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

FEDERAL TRADE COMMISSION,

Petitioner,

v.

Misc. No. 3:14mc5

INDIVIOR, INC.,

Respondent.

MEMORANDUM OPINION

This matter is before the Court on the SECOND INTERIM REPORT AND RECOMMENDATIONS OF SPECIAL MASTER (Docket No. 71) and the SUPPLEMENT TO SECOND INTERIM REPORT AND RECOMMENDATIONS OF SPECIAL MASTER (Docket No. 73) (collectively referred to as "Special Master's Report"). Also before the Court is the FEDERAL TRADE COMMISISON'S MOTION TO ADOPT SPECIAL MASTER'S RECOMMENDATION OR, IN THE ALTERNATIVE, TO ORDER PRODUCTION ("MOTION TO ADOPT/PRODUCE") (Docket No. 74) and the RESPONDENT INDIVIOR, INC.'S CORRECTED OBJECTIONS TO THE SPECIAL MASTER'S SECOND INTERIM REPORT AND RECOMMENDATIONS, AS WELL AS THE SUPPLEMENT THERETO (Docket No. 83) ("OBJECTIONS AND RECOMMENDATION").

BACKGROUND

The Federal Trade Commission ("FTC") issued a Civil Investigative Demand ("CID") to Reckitt Benckiser Pharmaceuticals, Inc. ("Reckitt"). During the course of these proceedings Reckitt was acquired by Indivior, Inc. and, pursuant to an ORDER entered herein on May 23, 2016 (Docket No. 100), Indivior, Inc. was substituted as the party respondent in place of Reckitt. However, because the documents and most of the briefing herein refer to the respondent as Reckitt, that appellation will be retained.

Pursuant to the CID, the FTC sought to determine whether Reckitt had engaged in unfair methods of competition with respect to its branded drug, Suboxone. PETITION OF THE FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING CIVIL INVESTIGATIVE DEMAND (Docket No. 2) ("FTC Initial Petition"). The conduct under investigation was particularized as follows:

investigating whether Reckitt abused public regulatory processes, including filing a citizen petition with the U.S. Food and Drug Administration ("FDA") and negotiating with competing manufacturers, to maintain its monopoly in the market for Suboxone, an opioid addiction treatment distributed through prescription, rather than by clinic-based methods.

FTC Initial Petition, p. 1. In response to the CID, Reckitt produced almost 600,000 documents, but withheld approximately

24,000 documents on the ground of attorney-client privilege.1 The FTC took the view that certain types of documents were not privileged and sought production of those documents. MEMORANDUM IN SUPPORT OF PETITION OF THE FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING CIVIL INVESTIGATIVE DEMAND (Docket Nos. 23 and The FTC contended therein that, under the law of the Fourth Circuit, Reckitt improperly withholding, was privileged, documents that were not at all privileged because the documents sought by the FTC fell within the rule of the Fourth Circuit that, "if 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." United States v. Under Seal, 33 F.3d 342, 354 (4th Cir. 1994) (quoting United States v. Under Seal, 748 F.2d 871, 875 (4th Cir. 1984).

Reckitt took the view that decisions of other circuits counsel a different result and that the cases relied upon by the FTC have been overruled, sub silento, by the Fourth Circuit's decision in <u>In re: Grand Jury Subpoena</u>, 341 F.3d 331 (4th Cir. 2003).

At the early stages of this litigation, the number of privileged documents was asserted to be approximately 28,000, but subsequently the number has been reduced to approximately 24,000.

By Memorandum Opinion issued on March 10, 2015 (Docket No. 42) ("March 10 Opinion"), the Court rejected the arguments made by Reckitt and (1) held that the rules of privilege to be applied in the production of documents herein would be as set forth under appropriate law of the Fourth Circuit; (2) required Reckitt to identify and produce all documents that, by virtue of the rulings in the Memorandum Opinion, required no further review by a Special Master; and (3) ordered that a Special Master would review the remaining documents in camera in accord with appropriate Fourth Circuit decisions. (ORDER, Docket No. 43). After affording the parties an opportunity for input into the selection of a Special Master to accomplish the document review of the remaining privileged documents, the Court appointed a Special Master (Docket No. 48). The Special Master was tasked with the responsibility to review the privileged documents as required by the law of the Fourth Circuit and to make a Report and Recommendation respecting the results of that review.

