UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

KEVIN L. DOUGHERTY, ET AL.,

Plaintiffs,

v.

ESPERION THERAPEUTICS, INC., ET AL.

Defendants.
_____ /

No. 16-10089

District Judge Arthur J. Tarnow
Magistrate Judge R. Steven Whalen

OPINION AND ORDER

This is a securities fraud case brought under Sections 10(b) and 20(a) of the Securities Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5. Before the Court is Plaintiffs' Motion to Compel Production of Document Withheld on Claims of Privilege [ECF No. 117]. For the reasons and under the terms discussed below, the motion is GRANTED.

I. BACKGROUND

Defendant Esperion Therapeutics, Inc. ("Esperion") is a pharmaceutical company that was engaged in the development of ETC-1002, a drug aimed at lowering high-density-lipoprotein cholesterol. Defendant Tim M. Mayleben is Esperion's CEO and a member of its Board of Directors. As such, he was heavily involved in Esperion's efforts to secure Food and Drug Administration ("FDA") approval for ETC-1002. An important factor in determining the likelihood and time line for FDA approval was whether the FDA would require a cardiovascular outcomes trial ("CVOT"), a lengthy and costly study. On August 11, 2015, Esperion had an End of Phase 2 Meeting ("EOP2 Meeting") with the

FDA. Six days later, on August 17, 2015 Esperion published a press release containing the following two statements:

> "The FDA confirmed that LDL-C remains an acceptable clinical surrogate endpoint for the approval of an LDL-C lowering therapy such as ETC-1002 in patient populations who have a high unmet medical need, including patients with [HeFH] ... or [ASCVD]."
>
> "Based upon feedback from the FDA, approval of ETC-1002 in the HeFH and ASCVD patient populations will not require the completion of a cardiovascular outcomes trial."

In its opinion reversing this Court's dismissal of the complaint[1], the Sixth Circuit explained the import of Esperion's public statements:

> "These statements require some explanation to be fully understood in context. A cardiovascular outcomes trial (CVOT) is a costly, lengthy study that measures a drug's effectiveness in reducing cardiovascular risk over several years. Because lower LDL-cholesterol is presumed to improve overall heart health, the FDA does not typically require companies seeking approval of a new cholesterol-lowering drug to complete a CVOT and prove that the drug actually reduces cardiovascular risk. Instead, the FDA treats LDL-cholesterol as a "surrogate endpoint," or proxy, for cardiovascular risk. In other words, if a new drug is shown to lower LDL-cholesterol, the FDA assumes that it also improves overall cardiovascular health. *By saying that the FDA would continue to use LDL-cholesterol as a proxy for cardiovascular risk, and that the FDA would not require a completed CVOT prior to approving ETC-1002, Esperion was essentially telling its investors that ETC-1002 had a clear path to regulatory approval*."
>
> *Dougherty v. Esperion Therapeutics, Inc*., 905 F.3d 971, 976 (6th Cir. 2018).

(Emphasis added).

Following this press release, Defendant Mayleben participated in a conference call with market analysts. In that call, he reiterated that the FDA would not require a CVOT in target populations. However, the FDA's final minutes of the EOP2 Meeting were at odds with Esperion's press release and Mayleben's statements to the market analysts regarding

[1] The Sixth Circuit held that this Court erred in finding that Plaintiffs had failed to show the element of scienter.

the necessity of a CVOT. When the minutes were released, Esperion issued another press release on September 28, 2015, stating, contrary to its earlier position, that the "FDA has encouraged the Company to initiate a cardiovascular outcomes trial promptly, which would be well underway at the time of the New Drug Application submission and review, since any concern regarding the benefit/risk assessment of ETC-1002 could necessitate a completed cardiovascular outcomes trial before approval." In a subsequent conference call, Mayleben characterized Esperion's latest press release as "slightly different" than the language used in the August release. As the Sixth Circuit observed, "Market analysts seized on this change in position, and Esperion's stock dropped 48% the next day, from $35.09 per share to $18.33 per share." *Dougherty*, 905 F.3d at 977.

The gravamen of Plaintiffs' complaint is that Esperion misled investors by falsely and publically stating on August 18, 2015 that the FDA would not require a CVOT before approval of ETC-1002, which had the effect of artificially inflating the trading value of Esperion stock during the class period. When Esperion issued its second public statement following the release of the FDC final meeting minutes, Esperion stock plummeted, causing damage to the investors.

