IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

FEDERAL TRADE COMMISSION, Petitioner, v. RECKITT BENCKISER PHARMACEUTICALS, INC., Respondent.	Misc. No.

MEMORANDUM IN SUPPORT OF PETITION OF THE FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING CIVIL INVESTIGATIVE DEMAND

I. INTRODUCTION

Pursuant to Section 20 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 57b-1, the Federal Trade Commission petitions this Court for an Order requiring Respondent Reckitt Benckiser Pharmaceuticals, Inc. ("Reckitt"), to comply with an FTC civil investigative demand ("CID").[1] The Court should grant the FTC's petition because Reckitt has improperly withheld relevant documents on conclusory assertions of attorney-client privilege.

[1] A CID is a form of administrative compulsory process akin to a subpoena *duces tecum* or subpoena *ad testificandum*. Section 20 of the FTC Act, 15 U.S.C. § 57b-1, authorizes the FTC to issue CIDs. *See also FTC v. O'Connell Assocs., Inc.*, 828 F. Supp. 165, 169 (E.D.N.Y. 1993).

The Commission is investigating whether Reckitt has engaged in unfair methods of competition with respect to its drugs Suboxone and Subutex, which are used to treat opioid dependence.[2] Specifically, the Commission is investigating whether Reckitt has abused U.S. Food and Drug Administration ("FDA") regulations and approval processes as a means to delay generic competition. Reckitt has impeded this investigation by asserting attorney-client privilege for numerous documents that go to the heart of the investigation. These include drafts of documents that Reckitt disclosed to third parties as well as documents related to these drafts, such as communications between Reckitt and in-house and outside counsel regarding the content of documents slated for disclosure. Pet. Exh. 1, ¶ 22.

Fourth Circuit precedent precludes Reckitt's reliance on attorney-client privilege to withhold these documents. As that court has made clear, drafts of documents intended to be made public "will not enjoy the privilege," even if they are exchanged between a client and its reviewing attorneys, and neither will "'the details underlying the data to be published,'" even if those details are revealed in attorney-client communications. *United States v. (Under Seal)*, 748 F.2d 871, 875 (4th Cir. 1984) (citing *In re Grand Jury Proceedings*, 727 F.2d 1352, 1356 (4th Cir. 1984)). In other words, when a client retains an attorney to help prepare a document for third-party consumption, "the client lose[s] the right to assert the

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[2] Suboxone is a branded drug with the active ingredients buprenorphine and nalaxone. Subutex is a branded drug containing only the active ingredient buprenorphine. Reckitt no longer sells Subutex, but generic versions are available.

privilege as to the subject matter of the communications" with that attorney. *(Under Seal)* at 875-76.

The withheld materials are central to the Commission's investigation into whether Reckitt may have misused FDA regulatory processes to achieve anticompetitive objectives in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. Pet. Exh. 1, ¶ 23; Pet. Exh. 2. Reckitt's failure to produce the requested materials would handicap the Commission in its efforts to investigate this potential misuse. Pet. Exh. 1, ¶ 25. The Commission therefore asks this Court to order Reckitt to show cause why it should not produce documents it has wrongfully withheld as attorney-client privileged.[3]

II. JURISDICTION

Section 20 of the FTC Act authorizes the Commission to issue CIDs to obtain documents, testimony, and responses to questions relating to any matter under investigation. 15 U.S.C. § 57b-1(c). If a CID recipient fails to comply, the Commission may petition the district court for an order directing the recipient to comply, and the court may "enter such order or orders as may be required" to enforce the CID. 15 U.S.C. §§ 57b-1(e), (h). The statute confers jurisdiction and venue on the district court of the United States in the judicial district where the CID recipient "resides, is found, or transacts business." 15 U.S.C. § 57b-1(e).

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[3] As noted below, the Commission is seeking only those materials that Reckitt has withheld solely on the basis of the *attorney-client* privilege. It is not here seeking documents as to which Reckitt has invoked the *work product* doctrine or other applicable privileges.

Reckitt resides, is found, and transacts business in this judicial district. Pet. Exh. 1, ¶ 3.