After consulting fully with the parties, holding an evidentiary hearing, and receiving briefing and reviewing the documents, the Special Master issued the Special Master's Report reflecting the results of the *in camera* review of 3,704 documents. Those documents were selected by Reckitt, upon the instruction of the Special Master, as documents related to the

preparation of the citizen's petition and other documents that are follow up communications between Reckitt and the FDA and certain public relations documents concerning the citizen's petition and the withdrawal of Suboxone tablets from the market and documents relating to the negotiations between Reckitt and the manufacturers of generic competing drugs to establish a Joint Risk Evaluation and Mitigation Strategy (the "shared REMS" documents) for the 1,695 documents. Those documents were selected to be reviewed first by the Special Master because they are the focus of the FTC's Initial Petition.

The Special Master made rulings on the privilege claims of the 3,704 documents and those recommendations are set out in the Second Master's Report and its attachments. Further, the Special Master's Report contained certain findings that are of particular note respecting the nature and reliability of the privilege log prepared by Reckitt. They are:

First, the privilege log is not a reliable source of evidence describing the withheld documents. If the condition of the privilege log with regard to the remaining documents is similar to that for the documents reviewed in this report, it is foreseeable that the review process will be time consuming and costly, an outcome the parties presumably wish to avoid.

Second, the presence of a significant number of 'outliers' that did not relate to the topics purportedly captured in the 'Citizen's Petition' and 'Shared REMS' folders is troublesome. The overinclusion

of documents in the 'Citizen's Petition' and 'Shared REMS' electronic folders invites the obvious question: was there equally significant under-inclusion? This issue must be addressed prior to the review of additional documents.

Third, many documents fail to evidence any privileged communications; some contain substantial non-privileged material along with privileged communications. If the non-privileged portion of the first tranche of 3,704 documents is representative of the remaining documents populating the privilege log, then a significant number of documents continues to be withheld without any basis.

In addition, the Special Master made a recommendation that certain documents (Appendix 1) be produced to the FTC by Reckitt with or without redactions as indicated; that the documents listed in Appendix 2 be withheld from production to the FTC; that the parties review items on Appendix 3 and report as directed; and that the parties identify any clerical errors in the Special Master's Report. After the parties complied with the instructions, the Special Master recommended that Reckitt be required to produce all documents listed on Appendix 3 with redactions to the extent indicated. The Special Master also made certain clerical corrections following the advices of the parties respecting the request for identification of clerical errors.

Thereafter, the FTC filed its MOTION TO ADOPT/PRODUCE wherein the FTC agreed with the Special Master's recommendations

and argued for adoption of the Special Master's Report.

Alternatively, the FTC urged that Reckitt should be ordered to produce all the requested documents because the Special Master's Report established that the privilege log does not sufficiently support the claims of privilege.

Reckitt filed its OBJECTIONS AND RECOMMENDATIONS (Docket Nos.78 and 83) as well as its opposition to the FTC's MOTION TO ADOPT/PRODUCE (Docket No. 87). In particular, Reckitt advised that it was "willing to accept the Special Master's report and recommendations as to the 3,704 documents addressed in the Second Interim Report and Recommendations" (Docket No. 83), p. 2. Also, Reckitt advised that it was filing objections merely to preserve its assertion that the legal test applied by the Special Master (pursuant to the decision of the Court) was not the proper test to be applied.

Reckitt also made a suggestion for further proceedings. To begin, Reckitt advised that, in Step 1, it would "categorize the remaining 19,000 documents in light of the Special Master's recommendation . . . using the same standards that [Reckitt] believes the Special Master would apply with any redactions intended to be consistent with the redactions recommended by the Special Master with respect to the initial documents." Reckitt advised that it had begun this process, and that the process was expected to be completed in approximately 45 days.

Next, Reckitt proposed that, in Step 2, the Special Master would review Reckitt's "proposed treatment of these 19,000 documents in order to confirm that it accords to the Court's legal rule as the Special Master would apply it, a process [Reckitt] estimates would take another two months, subject of course to the Special Master's availability during that time." Thirdly, in Step 3, the Special Master would issue a Report and Recommendation as to the remaining 19,000 documents.

