UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

IN RE: ONGLYZA (SAXAGLIPTIN) AND KOMBIGLYZE XR (SAXAGLIPTIN AND METFORMIN) PRODUCTS LIABILITY LITIGATION	)	**MASTER FILE NO. 5:18-MD-2809-KKC** **MDL DOCKET NO. 2809** **ALL CASES**

MEMORANDUM OPINION AND ORDER

This matter comes before the undersigned pursuant to a referral from Judge Caldwell to handle the discovery disputes in this case. Defendants filed a Motion for Supplemental Protective Order. [DE 434]. Plaintiffs filed a Motion for Sanctions. [DE 456]. Both motions are fully briefed and ripe for a decision. The Court also held a telephonic conference during which the parties argued the merits of the Motion for Supplemental Protective Order. [DE 461]. As a result of those arguments, the Court requested additional briefing from both parties on the implications of international law on the documents the Defendants seek to protect with the Supplemental Protective Order.

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

This case is a multidistrict litigation arising from allegations that the Type 2 diabetes medication saxagliptin, sold under the brand names Onglyza and Kombliglyze XR, allegedly caused heart failure and/or increased the risk of adverse cardiac events. Defendants Bristol-Myers

Squibb Company ("BMS") and AstraZeneca ("AZ") jointly studied, developed, and made submissions to the Food and Drug Administration ("FDA"). [DE 363 Page ID# 2205].

The District Court bifurcated discovery in this case to address general causation first. [DE 179]. The undersigned conducted a hearing on a discovery dispute on October 10, 2019. [DE 373 and 374]. As a result of this dispute the Court ultimately ordered Defendants to produce what the parties have referred to as "the eCTD production" or "Module 5." Essentially, this material is a broad range of studies and other information Defendants submitted to the Food and Drug Administration that relates to the drugs at issue in this case. The parties have generally referred to this as clinical trial data. At the time of the October 10, 2019, hearing, Defendants had produced some clinical trial data in TIFF format. Plaintiffs asked the Court to require Defendants to provide all clinical trials submitted to the FDA (about 150 trials) in native eCTD format, a request the Court granted. The Court granted this request for two reasons: (1) Defendants stated it would be relatively quick, inexpensive, and easy to produce the eCTD data, and (2) it became apparent at the hearing that the TIFF production of clinical trial data that had occurred up to that point was missing critical metadata, rendering it essentially useless to Plaintiffs and their experts. The current dispute between the parties relates to the international clinical trial data contained in Module 5. Defendants have discovered that it will be timely and costly to redact data from Module 5, thus, they proposed producing all of the data but pursuant to a Supplemental Protective Order. The parties previously entered into a Stipulated Protective Order on October 2, 2018.

II. ANALYSIS

FED. R. CIV. P. 26(c) permits a court, "for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" including requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way[.]" FED. R. CIV. P. 26(c)(1)(g).

"The burden of establishing good cause for a protective order rests with the movant. To show good cause, a movant for a protective order must articulate specific facts showing clearly defined and serious injury resulting from the discovery sought and cannot rely on mere conclusory statements." *Nix v. Sword*, 11 Fed. App'x. 498, 500 (6th Cir. 2001) (citations and quotation marks omitted).

A. SUPPLEMENTAL PROTECTIVE ORDER IS NOT NECESSARY

Here, Defendants do not seek to shield the Module 5 from discovery altogether, but instead seek a Supplemental Protective Order that greatly restricts access to and use of the materials. Yet, the Court finds the proposed Supplemental Protective Order is not necessary. Stated more precisely, the Court finds Defendants have failed to show that they will suffer serious injury or undue burden by proceeding under the existing Stipulated Protective Order. The parties jointly agreed upon a Stipulated Protective Order in this case that specifically resolves all of the concerns raised by Defendants in regard to Module 5. [DE 171]. The proposed Supplemental Protective Order is duplicative of many provisions in the Stipulated Protective Order and, thus, unnecessary. Even where the provisions that are not duplicative, the supplemental terms are so draconian that they make any production of documents under the Supplemental Protective Order essentially useless.