III. STATEMENT OF FACTS

A. The Commission's Investigation

The Commission has long been concerned about protecting competition between branded drugs and their generic alternatives. *See, e.g., FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2229-30 (2013); Brief of Federal Trade Commission as Amicus Curiae, *Mylan Pharma., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824, Doc. 116-2, at 2-4 (E.D. Pa. Nov. 21, 2012). Generic drugs are typically significantly cheaper than their branded versions and substitution is encouraged.[4] As a result, the vast majority of consumers switch from branded to generic drugs as soon as the generic version is available, realizing substantial cost savings.[5] Pet. Exh. 1, ¶ 11. These savings come at the expense of the branded drug manufacturer, which thus has an incentive to thwart generic competition. *Id.* Even a few months' delay of a generic's approval can cause millions of dollars of consumer harm and a concomitant increase in profits for the branded manufacturers. *Id.*

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4 Almost all states and the District of Columbia allow or require pharmacists to substitute a generic for an equivalent branded drug, unless specifically directed otherwise by a physician. *See* Pet. Exh. 1, ¶ 10.

5 *See generally* "The Generic Pharmaceutical Industry—Improving Lives For Less," The Generic Pharmaceutical Association (2011), available at http://gpha.hfwebdev.com/about-gpha/about-generics/case/generics-providing-savings-americans.

On May 2, 2013, the Commission issued a resolution authorizing the use of compulsory process to investigate whether Reckitt was engaging in anticompetitive conduct.[6] Pet. Exh. 2. As discussed in greater detail in the attached declaration of Daniel Butrymowicz (Pet. Exh. 1), the focus of the present investigation is whether Reckitt misused FDA regulatory processes, among them the FDA's process by which citizens can petition it for administrative action. 21 C.F.R. § 10.30.

FDA regulations authorize anyone to petition the FDA for a change in agency policy or regulations.[7] These so-called "citizen petitions" are typically used to alert the FDA to *bona fide* concerns about the safety or efficacy of a new drug.[8] However, any citizen petition that merely "appears to meet the requirements" of filing triggers FDA review and response procedures, regardless of its underlying merit. 21 C.F.R. § 10.30(c). Thus, even where those safety or efficacy concerns are not genuine, the practical effect of a citizen petition is typically to halt the approval

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6 Specifically, the investigation seeks to determine whether Reckitt is engaging in unfair methods of competition using "its monopoly position to switch the Suboxone market to a new, non-substitutable form of Suboxone, abusing FDA-mandated negotiations for a single shared [Risk Evaluation and Mitigation Strategy, or REMS,] system, filing a meritless or sham citizen petition with the FDA, or any related conduct involving these or other pharmaceutical products" in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. Pet. Exh. 2.

7 The petition must include: (1) the action requested; (2) a statement of the factual and legal grounds for the request; and (3) a certification that the petition includes all information on which it relies as well as unfavorable data known to the petitioner. 21 C.F.R. § 10.30(b).

8 *See* Seth C. Silber, Jonathan Lutinski, and Rachel Taylor, *Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?*, ABA ANTITRUST HEALTH CARE CHRON., at 28 (Jan. 2012).

process for new entrants while the FDA reviews and responds to the pending petition. *See, e.g.*, 21 C.F.R. 10.30(e); *see also* Pet. Exh. 1, ¶ 16.

In September 2012, just as generic versions of Suboxone tablets were poised to enter the market and after Reckitt had already launched a non-tablet version of the same drug, Reckitt filed a citizen petition with the FDA asking the agency to ban or limit the sale of these generic tablets based on allegations that their packaging was more likely to lead to accidental consumption by children than Reckitt's packaging of its newer branded film versions of the drug.[9] Pet. Exh. 1, ¶ 16; Pet. Exh. 7 at 002-003.[10] Ultimately, after a petition-induced delay of over five months, the FDA denied the petition as "unsupported" and referred the matter to the FTC "to investigate and address potentially anticompetitive business practices."[11] Pet. Exh. 1, ¶ 16; Pet. Exh. 8, at 016. Although Reckitt's citizen petition was disclosed to a third party (indeed, it is a public document), Reckitt's privilege log reflects that Reckitt has withheld hundreds of drafts and other documents relating to this petition, including draft memoranda, draft letters, draft press releases, draft public relations documents, and draft reports, among others.

