tr. 56:18-23		N
CX0325	Letter to Randolph Mall Management Office from Carolin Bakewell re: Illegal Tooth Whitening Kiosks	11/21/2007	JX0001 Tr. 56:18-23		N
CX0326	E-mail to ballen@plazassociatesinc.com from Bakewell re: Illegal Tooth Whitening Kiosks at Crabtree Valley Mall	11/21/2007	JX0001 Tr. 56:18-23	Tr. 2871:02,03	N
CX0327	Letter to NC Dental Board from Dr. Larry Tilley re: Brian Runsick Report	4/24/2008	JX0001 Tr. 56:18-23	Tr. 2024:10; 2029:05,13; 2033:01; 2038:01; 2072:25; 2073:01,14; 2074:01,06,09; 2076:13,15; 2077:13; 2079:15,20; 2082:08,17; 2083:18; 2093:15	N
CX0328	E-mail to Bakewell, Friddle & Smith from Feingold re: NCSBDE v. Signature Spas	6/24/2008	JX0001 Tr. 56:18-23		N
CX0329	E-mail to Bakewell from Wils re: Resolved Cases	2/13/2009	JX0001 Tr. 56:18-23		N
CX0330	Privileged Documents Log Re FTC Production by the NC Dental Board (Draft - June 26, 2008)	6/26/2008	JX0001 Tr. 56:18-23		N
CX0331	Privileged Documents Log Re FTC Supplemental Production by the NC Dental Board (April 20, 2009)	4/20/2009	JX0001 Tr. 56:18-23		N
CX0332	FTC Deposition Notice to Carolin Bakewell	9/10/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0333	FTC Deposition Notice to Dr. Brad Morgan Letter to Dr. Ronald Owens from Stacey Phipps re: Evaluation of Statement of Economic Interest Filed by Dr. Brad C. Morgan	9/10/2010	JX0001 Tr. 56:18-23		N
CX0334	E-mail to Smith from Friddle re: Thanks to Dr. Sharon Morgan and Matt Martin	7/22/2009	JX0001 Tr. 56:18-23		N
CX0335	E-mail to Morgan, White, Bendob et al. from Dr. Allen re: Brunson Jewelry	4/26/2005	JX0001 Tr. 56:18-23		N
CX0336	E-mail to Thompson from Dempsey re: Brunson Jewelry (gold teeth)	8/5/2004	JX0001 Tr. 56:18-23		N
CX0337	E-mail to Stanford from Friddle re: Report	12/15/2003	JX0001 Tr. 56:18-23		N
CX0338	E-mail to Friddle from Bakewell re: Gevawer CO.doc	9/3/2002	JX0001 Tr. 56:18-23		N
CX0339	Dr. Brad Morgan's Response to the FTC's Subpoena Duces Tecum	12/28/2009	JX0001 Tr. 56:18-23		N
CX0340	Board's Financial Report for 2004	9/23/2010	JX0001 Tr. 56:18-23		N
CX0341	Board's Financial Report for 2005	10/26/2005	JX0001 Tr. 56:18-23		N
CX0342	Board's Financial Report for 2006	8/8/2006	JX0001 Tr. 56:18-23		N
CX0343	Board's Financial Report for 2007	1/11/2008	JX0001 Tr. 56:18-23		N
CX0344	Board's Financial Report for 2008	10/30/2008	JX0001 Tr. 56:18-23		N
CX0345	Board's Financial Report for 2009	7/10/2009	JX0001 Tr. 56:18-23		N
CX0346	E-mail to Dempsey, Friddle, Smith from Hardesty re: Amazing Grace Spa	8/11/2010	JX0001 Tr. 56:18-23		N
CX0347	Investigative Memo to Holland & Bakewell from Dempsey re: Body, Mind, & Spirit Day Spa (Case 06- 217)	1/16/2008	JX0001 Tr. 56:18-23		N
CX0348		8/7/2007	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0349	E-mail to Dempsey, Friddle, Smith et al. from Feingold re: Case 07-146 Carmel Day Spa	9/29/2007	JX0001 Tr. 56:18-23		N
CX0350	E-mail to Dempsey, Friddle, Smith et al. from Owens re: Case 07-208 Celebrity Smiles (Southpoint)	11/26/2007	JX0001 Tr. 56:18-23		N
CX0351	Notice and Order to Cease & Desist to Christiane Dotson and Sherry Nelson (Celebrity Smiles) from Terry Friddle	11/20/2007	JX0001 Tr. 56:18-23		N
CX0352	E-mail to Anderson from Dempsey re: The Streets at Southpoint	11/16/2007	JX0001 Tr. 56:18-23		N
CX0353	Investigative Memo to Hardesty & Bakewell from Dempsey re: SheShe Studio Spa (Case 07-026)	8/7/2007	JX0001 Tr. 56:18-23		N
CX0354	E-mail to Dempsey from Neal re: Teeth Whitening	2/13/2008	JX0001 Tr. 56:18-23		N
CX0355	E-mail to Dempsey, Friddle, White et al. from Owens re: Case 09-047	3/4/2009	JX0001 Tr. 56:18-23		N
CX0356	E-mail to Owens & Bakewell from Dempsey re: Beach Bunz Tanning (Case 09-047)	3/4/2009	JX0001 Tr. 56:18-23		N
CX0357	FTC Deposition Notice to Line Dempsey	9/10/2010	JX0001 Tr. 56:18-23		N
CX0358	Investigative Memo to Dr. Benjamin Brown & Dr. Denise Stanford from Dempsey re: New York Jewelry (Case 04-090)	7/9/2004	JX0001 Tr. 56:18-23		N
CX0359	E-mail to Dempsey from Friddle re: New York Jewelry	6/3/2004	JX0001 Tr. 56:18-23		N
CX0360	E-mail to Dempsey from Robinson re: Sorry I meant N. Carolina	11/28/2009	JX0001 Tr. 56:18-23		N
CX0361	Investigative Memo to Feingold & Bakewell from Dempsey re: Carmel Day Spa and Salon (Case 07-146)	9/24/2007	JX0001 Tr. 56:18-23		N
CX0362	Investigative Memo to Owens & Bakewell from Dempsey re: Beach Bunz Tanning (Case 09-047)	3/4/2009	JX0001 Tr. 56:18-23		N
CX0363	Rodriguez Brunson Affidavit (Brunson Jewelry)	2/18/2004	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0364	Investigative Memo to Burnham & Stanford from Dempsey re: Armand Swain (Mr. Grillz; Case 06-041)	3/21/2006	JX0001 Tr. 56:18-23		N
CX0365	E-mail to Friddle from Owens re: Whitening Spa	11/20/2007	JX0001 Tr. 56:18-23	Tr. 2263:08; 2358:11	N
CX0366	Letter to Jack Tickle from Carolin Bakewell re: Signature Spas of Hickory	11/9/2006	JX0001 Tr. 56:18-23		N
CX0367	E-mail to Friddle from Hardesty re: Case Assignment 06-193	9/11/2006	JX0001 Tr. 56:18-23		N
CX0368	Memo to Members of the Board from Terry Friddle re: Closed Investigative Files	9/7/2007	JX0001 Tr. 56:18-23		N
CX0369	E-mail to White, Burnham, Hardesty et al. from Owens re: Teeth Whitening	3/17/2008	JX0001 Tr. 56:18-23		N
CX0370	E-mail to White & Bakewell from Hardesty re: Bleaching Co.	3/4/2008	JX0001 Tr. 56:18-23	Tr. 2874:17,25	N
CX0371	Letter to Enhanced Light Technologies from Carolin Bakewell re: Illegal Teeth Whitening	2/13/2007	JX0001 Tr. 56:18-23	Tr. 2862:25; 2863:01	N
CX0372	E-mail to Friddle from Link re: Salon Bleaching	1/25/2007	JX0001 Tr. 56:18-23		N
CX0373	FTC Deposition Notice to Dr. W. Stan Hardesty	9/10/2010	JX0001 Tr. 56:18-23		N
CX0374	E-mail to White, Feingold, Burnham et al. from Hardesty re: Signature Spa Case	7/14/2008	JX0001 Tr. 56:18-23	Tr. 2791:19	N
CX0375	Letter to Dr. Owens from Stacey Phipps re: Evaluation of Statement of Economic Interest Filed by Dr. W. Stan Hardesty Jr.	7/22/2009	JX0001 Tr. 56:18-23	Tr. 2786:04; 2787:13	N
CX0376	E-mail to Goode from Owens re: Patient Harm	2/11/2010	JX0001 Tr. 56:18-23		N
CX0377	Advocacy Policies 2009-10: Table of Contents	2009-2010	JX0001 Tr. 56:18-23		N
CX0378	Dr. W. Stan Hardesty's Response to the FTC's Subpoena Duces Tecum	9/7/2010	JX0001 Tr. 56:18-23		N
CX0379	Evaluation Criteria Sheet	00/00/0000	JX0001 Tr. 56:18-23	Tr. 2038:10,12; 2072:07,08,11,20	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0380	Webpage: http://www.3dwhite.com/crest-products/3D-white-whitestrips-professional-effects.aspx (Crest 3D White Whitestrips Professional Effects Teeth Whitening System)	N/A	JX0001 Tr. 56:18-23		N
CX0381	DentalCare.com: Taking Advantage of the Information Age; by Dr. Roger P. Levin	N/A	JX0001 Tr. 56:18-23		N
CX0382	Webpage: http://www.walmart.com/ip/Crest-WS-3D-WHITE-PRO-EFFECTS-8-20CT/13909414?sourceid=&srccode=cii_19483251&cpncode=21-6405367 (Crest 3D White Whitestrips with Advanced Seal Professional Effects Teeth Whitening Kit, 20 ct)	N/A	JX0001 Tr. 56:18-23		N
CX0383	AACD: Cosmetic Dentistry Continues to Surge - Market Estimated at \$2.75 Billion	12/13/2007	JX0001 Tr. 56:18-23		N
CX0384	TheHistoryOf.net: The History of Teeth Whitening - Smiles Through the Miles; by Gareth Marples	9/11/2008	JX0001 Tr. 56:18-23		N
CX0385	AACD Consumer Studies: Can a new smile make you appear more successful and intelligent?	N/A	JX0001 Tr. 56:18-23		N
CX0386	Notice and Order to Cease & Desist to Alan Elrod from Terry Friddle	1/31/2007	JX0001 Tr. 56:18-23		N
CX0387	Notice and Order to Cease & Desist to Bailey's Lightning Whitening from Terry Friddle	7/17/2008	JX0001 Tr. 56:18-23		N
CX0388	Notice and Order to Cease & Desist to Lite Brite from Terry Friddle	7/17/2008	JX0001 Tr. 56:18-23		N
CX0389	Notice and Order to Cease & Desist to Triad Body Secrets from Terry Friddle	9/24/2008	JX0001 Tr. 56:18-23	Tr. 785:20	N
CX0390	Notice and Order to Cease & Desist to Whitening on Wheels from Terry Friddle	11/12/2008	JX0001 Tr. 56:18-23		N
CX0391	Notice and Order to Cease & Desist to Cynthia Blust (The Extra Smile, Inc.) from Terry Friddle	12/31/2008	JX0001 Tr. 56:18-23		N
CX0392	Tooth Whitening/Bleaching: Treatment Considerations for Dentists and their Patients	9/00/2009	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0393	<p>Webpage: Smart Sense EasyFit Whitening Trays http://www.kmart.com/shc/s/p_10151_10104_038W022088190001P?vName=Health%20&%20Wellness&cName=OralCare&sName=Toothpaste&sid=KDX20070926x00003a&ci_src=14110944&ci_sku=038W022088190001P (14 count Smart Sense trays, \$26.99)</p>	N/A	JX0001 Tr. 56:18-23		N
CX0394	<p>Webpage: Aquafresh White Trays Kit http://www.walgreens.com/store/catalog/Tooth-Whitening/WHITE-TRAYS--Kit/ID=prod1478845-product?V=G&ec=frgl_&ci_src=14110944&ci_sku=sku1478834</p>	N/A	JX0001 Tr. 56:18-23		N
CX0395	Statement of Economic Interest by Dr. Brad C. Morgan for the NC State Ethics Commission	4/12/2010	JX0001 Tr. 56:18-23		N
CX0396	Statement of Economic Interest by Dr. Charles Wayne Holland for the NC State Ethics Commission	1/21/2010	JX0001 Tr. 56:18-23		N
CX0397	AACD: First It Was Atkins, Then It Was South Beach, Now It's the White Smile Diet	6/22/2006	JX0001 Tr. 56:18-23		N
CX0398	Letter to Daniel Meyer from Michael Sudzina re: 6/30/05 P&G Scientific Exchange Meeting	00/00/0000	JX0001 Tr. 56:18-23		N
CX0399	Letter to Daniel Meyer from J. Leslie Winston re: P&G's Initial Feedback on the Citizen's Petition Document	12/9/2009	JX0001 Tr. 56:18-23		N
CX0400	Critical Assessment of Safety and Regulatory Status of Crest Whitestrips (CWS) (Procter & Gamble)	11/28/2003	JX0001 Tr. 56:18-23		N
CX0401	JADA: Vital Bleaching with a Thin Peroxide Gel; by Dr. Robert Gerlach and Mr. Paul Sagel	01/00/2004	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
	Symposium on Esthetic Restorative Materials: History, Safety and Effectiveness of Current Bleaching Techniques: Applications of the Nightguard Vital Bleaching Technique; by Van B. Haywood	00/00/1991	JX0001 Tr. 56:18-23	Tr. 2590:07, 11, 25; 2697:02, 08,	N
CX0402	Journal of Dentistry: Effects of Tooth Whitening and Orange Juice on Surface Properties of Dental Enamel; by Yan-Fang Ren et al.	1/26/2009	JX0001 Tr. 56:18-23	Tr. 2654:23, 24; 2657:09	N
CX0403	E-mail to Casey & Bakewell from White re: Question E-mail to cbennett@wral.com & Bakewell from White re: Dental Board w/Attach: Meck Co. Spa (NCBDE vs Carmel Day Spa Complaint)	2/20/2008	JX0001 Tr. 56:18-23		N
CX0404	E-mail to White from Parker re: Florida White Smile	4/24/2008	JX0001 Tr. 56:18-23		N
CX0405	E-mail to Parker from White re: Unauthorized Practice w/Attach: Unauthorized Practice Memo [mar 08].doc	5/21/2008	JX0001 Tr. 56:18-23		N
CX0406	E-mail to Feingold, Morgan, Holland et al. from White re: Teeth Whitening Kiosks at the mall are not regulated WRAL.com	4/17/2008	JX0001 Tr. 56:18-23		N
CX0407	American Association of Dental Administrator 24th Annual Meeting Minutes: San Antonio, TX	5/22/2008	JX0001 Tr. 56:18-23		N
CX0408	Joint Legislative Commission on Governmental Operations - Subcommittee Reports	10/13/2008	JX0001 Tr. 56:18-23	Tr. 2257:20, 24	N
CX0409	Bobby White's Call Log Files: Referencing Whitening/Bleaching 2004 - 2010	2/6/2008	JX0001 Tr. 56:18-23		N
CX0410	Letter to NCBDE from Joshua Granson (Beyond WhiteSpa) re: Tooth Whitening Policy	2004-2010	JX0001 Tr. 56:18-23		N
CX0411	E-mail to Ogden, Cole, Wright et al. from Howell: re: FTC Complaint Charges Conspiracy	3/24/2010	JX0001 Tr. 56:18-23		N
CX0412	E-mail to Morgan, Holland & Owens from White re: Teeth Whitening	6/28/2010	JX0001 Tr. 56:18-23		N
CX0413		3/31/2010	JX0001 Tr. 56:18-23		N
CX0414					