In support of these recommendations, Reckitt represented that it:

expects that it will be in a similar position after the Special Master issues recommendations on the second set documents as [Reckitt] is now with respect the first set, i.e. that [Reckitt] disagrees with the legal rule underlying the Special Master's recommendations but will not dispute the recommendations. [Reckitt's] expectation is correct, it would therefore not object to the Special Master's second set of recommendations and it would also withdraw the present objections as to the first set of documents that are filed for preservation purposes.

(Docket No. 83, p. 11) (emphasis added). The FTC disagreed with the objections articulated by Reckitt, but did not object to the Reckitt proposal for reviewing the remaining documents.

The Court determined to allow Reckitt to proceed as proposed in Step 1 while the Court reviewed the FTC's MOTION TO ADOPT/PRODUCE and considered the FTC's alternative request for

relief. On June 22, 2016, counsel for Reckitt advised that Step 1 of its process has been completed.

DISCUSSION

Report proceeds from the fundamental premise that the objection must identify with specificity that part of the Special Master's Report to which objection is taken and must clearly articulate the objection that is made. Only if those requisites are satisfied can there be meaningful review by the district court. Those fundamental precepts are of a special importance where, as here, the Special Master has conducted a document-by-document review of more than 3,700 documents and has specified the documents that must be produced, many of which must be redacted in part before being produced and where, as here, the Special Master has made findings respecting the individual documents that are the subject of the Special Master's Report.

In reality, Reckitt has made but two objections. First, Reckitt challenges the legal standard applied by the Special Master in making the privileged review. However, in fact, that challenge is simply a re-argument of the legal position previously advanced by Reckitt (and previously rejected by the Court) respecting the applicable law that controls the issues of privilege presented here as those principles were set forth

fully in the March 10 Opinion. A review of the Special Master's Report reflects that the Special Master faithfully and carefully applied the principles set forth in the March 10 Opinion in conducting the review of these some 3,700 documents. An objection to the fact that the Special Master did what his charter required him to do is simply a way of re-arguing the matters as to which Reckitt did not prevail in the motion that was resolved by the March 10 Opinion and its implementing Order.

Second, Reckitt raised objections to two documents: SM_03676 and SM_00156. Reckitt says that these documents are "representative examples" of the point that it makes. However, where, as here, the Special Master has made individual findings as to individual documents, many of which have some redactions, objections cannot be presented by exemplar. Instead, objections must be presented specifically to the judgments made by the Special Master as to each document individually. Reckitt, having failed to do that, has waived all objections to the judgments made by the Special Master except as to SM_03676 and SM 00156. To those objections, we now turn.

And, as to those documents, Reckitt objects that the Special Master erred because he based the determination of an intent to publish, as to these documents, based on the "facts communicated, rather than the communication itself." (Docket No. 83, p. 8). As the FTC correctly explained, both documents

involved email strings, one relating to the 2012 Citizen Petition, and the other related to the REMS negotiation. Applying the test established by the Court, the Special Master recommended that both documents be produced in redacted form, and, in so doing, allowed some messages in the string to remain withheld while requiring disclosure of others. Further, the FTC correctly sets forth the rule that the confidentiality of attorney-client communications as respecting drafts of documents that are published does not depend on the subjective intent of the client with respect to each isolated communication. the question is whether the communication relates to preparation of a document that the client in fact does intend to publish, as shown by the record. See United States v. Under <u>Seal</u>, 748 F.2d 871, 875 (4th Cir. 1984). The appropriate manner for testing that question "must look to the services which the attorney has been employed to provide and to determine if those services would reasonably be expected to entail the publication of the client's communications." Id.

As to both documents, SM_003676 and SM_00156, the record is clear beyond question that the services rendered by the two law firms involved (preparing and filing the 2012 Citizen Petition and negotiating with Reckitt's generic competitors respecting the REMS matters) would reasonably be expected to entail the publication of the client's communications. In fact, the record

indicates that Reckitt agreed with that proposition at the May 8, 2015 evidentiary hearing (Docket No. 63 at 26-27, 34, 36).

