IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 22-1461-CJB
	)	CONSOLIDATED
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

1. Pending before the Court in this consolidated Hatch-Waxman litigation matter is the parties' Joint Motion for Teleconference to Resolve Protective Order Dispute ("Motion"). (D.I. 47) With the Motion, Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals, Inc. (together with Teva Pharmaceuticals USA, Inc., "Teva"), Lupin Ltd., Lupin Pharmaceuticals, Inc., Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. (collectively, "Defendants") request, pursuant to Federal Rule of Civil Procedure 26(c), that the Court include a "regulatory bar" in the proposed protective order in this case. The regulatory bar would bar persons who gain access to "Confidential" or "Highly Confidential Information" ("confidential information") in this case from participating in proceedings concerning migalastat before the United States Food and Drug Administration ("FDA") (or in other equivalent regulatory proceedings) for a specified period of time—including by filing a citizen petition with the FDA.[1]

[1] The Federal Food, Drug, and Cosmetic Act allows any person to file a "citizen petition" requesting that the FDA take, or refrain from taking, administrative action. 21 C.F.R. § 10.25(a)(2); *see also* 21 C.F.R. § 10.30.

Plaintiffs Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc. (collectively, "Plaintiffs") oppose Defendants' request.

2. A party seeking a protective order bears the burden of showing good cause for its issuance. *Xerox Corp. v. Google, Inc.*, 270 F.R.D 182, 183 (D. Del. 2010). Relatedly, where (as here) a protective order has not yet been entered, but one side wishes to include a more restrictive provision in the order than does the other side, the side promoting the more restrictive provision (here, Defendants) bears the burden to demonstrate good cause for its inclusion. Fed. R. Civ. P. 26(c)(1); *cf. Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, Civil Action No. 15-691-LPS-CJB, 2016 WL 447794, at *1 n.1 (D. Del. Feb. 4, 2016).

3. Before analyzing the merits of Defendants' request, the Court begins by making a few overarching points about regulatory bars.

4. First, the Court addresses what factors it should use in order to assess whether a party has demonstrated good cause to include a regulatory bar in a protective order. When it comes to the (somewhat similar) question about whether to include a patent prosecution bar in a protective order, the United States Court of Appeals for the Federal Circuit[2] has advised—in cases like *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373 (Fed. Cir. 2010)—that a court should examine whether the movant has demonstrated a sufficiently detailed risk of inadvertent

[2] The parties do not directly address the issue of whether regional circuit law or Federal Circuit law governs the determination of whether, and under what circumstances, an addition to a protective order, of the type at issue here, is appropriate. Even assuming that regional circuit law applies, *see Baystate Techs., Inc. v. Bowers*, 283 F. App'x. 808, 810 (Fed. Cir. 2008) (applying regional circuit law in resolving a protective order dispute), the Court will still—as have our Court and other courts in cases involving patent disputes—look to the Federal Circuit's case law for helpful guidance. *See, e.g.*, *PhishMe, Inc. v. Wombat Sec. Techs., Inc.*, Civil Action No. 16-403-LPS-CJB, 2017 WL 4138961, at *2 n.5 (D. Del. Sept. 8, 2017) (citing cases). It does so also because it believes that both the United States Court of Appeals for the Third Circuit and the Federal Circuit would apply the same law, in the same way, as the Court does herein, were they to be confronted with these issues.

disclosure of confidential information, so as to warrant inclusion of the bar. 605 F.3d at 1378 (citing *U.S. Steel Corp. v. United States*, 730 F.2d 1465 (Fed. Cir. 1984)). In doing so, the Federal Circuit explained that a court should consider: (1) the extent to which affected counsel is involved in "competitive decision[]making" with its client, and (2) the potential prejudice to the non-moving party in denying it the counsel of its choice. *Id.* at 1378-80. Despite this, some decisions from this District regarding whether regulatory bars should be inserted in a protective order[3] have not utilized the *In re Deutsche Bank* factors; instead, they have looked to the *Pansy* factors set out by the United States Court of Appeals for the Third Circuit.[4] In the Court's view (a view that both sides here agreed with during the hearing on the Motion), it makes more sense to utilize the *In re Deutsche Bank* factors in deciding this question. To a great degree, that is because (as with an assessment of whether to enter a prosecution bar), the consideration of a regulatory bar's appropriateness will largely be focused on the risk of *inadvertent* disclosure of discovery material. In contrast, the *Pansy* factors are typically used in determining whether *intentional* disclosure of certain case materials is called for (i.e., whether a confidentiality order or a redaction order should be entered to bar such materials from public disclosure, where one