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0415	E-mail to Hunt, Harris, Lundstrom et al. from Brengelman re: Teeth Whitening - National Article on Alabama Board of Dentistry	2/26/2009	JX0001 Tr. 56:18-23		N
CX0416	E-mail to Howell, Reitz, Ogden et al. from Wilkinson re: ADA News: Alabama Judge rules commercial teeth whitening within dental practice scope	3/5/2009	JX0001 Tr. 56:18-23		N
CX0417	E-mail to Howell, Cole, Wright et al. from Ogden re: Recent Alabama Supreme Court Ruling Regarding Tooth Whitening Kiosk Appeal	10/20/2009	JX0001 Tr. 56:18-23		N
CX0418	E-mail to White from Clark re: Anything New?	3/1/2010	JX0001 Tr. 56:18-23		N
CX0419	E-mail to White from Reitz re: Anything New?	3/2/2010	JX0001 Tr. 56:18-23		N
CX0420	E-mail to Wils & White from Bakewell re: Teeth Whitening	5/5/2009	JX0001 Tr. 56:18-23		N
CX0421	E-mail to White from Bakewell re: Teeth Whitening	4/10/2010	JX0001 Tr. 56:18-23		N
CX0422	E-mail to White from Lesan re: Spa Tooth Whitening	6/28/2010	JX0001 Tr. 56:18-23		N
CX0423	E-mail to White, Holland & Owens from Morgan re: Teeth Whitening	3/31/2010	JX0001 Tr. 56:18-23		N
CX0424	E-mail to White, Morgan, Owens from Holland re: Teeth Whitening	3/31/2010	JX0001 Tr. 56:18-23		N
CX0425	E-mail to White, Morgan, Hollans from Owens re: Teeth Whitening	3/31/2010	JX0001 Tr. 56:18-23		N
CX0426	E-mail to Owens from White re: Whitening Policy	4/7/2010	JX0001 Tr. 56:18-23		N
CX0427	E-mail to White from Holland re: Emailing 52010.htm	7/7/2010	JX0001 Tr. 56:18-23		N
CX0428	E-mail to White from Holland re: Emailing www.consumerdigestweekly.com.htm	7/7/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0429	ADA Definition of Dentistry	00/00/0000	JX0001 Tr. 56:18-23		N
CX0430	E-mail to White from Sheppard re: Whitening	11/11/2009	JX0001 Tr. 56:18-23		N
CX0431	ADA News: ADA Seeks FDA classification of whitening agents; by Jennifer Garvin	12/14/2009	JX0001 Tr. 56:18-23		N
CX0432	E-mail to White from Goode re: Request for Information	6/18/2010	JX0001 Tr. 56:18-23		N
CX0433	E-mail to White from Coe re: Seeking Comment on FTC administrative complaint	6/17/2010	JX0001 Tr. 56:18-23		N
CX0434	E-mail to White from Morgan re: Editorials	7/8/2010	JX0001 Tr. 56:18-23		N
CX0435	FTC's Subpoena Ad Testificandum to Brian Runsick	10/20/2010	JX0001 Tr. 56:18-23		N
CX0436	Florida Limited Liability Company: Celebrity Smiles	8/24/2007	JX0001 Tr. 56:18-23		N
CX0437	E-mail to Friddle, Stanford & White from Allen re: Edie's Salon Log #04-187	10/7/2004	JX0001 Tr. 56:18-23		N
CX0438	E-mail to Friddle & White from Owens re: Case Assignment 08-018	2/5/2008	JX0001 Tr. 56:18-23		N
CX0439	Open Investigative Files to Owens from Friddle	3/12/2008	JX0001 Tr. 56:18-23		N
CX0440	Log of Correspondences - Log Number 08-072 - BleachBright Crabtree Valley Mall - Complainant: Brian Runsick	4/16/2008	JX0001 Tr. 56:18-23		N
CX0441	Log of Correspondences - Log Number 08-256 - The Extra Smile - Complainant: Board	12/31/2008	JX0001 Tr. 56:18-23		N
CX0442	Subpoena Ad Testificandum to Dr. Larry F. Tilley	10/20/2010	JX0001 Tr. 56:18-23	Tr. 2050:09,24	N
CX0443	Log of Correspondences - Log Number 08-199 - iBrite Express/Joe Willett - Complainant: Board	9/18/2008	JX0001 Tr. 56:18-23		N
CX0444	Log of Correspondences - Log Number 08-018 - Port City Tanning - Complainant: Board	2/14/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0445	E-mail to Bakewell from Owens re: 20080714_152954_3184_8773dd706314	3/3/2009	JX0001 Tr. 56:18-23		N
CX0446	E-mail to White from Agricola re: Cosmetic Teeth Whitening Services	5/9/2008	JX0001 Tr. 56:18-23		N
CX0447	Log of Cases from 09/2006 to 04/2009	00/00/0000	JX0001 Tr. 56:18-23		N
CX0448	E-mail to Bakewell from Owens re: Teeth Whitening Letter to Ronald Owens from Bobby White re:	3/3/2009	JX0001 Tr. 56:18-23		N
CX0449	Welcome Letter & Training Information	7/8/2005	JX0001 Tr. 56:18-23		N
CX0450	Letter to Ronald Owens from Bobby White re: Welcome Letter & Training Information	6/25/2008	JX0001 Tr. 56:18-23		N
CX0451	Log of Correspondences - Log Number 09-192 - Serenity Total Body Care (Bleach Bright) - Complainant: Board	7/27/2009	JX0001 Tr. 56:18-23		N
CX0452	E-mail to info@ncdentalboard.org from Steinbicker re: Question about Serenity Total Body Care	9/1/2009	JX0001 Tr. 56:18-23		N
CX0453	Log of Correspondences - Log Number 09-199 - Confi-Dents/Renee Gregory - Complainant: Board	9/16/2009	JX0001 Tr. 56:18-23		N
CX0454	Letter to Casie Goode from Robert Brown re: Heather Wiecek (Buena Vista Smiles) w/Attach: Customer Consent Form	12/29/2009	JX0001 Tr. 56:18-23		N
CX0455	Two Buena Vista Smiles Advertisements	12/4/200?	JX0001 Tr. 56:18-23		N
CX0456	Log of Correspondences - Log Number 10-060 - Vivid Tan - Complainant: Board	4/6/2010	JX0001 Tr. 56:18-23		N
CX0457	Vivid Tan Advertisements	00/00/0000	JX0001 Tr. 56:18-23		N
CX0458	Log of Correspondences - Log Number 10-061 - Pro White - Complainant: Board	4/6/2010	JX0001 Tr. 56:18-23		N
CX0459	E-mail to Owens from Friddle re: Case Assignment 09-225	10/14/2009	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0460	E-mail to MacLeod from Friddle re: Triangle Whiting	10/14/2009	JX0001 Tr. 56:18-23	Tr. 2275:05	N
CX0461	Triangle Whitening Website	10/13/2009	JX0001 Tr. 56:18-23		N
CX0462	Open Investigative Files to Dr. Owens from Terry Friddle	8/12/2010	JX0001 Tr. 56:18-23		N
CX0463	E-mail to Ogden, Cole, Wright et al. from Howell re: Board of Dental Examiners w/Attach; bham news.pdf	4/23/2009	JX0001 Tr. 56:18-23		N
CX0464	The Dental Forum: NC State Board of Dental Examiners; Fall 2005; Editor: Clifford Feingold	00/00/2005	JX0001 Tr. 56:18-23		N
CX0465	E-mail to Friddle & White from Owens re: Case Assignment 10-061	4/6/2010	JX0001 Tr. 56:18-23		N
CX0466	E-mail to Friddle & White from Owens re: Teeth Whitening by Tanning Salon	4/6/2010	JX0001 Tr. 56:18-23		N
CX0467	Dr. Ronald K. Owens' Subpoena Duces Tecum Response	9/30/2010	JX0001 Tr. 56:18-23		N
CX0468	E-mail to Bakewell from Friddle re: Complaint Form Attached & Sworn Statement ***for Carolyn Bakewell** (Redacted Version of CX0277)	4/11/2008	JX0001 Tr. 56:18-23	Tr. 2163:05; 2164:18	N
CX0469	E-mail to Rhodes from Hansen re: Tooth Whitening w/Attach: 59 Whitening by Retail_Staff.docx	8/18/2009	JX0001 Tr. 56:18-23	Tr. 2720:07,08,19	N
CX0470	NCBDE Board Meeting Agenda in Morrisville, NC 1/7-9/2010	1/7/2010	JX0001 Tr. 56:18-23		N
CX0471	Closed Session Minutes from NCBDE Meeting in Morrisville, NC 1/7-9/2010	1/7/2010	JX0001 Tr. 56:18-23	Tr. 2315:03,13; 2316:05	N
CX0472	E-mail to Granson from Jenkins re: Spa Treatment	11/19/2009	JX0001 Tr. 56:18-23		N
CX0473	E-mail to White from Bakewell: re: Tooth Whitening Question	11/17/2009	JX0001 Tr. 56:18-23		N
CX0474	Excerpt of Docket No. 9343 Pretrial Conference (Cover Page, p1-2 & p10-15)	7/14/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0475	Unauthorized Practice of Dentistry - NCBDE Policy - Adopted 1/9/2010	1/9/2010	JX0001 Tr. 56:18-23	Tr. 2229:15, 19; 2312:16; 2313:20,21; 2314:03; 2370:17; 2375:25	N
CX0476	Michael Hasson's NCBDE Complaint Form Against Port City Tanning	2/20/2008	JX0001 Tr. 56:18-23		N
CX0477	Letter to NCBDE from Michael Hasson: re: Ms. Sharon Tran	1/12/2009	JX0001 Tr. 56:18-23		N
CX0478	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	5/1/2009	JX0001 Tr. 56:18-23		N
CX0479	Open Investigative Files to Brad Morgan from Terry Friddle	12/3/2009	JX0001 Tr. 56:18-23		N
CX0480	Open Investigative Files to Brad Morgan from Terry Friddle	1/6/2010	JX0001 Tr. 56:18-23		N
CX0481	Open Investigative Files to Brad Morgan from Terry Friddle	3/9/2010	JX0001 Tr. 56:18-23	Tr. 2636:21	N
CX0482	Open Investigative Files to Brad Morgan from Terry Friddle	6/15/2010	JX0001 Tr. 56:18-23		N
CX0483	Open Investigative Files to Brad Morgan from Terry Friddle	8/12/2010	JX0001 Tr. 56:18-23		N
CX0484	Subpoena Ad Testificandum to Dr. Michael Hasson	10/20/2010	JX0001 Tr. 56:18-23		N
CX0485	Letter to Commissioner Hamburg from W. Greg Collier (The Procter & Gamble Company)	4/28/2010	JX0001 Tr. 56:18-23		N
CX0486	Patient Disclosure Instructions from the files of Dr. Michael L. Hasson, DDS PA	2/18/2008	JX0001 Tr. 56:18-23		N
CX0487	Tooth Whitening by Retail Staff	4/29/2009	JX0001 Tr. 56:18-23	Tr. 2719:15; 2720:06; 2748:11,12,15	N
CX0488	E-mail to Hansen from Bowman: re: June BOT Report w/Attach Tooth Whitening.doc	5/20/2008	JX0001 Tr. 56:18-23		N
CX0489	Consumer Whitening Market Study by Maria Aguilar	11/00/2008	JX0001 Tr. 56:18-23	Tr. 17:05; 390:20; 411:13; 414:03	N
CX0490	Teeth Whitening Bulletin	N/A	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0491	E-mail to Holland, Morgan, White et al. from bendob@aol.com: re: Brunson Jewelry	8/5/2004	JX0001 Tr. 56:18-23		N
CX0492	The Food and Drug Administration and its Influence on Home Bleaching; by Van B. Haywood; Cosmetic Dentistry 1993: 12-18	00/00/1993	JX0001 Tr. 56:18-23		N
CX0493	Trayless Professional Whitening: A New Technology with Universal Appeal; Continuing Education in Dentistry; January 2002: Volume 23, Number 1A	1/00/2003	JX0001 Tr. 56:18-23		N
CX0494	Why, When and How to Whiten Your Patients' Teeth: World Expert Van Haywood Puts You on Track; Dr. Van B. Haywood; Irish Dentist September 2004	9/00/2004	JX0001 Tr. 56:18-23		N
CX0495	A Comparison of At-Home and In-Office Bleaching; Dr. Van B. Haywood; Dentistry Today 2000: Vol. 19, Number 4, 44-53	00/00/2000	JX0001 Tr. 56:18-23		N
CX0496	Letter to Margaret Hamburg, MD, from Greg Collier, PhD: re: Procter & Gamble's Comments on the November 20th, 2009 American Dental Association's Citizen Petition, Regulatory Treatment of Tooth Whitening Preparations	4/28/2010	JX0001 Tr. 56:18-23	Tr. 2907:09,24; 2908:12,15; 2910:04; 2929:11	N
CX0497	Review of ADA Report on Tooth Whitening/Bleaching; by Dr. Harald O. Heymann	00/00/0000	JX0001 Tr. 56:18-23	Tr. 2617:03,16,23; 2618:09; 2899:10	N
CX0498	6.1 CSA Report on Whitening/Bleaching (73H-2008) - Subcommittee Recommendations	11/8/2010	JX0001 Tr. 56:18-23		N
CX0499	Tooth Whitening and Total Patient Care; by Renee A. Marks	6/00/2003	JX0001 Tr. 56:18-23		N
CX0500	Hydrogen Peroxide with Periodontal Disease; by Chelsea Fitzgerald	10/22/2009	JX0001 Tr. 56:18-23		N
CX0501	Letter to North Carolina Board of Dental Examiners from Marilyn Ward: re: "Mail Teeth Whitening" / Unlicensed Practice of Dentistry	3/26/2009	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0502	E-mail to White, Goode, McCullough et al. from Friddle: re: Lasers for Bleaching NC - 2nd email	6/20/2008	JX0001 Tr. 56:18-23		N
CX0503	North Carolina State Board of Dental Examiners Financial Statements Year Ended December 31, 2009	12/31/2009	JX0001 Tr. 56:18-23		N
CX0504	Tooth Whitening: from webpage: http://www.netdds.net/ContentPages/contentBleach.html	00/00/0000	JX0001 Tr. 56:18-23		N
CX0505	Use of Hydrogen Peroxide-Based Tooth Whitening Products and its Relationship to Oral Cancer	00/00/2006	JX0001 Tr. 56:18-23		N
CX0506	Whitening Particulars; by Van B. Haywood	00/00/0000	JX0001 Tr. 56:18-23		N
CX0507	Whitening Particulars; by Van B. Haywood; from webpage: http://www.dimensionsofdentalhygiene.com	05/00/2006	JX0001 Tr. 56:18-23		N
CX0508	North Carolina Dental Gazette Vol. 30-2 (Summer 2008)	00/00/2008	JX0001 Tr. 56:18-23	Tr. 1408:22; 1670:21,22; 1940:12	N
CX0509	"Why Dentist Supervised"	00/00/0000	JX0001 Tr. 56:18-23		N
CX0510	Tray delivery of potassium nitrate-fluoride to reduce bleaching sensitivity; by Van B. Haywood et al.; Quintessence International Vol. 32-2, 105-109; abstract from NIH website included on last page	02/00/2001	JX0001 Tr. 56:18-23		N
CX0511	Clinical Evaluation of Chemical and Light-Activated Tooth Whitening Systems; by Gerard Kugel et al.; Compendium of Continuing Education in Dentistry (January 2006)	01/00/2006	JX0001 Tr. 56:18-23		N
CX0512	CRA Status Report: Why Resin Curing Lights Do Not Increase Tooth Lightening	3/16/2009	JX0001 Tr. 56:18-23		N
CX0513	The 2008 Gallup Study of Dentists' Attitudes Toward Tooth Whitening Products & Services - Summary Volume - September 2008	09/00/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0514	NCAC Title 21, Chapter 16	4/18/2008	JX0001 Tr. 56:18-23		N
CX0515	North Carolina Administrative Procedure Act: Chapter 150B, Article 1	00/00/0000	JX0001 Tr. 56:18-23	Tr. 2213:20; 2214:16; 2215:13; 2216:21	N
CX0516	E-mail to Elliott from Goode: re: Tooth Whitening	3/10/2008	JX0001 Tr. 56:18-23		N
CX0517	E-mail to Little and White from Bakewell: re: Certifications Question	7/10/2008	JX0001 Tr. 56:18-23		N
CX0518	E-mail to Harris and Bakewell from White: re: Teeth Whitening	3/25/2008	JX0001 Tr. 56:18-23		N
CX0519	E-mail to Harris, White, Dougherty et al. from Weeg: re: FTC Letter	5/24/2008	JX0001 Tr. 56:18-23		N
CX0520	Carmel Day Spa Complaint w/Attach: Cease and Desist Letter to Shohreh Raffie & Line Dempsey's Affidavit	1/17/2008	JX0001 Tr. 56:18-23		N
CX0521	Letter to Carolin Bakewell from Algis Augustine: re: White Science Out File No. N-147-1	2/27/2008	JX0001 Tr. 56:18-23	Tr. 783:20	N
CX0522	E-mail to Bakewell from Friddle: re: Teeth Whitening	1/16/2008	JX0001 Tr. 56:18-23		N
CX0523	E-mail to Francis from Bakewell: re: Practice of Dentistry Definition	2/12/2008	JX0001 Tr. 56:18-23		N
CX0524	Letter to Michael Catanese from Carolin Bakewell: re: Tooth Whitening Kiosks	1/23/2008	JX0001 Tr. 56:18-23		N
CX0525	E-mail to Mosley and White from Bakewell: re: Tooth Whitening Kiosks	3/24/2008	JX0001 Tr. 56:18-23	Tr. 629:24,25; 630:18; 631:08; 631:25; 632:06,12; 633:05; 639:16	N
CX0526	E-mail to Wright, Bloom, Harris et al. from Brengelman: re: Teeth whitening as a part of definition of dentistry/dental hygiene - informal response of Kentucky	8/12/2008	JX0001 Tr. 56:18-23		N
CX0527	North Carolina State Board of Dental Examiners Investigations Manual - Revised 6.30.03	6/30/2003	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0528	Letter to Casie Good from Tim Williams: re: Movie Star Smile	2/8/2008	JX0001 Tr. 56:18-23		N
CX0529	E-mail to Feingold, Bakewell, and White from Dempsey: re: 07-146 (Carmel Day Spa)	12/17/2007	JX0001 Tr. 56:18-23		N
CX0530	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	2/6/2008	JX0001 Tr. 56:18-23		N
CX0531	Warning Letters Sent to Makers of Teeth Whiteners; by Sharon Snider	10/30/1991	JX0001 Tr. 56:18-23		N
CX0532	Letter to Tim V...? from William Greenrose: re: Regulatory Opinion of the FDA Regulatory Classification for Tooth Whitening Product	12/2/2006	JX0001 Tr. 56:18-23		N
CX0533	510K Summary: Dental Diode Laser System	11/7/2006	JX0001 Tr. 56:18-23		N
CX0534	510K Summary: Brite White Teeth Whitening System	12/3/2006	JX0001 Tr. 56:18-23		N
CX0535	FDA Adverse Event Report: Discus Dental Zoom 2 Teeth Whitening System	6/4/2007	JX0001 Tr. 56:18-23		N
CX0536	E-mail to Owens from Goode: re: Teeth Whitening	10/6/2008	JX0001 Tr. 56:18-23		N
CX0537	Line Dempsey's Log of Assigned Cases	00/00/0000	JX0001 Tr. 56:18-23		N
CX0538	E-mail to Dempsey, Friddle, Smith et al. from Feingold: re: Movie Star Smiles (07-223)	1/16/2008	JX0001 Tr. 56:18-23		N
CX0539	E-mail to Feingold and Dempsey from Friddle: re: Case Assignment 07-223	1/4/2008	JX0001 Tr. 56:18-23		N
CX0540	E-mail to White, Burnham, Hardesty et al. from Owens: re: Teeth Whitening	3/17/2008	JX0001 Tr. 56:18-23		N
CX0541	E-mail to Bakewell from White: re: Teeth Whitening Info	2/12/2008	JX0001 Tr. 56:18-23		N
CX0542	E-mail to White from Francis: re: Teeth Whitening Info	2/11/2008	JX0001 Tr. 56:18-23		N
CX0543	Log of Correspondences - Log Number 08-206 - Fantasticians Inc - Complainant: Board	9/23/2008	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0544	E-mail to Barrister from White: re: Chemical Bleaching w/Attch: Unauthorized Practice Memo	3/24/2008	JX0001 Tr. 56:18-23		N
CX0545	E-mail to White from Barrister: re: Chemical Bleaching	3/24/2008	JX0001 Tr. 56:18-23		N
CX0546	Movie Star Smile Brochure	00/00/0000	JX0001 Tr. 56:18-23		N
CX0547	Movie Star Smile Photo	00/00/0000	JX0001 Tr. 56:18-23		N
CX0548	Movie Star Smile Larger Photo	00/00/0000	JX0001 Tr. 56:18-23		N
CX0549	Effect of bleaching on restorative materials and restorations - a systematic review; by Thomas Attin et al.; Dental Materials; 2004: Vol. 20 852-861	4/6/2004	JX0001 Tr. 56:18-23		N
CX0550	Biological Properties of Peroxide-containing Tooth Whiteners; by Y. Li; Food and Chemical Toxicology 1996: Vol. 34 887-904	5/14/1996	JX0001 Tr. 56:18-23		N
CX0551	Clinical trials on the use of whitening strips in children and adolescents; by Kevn J. Donly and Robert W. Gerlach; General Dentistry May-June 2002: 242-245	2/27/2002	JX0001 Tr. 56:18-23		N
CX0552	A Randomized Clinical Trial of In-Office Dental Bleaching with or without Light Activation; by Qasem Atomari and Ehsan El Daraa; The Journal of Contemporary Dental Practice January 2010: Vol. 11-1-1-8	1/1/2010	JX0001 Tr. 56:18-23		N
CX0553	Nightguard Vital Bleaching; by Van B. Haywood and Harald O. Heymann; Quintessence International 1989: Vol. 20-3 173-176	00/00/1989	JX0001 Tr. 56:18-23		N
CX0554	Designated Deposition Transcript of Stanley L. Allen, J.T., DDS	9/3/2010	JX0001 Tr. 56:18-23		N
CX0555	Designated Deposition Transcript of Benjamin Brown, DDS	9/2/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0556	Designated Deposition Transcript of Joseph Burnham, DDS	9/3/2010	JX0001 Tr. 56:18-23		N
CX0557	Designated Deposition Transcript of W. Linebaugh Dempsey, DDS	10/28/2010	JX0001 Tr. 56:18-23		N
CX0558	Designated Investigational Hearing Transcript of W. Linebaugh Dempsey, DDS	7/9/2009	JX0001 Tr. 56:18-23		N
CX0559	Designated Deposition Transcript of Efrid Zannie	9/1/2010	JX0001 Tr. 56:18-23		N
CX0560	Designated Deposition Transcript of Clifford Feingold, DDS	10/5/2010	JX0001 Tr. 56:18-23		N
CX0561	Designated Deposition Transcript of Terry W. Friddle	10/14/2010	JX0001 Tr. 56:18-23		N
CX0562	Designated Investigational Hearing Transcript of Terry W. Friddle	7/7/2009	JX0001 Tr. 56:18-23		N
CX0563	Designated Investigational Hearing Transcript of Casie Goode	7/8/2009	JX0001 Tr. 56:18-23		N
CX0564	Designated Deposition Transcript of Neplus Hall, DDS	9/1/2010	JX0001 Tr. 56:18-23		N
CX0565	Designated Deposition Transcript of W. Stan Hardesty, DDS	10/29/2010	JX0001 Tr. 56:18-23		N
CX0566	Designated Investigational Hearing Transcript of W. Stan Hardesty, DDS	7/23/2009	JX0001 Tr. 56:18-23		N
CX0567	Designated Deposition Transcript of Wayne Holland, DDS	9/17/2010	JX0001 Tr. 56:18-23		N
CX0568	Designated Deposition Transcript of Sean Kurdys, DDS	10/7/2010	JX0001 Tr. 56:18-23		N
CX0569	Designated Deposition Transcript of Brad Morgan, DDS	10/15/2010	JX0001 Tr. 56:18-23		N
CX0570	Designated Deposition Transcript of Ronald Owens, DDS	11/8/2010	JX0001 Tr. 56:18-23		N
CX0571	Designated Investigational Hearing Transcript of Ronald Owens, DDS	7/24/2009	JX0001 Tr. 56:18-23		N
CX0572	Designated Deposition Transcript of Millard Wester, DDS	9/3/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0573	Designated Deposition Transcript of Bobby White	11/9/2010	JX0001 Tr. 56:18-23		N
CX0574	Designated Investigational Hearing Transcript of Bobby White	7/6/2009	JX0001 Tr. 56:18-23		N
CX0575	Designated Deposition Transcript of Michael L. Hasson, DDS	11/16/2010	JX0001 Tr. 56:18-23		N
CX0576	Designated Deposition Transcript of William M. Litaker, Jr., DDS	9/24/2010	JX0001 Tr. 56:18-23		N
CX0577	Designated Deposition Transcript of Gary D. Oyster, DDS	9/24/2010	JX0001 Tr. 56:18-23		N
CX0578	Designated Deposition Transcript of Alec M. Parker, DDS	9/23/2010	JX0001 Tr. 56:18-23		N
CX0579	Designated Deposition Transcript of Brian Runsick	11/4/2010	JX0001 Tr. 56:18-23		N
CX0580	Designated Deposition Transcript of Larry F. Tilley, DDS	11/12/2010	JX0001 Tr. 56:18-23		N
CX0581	Designated Deposition Transcript of Carolin Bakewell Letter to Dr. O'Loughlin from Charles Pierce: re: ADA Petition questioning the safety of certain peroxide whitening products	10/13/2010	JX0001 Tr. 56:18-23		N
CX0582	The 2010 Gallup Study of Changing Use of Tooth Whitening Products in the Current Economic Environment - Summary Volume	3/31/2010	JX0001 Tr. 56:18-23		N
CX0583	2005 Oral-B Rembrandt US Dealer Pricing	5/00/2010	JX0001 Tr. 56:18-23		N
CX0584	Possible Edits to CSA Whitening Report: Consultant Comments	00/00/0000	JX0001 Tr. 56:18-23	Tr. 2670:06; 2671:21,22; 2672:03,15; 2673:11,16	N
CX0585	Proctor and Gamble Concerns followed by Responses from Drs. Li and Haywood	00/00/0000	JX0001 Tr. 56:18-23		N
CX0586	Tooth Whitening/Bleaching: Treatment Considerations for Dentists and their Patients (Updated August 2010)	08/00/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0588	TeethWhiteningReviews.com: Teeth Whitening: What Works and What Doesn't	1/2/2006	JX0001 Tr. 56:18-23		N
CX0589	American Academy of Pediatric Dentistry: Policy on the Use of Dental Bleaching for Child and Adolescent Patients; Adopted 2004; Revised 2009	00/00/2009	JX0001 Tr. 56:18-23		N
CX0590	ADF Medical Devices Commission: Tooth Bleaching Treatments: A Review	00/00/2007	JX0001 Tr. 56:18-23		N
CX0591	YourDentistryGuide.com: Teeth Whitening - How it Works and What is Costs?; by Linda Dyett	8/13/2010	JX0001 Tr. 56:18-23		N
CX0592	Letter to Dr. Stan Hardesty from Perry Newson: re: Evaluation of Statement of Economic Interest Filed by Dr. Millard W. Wester III	8/4/2008	JX0001 Tr. 56:18-23		N
CX0593	N.C.G.S. Section 93B-2: Occupational Licensing Boards	00/00/0000	JX0001 Tr. 56:18-23	Tr. 2212:01	N
CX0594	N.C.G.S. Section 138A: State Government Ethics Act E-mail to Pastorelli from Willey: re: Please Review ASAP for Good Morning America Interview in 1 hour! w/Attach: Whitening in office home or kiosk talking points May 20 2008.doc	00/00/0000	JX0001 Tr. 56:18-23	Tr. 2207:02,18; 2208:14; 2209:08; 2210:01,05	N
CX0595	Lasers Medical Science: Different light-activated in-office bleaching systems: a clinical evaluation	5/21/2008	JX0001 Tr. 56:18-23		N
CX0596	Program from the 2009 AAED Conference: Passion, Esthetics, & New Technology: The Future of Dentistry	5/14/2009	JX0001 Tr. 56:18-23		N
CX0597	Journal of Esthetic and Restorative Dentistry: Tooth Whitening: Why, Who, Where, What, and How; by Linda C. Niessen	8/2/2009	JX0001 Tr. 56:18-23		N
CX0598	Dr. Michael Catanese's Response to the FTC's Subpoena Duces Tecum	00/00/2001	JX0001 Tr. 56:18-23		N
CX0599	Dr. Mark Hyman's Response to the FTC's Subpoena Duces Tecum	9/1/2010	JX0001 Tr. 56:18-23		N
CX0600	Dr. Mark Hyman's Response to the FTC's Subpoena Duces Tecum	9/13/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0601	Dr. Kurt A. McKissick's Response to the FTC's Subpoena Duces Tecum	9/3/2010	JX0001 Tr. 56:18-23		N
CX0602	Dr. R. Kelly Kreeb's Response to the FTC's Subpoena Duces Tecum	9/9/2010	JX0001 Tr. 56:18-23	Tr. 34:13,15	N
CX0603	Dr. Michael Treman's Response to the FTC's Subpoena Duces Tecum	9/13/2010	JX0001 Tr. 56:18-23		N
CX0604	Perry Newson Declaration Including Exhibits 1-3: Exhibit 1- N.C.G.S. Chapter 138A; Exhibit 2- Blank Statement of Economic Interest Form; Exhibit 3- Executed Copies of Completed SEI's from Current and Former Board Members of the Board from 2006 to Present	10/12/2010	JX0001 Tr. 56:18-23		N
CX0605	Dr. Jessica L. Bishop's Response to the FTC's Subpoena Duces Tecum	9/1/2010	JX0001 Tr. 56:18-23		N
CX0606	Dr. Joseph S. Burnham's Response to the FTC's Subpoena Duces Tecum	9/17/2010	JX0001 Tr. 56:18-23		N
CX0607	Dr. Deana R. Fugate's Response to the FTC's Subpoena Duces Tecum	9/9/2010	JX0001 Tr. 56:18-23		N
CX0608	Dr. Scott P. Guice's Response to the FTC's Subpoena Duces Tecum	9/7/2010	JX0001 Tr. 56:18-23		N
CX0609	Dr. Douglas K. Macleod's Response to the FTC's Subpoena Duces Tecum	9/17/2010	JX0001 Tr. 56:18-23		N
CX0610	Dr. Annie P. Mathew's Response to the FTC's Subpoena Duces Tecum	8/30/2010	JX0001 Tr. 56:18-23		N
CX0611	Dr. Christopher N. Reese's Response to the FTC's Subpoena Duces Tecum	9/17/2010	JX0001 Tr. 56:18-23		N
CX0612	Dr. Christopher N. Reese's Response to the FTC's Subpoena Duces Tecum	9/17/2010	JX0001 Tr. 56:18-23		N
CX0613	Dr. Kyle W. Taylor's Response to the FTC's Subpoena Duces Tecum	9/17/2010	JX0001 Tr. 56:18-23		N
CX0614	Dr. Millard W. Wester's Response to the FTC's Subpoena Duces Tecum	9/27/2010	JX0001 Tr. 56:18-23		N
CX0615	Dr. D. Brian Williams' Response to the FTC's Subpoena Duces Tecum	9/20/2010	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0616	Dr. Craig Q. Adams' Response to the FTC's Subpoena Duces Tecum	9/2/2010	JX0001 Tr. 56:18-23		N
CX0617	Dr. Stephen M. Smith's Response to the FTC's Subpoena Duces Tecum	9/21/2010	JX0001 Tr. 56:18-23		N
CX0618	E-mail to Hardesty et al. from Dempsey: re: Amazing Grace Spa (07-021)	1/16/2008	JX0001 Tr. 56:18-23		N
CX0619	Fax to the NC State Board of Dental Examiners from Luis E. Arzola, D.M.D.: re: Complaint about spa teeth whitening	9/11/2006	JX0001 Tr. 56:18-23		N
CX0620	Investigative Memo to Terry Friddle from Andrea Smythe: re: Serenity Day Spa	11/3/2005	JX0001 Tr. 56:18-23		N
CX0621	Unsigned fax: re: Complaint about Sunsational Tanning	1/28/2007	JX0001 Tr. 56:18-23		N
CX0622	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	7/16/2007	JX0001 Tr. 56:18-23		N
CX0623	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	2/29/2008	JX0001 Tr. 56:18-23		N
CX0624	Open Investigative Files to Stan Hardesty from Terry Friddle	3/12/2008	JX0001 Tr. 56:18-23		N
CX0625	Open Investigative Files to Clifford Feingold from Terry Friddle	3/12/2008	JX0001 Tr. 56:18-23		N
CX0626	E-mail to Smith from Elliott: re: Tooth Whitening	3/7/2008	JX0001 Tr. 56:18-23		N
CX0627	Interview with Prof. Van B. Haywood, USA, about bleaching sensitivity; from http://www.dental-tribune.com/articles/content/id/406	5/28/2009	JX0001 Tr. 56:18-23		N
CX0628	Table showing teeth whitening cases	00/00/0000	JX0001 Tr. 56:18-23		N
CX0629	Letter to Steven J. Osnowitz from Brian Wyant: re: Mall leasing history	9/27/2010	JX0001 Tr. 56:18-23	Tr. 881:23; 882:20; 902:10; 903:10,16	N
CX0630	Council for Cosmetic Teeth Whitening (CCTW): Best Practices and Information for Cosmetic Teeth Whitening Product Manufacturers and Distributors	9/9/2008	JX0001 Tr. 56:18-23	Tr. 676:15; 677:06; 690:19	N