The examples best supporting this conclusion are as follows:

1. Attorney's Eyes Only

The existing Stipulated Protective Order sets forth mechanisms for designating documents Attorney's Eyes Only ("AEO"). Specifically, the Stipulated Protective Order specifically notes that materials should be designated AEO

> (2) where the Confidential Discovery Materials contain private and/or PHI [Protected Health Information] of plaintiffs or persons not a party to the Litigation, including private and/or personal health, medical, employment, financial, and

> residence information; and (3) where documents originate from a jurisdiction outside the United States that (a) are subject to the protection of privacy and data protection[.]

[DE 171 at Page ID # 850]. Plaintiffs all but admit that Module 5 likely contains information that would satisfy the requirements of the AEO designation in the Stipulated Protective Order. Thus, Defendants admit that they could use the Stipulated Protective Order to designate the entire Module 5 production as AEO. [DE 462 at Page ID # 3232].

Nevertheless, Defendants argue more is needed. Under the Stipulated Protective Order, Plaintiffs could challenge the AEO designation of any materials. The Supplemental Protective Order proposes designating the entire Module 5 production as AEO and demands that the entire production "will not be declassified," essentially making the AEO designation of the entire Module 5 unchallengeable. [DE 434-1 at Page ID # 2900]. In fact, Defendants openly admit that the entire purpose behind the AEO provisions in the proposed Supplemental Protective Order is to circumvent the process by which Plaintiffs could challenge Defendants' AEO designation of this production: "Given that Plaintiffs have indicated they may challenge Defendants' position that clinical trial information constitutes Protected Health Information, however, it is important for Defendants to have the propriety of the Attorneys' Eyes Only designation determined *prior* to the production of the eCTD documents." [DE 462, (emphasis in original)]. Defendants seek to designate the entire Module 5 as AEO, sight unseen, and have Plaintiffs forfeit their ability to challenge that designation on materials they have not reviewed. Defendants argue that producing this information without the oppressive provisions of the proposed Supplemental Protective Order means that they could be subject to penalty via international privacy law *if* Plaintiffs challenge the AEO designation and *if* the Court downgrades the designation.

Ultimately, Defendants may be correct that this information is properly protected as AEO, but the process the parties, including Defendants, agreed upon in the Stipulated Protective Order

should be allowed to play out. Defendants' argument that any protection less than AEO would violate the European Union's General Data Protection Regulation's rules and implicate foreign laws and treaties may be a legitimate argument to raise, but not at this juncture and not without the Court's ability to review specific documents.[1]

Defendants have failed to show that the Stipulated Protective Order does not adequately address AEO designation, or that, without the Supplemental Protective Order, Defendants will suffer harm. Defendants may designate materials AEO as they deem appropriate under the current protective order, and if Plaintiffs challenge that designation the Court will take up those issues at that time. But the Court will not impose a protective order on the parties, over Plaintiffs' objections, that strips Plaintiffs of the ability to request review of the AEO designation before any production is made.[2]

2. Prohibition on Use

Defendant's Supplemental Protective Order not only proposes that Defendants produce an unredacted Module 5 to Plaintiffs under an unchallengeable AEO designation, but also prohibits Plaintiff from using those documents "as exhibits at deposition, in exhibits to court filing, as evidence at motions or hearing, or otherwise in any context that could expose such material to

[1] Although the Court requested supplemental briefing on the application of international law, the Court does not feel it is appropriate or necessary to take additional specific actions and opinions until such time as specific documents are before the Court. At this time, the application of international law is a factor the Court considers, but it does not materially alter the Court's decision that Defendants have failed to show that they will suffer serious injury or undue burden by proceeding under the existing Stipulated Protective Order.