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9 The film form of Suboxone is individually packaged by dose and sold in 30-count boxes; the tablet form is sold in 30-count bottles.

10 Page references are to three-digit Bates numbers in the lower right corner of each document.

11 On the same date that it denied Reckitt's citizen petition, FDA approved two generic applications for Suboxone, and both launched in March 2013. Pet. Exh. 1, ¶ 17. Thus, 41 months after the expiration of Reckitt's rights to be the exclusive marketer of Suboxone had expired, generic competitors were finally able to enter the market.

Pet. Exh. 5 at 010-013. In correspondence with the Commission, Reckitt intimates that it has turned over some "drafts" but acknowledges that it has withheld all drafts that, in Reckitt's view, "were communicated in a privileged context"—*i.e.*, in exchanges between Reckitt and its attorneys. Pet. Exh. 4 at 037 & n.8.

The FTC is further investigating whether Reckitt pursued other strategies to maintain its monopoly in branded Suboxone in the face of potential generic competition. For instance, the FTC is investigating whether Reckitt deliberately thwarted generic entry by stalling FDA-mandated negotiations with the generic companies to develop an FDA-required safety program for the manufacture and distribution of this drug. *See* Pet. Exh. 1, ¶ 15 (discussing FDA's Risk Evaluation and Mitigation Strategy ("REMS") requirements); *see generally* 21 U.S.C. § 355-1(a). Reckitt's privilege log reflects that it has withheld hundreds of drafts of, and other documents relating to, materials that Reckitt disclosed to third parties, including the FDA, in connection with negotiations for that program. Pet. Exh. 5 at 014-017.

C. The Commission's CID and Reckitt's Claims of Attorney-Client Privilege

The Commission issued a CID to Reckitt on June 13, 2013. Among other requests, the CID requires Reckitt to produce documents, data, and responses to interrogatories relating to its citizen petition, the REMS negotiations, as well as Reckitt's sales and marketing of Suboxone in tablet and film form, generally. For instance, Specification 31 requests "all documents related to the citizen petitions reflected in FDA Docket Nos. 2009-P-0154, 2011-P-0869, and 2012-P-1028 . . . and all documents related to the merits of the citizen petitions, including those

documents currently not on the public record[,]" while Specification 25 requests "all documents constituting or relating to any communications with FDA regarding any version of Suboxone or Subutex, including but not limited to any documents relating to a REMS, RiskMAP, or other restricted distribution system." Pet. Exh. 3 at 007-009. The CID also included standard instructions for preparing a privilege log. *Id.* at 025. Among other requirements, the CID instructed Reckitt to supply "a description of the subject matter, with sufficient detail to assess the claim of privilege." *Id.*

From July 2013 to December 2013, Reckitt produced approximately 590,000 documents. In December, the company certified that compliance was complete and produced a privilege log in which it asserted attorney-client privilege as the sole basis for withholding approximately 37,000 documents. Pet. Exh. 1, ¶¶ 18-19. Most relevant to the current dispute are the thousands of log entries showing that Reckitt has withheld drafts of documents that were prepared for public disclosure, such as drafts of its 2012 citizen petition and communications with its generic competitors and the FDA for a single shared REMS. Pet. Exh. 5. Because Reckitt's privilege log contains only conclusory descriptions of the withheld documents, it is impossible to accurately identify which entries correspond to these draft documents.[12]

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12 Examples of the conclusory descriptions in such log entries include:

- "Draft Memorandum providing legal advice regarding Citizen Petition FDA Docket No. 2012-P-1028;"

FTC staff objected to Reckitt's assertion of attorney-client privilege for materials the company had prepared for publication. For example, staff cited Fourth Circuit precedent holding that when "a client communicates information to his attorney with the understanding that the information will be revealed to others, that information as well as 'the details underlying the data which was to be published' will not enjoy the privilege." Pet. Exh. 4 at 001 n.2 (citing *United States v. (Under Seal)*, 748 F.2d 871, 874-75 (4th Cir. 1984)). Ultimately, relying on this precedent, FTC staff asked Reckitt to de-designate the following types of documents as not privileged: (1) drafts of documents published or intended to be published; (2) attorney notes or edits related to those drafts; (3) emails related to or accompanying the drafts, and (4) attorney advice provided based on the drafts, such as in emails and memoranda. Pet. Exh. 4 at 018. Reckitt then produced approximately 14,000 additional documents and a revised log, but many of these newly produced documents appear to be only technically responsive to the CID and not related to the issues addressed by this petition.[13] *See* Pet. Exh. 1, ¶ 20. Reckitt continues to