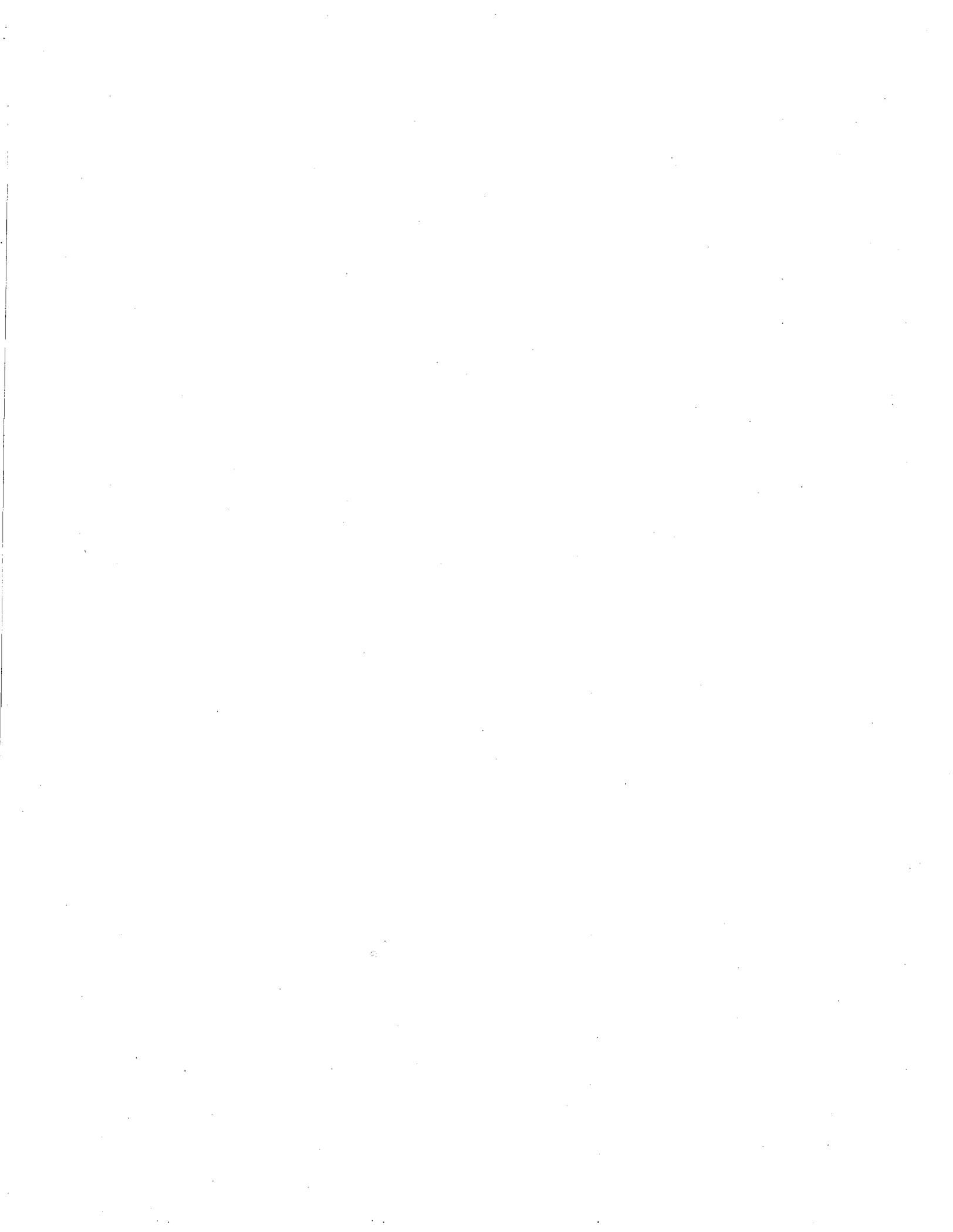
Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0631	Rebuttal Report of Professor John Kwoka	1/7/2011	JX0001 Tr. 56:18-23	Tr. 1702:16; 1873:10,11	N
CX0632	Rebuttal Report of Martin Giniger	1/7/2011	JX0001 Tr. 56:18-23		N
CX0633 - CX0636	Intentionally Not Used				
CX0637	BleachBright: Manual: For getting the most out of your BleachBright business	00/00/0000	JX0001 Tr. 56:18-23	Tr. 350:16; 351:15,16	N
CX0638	E-mail to Williams from Hansen: re: Whitening Info	5/20/2008	JX0001 Tr. 56:18-23		N
CX0639	Closed Session Minutes from NCBDE Meeting: Morrisville, NC April 1-2, 2005	4/1/2005	JX0001 Tr. 56:18-23		N
CX0640	Closed Session Minutes from NCBDE Meeting: Morrisville, NC May 5-7, 2005	5/5/2005	JX0001 Tr. 56:18-23		N
CX0641	Compilation of online teeth whitening advertisements from various websites	00/00/0000	JX0001 Tr. 56:18-23		N
CX0642	Letter to Joyce Osborn from Dr. Trelia Dutton: re: Commendation of product quality	11/9/2009	JX0001 Tr. 56:18-23	Tr. 658:11; 2696:25	N
CX0643	Compilation of BriteWhite Teeth Whitening Consent Forms	4/3/2006	JX0001 Tr. 56:18-23	Tr. 662:20; 663:21; 665:04;	N
CX0644	Compilation of Teeth Whitening Materials	2/10/2009	JX0001 Tr. 56:18-23		N
CX0645	North Carolina Board of Cosmetic Art Examiners Statutory Board Meeting: April 12, 2010	4/12/2010	JX0001 Tr. 56:18-23		N
CX0646	Letter to Mr. Goldman from Robert A. Eshelman: re: FDA stance on tooth whitening products	00/00/0000	JX0001 Tr. 56:18-23		N
CX0647	E-mail to Osnowitz from Feit: re: Teeth Whitening Inquiry	8/27/2009	JX0001 Tr. 56:18-23		N
CX0648	Letter to Jim Valentine from Melanie Brim: re: Michigan stance on teeth whitening businesses	6/3/2009	JX0001 Tr. 56:18-23		N
CX0649	Letter to Frank Recker from Lili C. Reitz: re: Ohio State Dental Board's stance on tooth whitening material sale	8/25/2006	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0650	Confidential Memorandum to Albert L. Partee, III, from Robert E. Cooper and Sue A. Sheldon: re: Validity of Tennessee Board of Dentistry Enforcement Actions with Respect to Teeth Whitening Activities	6/7/2010	JX0001 Tr. 56:18-23	Tr. 1924:11	N
CX0651	Letter to Sandra Rowe from Thomas J. Balistren: re: Opinion regarding teeth whitening	2/22/2005	JX0001 Tr. 56:18-23		N
CX0652	Letter to Margaret Hamburg, MD, from Greg Collier, PhD: re: Procter & Gamble's Comments on the November 20th, 2009 American Dental Association's Citizen Petition, Regulatory Treatment of Tooth Whitening Preparations	4/28/2010	JX0001 Tr. 56:18-23		N
CX0653	Expert Witness Report of Martin Giniger	11/26/2010	JX0001 Tr. 56:18-23	Tr. 77:19,24; 95:09; 1873:10	N
CX0654	Expert Witness Report of Professor John Kwoka	11/26/2010	JX0001 Tr. 56:18-23	Tr. 976:03; 978:01; 1873:10	N
CX0655	Letter to Terry Friddle from Margie Hughes: re: Response to complaint of practicing dentistry	3/3/2007	JX0001 Tr. 56:18-23		N
CX0656	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	8/21/2008	JX0001 Tr. 56:18-23		N
CX0657	Letter to Mrs. Goode from Nina Milano: re: Notification of ceasing of Bleach Bright offering	1/24/2009	JX0001 Tr. 56:18-23		N
CX0658	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	8/25/2008	JX0001 Tr. 56:18-23		N
CX0659	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	2/15/2008	JX0001 Tr. 56:18-23		N
CX0660	Memorandum to Members of the Board from Terry Friddle: re: Closed Investigative Files	5/11/2007	JX0001 Tr. 56:18-23		N
CX0661	Letter to the North Carolina State Board of Dental Examiners from Felicia Brown: re: Notification of Closure of Business	4/20/2009	JX0001 Tr. 56:18-23		N
CX0662	E-mail to Dempsey from Anderson: re: The Streets at Southpoint	11/16/2007	JX0001 Tr. 56:18-23		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0663	Patrick J. Anderson, CSM, CMD, Sr. General Manager - Business Card	00/00/0000	JX0001 Tr. 56:18-23		N
CX0664	Note to Self: Signed Lease for Dec. 08; Opened on Dec. 7, 2008	00/00/0000	JX0001 Tr. 56:18-23		N
CX0665	Letter to Bryan and Angela Wyant from Dana Bean: re: White Science at Carolina Place w/Attach: License Agreement between Carolina Place and White Science	12/14/2007	JX0001 Tr. 56:18-23	Tr. 871:12; 872:05; 947:13	N
CX0666	Letter to Bryan and Angela Wyant from Dana Bean: re: White Science at Carolina Place w/Attach: License Agreement between Carolina Place and White Science	4/17/2008	JX0001 Tr. 56:18-23		N
CX0667	Note to Self: Signed Lease for Jan 2008	00/00/0000	JX0001 Tr. 56:18-23		N
CX0668	License Agreement between Carolina Place and White Science	12/21/2007	JX0001 Tr. 56:18-23	Tr. 875:15,20,25	N
CX0669	Instructions for Use for Beyond Dental Take Home Product; available at http://www.beyonddent.com/main_en_us/contents/706/28.html	00/00/0000	JX0001 Tr. 56:18-23		N
CX0730	AAED Signed Declaration		Tr. 1272:24-1273:05	Tr. 1272:21,24	N
CX0731	ADA Signed Declaration		Tr. 1272:24-1273:05		N
CX0732	B/DH (Granson) Signed Declaration		Tr. 1272:24-1273:05		N
CX0733	BleachBright Signed Declaration		Tr. 1272:24-1273:05		N
CX0734	Discus Dental Signed Declaration		Tr. 1272:24-1273:05		N
CX0735	GGP Signed Declaration		Tr. 1272:24-1273:05		N
CX0736	Grater White Smile Signed Declaration		Tr. 1272:24-1273:05		N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0737	Johnson & Johnson Signed Declaration		Tr. 1272:24-1273:05		N
CX0738	NC Cosmetic Art Examiners Signed Declaration		Tr. 1272:24-1273:05		N
CX0739	NCDS Signed Declaration		Tr. 1272:24-1273:05		N
CX0740	Proctor & Gamble Signed Declarations (Collier, Landrigan & Sagal)		Tr. 1272:24-1273:05		N
CX0741	WhiteSmile USA Signed Declaration		Tr. 1272:24-1273:05		N
CX0742	Wyant Signed Declaration		Tr. 1272:24-1273:05		N
CX0743	BEKS Signed Declaration		Tr. 1272:24-1273:05	Tr. 1272:21,24	N
CX0800	BriteSmile YouTube video (remarked & entered into evidence as CX0825)	00/00/0000	See CX0825	Tr. 1267:09	N
CX0803	Giniger PowerPoint Demonstrative (remarked & entered into evidence as CX0824)		See CX0824	Tr. 421:22; 422:08	N
CX0805	Whiter Image Premium Prefilled Teeth Whitening Tray - Single Use		Tr. 237:19-20	Tr. 183:18,20,21; 192:09; 193:24; 236:25	N
CX0806	Whiter Image Teeth Whitening Gel Syringes - Premium Strength		Tr. 237:19-20	Tr. 190:02; 201:03,15,25; 202:17,19; 203:17,25; 236:25	N
CX0808	Crest 3D White Whitestrips with Advanced Seal No Slip Technology - Professional Effects		Tr. 237:19-20	Tr. 204:22; 236:25	N
CX0809	Dr. Marcus S. Tappan's White Smile Professional Teeth Whitening Kit 35% H2O2 - For Use by Dental Professionals Only		Tr. 237:19-20	Tr. 236:25	N
CX0810	Whiter Image Teeth Whitening Kit - Deluxe Home Edition		Tr. 237:19-20	Tr. 183:19; 193:03,08; 196:04; 203:15; 204:02; 236:25	N
CX0811	BY Lightnew LED Light		Tr. 237:19-20	Tr. 186:25; 236:25	N
CX0812	WhiteSmile USA Advanced Teeth Whitening System		Tr. 2894:25-2895:03-04	Tr. 521:01,05; 522:01; 2894:20,22	N