[2] Defendants may, predictably, argue that Plaintiffs have seen some of this production when they produced the unusable and redacted TIFF documents. The Court has addressed the TIFF documents, finding that the TIFF production that was missing metadata and parent/child information was useless and essentially no production at all. Had Defendants properly produced these documents in a useable and searchable (but redacted) TIFF format, the parties might not be in the current dispute over a supplemental protective order.

public access." [DE 434-1 at Page ID # 2903]. In short, Defendants propose providing discovery that Plaintiffs are plainly and wholly barred from using in any context in an unredacted format.

In contrast, the current Stipulated Protective Order requires the parties to go to certain lengths to ensure protection of confidential materials. For example, under that Order, Plaintiffs must provide notice to Defendants and an opportunity for Defendants to object if Plaintiffs intend to offer the confidential material as evidence. From there, the Stipulated Protective Order provides a mechanism by which either party can seek an in camera review with the Court. Moreover, the Stipulated Protective Order proscribes a procedure for filing protected documents under seal as well as objecting to such sealing. [DE 171 at Page ID # 856-57]. Like with AEO, the Stipulated Protective Order provides guardrails to prevent disclosure of confidential information while providing a mechanism to dispute any such improper uses.

Despite these (and many other) provisions outlining the use of confidential materials (including AEO material) in the Stipulated Protective Order, Defendants argue the Court should force Plaintiffs to abide by the Supplemental Protective Order's complete prohibition on using unredacted documents as exhibits or evidence. To be clear, the approach set forth in the proposed Supplemental Protective Order seems draconian and unmanageable. Without any judicial determination or even oversight and without any ability to object, Defendants seek to preemptively declare the unredacted version of Module 5 as something that can be produced, but never challenged, never used in discovery, and never used at any future trial.

Defendants counter that such a provision is necessary because unredacted Module 5 information could be "accidentally improperly disseminated outside the bounds of the [Stipulated P]rotective [O]rder" if Plaintiffs are permitted to use unredacted materials as exhibits or other evidence. [DE 434 at Page ID # 2895]. Defendants are correct that accidents occur, but even the

Supplemental Protective Order does not prevent such a possibility. The risk of accidental disclosure exists in every circumstance in which sensitive, confidential, and AEO documents are involved. Even if the Court were to grant Defendants the Supplemental Protective Order, Module 5 information could be "accidentally improperly disseminated outside the bounds of the [Supplemental P]rotective [O]rder" through incomplete redactions, document mix-ups, or any number of human errors that might occur in this or any other case. [DE 434 at Page ID # 2895].

Again, redacted versions of the Module 5 materials may very well be the most appropriate way to file that information in record; however, the Court will not hamstring itself or the Plaintiffs before that production is even made. Further, the existing Stipulated Protective Order requires Plaintiffs to give Defendants notice if they intend to use documents with a "confidential" or higher designation as evidence or exhibits. If Defendants so designate Module 5, then Plaintiffs are required to notify Defendants of any use of such documents. Then Defendant may, at that time, object to the documents' proposed use. Consequently, the Court will timely take up the issue. But, currently, there is no reason to impose wholesale restrictions on the use of Module 5 where the existing Stipulated Protective Order adequately protects those materials.

3. International Inquiry Clawback Provision

The proposed Supplemental Protective Order includes what Defendants refer to as a "clawback" provision, so that "[i]f Defendants receive inquiries or orders from international data protection authorities about this production, Plaintiffs would cease reviewing and sequester the production pending further relief by this Court." [DE 434 at Page ID # 2892]. "The proposed supplemental order requires, in a manner similar to the operation of a clawback provision, that Plaintiffs cease reviewing or using the data in question until any dispute resulting from such an agency's actions is resolved. This Court would remain the arbiter of such disputes." [DE 434 at Page ID # 2895]. This provision could effectively put discovery in this Court and this litigation at

the mercy of a "foreign data protection agency." [DE 434 at Page ID # 2895]. This Court will not so abdicate its power to direct this litigation, nor does this Court wish that discovery in this case be held hostage by a "foreign data protection agency."