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- "Draft Press Release requesting legal advice from Javier Rodriguez* regarding Citizen Petition FDA Docket No. 2012-P-1028;" and
- "Draft Public Relations Document providing legal advice regarding Citizen Petition FDA Docket No. 2012-P-1028."

Pet. Exh. 5 at 011. (The Commission's Rules of Practice provide that "each attorney who is an author, recipient, or person copied on the material shall be identified in the log by an asterisk." 16 C.F.R. § 2.11(a)(2).)

13 They include, for instance: (1) copies of documents previously produced to the

withhold thousands of additional documents falling into each of the categories identified above. *See* Pet. Exh. 4 at 021, 030-037. The log identifies over 7,800 documents as "drafts," including 1,521 documents relating to Reckitt's published 2012 citizen petition (599 of which are drafts), and over 2,000 documents relating to Reckitt's communications and negotiations with its generic competitors over a single shared REMS (233 of which are drafts).[14] Pet. Exh. 1, ¶ 22. (Examples of these log entries identified by staff are attached as Pet. Exh. 5.)

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staff by Reckitt (*e.g.*, letters to the FDA and the final citizen petition); (2) correspondence and contracts with parties outside the attorney-client relationship (*e.g.*, pharmacy benefit managers and generic drug companies); and (3) news articles; and (4) documents filed in related private litigation involving Reckitt. Pet. Exh. 1, ¶ 20.

[14] Because Reckitt's log entries fail to identify which documents were prepared for publication and then actually disclosed (or which documents relate to such disclosures), it is not possible to calculate the exact number of documents that were wrongfully withheld. Pet. Exh. 1, ¶ 22.

IV. ARGUMENT

A. The Fourth Circuit does not recognize attorney-client privilege for communications in connection with a proposed public disclosure.

Because attorney-client privilege obstructs the search for truth, the privilege must be "strictly construed" and "confined within the narrowest possible limits consistent with the logic of its principle." *(Under Seal)*, 748 F.2d at 875; *In re Grand Jury Proceedings*, 727 F. 2d at 1355 (citing *In re Grand Jury Investigation*, 599 F.2d 1224, 1235 (3d Cir. 1979)); *see also Solis v. Food Employers Labor Relations Ass'n*, 644 F.3d 221, 226 (4th Cir. 2011) (citing *United States v. Aramony*, 88 F.3d 1369, 1389 (4th Cir. 1996)). A communication is not privileged simply because the parties to the communication are an attorney and his or her client. *See United States v. Jones*, 696 F.2d 1069, 1072 (4th Cir. 1982); *In re Grand Jury Proceedings, Thursday Special Grand Jury September Term, 1991*, 33 F.3d 342, 354 (4th Cir. 1994) (citing *(Under Seal)*, 748 F.2d at 875). Most relevant here, the privilege protects only *confidential* attorney-client communications, "that is, communications not intended to be disclosed to third persons." *(Under Seal)*, 748 F.2d at 874.

Due to this confidentiality requirement, the Fourth Circuit has long held that "the attorney-client privilege does not apply to communications in connection with a proposed public disclosure." *In re Grand Jury Proceedings*, 33 F.3d at 354. When a client communicates information to counsel for use in connection with a public disclosure, the client does so with the understanding that the information "[will] be

published or made known to others," and is therefore not confidential.[15] *In re Grand Jury Proceedings*, 727 F.2d at 1356. Moreover, "when the attorney has been authorized to perform services that demonstrate the client's intent to have his communications published," then "the client lose[s] the right to assert the privilege as to the subject matter of the communications." *(Under Seal)*, 748 F.2d at 875-76.