In the present motion, Plaintiff seeks discovery of all drafts of the press releases of August 18 and September 28, 2015 as well as drafts of Esperion's SEC filings, including counsel's edits. Plaintiff also seeks other "subject matter waived documents" relating to the timing and materiality of the two press releases. Defendant has objected to production based on attorney-client privilege.

II. LEGAL PRINCIPLES REGARDING WAIVER OF PRIVILEGE

The federal common law governs privilege issues in this federal question action. *Reed v. Baxter,* 134 F.3d 351, 355 (6th Cir.1998). The elements of the privilege are: (1) where legal advice of any kind is sought; (2) from a professional legal adviser in his capacity as such; (3) the communications relating to that purpose; (4) made in confidence; (5) by the client; (6) are at his instance permanently protected; (7) from disclosure by himself or by the legal adviser; (8) unless the protection is waived. *Id.* at 355-56.

In general, the attorney-client privilege is narrowly construed, because it "reduces the amount of information discoverable during the course of a lawsuit." *United States v. Collis*, 128 F.3d 313, 320 (6th Cir. 1997); *In re Grand Jury Proceedings*, 78 F.3d 251, 254 (6th Cir. 1996). Furthermore, "[t]he burden of establishing the existence of the privilege rests with the person asserting it." *United States v. Dakota*, 188 F.3d 663, 667 (6th Cir. 1999). As a general rule, the attorney-client privilege is waived by voluntary disclosure of private communications by an individual or corporation to third parties. *In re Grand Jury Proceedings, supra*, at 254. The burden of showing that the privilege has not been waived also falls upon the person claiming the privilege. *United States v. Evans,* 113 F.3d 1457, 1461 (7th Cir.1997).

In *Fort James v. Solo Cup Co.*, 412 F.3d 1340, 1349 (Fed.Cir.2005), the Federal Circuit, citing *In re Grand Jury Proceedings* as well as numerous other cases, stated, "The widely applied standard for determining the scope of a waiver of attorney-client privilege is that the waiver applies to all other communications relating to the same subject matter." *See also United States v. Collis, supra*, 128 F.3d at 320 ("The scope of the waiver turns on the scope of the client's disclosure, and the inquiry is whether the client's disclosure involves the same 'subject matter' as the desired testimony"); *Edwards*

v. Whitaker, 868 F.Supp. 226, 229 (M.D.Tenn.1994)(citing *In re Grand Jury Proceedings*) ("[I]t is well-established that 'voluntary disclosure of the content of a privileged attorney communication constitutes waiver of the privilege as to all other such communications on the same subject'").

Under Fed.R.Ev. 502(a), subject matter waiver of otherwise privileged and undisclosed information occurs when (1) there is an intentional waiver of the disclosed material; (2) the disclosed and undisclosed information concern the same subject matter; and (3) the disclosed and undisclosed information "ought in fairness to be considered together." The explanatory notes to Rule 502 state that subject matter waiver is applicable in circumstances where "fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary."

In *In re Columbia/HCA Healthcare Corporation Billing Practices Litigation*, 293 F.3d 289, 302 (6th Cir. 2002), the Sixth Circuit rejected the concept of "selective waiver," holding that when a party releases otherwise privileged information to a government agency, that party cannot then claim attorney-client privilege as to other parties. The court found that the defendant's release of privileged information to the Department of Justice in a separate investigation effected a waiver of the privilege as to the plaintiffs in a subsequent civil case, notwithstanding a confidentiality agreement between the defendant and the Department of Justice providing that the disclosure would *not* be considered a waiver. The court stated:

> "[A]ny form of selective waiver, even that which stems from a confidentiality agreement, transforms the attorney-client privilege into 'merely another brush on an attorney's palette, utilized and manipulated to gain tactical or strategic advantage.'" *Id.* at 302-303 (*Citing In re Steinhardt Partners, L.P.*, 9 F.3d 230, 235 (2d Cir. 1993)).

Columbia/HCA also cited with approval *Permian Corporation v. United States*, 665 F.2d 1214, 1221 (D.C. Cir. 1981), where the D.C. Circuit, rejecting the concept of selective waiver, observed, "The client cannot be permitted to pick and choose among his opponents, waiving the privilege for some and resurrecting the claim of confidentiality as to others, or to invoke the privilege as to communications whose confidentiality he has already compromised for his own benefit."