Reckitt's argument overlooks two other essential points. First, it ignores the settled principle in this circuit that an intent to disclose a document includes the "details underlying the data" therein. United States v. Under Seal, 748 F.2d at 875 and n. 7. Thus, the contention made by Reckitt that the Special Master erred in looking for an intent to publish the facts communicated rather than the intent to publish the communication itself is in error. Secondly, where publication actually occurs, it is impermissible to attempt to re-characterize the nature of the attorneys' services. In re Grand Jury Proceedings, Thursday's Special Grand Jury September Term, 1991, 33 F.3d 342, 355 (4th Cir. 1994).

In sum, the specific objections made by Reckitt are without merit and are overruled. Accordingly, and having reviewed the Special Master's Report and his recommendation in detail, the Special Master's Report will be adopted and all objections by Reckitt will be overruled.

That said, there remains the question of when to order production and what to do about the 19,000 documents that are outstanding and waiting review by the Special Master. Also, remaining for resolution is the contention of the FTC that the identified difficulties and inadequacies in the privilege log

constitute a waiver as to all privileged claims advanced by Reckitt. Those questions will be resolved as set forth below.

Having reviewed the MOTION TO ADOPT/PRODUCE OBJECTIONS AND RECOMMENDATIONS, as well as the Special Master's Report, the Court is of the view that, to some extent, Reckitt's suggestion for further proceedings have merit. To begin, Step 1 as suggested by Reckitt, has been completed. Therefore, the parties shall proceed forthwith to communicate with the Special Master as to how, if at all, to proceed with Steps 2 and 3 of Reckitt's recommendations. The Special Master may well desire suggest another approach that may ease the burden of reviewing the other 19,000 documents. And, the Special Master may decide to expand or limit further proceedings. In any event, that process shall proceed with a view to concluding the Special Master's assignment as promptly as possible.

Further, having adopted the Special Master's Report and overruled Reckitt's objections, the Court considers it appropriate that Reckitt must now produce to the FTC the documents required to be produced by the Special Master's Report, to the extent directed therein. Reckitt has expressed concern that to do so could be construed as a waiver of its position on the privilege issue as to the remaining 19,000 documents. However, the FTC has represented that it will not assert, now or later, that production, as required by the

Special Master's Report constitutes a waiver of any claim of privilege as respects the remaining 19,000 documents. That agreement will be reflected in an Order to be entered herein, and, the FTC will be required not to disclose those documents to any person or entity (other than the FTC's lawyers or the staff working on the CID) without further order from this Court.

Finally, the Court will continue to assess the validity of the alternative argument made by the FTC in its MOTION TO ADOPT/PRODUCE. To that end, the Court requests that the Special Master supplement the Special Master's Report describing the extent to which the privilege log herein is inadequate so that the Court can assess the FTC's argument that the defect in the privilege log itself constitutes a waiver of the privileges The principal problem appears to be not so claimed therein. much that the descriptions in the log are per se defective (although there appears to be many instances where that is so), but that the descriptions in the log are so at odds with the text of the documents that are being identified as to make the log a functionally useless document, thereby rendering it no log A determination on that point by the Court requires some assessment from the Special Master as to the percentage of documents in the 3,704 documents already reviewed wherein the description of a document is so at odds with the document itself as to render the description in the log meaningless. The Court

will confer with the Special Master about a schedule for this supplement after the Special Master and the parties have conferred respecting further review of the remaining 19,000 documents.

CONCLUSION

For the foregoing reasons, the objections in RESPONDENT INDIVIOR, INC.'S CORRECTED OBJECTIONS TO THE SPECIAL MASTER'S SECOND INTERIM REPORT AND RECOMMENDATIONS, AS WELL AS THE SUPPLEMENT THERETO (Docket No. 83) filed by Reckitt will be overruled, the MOTION TO ADOPT/PRODUCE (Docket No. 74) filed by the FTC will be granted, the 3,704 documents will be produced to the FTC forthwith, the Special Master Report (Docket Nos. 71 and 73) will be adopted, the parties will forthwith confer with the Special Master, and the Special Master will be tasked with preparing the supplemental report respecting the FTC's alternate waiver agreement.

The Clerk is directed to send a copy of this Order to the Special Master.

It is so ORDERED.

/s/ /CEF Robert E. Payne

Senior United States District Judge

Richmond, Virginia
Date: August 1, 2016