The Fourth Circuit has applied this principle to order production of a broad variety of materials reflecting or embodying attorney-client communications. First, it has held that drafts of documents that are ultimately intended for disclosure outside the attorney-client relationship are not privileged. *See In re Grand Jury Proceedings*, 33 F.3d at 354-55 (finding unprivileged "drafts of securities filings ultimately filed with the Securities Exchange Commission (SEC) and related documents[,]" among others); *accord Neuberger Berman Real Estate Income Fund, Inc. v. Lola Brown Trust No. 1B*, 230 F.R.D. 398, 412-13 (D. Md. 2005) (finding unprivileged "drafts and accompanying communications made in connection with [a regulatory filing]"); *Republican Party of N.C. v. Martin*, 136 F.R.D. 421, 428 (E.D.N.C. 1991) (finding unprivileged "drafts of letters and speeches, whose contents of necessity were intended to be disclosed to third parties"). Indeed, a draft is non-privileged even when a client has submitted it to counsel for legal advice. *See In re N.Y. Renu with Moistureloc Prod. Liability Litig.*, No. MDL 1785,

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15 A "public" disclosure refers to a disclosure to "any third party outside the attorney-client relationship." *Neuberger Berman Real Estate Income Fund, Inc. v. Lola Brown Trust No. 1B*, 230 F.R.D. 398, 415 (D. Md. 2005).

2008 WL 2338552, at *5 (D.S.C. May 8, 2008) (explaining that, under Fourth Circuit law, a draft of a presentation to the FDA, submitted to in-house counsel for legal advice, would be "unprivileged in its entirety, as are any pertinent lawyer notes . . . because defendant made the decision to present the powerpoint to the FDA, in some form, by the time the draft was sent to [counsel]").

Second, the Fourth Circuit has held that communications *from* an attorney *to* a client are only privileged to the extent they "reveal confidential client communications." *(Under Seal)*, 748 F.2d at 874; *Neuberger Berman*, 230 F.R.D. at 412 ("The narrow approach, espoused by the Fourth Circuit in *(Under Seal)*, protects only those communications from attorney to client that would reveal a confidential communication from the client if disclosed."). Thus, because information submitted by the client in connection with a proposed public disclosure is not confidential, attorney advice related to that information would not reveal a confidential communication and is not protected.

Finally, the Fourth Circuit has held that the loss of the privilege for communications in connection with a proposed public disclosure also extends to "the details underlying the data which was to be published." *(Under Seal)*, 748 F.2d at 875 (quoting *In re Grand Jury Proceedings*, 727 F.2d at 1356).[16] As the Fourth

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[16] District courts throughout the Fourth Circuit consistently adhere to this rule. *See ePlus Inc. v. Lawson Software, Inc.*, Civ. No. 3:09cv620, 2012 WL 6562735, *5 (E.D. Va. Dec. 14, 2012); *Neuberger Berman*, 230 F.R.D. 398 at 409-15; *United States ex rel. Mayman v. Martin Marietta Corp.*, 886 F. Supp. 1243, 1248-52 (D. Md. 1995); *Martin*, 136 F.R.D. at 427.

Circuit has made clear, the "details underlying the data" – *i.e.*, the category of information for which any privilege is inapplicable or waived – include not only "all *preliminary drafts* of the document," but also:

- The attorney-client "communications relating to the data" in the filed document;
- "any *attorney's notes* containing material necessary to the preparation of the document," and
- "[c]opies of other documents, the contents of which were necessary to the preparation of the published document . . . ."

(Under Seal), 748 F.2d at 875 n.7 (emphasis added); *accord In re Grand Jury Proceedings*, 33 F.3d at 354-55 (reaffirming that Fourth Circuit law compels discovery of attorney-client "communications and data" underlying documents subsequently disclosed to the public or to third parties, and rejecting the contrary position adopted in *Schenet v. Anderson*, 678 F. Supp. 1280 (E.D. Mich. 1988)).

