IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVION PHARMACEUTICALS, LLC and RxOMEG THERAPEUTICS, LLC, a/k/a ROMEG THERAPEUTICS, LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 20-898-LPS
GRANULES PHARMACEUTICALS, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this **5th** day of **May, 2021**, the court having considered the parties' letter submissions regarding whether to include prosecution and regulatory bars in the proposed protective order (D.I. 36; D.I. 39), IT IS HEREBY ORDERED THAT defendant Granules Pharmaceuticals, Inc.'s ("Defendant") letter request is GRANTED-IN-PART for the reasons set forth below.

1. Background. Plaintiffs Avion Pharmaceuticals, LLC ("Avion") and R_x Omeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC ("Romeg") (collectively, "Plaintiffs"), brought this action against Granules for infringement of U.S. Patent Nos. 9,907,751 ("the '751 patent"), 10,226,423 ("the '423 patent"), 10,383,820 ("the '820 patent") and 10,383,821 ("the '821 patent") (collectively, the "patents-in-suit"). (D.I. 9) Dr. Indu Muni and Dr. Naomi Visnhupad are the named co-inventors of the patents-in-suit, which cover colchicine solutions and methods for the treatment of gout flares. (*Id.* at ¶¶ 19, 25, 31, 37, 44; Exs. A-D) Plaintiffs filed this action in response to Defendant's filing of Abbreviated New Drug Application

("ANDA") No. 214808, which seeks FDA approval to sell a generic version of Plaintiffs' branded drug, Gloperba®, prior to the expiration of the patents-in-suit. (*Id.* at ¶ 1)

2. Romeg is a small company that was founded in May 2015 by Dr. Indu Muni and Ms. Gita Muni. (D.I. 39, Ex. 2 at ¶ 5) Dr. Muni is the CEO of the company and is involved in product innovation. (*Id.*) Ms. Muni is the Executive Vice President of Romeg who performs part-time bookkeeping for the company and is not involved in the company's day-to-day activities. (*Id.*) In September 2015, Dr. Naomi Vishnupad joined Romeg as the company's Chief Science Officer, with responsibilities that include creating new products and bringing those new products to the prescription and life sciences market. (*Id.* at ¶ 2) Romeg has no other employees. (*Id.* at ¶ 6)

3. Due to the small nature of the company, Dr. Muni and Dr. Vishnupad wear many hats at Romeg. As the named inventors, they are the only individuals at Romeg with knowledge of the technology covered by the patents-in-suit. (D.I. 39, Ex. 2 at ¶ 8) Accordingly, they are solely responsible for reviewing patent applications and submissions to the United States Patent and Trademark Office and directing outside prosecution counsel. (*Id.* at ¶ 9) Dr. Muni and Dr. Vishnupad also oversee all litigation matters involving Romeg because they do not have in-house counsel, and they are responsible for regulatory submissions to the FDA. (*Id.* at ¶¶ 7, 10)

4. **Legal standard.** Under Federal Rule of Civil Procedure 26(c)(1), "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ." Fed. R. Civ. P. 26(c)(1). Inherent in a court's power under Rule 26 is the ability to restrict an individual attorney's access to a trade secret or other confidential information when there is "an unacceptable opportunity for inadvertent disclosure." *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984); *see* Fed. R.

Civ. P. 26(c)(1)(G). In *U.S. Steel*, the Federal Circuit explained that in cases where in-house counsel are involved in competitive decision-making, "it may well be that a party seeking access [to confidential information] should be forced to retain outside counsel or be denied the access recognized as needed." *Id.* at 1468. The term "competitive decision-making" is "shorthand for a counsel's activities, association, and relationship with a client that are such as to involve counsel's advice and participation in any or all of the client's decisions . . . made in light of similar or corresponding information about a competitor." *Id.* at 1467.

5. Analysis. Before the court is the parties' dispute about whether to include prosecution and regulatory bars in the proposed protective order. Defendant seeks to impose restrictions on the individuals who access its confidential information in this litigation because Romeg is a competitor. (D.I. 36 at 2) To lessen the risks inherent in the disclosure of its confidential information, Defendant proposes a division of duties among Romeg executives between managing the litigation and engaging in competitive decision-making, such as prosecuting patents and engaging in regulatory communications with the FDA. (*Id.* at 1) In response, Romeg argues that the proposed prosecution and regulatory bars would force Romeg to choose between running the day-to-day activities of its business and prosecuting this litigation, because there are no individuals besides Dr. Muni and Dr. Vishnupad at Romeg who can oversee Romeg's litigation, prosecution, and regulatory activities. (D.I. 39 at 2-3) For the reasons set forth below, Defendant's letter request to include a prosecution bar in the proposed protective order is GRANTED-IN-PART, and Defendant's request to include a regulatory bar in the proposed protective order is DENIED.