Trial Exhibit No.	Exhibit Title	Date	Admissibility	Trial Citation	In Camera
CX0813	iBrite Chairside LED Teeth Whitening Lamp		Tr. 2894:25-2895:05-06	Tr. 525:16; 2894:20,22	N
CX0814	E-mail to Nelson from Nelson: re: Fwd: Savvy Salon Letter to Joyce from Unknown: re: North Carolina correspondence	8/31/2010	Tr. 788:03-05	Tr. 786:22,24,25; 788:01	N
CX0815		00/00/0000	Tr. 779:18-20	Tr. 779:01,15	N
CX0817	SpaWhite WhiteScience Teeth Whitening Kit		Tr. 761:11-12	Tr. 757:23; 761:06; 1958:25; 1959:03	N
CX0817A	Information Sheet within the SpaWhite WhiteScience Teeth Whitening Kit (CX0817)		Tr. 761:13-14	Tr. 761:07; 847:03; 1952:15,18; 1959:04	N
CX0820	NBC Video re White Science Teeth Whitening - Entire 12 Minute Video		Tr. 755:20-21	Tr. 754:12; 755:12,13,14	N
CX0820A	NBC Video re White Science Teeth Whitening - Only 3 segments shown in court on 2/23/2011 (about 3 minutes long)		Tr. 755:22-23	Tr. 755:14	N
CX0821	E-mail to Psherman@J.J.org from George Nelson: re: George Nelson	4/28/2010	Tr. 843:12-14	Tr. 842:25; 853:12,13; 922:24	N
CX0822	Dr. Kwoka Demonstrative PowerPoint Presentation		Tr. 978:06-08	Tr. 978:03,04; 1704:09,22	N
CX0823	Designated Deposition Transcript of Dr. Van B. Haywood		Tr. 1529:19,22-23	Tr. 1527:18	N
CX0824	Giniger PowerPoint Demonstrative (originally used at trial as CX0803)		Tr. 1264:05,07-08	Tr. 1263:22	N
CX0825	BriteSmile YouTube video (originally used at trial as CX0800)		Tr. 1264:05,09-10	Tr. 1264:01; 1267:08,10	N
CX0826	Designated Deposition Transcript of Dr. David Baumer		Tr. 1529:19,24-25	Tr. 1527:16	N
CX0827	21 NCAC 14H - Sanitation		Tr. 1647:10-11	Tr. 1646:09; 1647:03; 2860:21,25	N
CX0828	21 NCAC 16J - Sanitation		Tr. 1647:12-13	Tr. 1643:14,21; 1647:06; 2860:21	N
			Tr. 2861:09,12-13		
			13		

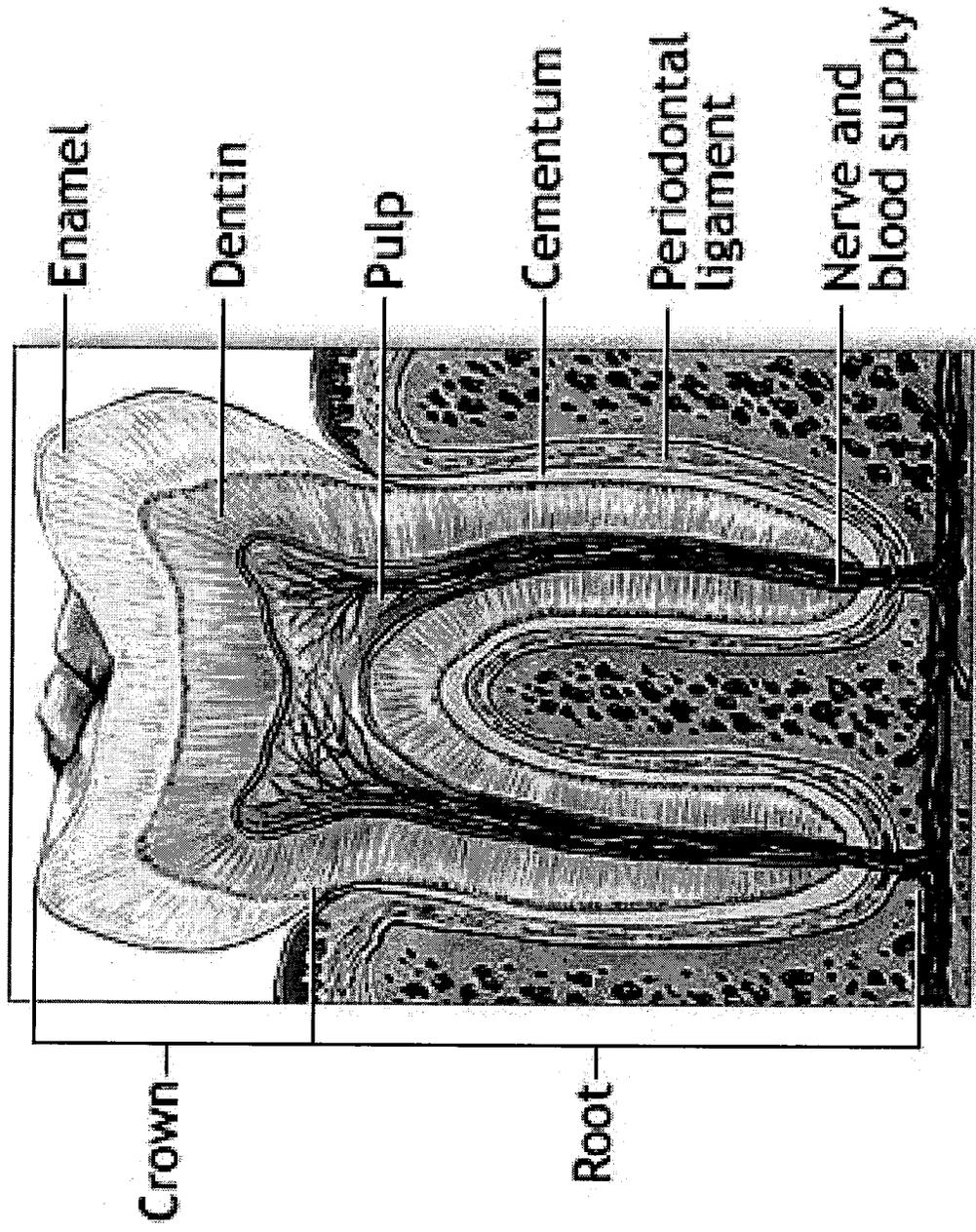


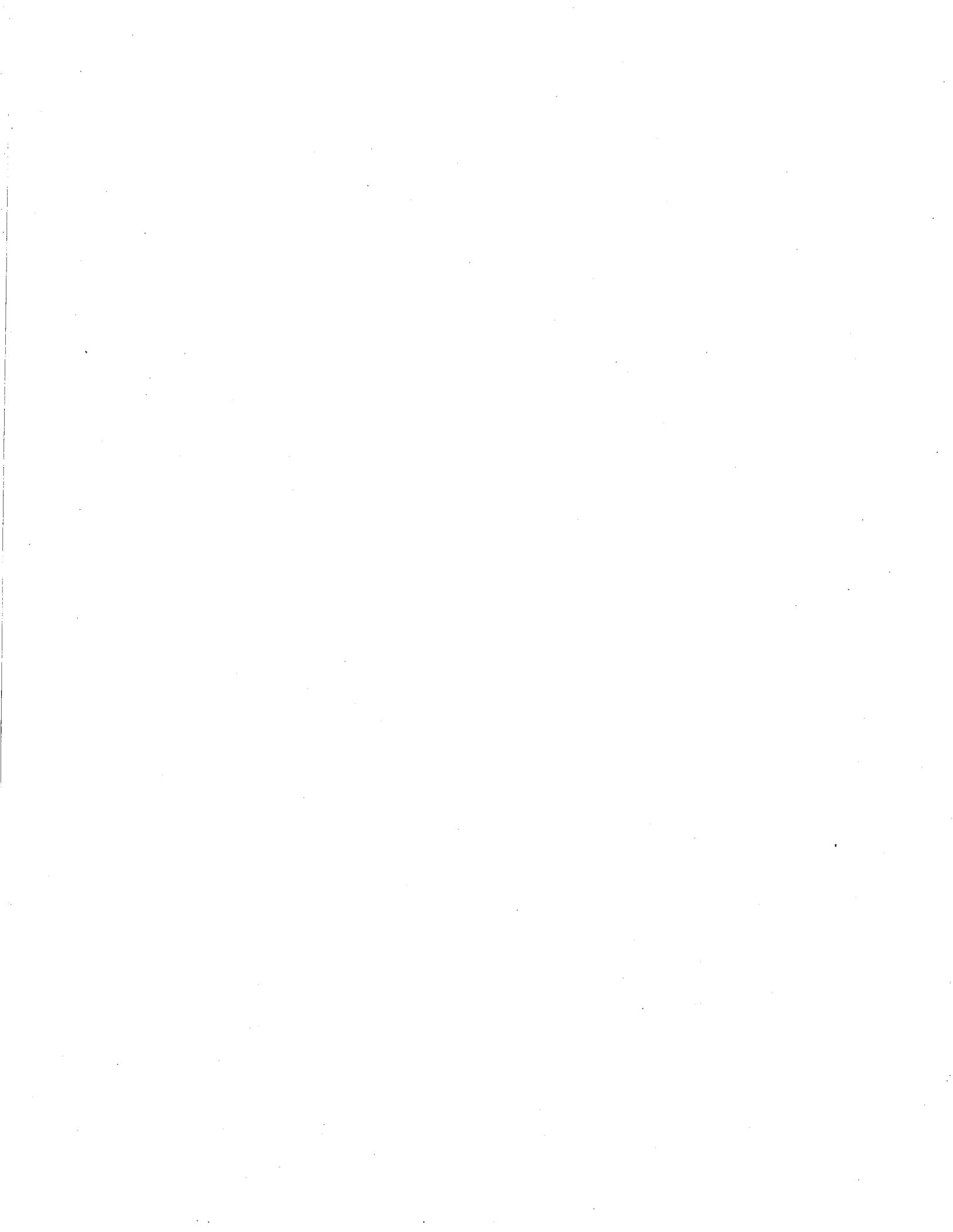
WITNESS INDEX



TAB 1

Anatomy of the Tooth





TAB 2

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#1

*Attorneys for Plaintiff
Colgate-Palmolive Company*

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE STANTON

----- x
COLGATE-PALMOLIVE COMPANY, : **03 CV 9348**
 : 03 Civ. _____
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 Plaintiff, :
 :
 v. : **COMPLAINT**
 :
 THE PROCTER & GAMBLE COMPANY, :
 :
 Defendant. :
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Plaintiff, Colgate-Palmolive Company ("**Colgate**"), by its attorneys, Proskauer Rose LLP, as and for its Complaint against defendant The Procter & Gamble Company ("**P&G**"), alleges as follows:

Nature of the Action

1. This is an action for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and for related violations of state law. The parties are the two leading manufacturers of over-the-counter "at-home" tooth whitening systems in the United States. This action arises out of a broad-based advertising campaign in which P&G makes materially false and misleading claims about the supposed superiority of P&G's tooth whitening products, CREST NIGHT EFFECTS ("**Night Effects**") and CREST WHITESTRIPS ("**Whitestrips**"), compared to

Colgate's competing products, COLGATE SIMPLY WHITE NIGHT ("**Simply White Night**") and COLGATE SIMPLY WHITE ("**Simply White**"), and about the efficacy of Colgate's products. Most recently P&G has begun airing two television commercials that are highly disparaging of Colgate's products, portraying them as ineffective and essentially worthless. Unless they are immediately enjoined, these commercials will cause Colgate substantial and irreparable harm, including a loss of consumer confidence, loss of goodwill and lost sales, and could well destroy Colgate's tooth whitening business.

2. P&G's campaign of false advertising targeted at Colgate's products is hardly an isolated occurrence. Indeed, this year alone, in three separate federal court cases, P&G has been found to have engaged in false advertising or had its advertisements enjoined as likely false. For example:

- A. According to news reports, in May 2003, following a trial, P&G was found liable by a federal court jury in the Southern District of New York for false advertising, was permanently enjoined from making the advertising claims sued upon and was ordered by the jury to pay Playtex Products, Inc. \$2.96 million in damages for lost profits based on P&G's false advertising of its Tampax Pearl brand.
- B. It was also reported that, in May 2003, the U.S. District Court for the Eastern District of Wisconsin granted a temporary restraining order sought by the Kimberly Clark Corporation, enjoining P&G from broadcasting a commercial disparaging Kimberly Clark's toilet training pants for children as a defective product.
- C. In late September 2003, P&G was preliminarily enjoined by this Court (Sprizzo, J.), which found in an action brought by Johnson & Johnson –

Merck that certain P&G advertising claims for its Prilosec heartburn medication were likely literally false.

3. In this action, Colgate seeks preliminary and permanent injunctive relief, corrective advertising, statutory and compensatory damages, and attorneys' fees. P&G's conduct here is egregious. Through its enormous investment of time, money and resources, Colgate has developed highly effective products that offer substantial advantages in comparison to P&G's products (including price and relative ease of use). P&G's false comparative advertising, particularly its most recent television commercials, threaten to irreparably impair, and potentially destroy, the value of Colgate's investment by falsely portraying Colgate's products as ineffective, in utter disregard for the truth, and by making claims about the extent of the difference in whitening efficacy between the tooth products that are simply bogus.

The Parties

4. Colgate is a Delaware corporation with its principal place of business at 300 Park Avenue, New York, New York 10022. Colgate is a publicly traded company that manufactures and sells numerous household and personal care products, including a line of oral care products marketed under the COLGATE brand name. Colgate's products, including Simply White and Simply White Night, are sold throughout the United States and in the State of New York, including this judicial district.

5. Upon information and belief, P&G is an Ohio corporation with its principal place of business located at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. P&G is engaged in the manufacture and sale of various consumer products, including Whitestrips and Night Effects. P&G's products, including Whitestrips and Night Effects, are sold throughout the United States and in the State of New York, including this judicial district.

Jurisdiction and Venue

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338 because the action arises under the Lanham Act, 15 U.S.C. § 1051, *et seq.*, and pursuant to 28 U.S.C. § 1332 because there is complete diversity between the parties and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

7. This Court has personal jurisdiction over P&G because P&G sells products, offers products for sale (including via the advertisements that are the subject of this lawsuit) and otherwise conducts business in the State of New York, including this judicial district.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) because a substantial part of the events giving rise to Colgate's claims occurred in this district and because P&G is deemed to be a resident of this district under 28 U.S.C. § 1391(c).

I. Background

9. Millions of Americans are interested in improving their personal appearance, and consumer products that can help them achieve this are often highly popular. One such type of product -- over-the-counter, "at-home" tooth whitening systems -- has merited substantial attention from the media and the general public. The popularity of "at home" tooth whitening systems is largely attributable to the fact that they offer consumers the ability to whiten their teeth on their own, in a relatively short amount of time, at a fraction of the cost of whitening treatments at a dentist's office. As a consequence of their effectiveness and relatively low cost, the market for "at home" tooth whiteners has grown significantly.

10. Launched by P&G in early 2000, Whitestrips are thin, flexible strips that conform to the shape of the teeth. The active whitening ingredient of Whitestrips is 6.0% hydrogen peroxide. Compared to the Colgate tooth whitening products at issue, Whitestrips are less convenient to use. Product label directions for Whitestrips instruct the user to apply the strips to the top and bottom

rows of teeth twice a day, for thirty minutes each time. To apply Whitestrips, the gel side of each strip must be carefully aligned with the gumline and placed against the teeth; the remainder of the strip must be gently folded over and placed behind the teeth to keep the strip in place. Although it is possible to apply strips to the top and bottom rows of teeth simultaneously, the use instructions included with Whitestrips caution that some people may find it easier to wear the top and bottom strips at separate times. Of course, if a consumer were to follow this instruction and apply the product twice a day, it would double the amount of time -- to two hours -- that the user would have to wear Whitestrips each day. (Or, if a consumer were to follow this instruction but only apply the product one time each day, that would double the number of days -- from 14 to 28 -- during which the consumer would use the product.) Consumers are directed not to apply Whitestrips immediately after brushing their teeth, and not to eat or drink anything while wearing Whitestrips.

11. As noted, Whitestrips is designed to be used for at least 14 days, as are P&G's Night Effects and Colgate's Simply White and Simply White Night. When first sold to the general public, Whitestrips had a manufacturer's suggested retail price ("MSRP") of \$40, significantly greater than Simply White's initial MSRP of \$14.99. Although P&G has reduced the MSRP for Whitestrips in an attempt to make it more price-competitive with Colgate's products, Whitestrips' current MSRP, approximately \$28, remains substantially greater than Simply White's MSRP, which is currently \$9.99.

12. Colgate's Simply White became available for sale to the general public in August, 2002. Simply White is easier and more convenient to use than Whitestrips -- consumers need only paint a transparent gel onto the teeth twice a day using an applicator included with the product.

13. Simply White contains 18% carbamide peroxide, a different whitening ingredient than the one used in Whitestrips. When carbamide peroxide comes into contact with water, it immediately dissociates into two components, urea and hydrogen peroxide. Carbamide peroxide is

a well known whitening ingredient that is widely used in the industry for professionally dispensed tooth whitening products.

14. Simply White is formulated so that hydrogen peroxide will be released and begin to absorb into the tooth surface immediately upon application, and will continue to be absorbed for approximately 5 minutes following application. This allows for the removal of undesirable color and stains from both the surface of the teeth and from within the tooth enamel. Simply White also contains two water-soluble polymers, Carbopol® and Polyox®, which enable the Simply White gel to adhere and efficiently spread onto the tooth surface while being applied and do not interfere with absorption of hydrogen peroxide into the tooth structure.

15. In March, 2003, Colgate introduced to the general public a second at-home tooth whitener, Simply White Night. This was the first at-home product specifically designed for nighttime use, and its rollout was designed to build upon consumer recognition of, and satisfaction with, Simply White. Simply White Night is designed specifically for use only once a day, and is meant to attract those consumers who do not have the time or inclination to use a tooth whitening product twice a day. Simply White Night contains hydrogen peroxide, the same active ingredient used in Whitestrips, but in a higher dose (8.75% compared to 6% for Whitestrips).

16. Hydrogen peroxide is fully water soluble and available in the water-based Simply White Night product. Thus, hydrogen peroxide, when delivered from Simply White Night, does not need to come into contact with any other substance (such as water or saliva) before absorbing into the teeth (i.e., it is "fully available" immediately upon application). Like Simply White, Simply White Night is an easy-to-use gel designed to be painted onto the teeth using the applicator that comes with the product. Also like Simply White, Simply White Night adheres to the teeth and begins to be absorbed into the tooth enamel virtually instantly upon application. As with Simply White, Simply White Night's immediate adherence and absorption is a function of the fact that it

includes the same two water-soluble polymers that facilitate adherence and efficient spreading of the gel while being applied and do not interfere with absorption of hydrogen peroxide into the tooth structure. A 14-day supply of Simply White Night currently has an MSRP of \$14.99.

17. P&G launched Night Effects in May, 2003. Night Effects is also designed to be used once a day, immediately before a user goes to sleep; thus, Night Effects and Simply White Night compete directly against each other. However, while Simply White Night releases peroxide so that it can absorb into the user's teeth immediately upon application, Night Effects does so only gradually.

18. Night Effects' gradual release of peroxide, as opposed to the Colgate products' immediate release of peroxide, is a result of two significant formulation differences. First, Night Effects' active ingredient is sodium percarbonate. Chemically, sodium percarbonate is a precursor to hydrogen peroxide, and in order for the peroxide in sodium percarbonate to be released, the sodium percarbonate must first come into contact with water. However, unlike Simply White, Night Effects does not include water as one of its ingredients. Thus, immediate absorption of peroxide is not possible with Night Effects. Furthermore, users are instructed to dry their teeth before applying Night Effects, further delaying the release of peroxide.

19. Second, Night Effects also does not contain the two polymers discussed above (or polymers of a similar nature) that enable the active ingredients in Simply White Night and Simply White to immediately adhere and efficiently spread onto the tooth surface. Rather, the polymers included in Night Effects create a hydrophobic, silicone-based, water repellent environment that, even after water (saliva) is introduced, allow only for a very slow, gradual release of peroxide onto the tooth surface. This means that the product must stay on the tooth surface for an extended period of time for there to be a release of peroxide.

20. Although like Simply White and Simply White Night, Night Effects is a gel that is painted onto the teeth, Night Effects is not as convenient to use as the Colgate products. Whereas each package of Simply White Night and Simply White comes with one bottle and one easy-to-use paint-on applicator, Night Effects comes with individual gel packets and individual disposable applicators; these packets and applicators must be removed from their wrappings by the user every time the product is applied. Moreover, unlike Simply White Night, which absorbs quickly and need not be removed by a user after it is applied, Night Effects must be brushed off of a user's teeth each morning. Also, users of Night Effects are instructed to dry their teeth with a tissue before applying the product and are told that they must hold their mouth open after application until the product dries.

21. In sum, Whitestrips is far more expensive than the Colgate products, and both Whitestrips and Night Effects are less convenient to use than the Colgate products. Upon information and belief, a primary purpose of the false and disparaging P&G advertising campaign described below is to persuade consumers to disregard the substantial price and convenience benefits that the Colgate products offer by falsely representing to consumers that the Colgate products are ineffective and that the P&G products provide vastly superior tooth whitening compared to the Colgate products.