This rule comports with the Fourth Circuit's approach to evaluating privilege claims more generally. In *Jones*, the Court held that "[a]ny voluntary disclosure by the client to a third party waives the privilege not only as to the specific communication disclosed, but often as to *all other communications relating to the same subject matter*." *Jones*, 696 F.2d at 1072 (citing *In re Sealed Case*, 676 F.2d 793, 808-09 (D.C. Cir. 1982)) (emphasis added); *see also (Under Seal)*, 748 F.2d at 875-76 (holding that retaining an attorney to help prepare a document for third-party consumption causes the client to "lose the right to assert the privilege as to

the subject matter of those communications.").[17] Disclosure sufficient to lose the right to assert the privilege can occur "not only when a party reveals part of one privileged communication, but also when a party reveals one beneficial communication but fails to reveal another, less helpful, communication on the same matter." *Mayman*, 886 F.2d at 1252.

B. Reckitt has not sustained its burden of proving the attorney client privilege protects the documents at issue.

Fourth Circuit precedent forecloses Reckitt's reliance on attorney-client privilege to conceal drafts and other materials relating to its public disclosures, including its citizen petition and other regulatory filings and its REMS-related communications with its generic competitors and the FDA.[18] Reckitt's privilege log shows that Reckitt communicated with its counsel to help it prepare these disclosures, and provided information "necessary to [the documents'] preparation." Pet. Exh. 5. Those communications and the related "details underlying the data" are therefore not privileged and must be produced.[19] *(Under Seal)*, 748 F.2d at 875

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17 *Accord In re Martin Marietta*, 856 F.2d 619, 623-24 (4th Cir. 1988); *In re Grand Jury Proceedings*, 727 F.2d at 1357; *Mayman*, 886 F. Supp. at 1252.

18 Of course, *other* privileges may protect attorney-related materials in some circumstances, such as the work-product privilege for materials prepared in anticipation of litigation. Although Reckitt has withheld some documents on the basis of the work product privilege, those documents are not at issue in this proceeding. The FTC is here seeking documents that do not qualify as "work product" because, for example, they were not prepared in anticipation of litigation.

19 In the context of communications with an attorney for a public disclosure, the Fourth Circuit has limited the scope of the subject matter waiver to the disclosure itself and the underlying details "necessary to [its] preparation." *(Under Seal)*, 748 F.2d at 875 n.7; *see also Hawkins v. Stables*, 148 F.3d 379, 384 n.4 (4th Cir. 1998)

& n.7; *In re Grand Jury Proceedings*, 727 F.2d at 1356, 1358 (citing *United States v. Cote*, 456 F.2d 142, 145 (8th Cir. 1972)); *see also Jones*, 696 F.2d at 1072.

In refusing to produce the types of documents identified by FTC staff, Reckitt appears to misunderstand Fourth Circuit precedent. Rather than analyze each individual communication for "the existence or absence of a specific request for confidentiality" with respect to a particular document, courts in this Circuit instead must "look to the services which the attorney has been employed to provide and determine if those services would reasonably be expected to entail the publication of the clients' communications." *(Under Seal)*, 748 F.2d at 875 (citing *Jones*, 696 F.2d at 1072-73). Again, "when the attorney has been authorized to perform services that demonstrate the client's intent to have his communications published," then "the client lose[s] the right to assert the privilege *as to the subject matter* of the communications." *Id.* at 875-76 (emphasis added).

Critically, *where a disclosure has actually occurred*, that disclosure defeats retroactive attempts to recast the nature and purpose of the communications with counsel. In two separate cases, clients sought to withhold drafts and communications related to filings with the SEC by claiming retroactively that the

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(where client waived privilege on communications with divorce attorney regarding illegal phone tap of her ex-husband, subject matter of waiver was the phone tap); *In re Martin Marietta Corp.*, 856 F.2d at 623 (where "Position Paper" was disclosed to government, company waived privilege over "audit papers" and "witness statements from which the Position Paper statements were derived."). The Fourth Circuit has not held, and the FTC does not argue, that waiver of privilege related to a public disclosure waives the privilege for *all* attorney-client communications. *See, e.g.*, *Hawkins*, 148 F.3d at 384 n.4.