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[3] *See, e.g.*, *Avion Pharms., LLC v. Granules Pharms., Inc.*, Civil Action No. 20-898-LPS, 2021 WL 1785580, at *3 (D. Del. May 5, 2021); *Mayne Pharma Int'l Pty. Ltd. v. Merck & Co., Inc.*, C.A. No. 15-438-LPS, D.I. 47 at 13-14 (D. Del. Mar. 4, 2016).

[4] *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787-88 (3d Cir. 1994). In applying the seven *Pansy* factors, courts engage in a balancing test to weigh: "(1) the interest in privacy of the party seeking protection; (2) whether the information is being sought for a legitimate purpose or an improper purpose; (3) the prevention of embarrassment, and whether that embarrassment would be particularly serious; (4) whether the information sought is important to public health and safety; (5) whether sharing of the information among litigants would promote fairness and efficiency; (6) whether the party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public." *Arnold v. Pa. Dep't of Transp.*, 477 F.3d 105, 108 (3d Cir. 2007) (citing *Pansy*, 23 F.3d at 787-88).

side *intentionally* seeks to make public the material at issue). Additionally (and relatedly), a number of the *Pansy* factors are just not that likely to be particularly relevant to the regulatory bar/protective order calculus.[5] So for these reasons, the Court will utilize the *In re Deutsche Bank* factors here. *See Reckitt Benckiser Inc. v. Watson Labs., Inc.-Fla.*, CASE NO. 09-60609-CIV-DIMITROULEAS/SNOW, 2010 WL 11505200, at *2-3 (S.D. Fla. Mar. 11, 2010) (concluding the same).

5. Second, the Court addresses, as a general matter, the propriety of regulatory bars like the one at issue here. In Plaintiffs' briefing, Plaintiffs emphasized that when the issue of whether to include a regulatory bar has been contested in this District, each time (or at least each time that the decision was publicly issued) our Court has declined to do so.[6] Plaintiffs seemed to be suggesting that this means that the matter is settled in this District—i.e., that a judge in the District will simply never include such a disputed provision in a protective order going forward. (D.I. 54 at 2) But the Court does not necessarily think that is so. Although it is true that our judges have denied the inclusion of regulatory bars in the past, those decisions have rested, at least in significant part, on the fact that in each case, the movant was suggesting that the bar was needed in order to stop its opponent from *directly and explicitly* citing to the movant's

[5] For example, the second *Pansy* factor, which asks whether the information being sought is for a legitimate or improper purpose, again seems more relevant to cases where a party *intentionally* wishes to place the information into the public realm—unlike our scenario here, where the concern is largely about whether a party will *inadvertently* utilize information learned in discovery when interacting with a regulatory agency. And some of the other *Pansy* factors (like the third factor relating to the prevention of embarrassment) do not seem like they will often come up in this setting.

[6] (D.I. 54 at 2 (citing *Avion Pharms., LLC*, 2021 WL 1785580, at *3-4; *Mayne Pharma*, D.I. 47 at 13-14; *Alza Corp. v. Par Pharm. Inc.*, No. 13-1104-RGA, D.I. 78 at 26 (D. Del. Dec. 13, 2013); *Cephalon, Inc. v. Impax Lab'ys, Inc.*, Civil Action No. 11-1152-SLR, D.I. 56 at 1-2 (D. Del. June 29, 2012)))