II. The False P&G Advertisements

22. P&G advertises and sells Whitestrips and Night Effects to consumers in direct competition with Simply White and Simply White Night. P&G has disseminated various advertisements comparing its tooth whitening products with Colgate's, including television commercials, radio advertisements, print advertisements, promotional materials, point of purchase displays, and other media throughout the United States, including in this judicial district. P&G also maintains elaborate websites for each of its two whitening products, which can be viewed

throughout the United States, including this judicial district. These websites also contain advertising claims comparing P&G's tooth whitening products with those of Colgate. (Collectively, all of the comparative Night Effects advertisements and advertising claims described herein are referred to as the "**Night Effects Advertisements**," and all of the Whitestrips advertisements and advertising claims described herein are referred to as the "**Whitestrips Advertisements**.")

A. The False Night Effects Advertisements

1. The False Night Effects Television Commercials

23. On or about November 5, 2003, P&G began airing a television commercial comparing Night Effects to Simply White Night (the "**Washes Away Commercial**"; a "storyboard" of this commercial is attached as Exhibit 1). The Washes Away Commercial begins with an extraordinarily disparaging series of images of a product that P&G intended to conjure up, and that consumers will readily recognize as, Simply White Night. The Washes Away Commercial portrays Simply White Night as ineffective because "most of it washes away" quickly, and then informs consumers that because of this alleged fact, Night Effects is "clinically proven to whiten two times better" than Simply White Night. The "clinically proven" claim in the Washes Away Commercial is an "establishment" claim within the meaning of the Lanham Act.

24. The Washes Away Commercial begins with a shot of the packaging of a product identified as "Simple Gel Night." Inside this package, a bottle of "Simple Gel Night" is clearly visible. This packaging and product closely and unmistakably simulate the name and trade dress of, and were expressly intended by P&G to represent, Simply White Night. In light of the competitive marketplace, a significant percentage of consumers will understand, as P&G intended them to, that "Simple Gel Night" is Simply White Night.

25. As the Washes Away Commercial begins, and the "Simple Gel Night" product is depicted, an off-screen announcer states "Apply this nighttime tooth whitener" After these

words are spoken, a cascade of water gushes over the "Simple Gel Night" product packaging, causing the product packaging quickly and immediately to dissolve. As the "Simple Gel Night" packaging dissolves, the announcer completes his earlier statement ("Apply this nighttime tooth whitener") with the words, "and after five minutes, most of it washes away." At the same time, the sound of a what appears to be toilet flushing or water flowing quickly down a drain is clearly audible. By the time the announcer has concluded this statement, all that remains of the "Simple Gel Night" product are shards of the product packaging.

26. The camera then pans to a package of Night Effects, and a similar downpour of water streams over the Night Effects packaging. Unlike "Simple Gel Night," the Night Effects package is impervious to the water, and does not disintegrate in any respect.

27. During the time the Night Effects package is shown being inundated, the announcer proclaims: "But Crest Night Effects forms a liquid-strip coating that stays on teeth. No wonder it's clinically proven to whiten two times better."

28. After the Night Effects package is deluged, and for the remainder of the commercial, prominently displayed on screen below the package is the phrase "Whitens 2x better."

29. In addition to the Washing Away Commercial, P&G has previously broadcast other commercials claiming that Night Effects provides twice the whitening compared to Simply White Night and/or Simply White. Storyboards of these commercials are annexed as Exhibit 2.

2. The False Night Effects Radio Advertisement

30. P&G has also aired a radio advertisement that specifically refers to Simply White Night, and includes the following spoken text: "... unlike Colgate Simply White Night, it [Night Effects] forms a liquid strip coating that stays on my teeth all night, so in two weeks, it whitens twice as well" (the "Night Effects Radio Advertisement"; the text of which is Exhibit 3).

3. The False Night Effects Promotional Materials

31. Print materials that P&G caused to be distributed at a dental convention along with Night Effects packages stated that Night Effects provides “Twice the Whitening of the Competitive Paint-On Whitener” (the “**Night Effects Promotional Materials**,” attached as Exhibit 4). A footnote linked to this statement identifies the competing product as Simply White. A bar chart is shown, where the “Improvement in Whiteness” for Crest Night Effects is identified by the number 1.42, and the Simply White improvement is identified by the number 0.44. A second footnote indicates that these numbers refer to “negative Δb at 2 weeks,” based upon clinical testing.

32. Other Night Effects advertisements have also explicitly claimed that Night Effects is clinically proven to whiten teeth twice as well as Simply White. These advertisements (Exhibit 5) include the “**Night Effects Beverage Holder Advertisement**” (in the form of a cardboard strip that can be placed around a drinking cup, so that a hot beverage can be comfortably held), and a free-standing newspaper coupon insert (the “**Night Effects Coupon Insert**”).

4. The False Night Effects Print Advertisements

33. P&G has also caused several print advertisements for Night Effects to have been published that, like the advertisements discussed above, make express claims regarding Night Effects’ alleged superiority over competing Colgate teeth whiteners (collectively, the “**Night Effects Print Advertisements**,” annexed as Exhibit 6). One such Night Effects Print Advertisement (the “**Dream Whiter Advertisement**”) states that “Crest Night Effects provides twice the whitening of the competitive paint-on product.” A footnote specifically identifies the comparison as “Average whitening improvement over 14 nights versus Colgate Simply White.” The other Night Effects Print Advertisements contain materially-identical language.

5. The False Night Effects Website Advertisements

34. P&G's Night Effects website also includes express claims regarding Night Effects' alleged superiority over competing Colgate products (the "**Night Effects Website Advertisements**," relevant pages attached as Exhibit 7). Claims made in the Night Effects Website Advertisements include that Night Effects "is clinically proven to whiten two times better than Colgate Simply White Night!" (Exclamation in original). This statement is made on the "home" page of the website, and is therefore likely to be seen by anyone who visits the website.

6. The Night Effects Advertisements Are False In Numerous Respects

35. Each of the Night Effects Advertisements is literally false because it falsely represents that Night Effects whitens teeth "two times better" than the corresponding Colgate product (with this "two times" disparity often alleged, falsely, to be "clinically proven"). The Washes Away Commercial is also false in addition to the above reason because it falsely portrays Colgate's products as ineffective tooth whiteners that wash away before they work, and expressly links this claim with a "clinically proven two times better" claim, by falsely claiming that the former is the reason for the latter.

B. The False Whitestrips Advertisements

1. The False Whitestrips Television Commercials

36. Upon information and belief, on or about October 20, 2003, P&G began airing a television commercial that visually compares the allegedly extreme difference in whitening results that consumers will achieve using Whitestrips compared to the Colgate products (the "**Paint Tiles Commercial**") (storyboard at Exhibit 8).

37. The Paint Tiles Commercial begins with a close-up shot of an actress. Behind the actress, a viewer initially can see portions of four large tiles. The tiles on the viewer's right side of the screen appear whiter than the tiles on the left side of the screen.

38. As the actress says "If you ever had to choose a paint color . . .", the camera shot is pulled back, so that the actress is now shown to be standing in front of significantly more tiles, four vertical rows in total, stretching from below the speaker's waist to above her head. Again, the tiles on the viewer's right are noticeably whiter than the tiles on the viewer's left.

39. The actress continues her previous sentence by proclaiming, ". . . you know there are whites [she motions first to the relatively darker tiles on the viewer's left], and there are whites [the actress says "and there are whites" with notable emphasis in her voice, as she motions to the obviously whiter tiles on the viewer's right]." As the actress motions to these noticeably whiter tiles, the camera is pulled back even further, so that she is now shown standing in front of a massive wall of tiles that dwarf her. Again, the tiles on the viewer's left are significantly darker than the white tiles on the viewer's right. However, because more rows of tiles are now visible, the color disparity between the darker tiles on the viewer's left and the whiter tiles on the viewer's right is even greater than before.

40. A close up is then shown of the actress, who concludes her thought regarding different levels of white by stating "Same with teeth." At this point, the actress takes one of the relatively darker tiles off of the wall. As she shows this tile to the camera, she states: "Let's say this is how white your teeth are now." The actress then takes a second tile off the wall from a row that is evidently close in proximity to the first removed tile. She then holds the two tiles next to each other in her right hand, and allows the camera to focus upon them. The second tile is only barely whiter than the first tile, and the difference between them is imperceptible, or virtually so.

41. As the two tiles are shown together, the actress, referring to the second tile, states: "This is the white you get using this night time whitener," referring to the package she is holding in her left hand labeled "Simple Gel Night." Inside the package, the "Simple Gel Night" bottle is clearly visible. On the screen, during the entire time the "Simple Gel Night" product is shown, the

second tile, representing the non-existent or minimal whitening effect of this product, is continually shown.

42. The "Simple Gel Night" packaging and product unmistakably simulate, and were intended by P&G to represent, Simply White Night. In light of the competitive marketplace, a significant percentage of consumers will understand, as P&G intended them to, that "Simple Gel Night" is Simply White or Simply White Night.

43. After this close up, a wide shot of the entire tile wall is again shown. At this point, the viewer can now see that the two tiles previously removed from the wall were only separated by one vertical row, which accentuates the message that Simply White Night has, at most, only a minimal whitening effect. This message is further communicated by the fact that the tile wall now resembles (and upon information and belief was intended to resemble) a tooth shade guide of the sort that is present in dentist's offices. Ironically, P&G makes this visual reference to shade guides despite that the testing it relies upon as purported substantiation for its "five times" and "two times" better whitening claims do not involve, and bear no relation to, shade guide testing.

44. While this wide shot of the tile wall is still being shown, the actress becomes mobile for the first time in the commercial. She walks from the "dark side" of the tile wall where the first two tiles were taken to the "white side." Because of the camera shots used at this point, the actress's procession from one side of the wall to the other is extremely pronounced. Ultimately, the actress walks so far that she walks off the screen entirely. Finally, she reaches her "destination," at the side of the tile wall that contains the whitest tiles.

45. As the actress begins this exaggerated march, she exclaims: "Now compare it [the poor results you get with "Simple Gel Night"] to the white you get with [dramatic pause] Crest Whitestrips." As "Crest Whitestrips" is spoken, the actress stops walking, reaches down, and takes a white tile off the wall. She then places the Whitestrips tile in the hand that is holding the other

two tiles, so that the Whitestrips tile is in front of the other two. The color disparity between the Whitestrips tile and the previous two tiles is extremely stark. The third tile is dramatically whiter than the "Simple Gel Night" tile and the first tile. The camera holds this close-up of the three tiles, highlighting the dramatic color disparity.

46. The camera cuts to a person's hand reaching into a box of Whitestrips. As an individual Whitestrips is taken out of the box, the actress, referring to Whitestrips, exclaims: "They're clinically proven to whiten five times better." Then, a close-up of a mouth is shown, with the top row of teeth visible. At the point that "five times better" is spoken, the color of the teeth instantly and dramatically change, from a darker shade to a much whiter color. During the entire time that the close-up of the mouth is shown, the text "Whitens 5x better" is written on the screen in a prominent font, immediately below the teeth. Beneath this text, in a much smaller font, is the text "Average improvement over 14 days." P&G's claim that Whitestrips is "clinically proven to whiten five times better" is an establishment claim within the meaning of the Lanham Act.

47. The actress is then shown again. This time, she is holding two tiles, the Whitestrips white tile and what appears to be the darker "Simple Gel Night" tile. The camera is quite close to the actress, so the significant color difference between the two tiles is again conspicuous. Finally, the actress proclaims: "So your teeth will not only be white [she holds the relatively dark, "Simple Gel Night" tile towards the camera], they'll be white [she says these last words with emphasis as she holds the Whitestrips white tile towards the camera]."

48. In addition to the Paint Tiles Commercial, P&G has broadcast other television commercials and programs in other media that claim that Whitestrips provide five times better whitening compared to Simply White Night and/or Simply White. Storyboards of the other commercials are annexed as Exhibit 9.

49. In addition to the false U.S. commercials, P&G has begun to make false claims in foreign advertising that Whitestrips whiten multiple times better than a competitive paint-on tooth whitener that is a Colgate product. Upon information and belief, this advertising is orchestrated by P&G in the United States.

2. The False Whitestrips Print Advertisements

50. Several P&G print advertisements for Whitestrips have also made express claims that Whitestrips whiten five times better than Simply White (collectively, the “**Whitestrips Print Advertisements**”) (Exhibit 10). Certain of these print advertisements describe Whitestrips’ supposed five times better whitening to be “clinically proven.” The print advertisements attached as Exhibit 10 include free-standing coupon inserts.

3. The False Whitestrips Website Advertisements

51. P&G’s Whitestrips website (the “**Whitestrips Website Advertisement**,” attached as Exhibit 11) also claims that Crest Whitestrips are “clinically proven to whiten 5x better than the leading competitive paint-on whitener.” This statement is made on the “home” page of the Whitestrips website, and is therefore likely to be seen by anyone who visits the website.

4. The False Whitestrips Point Of Purchase Displays

52. Point of purchase displays for Whitestrips – in other words, in store advertising – also include the explicit “clinically proven,” “five times better” whitening claim (the “**Whitestrips Point of Purchase Displays**”) (Exhibit 12). The Whitestrips Point of Purchase Displays are very large and eye-catching.

5. The Whitestrips Advertisements Are False In Numerous Respects

53. Each of the Whitestrips Advertisements is literally false because it falsely represents that Whitestrips whiten teeth “five times better” than the corresponding Colgate product (with this “five times” disparity often alleged, falsely, to be “clinically proven”). The Paint Tiles Commercial

is false in addition to the above reason because it falsely represents, through the enormous difference in the colors of the tiles intended to represent the results of using Simply White Night and Whitestrips, that consumers can perceive a dramatic difference between the whitening ability of Whitestrips and Simply White Night when, in fact, there is not such a vast perceptible difference. Finally, select Whitestrips Advertisements are false because they falsely portray Colgate's products as ineffective tooth whiteners.

III. P&G's Fatally Flawed Method Of Claim Substantiation

54. Traditionally, tooth color change resulting from the use of whitening products has been measured by comparing pre- and post-treatment tooth color to a shade guide that consists of multiple panels of shades of white reflecting a wide range of tooth color. Both before and after a tooth whitening treatment, the color of the teeth is visually matched by an experienced dental evaluator to one of the panels of the shade guide to determine where the tooth color falls on the scale. The whitening effect of a treatment is assessed by the improvement of tooth color (measured by the number of shades improved) toward the whiter end of the shade guide.

55. Based upon articles published by P&G, P&G's 2X and 5X better whitening claims for Night Effects and Whitestrips compared to Simply White and Simply White Night (the "**Ratio Claims**") are not based on traditional shade guide tests, but instead consist of instrumental measurements of tooth color change (the "**Tests**"). The methodology used in P&G's Tests has not been adopted by the dental industry as an appropriate means of measuring the relative efficacy of tooth whitening products, or the extent of the difference in efficacy of such products. Upon information and belief, P&G's measurements of tooth color change are flawed and inaccurate. Moreover, even if the underlying measurements are accurate, they fail to substantiate the Ratio Claims, which claims are literally false.

56. According to published articles authored by P&G employees, P&G used a digital camera to photograph the teeth of the test participants both before and after the period of product use. P&G then used a software program to read from the digital camera RGB numbers for the photographed teeth. RGB (red, green and blue) numbers are generated by the camera system and represent the amount of red, green and blue light the camera captures.

57. Upon information and belief, in a process that requires several stages, each involving multiple complex equations, the software program then transforms these RGB numbers to a different set of numbers known as CIELAB values. CIELAB values were created by the International Commission on Illumination, an international body that developed a system to mathematically measure and represent color values. There are three CIELAB values: L^* , a^* and b^* , each of which can be positive or negative. Color is three-dimensional, and the L^* , a^* and b^* values allow a particular color to be represented by a set of positive or negative numerical values, which are plotted on a three-dimensional graph. The L^* value measures the lightness of an object; the greater the L^* value, the lighter the object appears, and conversely the greater the negative L^* value, the darker the object appears. The a^* value measures the degree of red or green reflected from an object. Generally, but not always, the more towards the positive end of the a^* axis an object lies, the redder the object appears, and the more towards the negative end of the a^* axis, the greener the object appears. The b^* value measures the degree of yellow or blue reflected from an object. Generally, but not always, the more towards the positive end of the b^* axis an object lies, the yellower the object appears, and the more towards the negative end of the b^* axis an object lies, the bluer it appears.

58. The CIELAB measurement system was designed to predict when two objects illuminated by the same light source would look to the eye to be the same color. It is widely accepted as a means of *matching* colored objects based on numerical values. However, the

CIELAB measurement system was not designed to determine, and cannot presently be used to measure, how much whiter one tooth is compared to another. Upon information and belief, P&G's Ratio Claims rely on CIELAB values for this latter purpose. Consequently, P&G's Tests are flawed, unreliable and do not substantiate the Ratio Claims. Thus, the Ratio Claims are literally false.

59. Upon information and belief, P&G's Ratio Claims are based on comparisons of the mean post-treatment changes of one or more CIELAB values achieved on the one hand by the P&G products and on the other hand by the Colgate products. Published articles by its employees report that the average post-treatment change achieved by Whitestrips users was at least five times larger than that achieved by Simply White, and that the average post-treatment change achieved by Night Effects was at least twice as large as that achieved by Simply White or Simply White Night.

60. P&G's Ratio Claims are premised on the accuracy of its CIELAB calculations. However, upon information and belief, P&G's methodology for calculating CIELAB values for teeth is inaccurate and imprecise. Thus, upon information and belief, the CIELAB values reported by P&G for the P&G products and the Colgate products, as well as the ratio of the post-treatment change in those values between the P&G products and the Colgate products, are materially incorrect and inaccurate.

61. Even if P&G's measurements are accurate, they would not substantiate P&G's false claims that Night Effects whitens 2X better than the Colgate products or that Whitestrips whitens 5X better than the Colgate products. P&G's Ratio Claims necessarily depend on the assumption that color space is linear, and that a 2 to 1 or 5 to 1 ratio between the post-treatment CIELAB value change achieved by the P&G products and that achieved by the Colgate products translate to two or five times greater perceived whitening. But, in fact, color space is not linear or perceptually

uniform. As a consequence, doubling or quintupling the change in CIELAB values does not result in double or quintuple the visible increase in the whiteness of teeth.

62. By way of example, the Richter scale, which measures the force of an earthquake, is also non-linear. In normal counting, the number 2 is twice as much as the number 1. But on the Richter Scale, an earthquake that has a magnitude of 2 is not twice as strong as a magnitude 1 earthquake; it is actually 10 times stronger. Moreover, the difference between a magnitude 1 and 2 earthquake is much smaller than the difference between a magnitude 7 and 8 earthquake, even though the numerical difference between each on the Richter Scale is the same, 1.

63. With regard to the products in question, even if it were true, for example, that the post-treatment change in CIELAB numerical values for Night Effects users was twice that for Simply White or Simply White Night users, this would not mean that the visible whitening effect of Night Effects was twice that of Simply White or Simply White Night. Indeed, in the portion of color space in which tooth color lies, no whitening difference between Night Effects and the Colgate products would likely be perceptible at all, let alone at a 2 to 1 ratio P&G claims in the Night Effects Advertisements.

64. The literal falsity of the Ratio Claims is confirmed by independent testing sponsored by Colgate, which showed no statistically significant or noticeable difference in whitening effect between Night Effects and Simply White Night, as determined by dental evaluators experienced in shade guide testing.

IV. The Claims Made In The Night Effects Advertisements, Including Those Made In The Washes Away Commercial, Are False

65. The Washes Away Commercial is false. The Washes Away Commercial intentionally and unambiguously misleads, confuses and deceives consumers, through words and visual images, and through a combination of words and visual images, into believing that Night Effects is clinically proven to provide twice the whitening compared to Simply White and/or

Simply White Night. This message is materially and literally false because P&G's Tests do not clinically prove that Night Effects provides twice the visible teeth whitening compared to either Simply White or Simply White Night.

66. The Washes Away Commercial further intentionally and unambiguously misleads, confuses and deceives consumers, through words and visual images, and through a combination of words and visual images, into believing that it is directly because Simply White Night and/or Simply White quickly and easily wash off of a user's teeth following application that Night Effects whitens twice as well as Simply White and/or Simply White Night. This message is materially false and deceptive, because Simply White and Simply White Night are highly effective: they do not quickly and easily wash off a user's teeth before working.

67. The Washes Away Commercial further intentionally and unambiguously misleads, confuses and deceives consumers, through words and visual images, and through a combination of words and visual images, into believing that because Simply White and/or Simply White Night quickly and easily wash off of a user's teeth following application, the Colgate products thus are ineffective in whitening teeth. This message is materially false and deceptive because Simply White and Simply White Night are highly effective, begin working immediately upon application and deliver the necessary amount of hydrogen peroxide within 5 minutes of application to effectively remove stains from and whiten teeth. The fact that a portion of the Simply White Night gel that has not already been absorbed into the teeth within five minutes may thereafter wash away when it mixes with saliva does not prevent Simply White Night from whitening teeth effectively, contrary to the clear but false image of the Washes Away Commercial.

68. Each of the remaining Night Effects Advertisements contains one or more of the false elements discussed above with respect to the Washes Away Commercial, and for the same reasons are also false.