communications were not for the purpose of publication. In both cases, the court rejected this attempt, finding that, because the disclosures had occurred, these attempts were "fruitless" and the documents were not privileged. *See In re Grand Jury Proceedings*, 33 F.3d at 355 ("[T]he only way appellants can prevail is to demonstrate to the court that they did not retain the services of the attorneys for the purpose of advice on publication. Because the SEC filings were actually completed and filed, that endeavor would be fruitless."); *see also Neuberger Berman*, 230 F.R.D. at 414 ("Counsel was employed to convey information passed from the defendants to the SEC. To demonstrate otherwise would be fruitless."). Here, Reckitt's privilege log shows that Reckitt communicated with its counsel for the purpose of advice on disclosures to third parties, including the FDA, its competitors, and the general public, Pet. Exh. 5, and that these disclosures actually occurred.[20] *See, e.g.*, Pet. Exh. 7. Under these circumstances, Reckitt's attempts to recast its communications with counsel as not involving the reasonable expectation of publication are also "fruitless."

Finally, Reckitt can derive no support from *In re Grand Jury Subpoena*, 341 F.3d 331 (4th Cir. 2003), which it has highlighted in correspondence with the Commission. Pet. Exh. 4 at 012, 021, 034-035. In that case, the Fourth Circuit stated in *dicta* that a client's communications with his attorney were privileged

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20 It may be that Reckitt communicated with counsel regarding matters that remain undisclosed. If so, those communications would remain privileged. *(Under Seal)*, 748 F.2d at 876. However, Reckitt's log does not contain sufficient information for FTC staff to identify such documents. Pet. Exh. 1, ¶ 22.

when the client sought legal advice independently of making any disclosures. 341 F.3d at 336. That the client later disclosed the advice on an immigration form did not change the fact the he had not sought advice for the purpose of filing the form. *Id.* Here, in contrast, Reckitt's communications with counsel were for the purpose of preparing documents for public disclosure. Thus, Reckett's conclusory statements on its privilege log and after-the-fact arguments of counsel that it intended its communications with counsel to remain confidential are beside the point. The communications were made for the purpose of preparing materials for publication. Reckitt has not shown that its communications are privileged.

C. The withheld documents are highly relevant to the FTC's investigation.

The withheld documents are central to the investigation because they provide crucial insights into Reckitt's factual basis (if any) and reasons for filing the citizen petition and its motivation for its conduct during the REMS negotiations. Pet. Exh. 1, ¶ 23. For example, was Reckitt expressing well-founded concerns about the safety of Suboxone and its generic competitors when it availed itself of FDA regulatory processes? Or was it exploiting that process to prevent FDA from approving cheaper generic entrants and thereby force a particularly vulnerable population – patients suffering from opioid addiction – to pay higher prices for a branded drug? Drafts of the disclosed documents, and the related communications, can help FTC staff answer these questions.

The document attached as Pet. Exh. 6 shows how. Exhibit 6 is an executive summary of a scientific study that Reckitt had commissioned to support its citizen

petition, which Reckitt filed eleven days after the executive summary was initially submitted to Reckitt. This document contains handwritten edits and typewritten "riders," all apparently prepared by Reckitt's counsel (who were also the principal drafters of the citizen petition).[21] Although Reckitt appears to have withheld this document as privileged,[22] the third-party consultant (Venebio) that Reckitt had hired to conduct the scientific study independently provided this document to the FTC because the consultant, unlike Reckitt, was willing to follow Fourth Circuit law concerning the inapplicability of the attorney-client privilege to materials relating to public disclosures. Pet. Exh. 1, ¶ 24.

By showing what Reckitt's counsel revised, added, or deleted, this draft sheds valuable light on whether Reckitt had a valid basis for its filing its competition-thwarting citizen petition with the FDA. One key issue relevant to that petition was whether, as Reckitt argued, its patent-protected Suboxone film was safer for children than the packaging of generic buprenorphine tablets. Pet. Exh. 7 at 024-026. [redacted]

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21 Reckitt's privilege log reflects that, in preparing the citizen petition and executive summary, it consulted with the outside law firm of Hyman, Phillips, and McNamara, and in particular with attorneys David Clissold, and Josephine Torrente at that firm. Reckitt also consulted with in-house counsel Javier Rodriguez.