B. COST SHIFTING

Defendants argue that if the Court denies its request for a Supplemental Protective Order, the Court should require Plaintiffs to bear the cost of redactions of Module 5. Defendants claim that "[w]ithout the supplemental protective order, an eCTD production is no longer minimally burdensome; indeed, it would be tremendously expensive. Since that expense would be incurred solely for Plaintiffs' convenience, they should be required to pay for it." [DE 434 at Page ID # 2896]. As the Court has addressed, there appears to be no need for the Supplemental Protective Order because the existing Stipulated Protective Order sufficiently safeguards the information Defendants claim they need to redact. Thus, Defendants have the option at this juncture to produce Module 5 with or without redactions, depending on how they wish to proceed. Another Magistrate Judge in this district addressed this issue thoroughly:

> "Generally the party responding to a discovery request bears the cost of compliance." *Medtronic Sofamor Danek, Inc. v. Michelson*, 229 F.R.D. 550, 553 (W.D. Tenn. 2003). However, Rule 26(c) vests the Court with authority to condition discovery upon a requesting party's payment of the costs in order to protect the responding party from undue burden or expenses. . . . "The inquiry in a cost-shifting analysis is not necessarily whether the cost is substantial but whether it is 'undue.'" *Michelson*, 229 F.R.D. at 553.

SMA Portfolio Owner, LLC v. Corporex Realty & Investment, LLC, 2014 WL 12647934, at *4 (E.D. Ky., March 5, 2014). Although FED. R. CIV. P. 26(b)(2) and (c) permit cost-shifting, it is only permitted where the producing party can show that production is unduly burdensome. Defendants have made no showing here that the cost of redactions is an "undue" burden; in fact, Defendants describe redactions as merely "inefficient" in their Reply, despite previously calling the potential redactions "tremendously expensive." [DE 462 at Page ID # 3231 and DE 434 at

Page ID # 2896]. The Court will not order Plaintiffs to pay for redactions based upon the record before it to date.

C. MOTION FOR SANCTIONS

The document production in this case has been undeniably slow, at best. Defendants have zealously advocated for limitations on the production and its future use, advocacy that is walking the line of obstruction at this point. Defendants waited five months between the Court's prior Order requiring production of the Module 5 data and filing the instant motion for a supplemental protective order.

Meanwhile, as Defendants fairly point out, the Court admonished Plaintiffs for their excessive delay in filing a Motion to Compel that production.

Plaintiffs now felt it appropriate to file a Motion for Sanctions [DE 456] on April 13, 2020, and—before the Court has had the opportunity to rule on that motion—filed another Motion for Sanctions on May 18, 2020.[3] The parties spent nearly as much brief space on allegations of delay hurled at one another as they did on the substance of the of discovery dispute. The Court implores—nay—*begs* the parties to cease this conduct. This litigation cannot move forward if the parties spend all of their time, energy, and resources on trying to avoid their discovery obligations, cause delay, and filing motions for sanctions. The Court finds that both parties are culpable in the delays that have led to this moment and denies Plaintiffs' Motion for Sanctions. Or, more eloquently stated, "a plague o' both your houses."[4]

In the future, however, the Court will consider use of all power available to it to discourage continued dilatory behavior from either party.

[3] The May 18, 2020, Motion for Sanctions is not yet ripe, thus the Court makes no ruling on it herein.

[4] WILLIAM SHAKESPEARE, ROMEO & JULIET, act III, sc. 1.

III. CONCLUSION

For the reasons stated herein, **IT IS ORDERED** that:

(1) Defendants' Motion for Supplemental Protective Order [DE 434] is **DENIED**;

(2) Plaintiff's Motion for Sanctions [DE 456] is **DENIED**; and

The undersigned enters this Memorandum Opinion pursuant to 28 U.S.C. § 636(b)(1)(A). Within fourteen (14) days after being served with a copy of this Memorandum Opinion, either party may appeal this decision to Judge Caldwell pursuant § 636(b)(1)(A) and FED. R. CIV. P. 72(a).

Entered this 22nd day of May, 2020.

Signed By:
Matthew A. Stinnett
United States Magistrate Judge