69. As a direct and proximate result of P&G's false and misleading claims in the Night Effects Advertisements, Colgate is suffering and will continue to suffer irreparable injury, for which there is no adequate remedy at law.

70. Further, P&G's Night Effects Advertisements are likely to have caused and will likely continue to cause Colgate to suffer substantial damages, including lost sales, lost profits and loss of good will.

71. Upon information and belief, the Night Effects Advertisements were and are intended to mislead and deceive purchasers into purchasing P&G's Night Effects instead of Colgate's Simply White or Simply White Night.

72. Upon information and belief, the foregoing actions of P&G were undertaken wilfully and wantonly, and with a conscious disregard for Colgate's rights.

73. The foregoing acts have occurred in, or in a manner affecting, interstate commerce.

V. The Claims Made in the Whitestrips Advertisements, Including Those Made in the Paint Tiles Commercial, are False

74. The Paint Tiles Commercial intentionally and unambiguously misleads, confuses and deceives consumers, through words and visual images, and through a combination of words and visual images, into believing that Whitestrips is clinically proven to whiten teeth five times better than Simply White and/or Simply White Night. This message is materially and literally false and deceptive because P&G's Tests do not prove that Whitestrips provides five times better visible whitening compared to Simply White or Simply White Night, and Whitestrips does not in fact provide five times better visible whitening than Simply White or Simply White Night.

75. The Paint Tiles Commercial further intentionally and unambiguously misleads, confuses and deceives consumers, through words and visual images, and through a combination of words and visual images, as to the ineffectiveness of Simply White Night and/or Simply White with respect to whitening teeth. In particular, the Paint Tiles Commercial's visual depiction of the

degree of whitening achieved by the use of Simply White Night and/or Simply White, through the use of similarly colored tiles, is extremely understated and false. In fact, Simply White and Simply White Night are very effective teeth whiteners, and the whitening that is achieved through the use of Simply White Night and Simply White is much more pronounced than what is depicted in the Paint Tiles Commercial.

76. The Paint Tiles Commercial further intentionally and unambiguously misleads, confuses and deceives consumers, through words and visual images, and through a combination of words and visual images, as to the extent of Whitestrips' ability to whiten teeth. In particular, the Commercial's visual depiction of the degree of whitening achieved by the use of Whitestrips, through the use of differently colored tiles, is exaggerated and false. In fact, any whitening that does occur based upon the use of Whitestrips does not match the exaggerated level depicted in the Paint Tiles Commercial.

77. Each of the remaining Whitestrips Advertisements contains one or more of the false elements discussed above with respect to the Paint Tiles Commercial, and for the same reasons are also false.

78. As a direct and proximate result of P&G's false and misleading claims in the Whitestrips Advertisements, Colgate is suffering and will continue to suffer irreparable injury, for which there is no adequate remedy at law.

79. Further, P&G's Whitestrips Advertisements are likely to have caused and will likely to continue to cause Colgate to suffer substantial damages, including lost sales, lost profits and loss of good will.

80. Upon information and belief, P&G's Whitestrips Advertisements were and are intended to mislead and deceive purchasers into purchasing P&G's Whitestrips instead of Colgate's Simply White or Simply White Night.

81. Upon information and belief, the foregoing actions of P&G were undertaken wilfully and wantonly, and with a conscious disregard for Colgate's rights.

82. The foregoing acts have occurred in, or in a manner affecting, interstate commerce.

First Claim For Relief
(Violation of the Lanham Act)

83. Colgate repeats and realleges each and every allegation contained in paragraphs 1 through 82 as if fully set forth herein.

84. The foregoing acts of P&G constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

85. This is an exceptional case within the meaning of Section 35 of the Lanham Act, 15 U.S.C. § 1117.

Second Claim For Relief
(Violation of the New York General Business Law)

86. Colgate repeats and realleges each and every allegation contained in paragraphs 1 through 85 as if fully set forth herein.

87. The foregoing acts of P&G constitute deceptive acts and practices and false advertising in violation of Sections 349 and 350 of the New York General Business Law.

Third Claim For Relief
(Common Law Unfair Competition)

88. Colgate repeats and realleges each and every allegation contained in paragraphs 1 through 87 as if fully set forth herein.

89. The foregoing acts of P&G constitute unfair competition under the common law of New York.

Prayer For Relief

WHEREFORE, Colgate prays for judgment:

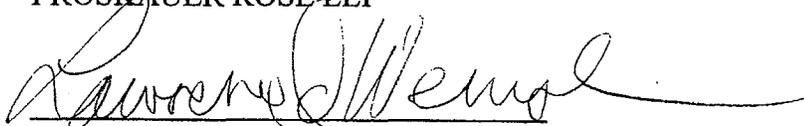
- A. Preliminarily and/or permanently enjoining P&G, its officers, agents, servants and employees, and all persons in active concert and participation with them, from further dissemination of the Night Effects Advertisements and Whitestrips Advertisements;
- B. Preliminarily and/or permanently enjoining P&G, its officers, agents, servants and employees, and all persons in active concert and participation with them, from disseminating (i) the claim that Colgate tooth whiteners are ineffective because they wash away before they work, (ii) the Ratio Claims; (iii) a claim that expressly links (i) and (ii) by claiming that the former is the reason for the latter;
- C. Enjoining P&G, its officers, agents, servants and employees, and all persons in active concert and participation with them, from making any numerical or ratio-related claims concerning the relative tooth whitening ability of two or more products based on differences in CIELAB values until such time as P&G demonstrates to the Court that such a methodology has been generally accepted within the oral care community as a basis for measuring the relative tooth whitening ability and the extent of the difference in tooth whitening ability of two or more products;
- D. Requiring P&G to disseminate among consumers corrective advertising to dispel the false and deceptive messages contained in the Night Effects Advertisements and Whitestrips Advertisements;
- E. Requiring P&G to recall and withdraw all tangible copies of the Night Effects Advertisements and Whitestrips Advertisements, and any other

advertisements, that make the product claims, or similar claims,
complained of herein.

- F. Directing that P&G account to Colgate for all gains, profits and advantages derived from P&G's wrongful acts above described;
- G. Directing that P&G pay Colgate such damages as Colgate has sustained as a consequence of P&G's wrongful acts complained of herein, the precise amount to be determined at trial;
- H. Directing that the aforesaid amounts be multiplied or otherwise enhanced as authorized by law;
- I. Directing that P&G pay Colgate the costs of this action and its reasonable attorneys' fees herein; and
- J. Granting Colgate such other and further relief as the Court may deem just and proper.

Dated: New York, New York
November 24, 2003

PROSKAUER ROSE LLP

By: 

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Colgate-Palmolive Company

Exhibit

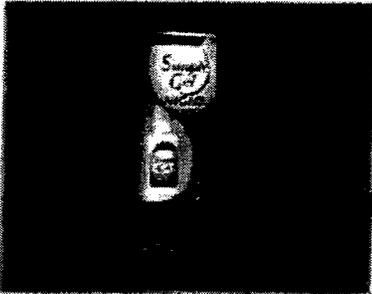
1



vms

PRODUCT Crest Night Effects
MARKET Network
PROGRAM Becker
CODE # 031100963
TITLE Simple Gel Box Washes Away

LENGTH 15
STATION ABC
DATE 11/05/2003
TIME 01:04 PM



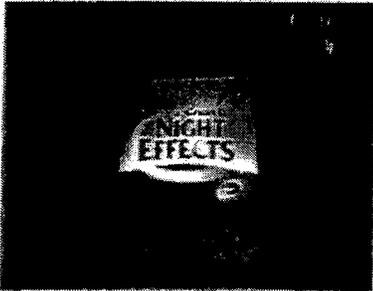
(MUSIC IN) MALE ANNCR: Apply this nighttime tooth whitener,



(SFX: WATER IN & OUT) and after five minutes



(SFX: WATER IN & OUT) most of it washes away.



But Crest Night Effects



(SFX: WATER IN & OUT) forms a liquid-strip coating that stays on teeth.



No wonder it's clinically proven to whiten 2X better. (MUSIC OUT)

VIDEO ALSO AVAILABLE

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330 West 42nd Street, New York, NY 10036 T 212 736 2010

Exhibit

2



vms

PRODUCT Crest Night Effects
MARKET Network
PROGRAM Country Music Awards
CODE # 030506288
TITLE Don't Waste Nights/Drop Coming Soon,Camp

LENGTH 30
STATION CBS
DATE 05/21/2003
TIME 10:26 PM
REV OF # 030405560



(MUSIC IN) (SFX: PEOPLE SNORING)



(MUSIC/SFX)



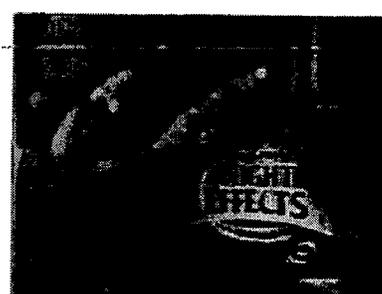
FEMALE ANNCR: These people aren't



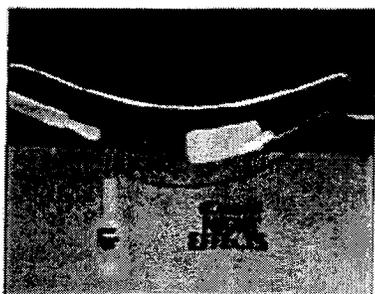
just sleeping, they're whitening their teeth



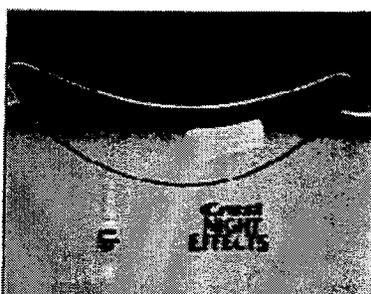
a better way (SFX: WOMAN SLAPS
MAN'S FACE IN & OUT)



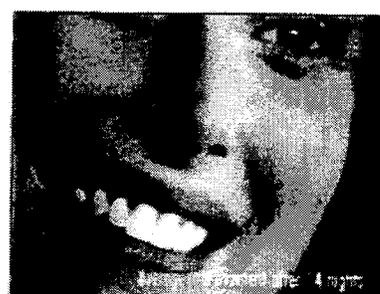
with new Crest Night Effects. Crest
Night Effects



forms a liquid strip coating that stays on
teeth all night



while most of that other paint on whiter
washes off.



It's clinically proven to give you twice
the whitening. Why waste the night



just sleeping? (SFX OUT)



Spend it creating a whiter smile.



Sleep your way to a whiter smile.
Crest Night Effects. Sleep your way to a
whiter smile. (MUSIC OUT)

VIDEO ALSO AVAILABLE

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220 West 170th Street, New York, NY 10038 T: 212 758 2010



vms

PRODUCT Crest Night Effects
 MARKET Network
 PROGRAM Guiding Light
 CODE # 030405560
 TITLE Coming Soon So You Don't Waste Nights

LENGTH 30
 STATION CBS
 DATE 04/21/2003
 TIME 10:56 AM



(MUSIC IN) (SFX: SNORING IN BKGD)



FEMALE ANNCR: It will soon be here,



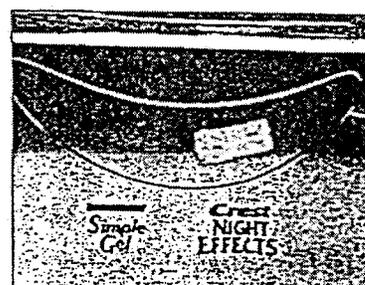
a product that works while you sleep, whitening your teeth a new and better way.



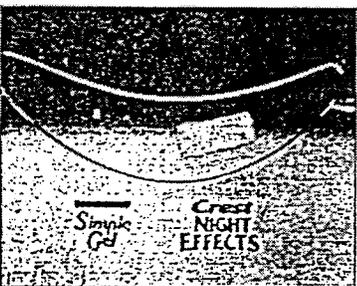
(MUSIC)



It's called Crest Night Effects.



It forms a liquid-strip coating that stays on teeth all night,



while most of that other paint-on whitener washes off,



so you'll get twice the whitening.



You'll never again waste a perfectly good night--



just sleeping. (SFX: OUT)



You'll spend it creating a whiter smile.



Coming soon.
New Crest Night Effects. (MUSIC OUT)

VIDEO ALSO AVAILABLE

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 330 West 42nd Street, New York, NY 10018 T: 212 916 2010

Exhibit

3



vms

TRANSCRIPT

DATE: AUGUST 11, 2003
TIME: 6:38 AM
STATION: WKLH-FM
LOCATION: MILWAUKEE
PRODUCT: CREST NIGHT EFFECTS
LENGTH: :60
CODE: 030803546

TITLE: MRS. C. HAS NEW NIGHT TIME LOVE

MRS. C.: You can call me Mrs. C. I prefer not to reveal my full name. I have been happily married for 10 years, but recently, I've found a new night time love. And every morning, I wake up with a smile on my face. And that smile gets brighter every day. That's because I've been going to bed with-- Crest Night Effects. They say unlike Colgate Simply White Night, it forms a liquid strip coating that stays on my teeth all night, so in two weeks, it whitens twice as well. My teeth became so white, my husband became suspicious. He confronted me. I couldn't lie. I told him about Crest Night Effects. Naturally, he was jealous. My teeth were so white; his were so yellow. So, he started using Crest Night Effects, and his teeth got whiter, too. Which just shows you, choose the whitener that performs better in bed, and in the morning, you'll only have one regret: that you didn't discover it sooner.

MALE ANNCR: Crest Night Effects. Sleep your way to a whiter smile.

###

Exhibit

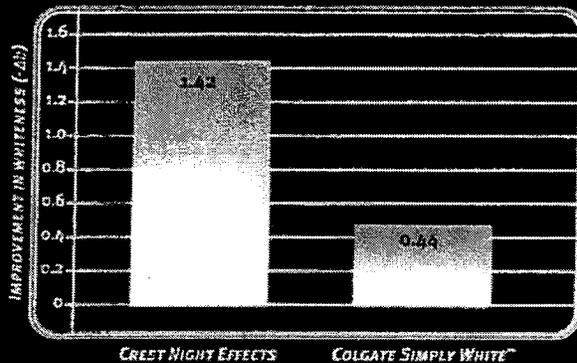
4

Crest NIGHT EFFECTS™

NIGHTTIME WHITENING SYSTEM

TWICE THE WHITENING OF THE COMPETITIVE PAINT-ON WHITENER*†‡

**CLINICALLY SIGNIFICANT IMPROVEMENT
IN WHITENESS VS BASELINE AFTER
2 WEEKS' USE†‡**



In another study, Crest Night Effects significantly improved tooth brightness (a positive ΔL) vs placebo

Reference: 1. Data on file, Procter & Gamble.

* Colgate Simply White™.

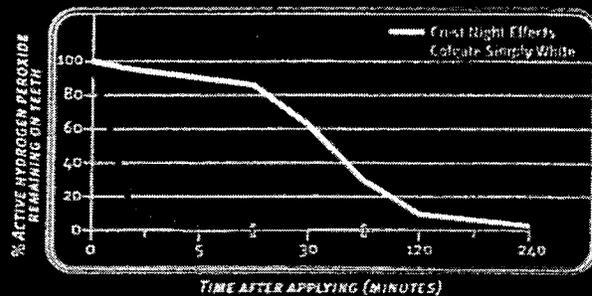
† Preliminary results of whitening improvement in clinical testing.

‡ As measured by negative Δb at 2 weeks.

§ Based on separate single-product clinical studies.

Colgate Simply White is a trademark of Colgate-Palmolive Company.

**CREST® NIGHT EFFECTS™
DELIVERS HYDROGEN PEROXIDE
SUBSTANTIVITY OVER TIME§‡**



In clinical studies, the hydrogen peroxide from Crest Night Effects remained available for hours. The hydrogen peroxide from the competitive paint-on whitener* was virtually gone after only 5 minutes§‡

Crest Night Effects is easily removed with brushing

Crest NIGHT EFFECTS
NIGHTTIME WHITENING SYSTEM

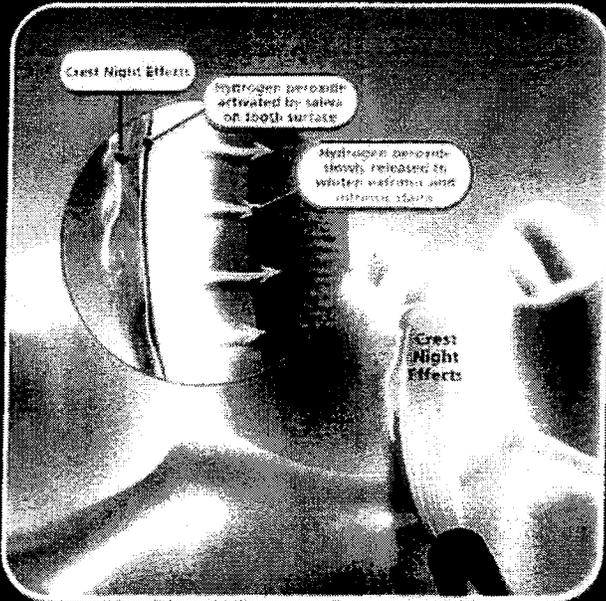
A WHITER SMILE WHILE THEY SLEEP

Crest NIGHT EFFECTS™

NIGHTTIME WHITENING SYSTEM

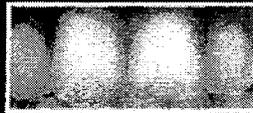
RECOMMEND THE ONLY WHITENING SYSTEM WITH LIQUIDSTRIP™ TECHNOLOGY

**THE PATENTED FILM-FORMING TECHNOLOGY
HOLDS ONTO THE TOOTH SURFACE AND
GRADUALLY RELEASES HYDROGEN PEROXIDE
TO WHITEN TEETH WHILE PATIENTS SLEEP**



**VISIBLE COLOR IMPROVEMENT AFTER
14 NIGHTS OF CREST NIGHT EFFECTS**

BEFORE



AFTER



**RECOMMEND NEW CREST NIGHT EFFECTS—
WHITENING THAT IS PATIENT FRIENDLY**

Safe on enamel

Priced to appeal to many patients—
\$14.99 for a 14-night supply

© 2003 P&G

PGC-1319

8153-4003

OKIT03125R4

Exhibit
5

Crest®

NIGHT EFFECTS

NIGHTTIME WHITENING SYSTEM

WAKE UP TO A WHITER SMILE.

CLINICALLY PROVEN -
TWICE THE WHITENING VERSUS THE
COMPETITIVE PAINT-ON WHITENER,**
WHILE YOU SLEEP.

* After 14 Nights,
**Average Improvement
over 14 nights versus
Colgate Simply White™,
Colgate Simply White
is a registered
trademark of the
Colgate-Palmolive
Company.

CAUTION! HOT BEVERAGE

To Advertise Call: 1.877.479.7777 www.britevision.com Patent # 5,425,497



0M1803200

Crest
NIGHT
EFFECTS

NIGHTTIME WHITENING SYSTEM

**TAKE YOUR COFFEE BLACK.
MAKE YOUR TEETH WHITE.**

**CLINICALLY PROVEN —
TWICE THE WHITENING VERSUS THE
COMPETITIVE PAINT-ON WHITENER*,
WHILE YOU SLEEP.**

To Advantages Call 1-877-497-1171 www.colgate.com powered by a3s.net

CAUTION! HOT BEVERAGE

*Average improvement
over 14 nights versus
Colgate Simply White™
Colgate Simply White
is a registered
trademark of the
Colgate-Palmolive
Company.



DM1503200

Exhibit

6



CLINICALLY PROVEN-
**TWICE THE
 WHITENING**
 VERSUS THE
 COMPETITIVE PAINT-ON
 WHITENER*

Can't find the time to whiten your smile? You don't have to. Crest Night Effects is clinically proven to whiten better versus the competitive paint-on whitener.*

The unique LiquidStrip™ coating stays on your teeth overnight to whiten while you sleep.

www.crestnighteffects.com

Crest NIGHT EFFECTS™

NIGHTTIME WHITENING SYSTEM

* Average improvement over 14 nights versus Colgate Simply White, a registered trademark of the Colgate-Palmolive Company.