22 Reckitt's privilege log lacks sufficient detail to identify this document definitively. Based on the sender, date, and number of pages, FTC staff believes the document is identified on the privilege log as "Draft Report reflecting confidential Attorney-Client communications with Javier Rodriguez* regarding communications

This document and its marginalia, and documents like it, are directly relevant to the FTC's ongoing investigation into whether Reckitt's citizen petition was based on genuine scientific findings or whether it was instead a "sham" intended to delay FDA approval for generic entrants. Since Reckitt disclosed these communications with counsel in the forms of this summary document and the resulting citizen petition, Reckitt may not now claim privilege for the underlying "details" and other related communications on the same subject matter. *(Under Seal)*, 748 F.2d at 875; *In re Grand Jury Proceedings*, 727 F.2d at 1356 (citing *Cote*, 456 F.2d at 145).

D. The Fourth Circuit has ordered production in analogous circumstances.

The Fourth Circuit has ordered production of attorney-client communications in analogous cases involving other types of regulatory filings. For example, in *In re*

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with the FDA concerning Suboxone or Subutex." Pet. Exh. 1, ¶ 24.

Grand Jury Proceedings, the defendants' law firm had claimed privilege for "drafts, notes, and memoranda generated in connection with audit responses to an outside auditor," and one of the defendants "refused to produce drafts of securities filings ultimately filed with the Securities Exchange Commission (SEC) and related documents." 33 F.3d at 354. The defendants urged the Court of Appeals to apply a rule, adopted in other circuits, that the attorney-client privilege protects information conveyed to attorneys for the purpose of drafting public documents "*to the extent that* such information is not contained in the document published and is not otherwise disclosed to third persons." *Id.* at 354-55 (quoting *Schenet*, 678 F. Supp. at 1283) (emphasis in original). In other words, attorney-client communications related to drafts would be privileged except for the specific information that was published in the final version. The *Schenet* rule would also protect "preliminary drafts of documents intended to be made public." *In re Grand Jury Proceedings*, 33 F.3d at 355. The Fourth Circuit expressly rejected this approach, and found that, because the defendants had "retain[ed] the services of the attorneys for the purpose of advice on publication," all underlying drafts, notes, and memoranda were unprivileged. *Id.*; *see also Neuberger Berman*, 230 F.R.D. at 414-15 (no privilege for drafts of section 13D filing to the SEC and related documents).

The Fourth Circuit reached the same result in *Jones*, which likewise involved disclosures to the general public. In that case, the clients, a group of individuals and companies, engaged in the sales of coal leases and retained counsel to prepare tax opinions that they used to promote their business. The court rejected the

attorneys' assertion of attorney-client privilege for "all records" related to those opinions, including "correspondence and instructions" and "any documents and research notes used in preparation of the three written opinions." *Jones*, 696 F.2d at 1071. *See also (Under Seal)*, 748 F.2d at 876-77 (attorney-client privilege does not protect proposed or actual public filings); *Neuberger Berman*, 230 F.R.D. at 415 (attorney-client privilege does not protect drafts and communications relating to a purchase offer and public notice of the offer).

In short, all information available to FTC staff indicates that Reckitt cannot claim with respect to drafts and other documents relating to disclosures to its competitors and to the FDA, and the conclusory descriptions in Reckitt's privilege log are insufficient to overcome this conclusion. *Hawkins*, 148 F.3d at 383 (finding that one element of attorney-client privilege is to prove that it was not waived). Because Reckitt has not met its burden of showing these documents are privileged, it must produce them. *Solis*, 644 F.3d at 233; *Rambus, Inc. v. Infineon Technologies AG*, 220 F.R.D. 264, 274 (E.D. Va. 2004) ("The finding of inadequacy [in a privilege log] . . . conceptually is sufficient to warrant a finding that the privileges have been waived.").

V. CONCLUSION

The Court should direct Reckitt to produce, within 10 days of the date of its order, the drafts of any documents the company ultimately published or shared with third parties, as well as the "the details underlying the data which was to be published" in each of the disclosed documents.

Respectfully submitted,

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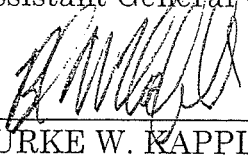

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of September, 2014, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System which will then send a notification of such filing (NEF) to the following:

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