III. DISCUSSION

It is significant that on August 13, 2015 Esperion communicated to the FDA that its legal counsel had advised it to issue a press release publically disclosing information regarding the FDA's Preliminary Meeting Comments, and that on August 14, Esperion sent a copy of a draft press release to the FDA. On August 16, Esperion released what is alleged to be the misleading press release. In addition, Esperion filed with the SEC a Form 8-K, to which it attached a copy of the September 28 press release. Esperion's voluntary disclosure of these drafts, along with its statement to the FDA that they were drafted on the advice of counsel, operates as a waiver of attorney-client privilege. *In re Grand Jury Proceedings*. Esperion has also waived the privilege as to undisclosed material concerning the same subject matter, the scope of which will be discussed below.

In this regard, Plaintiff has satisfied all three prongs of Rule 502(a). First, the information was voluntarily disclosed to the FDA and the SEC. Second, the heretofore undisclosed drafts, as well as counsel's (or others') editorial comments, concern the same subject matter as the disclosures to the government agencies.

Third, and perhaps most important, fairness dictates that the previous drafts of both press releases, as well as the SEC filings, be disclosed. The Explanatory Note to Subdivision (a) states that subject-matter waiver is "reserved for those unusual situations

in which fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary." Fed.R.Evid. 502, Explanatory Note to Subdivision (a)(quoting *In re United Mine Workers of America Employee Benefit Plans Litig*., 159 F.R.D. 307, 312 (D.D.C.1994).

Esperion's August 13, 2015 email to the FDA specifically referenced its intention, on the advice of counsel, to issue a press release, and the following day, Esperion sent a draft of the press release. *See* Exhibit 13 to the Declaration of Alexander L. Burns, ECF No. 117-14, PageID.5613-5615. This was two days before Esperion's public August press release. Subsequently, Esperion sent the FDA a draft of the September press release. In response, the FDA questioned its accuracy. Following a number of email communications, including the FDA's suggestions for revisions, Esperion revised the press release, and sent the revision to the FDA. The final version of Esperion's press release was published on September 28. Those communications are contained at ECF No. 117-17, PageID.5621-5629.

The effect on Esperion's stock of its August 18 disclosure, which misrepresented the FDA's position on the requirement of a CVOT, and its corrective September 28 disclosure, is central to the Plaintiff's claims, and the various drafts and revisions of the September 28 press release, which stood at odds with both the earlier release and the FDA's assessment of one of the earlier drafts, are clearly relevant to Plaintiff's claims. Fairness is a critical factor underlying the waiver issue. *See United States v. Skeddle*, 989 F. Supp. 905, 909, fn. 2 (N.D. Ohio 1997); F.R.Ev. 502(a)(3). A failure to make this material available to Plaintiff would unfairly result in a "selective and misleading presentation of evidence to the disadvantage of the [Plaintiff]."

The final issue is the extent of the subject matter waiver, a question that is addressed to the Court's discretion. In *Yarberry v. Gregg Appliances, Inc*., 2013 WL 4476681, at *3 (S.D. Ohio Aug. 19, 2013), the Court noted:

> "If the court concludes the privilege has been waived, it must then determine the scope of the waiver. The waiver applies to the rest of the communications on the same subject matter. *Grand Jury Proceedings*, 78 F.3d at 255. The subject matter of the waiver can be defined broadly or narrowly. *Id*. Ultimately, the scope of the waiver must be based upon the facts of each case; and the court must be guided by fairness concerns."

In footnote 2 of *Skeddle*, 989 F.Supp. at 909, the Court observed that "[r]ealizing that fairness is at the heart of the waiver issue, courts have generally held that the 'same subject matter' is to be viewed narrowly." (Citing cases). Here, the narrowest subject matter waiver, under the facts of this case, that would provide important context to the Esperion's disclosed communications and guard against a selective and misleading presentation of evidence, while at the same time avoiding an overly broad disclosure of otherwise privileged material, would apply to all drafts of both the August and September press releases, in addition to the drafts that Esperion voluntarily disclosed to the FDA and the SEC. The waiver also applies to counsel's notes, editorial comments, memoranda, and emails related to the drafting of and revisions to the various drafts. Esperion is ordered to produce this material.

If particular communications contain both material that is described in the preceding paragraph and privileged material that does not fall within the scope of the subject matter waiver, Esperion may redact the latter material, and produce a privilege log explaining the redaction.

IV. CONCLUSION

Under the terms set forth above, Plaintiff's Motion to Compel Production of Document Withheld on Claims of Privilege [ECF No. 117] is GRANTED.

IT IS SO ORDERED.

Date: November 30, 2020

Steven Whalen
R. Steven Whalen
United States Magistrate Judge

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was sent to parties of record on November 30, 2020 electronically and/or by U.S. mail.

s/Carolyn M. Ciesla
Case Manager