©2003 P&G
 OCOU03208

EXPIRES 12/31/03

SAVE
\$5.00

ON ONE CREST NIGHT EFFECTS NIGHTTIME WHITENING SYSTEM

Twice the Whitening Versus The Competitive Paint-On Whitener*



CONSUMER: This offer is good only on the purchase of one Crest Night Effects Nighttime Whitening System. Limit one redemption per household. Offer good while supplies last. See store for details. ©2003 P&G. OCOU03208

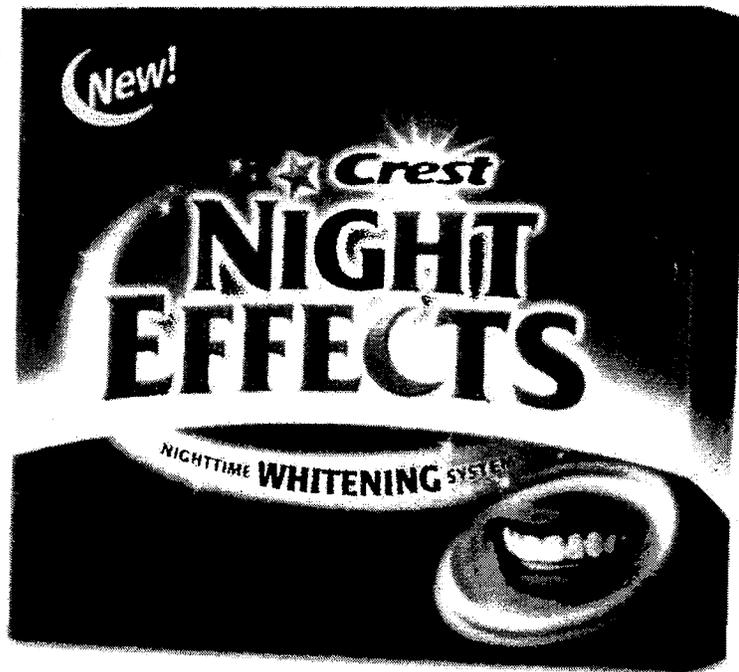


Innovation from Crest continues with a new product that whitens teeth while you sleep.

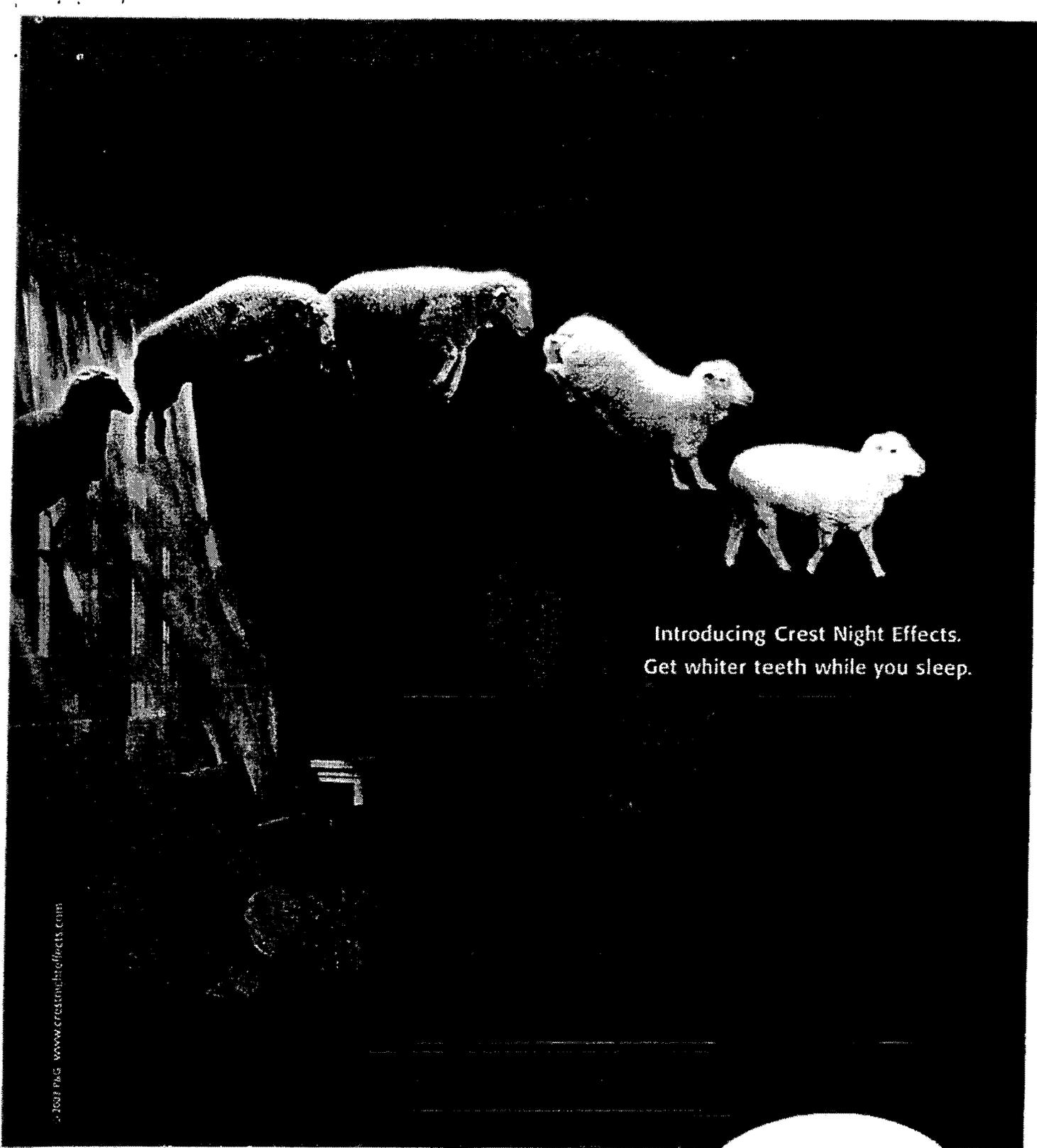
Introducing a new nighttime tooth whitening system from Crest: Crest Night Effects.

Introducing a new nighttime tooth whitening system from Crest: Crest Night Effects! The first overnight tooth whitener of its kind, Crest Night Effects provides twice the whitening of the competitive paint-on product* because the unique LiquidStrip Technology¹ forms a coating that stays on teeth overnight to whiten while you sleep. Simply apply Crest Night Effects before bedtime and let the product work to remove stains and loosen stain-causing build-up. In the morning, brush the LiquidStrip coating and stains away. After just two nights, you'll notice a clean, smooth feeling on the surface of the teeth that tells you the product is working and after just 14 nights, you'll be rewarded with a whiter, brighter smile. Why not whiten while you sleep? Crest Night Effects is available for a suggested retail price of \$14.99 wherever Crest toothpaste is sold.

*Average whitening improvement over 14 nights versus Colgate Simply White. Colgate Simply White is a registered trademark of the Colgate-Palmolive Company.



For more information, visit www.whitestrips.com and www.crestnighteffects.com



Introducing Crest Night Effects.
Get whiter teeth while you sleep.

© 2001 P&G www.crestnighteffects.com

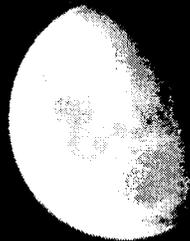
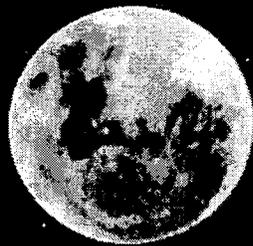
All you need is 14 nights. And new Crest[®] Night Effects™. Apply it with its handy little brush and a LiquidStrip™ coating forms on your teeth immediately. And it stays on, whitening while you sleep.

Unlike that other paint-on whitener,* Crest Night Effects won't wash away in minutes. So it's 2 times as effective. It even leaves your teeth feeling cleaner and smoother after only 2 nights. Now that's a lot of reasons to try it. But who's counting?



*Average improvement over 14 nights versus Colgate Simply White™. Colgate Simply White is a registered trademark of the Colgate-Palmolive Company.

Sleep your way to a whiter smile.



Introducing Crest Night Effects.
Get whiter teeth while you sleep.

© 2007 P&G www.crestnighteffects.com

All you need is 14 nights. And new Crest[®] Night Effects[™]. Apply it with its handy little brush. A LiquidStrip[™] coating forms on your teeth immediately. And it stays on, whitening while you sleep.

Unlike that paint-on, Crest Night Effects won't wash away in minutes. So it's twice as effective. It even leaves your teeth feeling cleaner and smoother after only two nights. Which means we're not just promising the moon, we're delivering.



Sleep your way to a whiter smile.

Exhibit

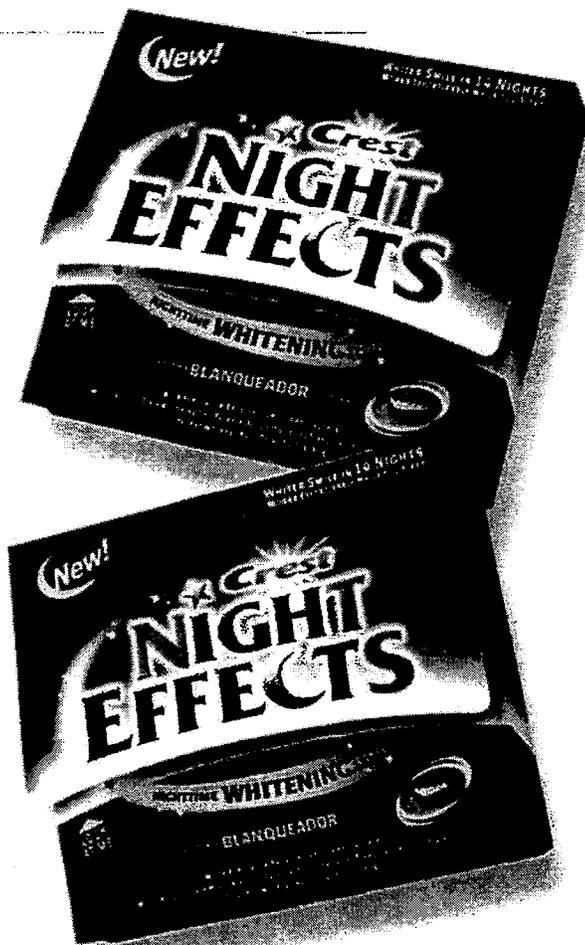
7

WHITE HOT SUMMER

White is in for summer. In fact, you can't wear too much white this season, even if you're dressed in it from head to toe. A bright, white smile is always in style, too. If your teeth are a little lackluster, lighten them up with an overnight tooth whitener. The whitener will work its magic while you sleep, so you have time to concentrate on the million other things you take care of every day.

CREST NIGHT EFFECTS

Get your smile white hot for summer with the help of Crest Night Effects—a new nighttime tooth whitener from Crest. Spend the days safely working on your tan and the nights working on your smile. Crest Night Effects works while you sleep to remove stains and loosen stain-causing build-up. The unique LiquidStrip Technology™ provides twice the whitening of the competition, forming a LiquidStrip™ coating that stays on the teeth overnight. In the morning, simply brush the LiquidStrip coating and stains away. After 14 nights of use, you'll be rewarded with a whiter, brighter smile.



summer essential tip

SAY CHEESE. Everyone looks better with a little color in the summer—and you'll really glow when your teeth are their whitest. So before a neighborhood barbecue or cocktail party, stay away from food and drinks that may stain your teeth, like coffee, tea, colored soft drinks and even strawberries—because it's always better to flash a dazzling smile when it's pearly-white.

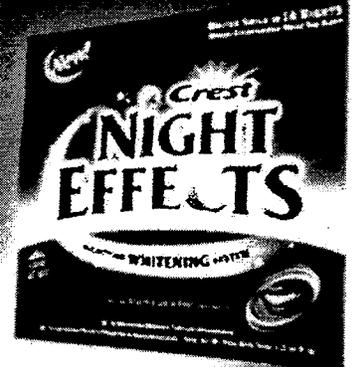
Crest **NIGHT EFFECTS**

Crest NIGHT EFFECTS

NIGHTTIME WHITENING SYSTEM



SLEEP YOUR WAY
TO A WHITER SMILE.



ABOUT CREST® NIGHT EFFECTS™

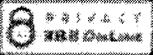
WHY IT'S SO CONVENIENT

WHY IT'S SO EFFECTIVE

ASK CREST® NIGHT EFFECTS™

SPECIAL OFFERS

DISCOVER HOW CREST® NIGHT EFFECTS™, WITH OUR UNIQUE LIQUIDSTRIP TECHNOLOGY™ IS CLINICALLY PROVEN TO WHITEN TWO TIMES BETTER THAN COLGATE SIMPLY WHITE NIGHT!®* YOU'LL GET A NOTICEABLY WHITER SMILE — WHILE YOU SLEEP OVER 14 NIGHTS — LIKE A DREAM COME TRUE.



Save on
Crest Night Effects

Share a Smile.
Tell your friends about
Crest Night Effects

A whiter smile
guaranteed.
Find out more



Visit Crest

Crest® Whitestrips™

U.S. Dental Professionals

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* Average improvement over 14 nights. Colgate® Simply White Night® is a registered trademark of the Colgate-Palmolive Company.

Crest NIGHT EFFECTS

NIGHTTIME WHITENING SYSTEM

HOME

ABOUT CREST® NIGHT EFFECTS™

WHY IT'S SO CONVENIENT

WHY IT'S SO EFFECTIVE

ASK CREST® NIGHT EFFECTS™

SPECIAL OFFERS

WHY IT'S SO EFFECTIVE

Crest Night Effects is clinically proven to whiten two times better than Colgate Simply White Night!*. It even works on tough, everyday stains, including coffee and tobacco. Why is Crest Night Effects so effective? The secret is our patented LiquidStrip Technology™ coating that stays on your teeth overnight. It whitens while you sleep.

The Color of Your Teeth

When you look at your teeth, the color you see is more than just the color of the surface. Because the top enamel layer is translucent, the color beneath is also visible. And since the things we eat and drink contain coloring agents that actually soak into our teeth, the layer beneath the surface of the enamel becomes stained, too. Juice, coffee, tar and tobacco for those who smoke, all contribute to making your teeth look yellow and dingy.

Whitening Dilemmas

Whitening toothpastes only clean the surface of your teeth and don't have any way to actually whiten the stains below the surface of the enamel. Special whitening systems are available to penetrate the enamel — including paint-on systems. Many of these are water-soluble, though, and mostly dissolve away in as little as five minutes when they come into contact with saliva.

The Crest Night Effects Difference

Crest Night Effects' unique gel forms a LiquidStrip™ coating. The water-resistant coating holds the whitening agent in place, slowly releasing hydrogen peroxide while you sleep. The LiquidStrip coating works to remove stains and loosen stain-causing buildup. In the morning, just brush the LiquidStrip coating and the stains away. After just two nights of using Crest Night Effects, you'll notice a clean, smooth feeling on the surface of your teeth.

How to Use Crest Night Effects

For the best effect, apply Crest Night Effects immediately before going to sleep. Don't forget to review our important tips for maximum benefit.



1. Prepare

- Brush teeth as normal.
- Dry teeth thoroughly. This will help hold the LiquidStrip coating on your teeth.



2. Apply

- Apply ONLY ONE THIN LAYER of the gel to each of your top and bottom smile teeth.
- Keep mouth open to allow the LiquidStrip coating to set.





3. Sleep

- The LiquidStrip coating stays on overnight and whitens while you sleep.



4. Reveal

- Brush in the morning.
- Reveal your whiter smile in just 14 nights.

[Back to Top](#)

Important Tips

- You may find it easier to start with your bottom teeth.
- Apply Crest Night Effects immediately after drying your teeth.
- Do not apply multiple coats. Reapplication may remove the previous layer.
- As you brush it on, you may find that Crest Night Effects does not form a complete or even coating on your teeth. This will not affect the whitening result.
- You will know Crest Night Effects is working because you can feel the LiquidStrip coating on your teeth right after you apply until you brush it away in the morning.
- You can sip water while wearing Crest Night Effects. We recommend that you do not eat or smoke.
- You may find that wiping your teeth with a tissue before brushing in the morning will help prevent the LiquidStrip coating from accumulating on your toothbrush.
- Most people find keeping their mouth open for about 30 seconds helps the LiquidStrip coating set.

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Visit Crest

Crest® Whitestrips™

U.S. Dental Professionals

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* Average improvement over 14 nights. Colgate® Simply White Night® is a registered trademark of the Colgate-Palmolive Company.

IF YOU
SMOKE,
MAKE SURE
YOU REACH
FOR THE
RIGHT PACK.

CREST NIGHT EFFECTS
WHITENS TWICE AS WELL AS COLGATE SIMPLY WHITE NIGHT.
SLEEP YOUR WAY TO A WHITER SMILE.



GET
TWICE THE
SATISFACTION
IN BED.

CREST NIGHT EFFECTS
WHITENS TWICE AS WELL AS COLGATE SIMPLY WHITE NIGHT
TOOTH PASTE. CREST NIGHT EFFECTS TOOTH PASTE IS THE ONLY
TOOTH PASTE THAT WHITENS WHILE YOU SLEEP. SLEEP YOUR WAY
TO A WHITER SMILE.



Exhibit
8



vms

PRODUCT Crest Whitestrips
MARKET Network
PROGRAM Ellen
CODE # 031005685
TITLE Teeth Are Like Paint Colors

LENGTH 30
STATION NBC
DATE 10/20/2003
TIME 10:28 AM



(MUSIC IN) WOMAN: If you ever had to choose a paint color,



you know there are whites



and there are whites. Same with teeth.



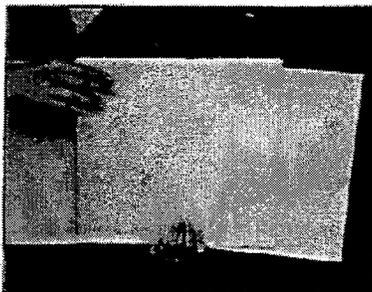
Let's say this is how white your teeth are now,



this is the white you get using this night time whitener.



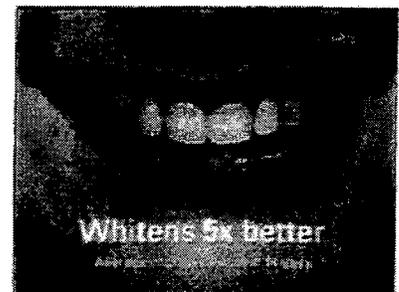
Now, compare it to the white you get



with Crest Whitestrips.



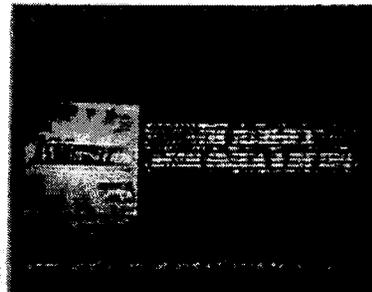
They're clinically proven



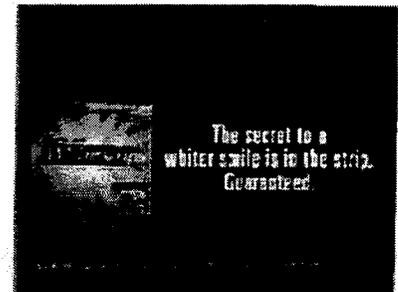
to whiten 5 times better.



So your teeth will not only be white, they'll be white.



Crest Whitestrips.



The secret to a whiter smile is in the strip. Guaranteed. (MUSIC OUT)

ALSO AVAILABLE ON VIDEO CASSETTE

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Exhibit
9



vms

PRODUCT Crest Whitestrips
MARKET Network
PROGRAM Survivor: Thailand
CODE # 021108656
TITLE Woman Talks...Teeth/Add "Well" GRFX

LENGTH 30
STATION CBS
DATE 11/27/2002
TIME 08:02 PM
REV OF # 021104269



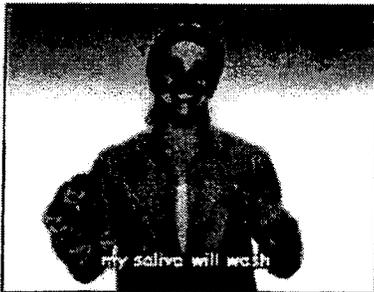
(MUSIC IN)



(SFX: WOMAN MUMBLING IN) (GRFX: I CAN'T TALK. I'M USING THAT PAINT ON)



(MUSIC/SFX) (GRFX: TEETH WHITENER. IF I MOVE MY LIPS,)



(MUSIC/SFX) (GRFX: MY SALIVA WILL WASH)



(MUSIC/SFX) (GRFX: MOST OF IT AWAY IN 2 MINUTES. WASHES AWAY?)



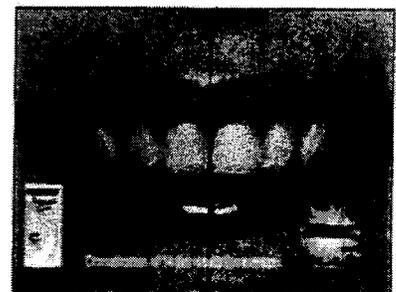
(MUSIC/SFX) (GRFX: HOW WELL CAN IT WHITEN? SNORT!)