confidential information in a future FDA citizen petition. The problem for those movants was that (as here) the respective protective orders at issue already prohibited the *direct, explicit* use of the movant's confidential information for any purpose other than one associated with the instant litigation. *See, e.g.*, *Avion Pharms., LLC v. Granules Pharms., Inc.*, Civil Action No. 20-898-LPS, 2021 WL 1785580, at *3-4 (D. Del. May 5, 2021) ("If Romeg submits a citizen petition to the FDA *citing Defendant's confidential information* in an effort to prevent approval of Defendant's ANDA product, it will be apparent that Romeg has violated the terms of the protective order even without an express regulatory bar.") (emphasis added); *Mayne Pharma Int'l Pty. Ltd. v. Merck & Co., Inc*., Civil Action No. 15-438-LPS, D.I. 47 at 13-14 (D. Del. Mar. 4, 2016) ("It [] seems to [the Court] that all of the examples that the plaintiff points to for what it is concerned with are in reality intentional acts that are already prohibited under the agreed-upon portions of the protective order."); *Cephalon, Inc. v. Impax Lab'ys, Inc.*, Civil Action No. 11-1152-SLR, D.I. 56 at 2 (D. Del. June 29, 2012) (noting that the only evidence cited by the movant in support of the proposed bar was that the plaintiff had "sought, and received, permission from the court to disclose confidential, litigation-generated information to the FDA in support of its [citizen] petition" filed in connection with a third party's ANDA, which was "very much an intentional disclosure already governed by the protective order in place"). In other words, in those cases, the proposed regulatory bar was not needed in order to prevent a branded drug manufacturer from filing a citizen petition that included *clear and direct citation* to a generic drug manufacturer's confidential information—because another provision of that same protective order would already have prohibited this type of explicit conduct in the first place.

6. But that does not mean that a regulatory bar would always be redundant in a protective order like the one at issue here.[7] As Teva's counsel noted during the Motion hearing, one can certainly posit scenarios in which representatives of a party like Plaintiffs could: (1) learn confidential information during litigation about a generic manufacturer's processes and procedures for testing and/or manufacturing a drug product at issue; and (2) thereafter file a citizen petition with the FDA regarding the same drug product (or related subject matter), in which it requested the FDA to take certain action; but (3) do so in a way where it *did not explicitly cite to* the generic manufacturer's documents *or otherwise make clear that* the request was informed by receipt of the generic manufacturer's confidential information (even though what it learned from those documents was, in fact, inadvertently driving the request). (*See also* D.I. 60 at 2) Such an act could have significant negative consequences for the generic manufacturer, in that this type of a request (and the FDA's subsequent investigation thereof) could cause "considerable delay" of "FDA approval of a competing generic." *In re Restasis*, 333 F. Supp. 3d 135, 145 (E.D.N.Y. 2018); *see also Reckitt Benckiser Inc.*, 2010 WL 11505200, at *6. The Court points all of this out not to suggest that there is anything inherently wrong with the filing of a citizen petition, nor that regulatory bars should always be included in protective orders. Instead, it does so simply to explain why it does not agree with the suggestion that a request to include a regulatory bar in a protective order should always be denied as a matter of course. *See Reckitt Benckiser Inc.*, 2010 WL 11505200, at *6 (granting a request for inclusion of

[7] Indeed, as Defendants note, parties to Hatch-Waxman litigation in our Court and in federal courts around the country regularly agree to include regulatory bars in protective orders. (D.I. 55 at 2 (citing cases)); *see also Reckitt Benckiser Inc.*, 2010 WL 11505200, at *6 (noting that the court had been provided with numerous examples of protective orders in patent cases in various federal district courts that included a regulatory bar). So the idea that the inclusion of such a bar is somehow anomalous in cases like this one is just not so.

a regulatory bar in a protective order); *see also In re Impax Labs., Inc*., 495 F. App'x 82, 84 (Fed. Cir. 2012) (declining a petition for a writ of mandamus regarding the district court's decision not to impose a regulatory bar, in part because the "district court . . . left open the possibility that [the movant] could present specific circumstances to the district court for reconsideration"). Instead, just like in other matters involving analysis of the *In re Deutsche Bank* factors, the outcome of this type of request should depend on the particular facts at issue in a given case. *In re Deutsche Bank*, 605 F.3d at 1379 (noting that each case "should be decided based on the specific facts involved therein") (internal quotation marks and citation omitted).

7. With that as prelude, the Court now turns to the particular facts relating to the instant Motion. Review of those facts indicates that, at least on this record, Defendants have not demonstrated good cause.