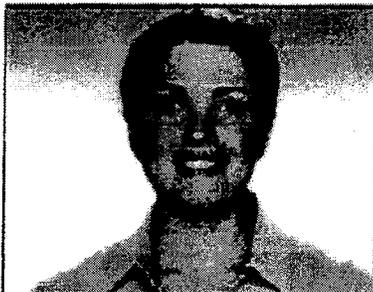
(SFX OUT) FEMALE ANNCR: With Crest Whitestrips,



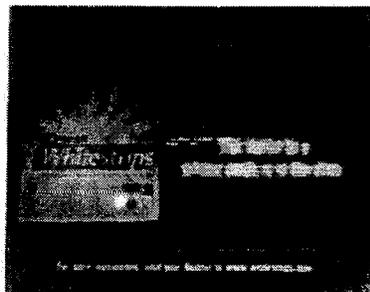
the strip stays for 30 minutes



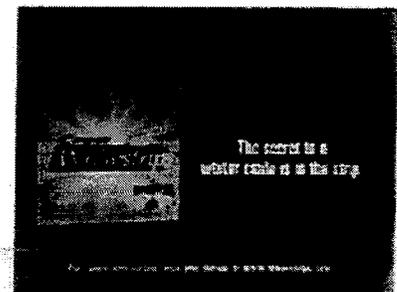
so it whitens five times better.



WOMAN. Now we're talking.



ANNCR: Crest Whitestrips.



The secret to a whiter smile is in the strip. (MUSIC OUT)

VIDEO ALSO AVAILABLE

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330 West 42nd Street, New York, NY 10018 T. 212 724 2016



vms

PRODUCT Crest Whitestrips
MARKET Network
PROGRAM Figure Skating
CODE # 021104269
TITLE Woman Talks Through Her Teeth

LENGTH 30
STATION ABC
DATE 11/17/2002
TIME 02:14 PM



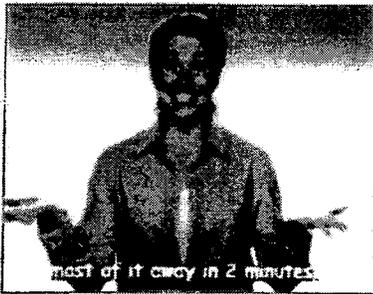
(MUSIC IN)



(SFX: WOMAN MUMBLING IN)



(MUSIC/SFX)



(MUSIC/SFX)



(MUSIC/SFX)



(MUSIC/SFX) (GRFX: (SNORT!))



FEMALE ANNCR: With Crest Whitestrips,



the strip stays for 30 minutes



so it whitens



5 times better.



WOMAN. Now we're talking.



ANNCr: Crest Whitestrips. The secret to a whiter smile is in the strip. (MUSIC OUT)

VIDEO ALSO AVAILABLE

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Exhibit
10



vms

PRODUCT Crest Whitestrips
MARKET Chicago, IL
PROGRAM Fox Thing In The Morning
CODE # 030702738
TITLE Woman Applies Makeup: Beauty Secret/5x

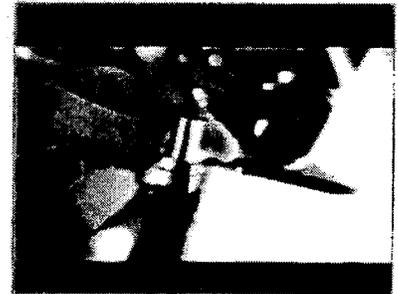
LENGTH 30
STATION WFLD
DATE 07/11/2003
TIME 06:49 AM
REV OF # 030306654



(MUSIC IN)



FEMALE ANNCR: You take great care of getting yourself ready to face the world.



But what about your most important feature?



Your smile.



Here's a beauty secret. Crest White Strips.



Clinically proven to whiten 5x



better than the leading competitive whitener. (GRFX: WHITENS 5X BETTER)



They leave you with a smile so beautiful,



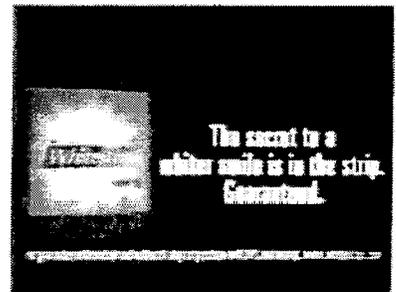
everyone will notice.



Including your toughest critic.



You.



The secret to a whiter smile is in the strip. Guaranteed. (MUSIC OUT)

ALSO AVAILABLE ON VIDEO CASSETTE

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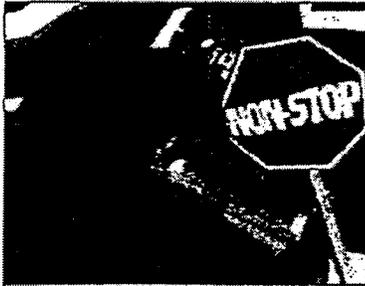
330 West 42nd Street, New York, NY 10036 T 212 736 2016



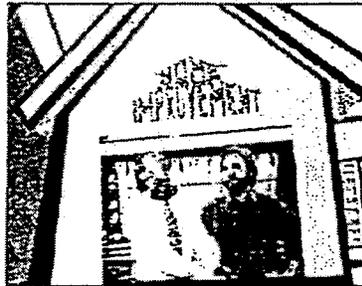
vms

PRODUCT Non-Stop Comedy Block: TBS/Crest White.
MARKET New York, NY
PROGRAM Drew Carey Show
CODE # 030200529
TITLE Animated City: Whitens 5 Times Better

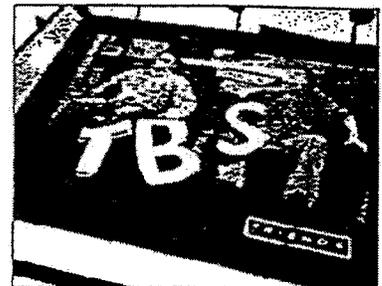
LENGTH 30
STATION TBS
DATE 02/03/2003
TIME 04:30 PM



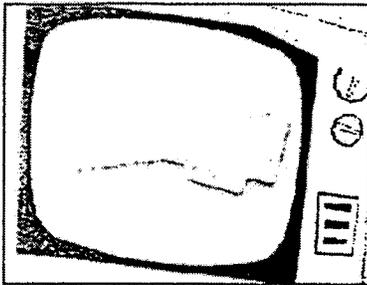
(MUSIC IN) (SFX: CAR SPEEDING IN)



(MUSIC)



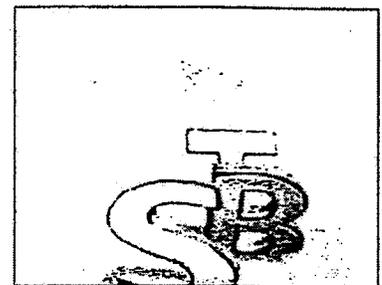
(SFX: OUT)



(MUSIC)



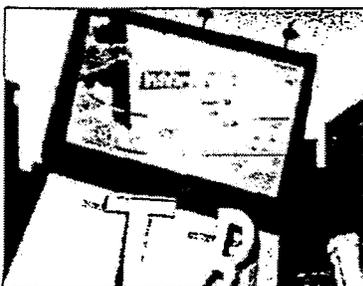
(MUSIC)



(MUSIC)



(MUSIC)



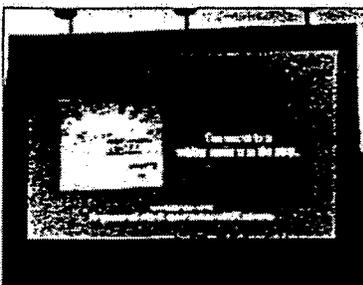
MALE ANNCR: With Crest Whitestrips,



the strip stays, holding the gel for 30 minutes.



So it whitens 5 times better than paint-on teeth whiteners. (GRFX: TAKE 10 YEARS OFF IN 2 WEEKS)



Crest Whitestrips. The secret to a whiter smile is in the strip. (GRFX: THE SECRET TO A WHITER SMILE IS IN THE STRIP.)



(MUSIC OUT)

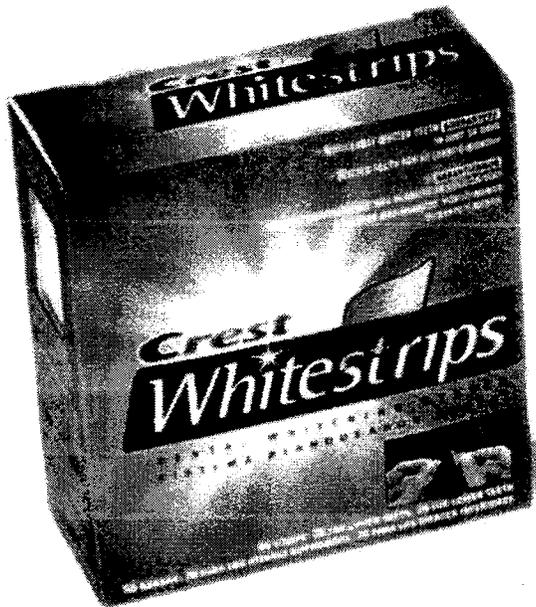
VIDEO ALSO AVAILABLE

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Exhibit
11

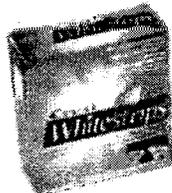
CLINICALLY
 PROVEN TO
 WHITEN **5X** BETTER
 THAN THE LEADING
 DAYTIME PAINT-ON
 WHITENING GEL.



THE SECRET TO A
 WHITER SMILE
 IS IN THE STRIP.
 GUARANTEED.

www.whitestrips.com

SAVE \$7.00



ON ONE
 CREST WHITESTRIPS
 BOX

MANUFACTURER COUPON EXPIRES 07/31/03

CONSUMER: Redeem \$7.00 by purchasing the brand/size(s) indicated. May be reproduced and transferred to any person, firm or group prior to store redemption. You pay any sales tax. See other use restrictions. **LIMIT ONE COUPON PER PURCHASE**
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©2003 P&G. *BASED ON TWO WEEK AVERAGE OF USE.
 000003100 VS. ORIGINAL SIMPLY WHITE.

Special
Summer
Offer.
\$700
OFF



*your next purchase
of Crest Whitestrips™
see coupon on back for details*



Clinically proven to whiten 5x better than the leading paint-on whitening gel.*

www.whitestrips.com

*Average 14-day improvement vs. Colgate Simply White™ a registered trademark of the Colgate-Palmolive Co. ©2003 P&G

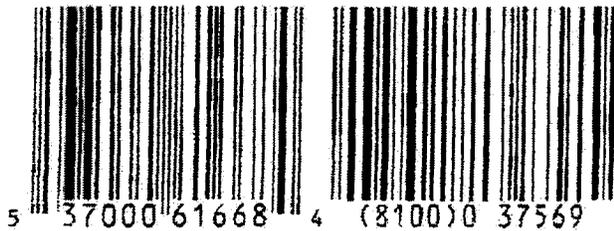
37569

MANUFACTURER'S COUPON EXPIRES 7/31/03

SAVE \$7.00

On Crest Whitestrips™

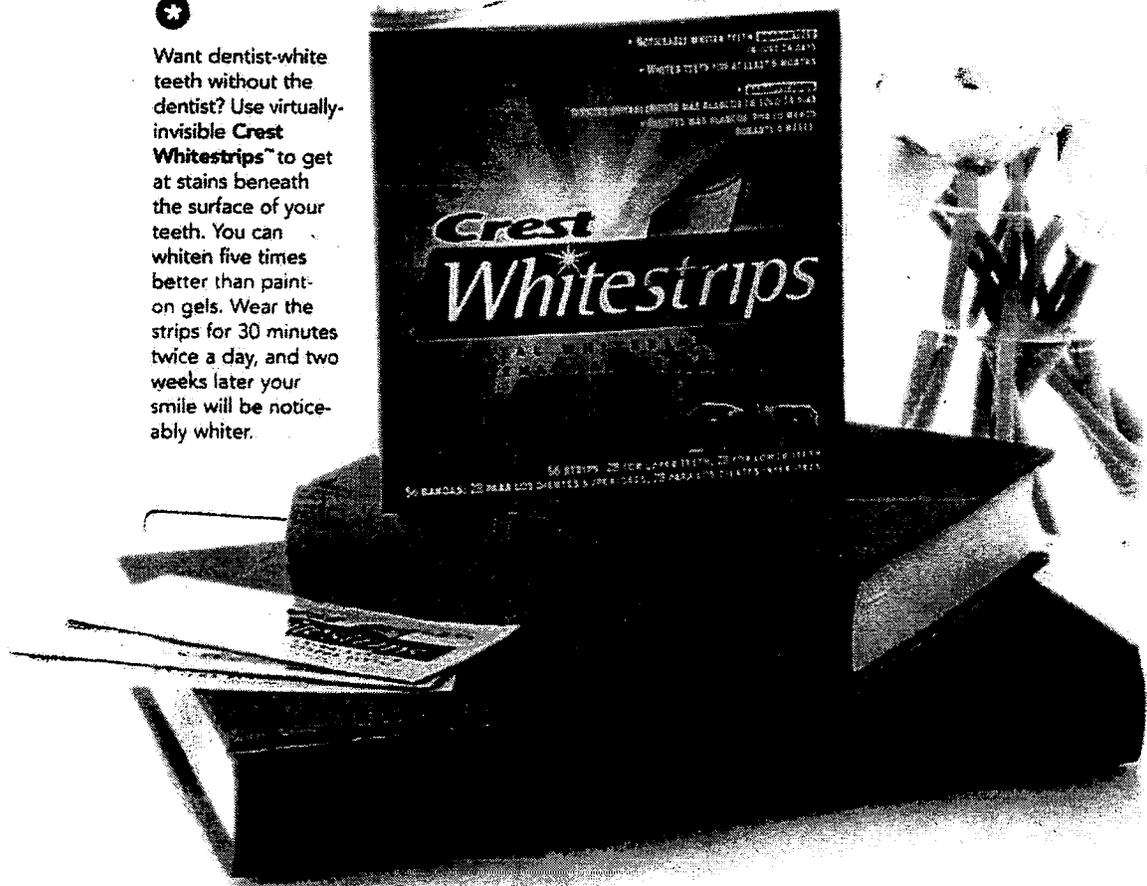
CONSUMER: Redeem ONLY by purchasing the brand size(s) indicated. May not be reproduced. Void if transferred to any person, firm or group prior to store redemption. You may pay any sales tax. Any other use constitutes fraud. **LIMIT ONE COUPON PER PURCHASE.**
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37569

Whiten while you work

*
 Want dentist-white teeth without the dentist? Use virtually-invisible **Crest Whitestrips™** to get at stains beneath the surface of your teeth. You can whiten five times better than paint-on gels. Wear the strips for 30 minutes twice a day, and two weeks later your smile will be noticeably whiter.



Joe Boveri Mercuri floor lamp, \$24.99

"There's no better beauty accessory than a brilliant, white smile. Now it's easier than ever to get one with **Crest Whitestrips™**". They whiten at home, in the car, at work or while you shop for a hot lipstick to show off your new smile." — Dana Aristone



Free Glamour gift exclusively at Kmart!

Get a \$5 Kmart Gift Card FREE when you purchase two or more participating products.

See us at Kmart.com

CLINICALLY
 PROVEN TO
 WHITEN **5X** BETTER
 THAN THE LEADING
 DAYTIME PAINT-ON
 WHITENING GEL.**

THE SECRET TO A WHITER SMILE
 IS IN THE STRIP. GUARANTEED.**



WebMD Health*

For more information about
 oral health, visit
www.whiteninginfo.webmd.com
 WebMD does not endorse any specific
 product, service or treatment.

www.whitestrips.com

*AVERAGE 2-WEEK IMPROVEMENT VERSUS
 COUGARSM SMILEY WHITESM
 A REGISTERED TRADEMARK OF THE
 COUGAR PAIN-RELIEF COMPANY
 **FOR GUARANTEE, CALL WITHIN
 60 DAYS OF PURCHASE WITH UPC AND RECEIPT

SAVE \$700



ON ONE
 CRESTSM WHITESTRIPSSM
 DENTAL WHITENING SYSTEM

MANUFACTURER COUPON EXPIRES 11/30/03

CONSUMER: Redeem ONLY by purchasing the brand size(s)
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 other use constitutes fraud. LIMIT ONE COUPON PER PURCHASE.
 DEALER: Sending coupons to Procter & Gamble, 2150 Sunningbrook
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 "Requirements for Proper Coupon Redemption" Copy available by
 visiting to the above address. Cash Value 1/100 of \$.



P&G brands SAVER

CLINICALLY
 PROVEN TO
 WHITEN **5X** BETTER
 THAN THE LEADING
 DAYTIME PAINT-ON
 WHITENING GEL.*



THE SECRET TO A WHITER SMILE
 IS IN THE STRIP. GUARANTEED.**

www.whitestrips.com

*AVERAGE 3 WEEK IMPROVEMENT VERSUS LEADING PAINT-ON WHITENING GEL. **FOR GUARANTEE, CALL WITHIN 60 DAYS OF PURCHASE WITH UPC AND RECEIPT



MANUFACTURER COUPON EXPIRES 11/30/03

SAVE \$7.00
 ON ANY ONE



4005R

CREST™ WHITESTRIPS®
 DENTAL WHITENING FORMULA

CONSUMER: Receive **\$7.00** by purchasing the **CREST Whitestrips** Dental Whitening Formula. May not be redeemed for cash. Good for one use only. Good through 11/30/03. See store for details. See www.whitestrips.com for complete terms. **LIMIT ONE COUPON PER PURCHASE.**

DEALER: Send coupon to Procter & Gamble, 2150 Sunbuck Drive, Cincinnati, Ohio 45237. Includes postage with "Reserve this for Proper Coupon Redemption" Copy machine by sending to the above address. Date Year 11/03 of 11. 01102



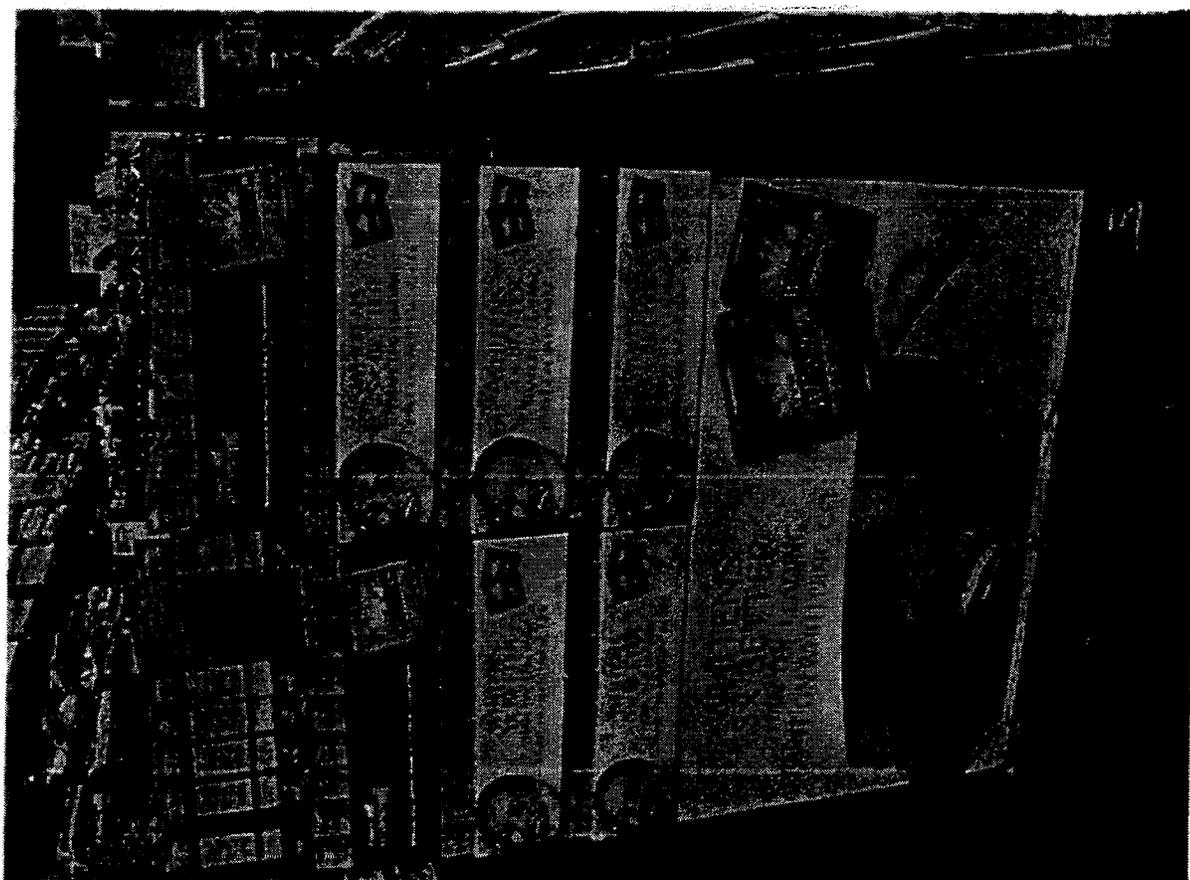
4005R

GET NOISE OFF



Exhibit 12







WHITENS
5X BETTER
THAN THE LEADING
PAINT ON WHITENING GEL