8. The first *In re Deutsche Bank* factor assesses the risk that any person obtaining access to confidential information via the protective order in this case will actually be involved in competitive decision making relating to a future FDA proceeding regarding migalastat. On this score, the Court concludes that Defendants have not made a strong showing as to the potential for inadvertent misuse. It is not disputed that Plaintiffs' counsel working on this case could or would be considered "competitive decision makers." But what is wanting is a demonstration that there is anything more than a generalized or speculative risk that such counsel will actually participate in a future FDA proceeding involving migalastat (and inadvertently disclose Defendants' confidential information in the process). *See Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc*., Civil Action No. 08-6304(WJM), 2009 WL 3627947, at *3 (D.N.J. Oct. 29, 2009) ("The teaching of *U.S. Steel* and its progeny is that restrictions on . . . the activities of counsel will not be imposed absent some specific, identifiable showing and not on

the basis of broad generalizations of potential harm."). In attempting to argue that the risk of inadvertent disclosure was great here, Defendants primarily relied on the fact that Plaintiffs had moved in this case for the *pro hac vice* admission of Daniel Orr. Defendants asserted that Mr. Orr is "a former U.S. Food & Drug Administration Regulatory Counsel[,] whose firm biography identifies *no* litigation experience, but rather 'more than fifteen years of life sciences regulatory experience.'" (D.I. 55 at 2 (emphasis in original); *see also* D.I. 15; D.I. 60 at 1) Defendants suggestion seemed to be that Mr. Orr is not really going to do much (if any) litigating in this case, and that his presence here was simply intended to allow him to gain access to Defendants' highly confidential information, which he later might inadvertently misuse when he participates in FDA proceedings regarding the drug product at issue. (D.I. 55 at 2 ("Here, the risk of inadvertent disclosure is high, given that Plaintiffs have retained regulatory counsel for whom there is no apparent litigation role.")) Had Defendants been able to make a strong showing in this regard, this might have supported grant of their request.

9. But in the Court's view, Plaintiffs sufficiently rebutted Defendants' argument. On that score, Plaintiffs represented that: (1) Mr. Orr is not simply a regulatory attorney but instead has at least seven years' worth of litigation experience at his prior law firm, including experience litigating intellectual property matters; (2) while at the FDA, Mr. Orr was the statutory notice officer for biosimilar patent litigation and was a part of the federal government's litigation team in *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1 (2017); (3) Mr. Orr will play an important litigation role in this Hatch-Waxman case—one in which he will draw on his regulatory experience in order to benefit Plaintiffs' litigation efforts. (D.I. 59 at 1)[8] In light of

[8] In light of the subject matter, the Court will accept Plaintiffs' counsels' representations about the substance of Mr. Orr's professional experience. But Plaintiffs really should have filed a sworn declaration making these same points. Parties need to be mindful

this, the Court cannot conclude that Mr. Orr's participation in this litigation alone sets off alarm bells, or suggests anything more than a generalized risk of inadvertent disclosure. So this factor appears to be about neutral.

10. The second *In re Deutsche Bank* factor relates to the potential prejudice to the non-moving party (here Plaintiffs) of being denied their counsel of choice. On this score, the record before the Court is not great. The Court really does not have any information about the extent to which Plaintiffs would be prejudiced were their litigation counsel here prevented from participating in FDA or other regulatory proceedings regarding the drug product at issue. The answer to this prejudice inquiry might turn on questions like "How indispensable are Plaintiffs' litigation counsel to Plaintiffs' overall legal efforts regarding migalastat?" or "What amount of resources do Plaintiffs have to bring to bear on migalastat-related legal proceedings?" or "How many other law firms or attorneys have Plaintiffs worked with in this space in the past?" The Court has little information, one way or the other, about the answers to these questions. So this factor too is basically neutral.

11. With neither factor favoring imposition of the regulatory bar (and with the evidence in equipoise overall), Defendants have not met their burden to demonstrate good cause for the inclusion of the bar. Therefore, the Motion is DENIED.

Dated: August 17, 2023

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

about making a *factual record* with regard to key matters relating to discovery disputes. *See Immervision, Inc. v. Apple, Inc.*, Civil Action No. 21-1484-MN-CJB, D.I. 136 (D. Del. Aug. 4, 2023).