6. *Prosecution bar.* Defendant's request for the inclusion of a prosecution bar in the protective order is GRANTED-IN-PART. Courts in this district have recognized that, upon a

showing of good cause, a protective order may include a prosecution bar against trial counsel who have access to the opposing party's confidential information. *See In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). In adjudicating disputes over what kind of prosecution bar should be entered, a court must first consider whether there is an "unacceptable" risk of inadvertent disclosure or competitive use of confidential information, determined by the extent to which affected counsel is involved in "competitive decisionmaking" with its client. *Id.* at 1378–79 (citation omitted). The court must then "balanc[e]" that risk against the potential harm the party affected by the portion of the bar at issue would face, were it to be denied its counsel of its choice if that portion of the bar were adopted. *Id.* at 1380. The court has "broad discretion" to decide the appropriate degree of protection. *Id.*

7. Under the standard set forth in *Deutsche Bank*, Defendant bears the burden of showing good cause for the inclusion of the prosecution bar. *Id.* at 1378. The court finds that Defendant has met the good cause requirement. The risk of inadvertent disclosure is particularly high where, as here, Romeg's in-house, non-attorney executives are admittedly competitive decisionmakers and the company is very small. *See Blackbird Tech LLC v. Serv. Lighting & Elec. Supplies, Inc.*, C.A. No. 15-53-RGA *et al.*; 2016 WL 2904592, at *5-6 (D. Del. May 18, 2016) (applying prosecution bar and covenant not to sue to Plaintiff's in-house/lead litigation counsel despite Plaintiff's small size due to the "concrete, particularized risk of inadvertent disclosure and misuse here."); *PhishMe, Inc. v. Wombat Sec. Techs., Inc.*, C.A. No. 16-403-LPS-CJB; 2017 WL 4138961 (D. Del. Sept. 18, 2017). "[T]he risk of inadvertent disclosure cannot be overcome by the mere contention that access to confidential information is necessary for case management" unless the lack of access "would impede a party's ability to litigate through outside counsel." *R.R. Donnelley & Sons Co. v. Quark, Inc.*, C.A. No. 06-32-JJF, 2007 WL

61885, at *1 (D. Del. Jan. 4, 2007) (denying access to confidential information to non-attorney executive engaged in competitive decision-making). The risk of harm is heightened where, as here, the non-movant is a direct competitor of the movant in the particular market. *See PhishMe*, 2017 WL 4138961, at *8 (citing cases).

8. The risk of inadvertent disclosure must be balanced against the potential harm to Romeg resulting from the prosecution bar. Because such harm is typically framed in the context of navigating restrictions on choice of counsel, the case law regarding prosecution bars provides little guidance in this case involving non-attorney employee access to confidential information. Nonetheless, the harm to Romeg is significant because a prosecution bar would impair Romeg's ability to continue prosecuting its pending patent applications for the duration of the bar.[1]

9. On balance, the risk of inadvertent disclosure outweighs the potential harm to Romeg. Limiting access to confidential information is particularly important in cases involving a small, closely held company because there are limited options to divide in-house responsibilities among a few key employees. *See Blackbird Tech*, 2016 WL 2904592, at *4. A competitive decision maker is at great risk of strategically amending claim scope based on the inadvertent disclosure of confidential information produced by a competitor. *See PhishMe*, 2017 WL 4138961, at *8 (citing cases).

10. However, Defendant's proposed prosecution bar is overbroad. Defendant has not convincingly argued that the prosecution bar should extend to all post-grant proceedings.[2] Consequently, the bar shall be limited to reissue proceedings and no other post-grant

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[1] The duration of the prosecution and regulatory bar is for a period of one year after the conclusion of the case and any related appeals. (D.I. 36, Ex. A at ¶ 17)

[2] In particular, Defendant has not identified why a prosecution bar should extend to re-examination proceedings, where the focus is on claims narrowing, or *inter partes* review proceedings, which address invalidity challenges pursuant to 35 U.S.C. §§ 102 and 103.

proceedings. Moreover, the definition of "related litigation" for purposes of the prosecution bar shall be limited, in accordance with the agreement of the parties, to "any litigation related to Goperba (NDA 210942) stemming from an ANDA being filed, such as a second filer in a separate but related case." (D.I. 36, Ex. B at 3)

11. ***Regulatory bar.*** Defendant's request for the inclusion of a regulatory bar in the protective order is DENIED. Courts in this district have evaluated requests for regulatory bars by considering the *Pansy* factors,[3] which govern requests to preserve the confidentiality of discovery materials pursuant to a protective order. *See, e.g.*, *Mayne Pharma Int'l Pty. Ltd. v. Merck & Co., Inc.*, C.A. No. 15-438-LPS, D.I. 47 at 13:15-14:16 (D. Del. Mar. 4, 2016) (attached as Exhibit 3 to D.I. 39). Because there is little risk of "inadvertent" disclosure of confidential materials to the FDA, requests for regulatory bars are routinely denied in this district. *See id.*; *Alza Corp. v. Par Pharm. Inc.*, C.A. No. 13-1104-RGA, D.I. 78 at 26:7-15 (D. Del. Dec. 17, 2013) (attached as Exhibit 4 to D.I. 39); *Cephalon, Inc. v. Impax Labs., Inc.*, C.A. No. 11-1152-SLR, D.I. 56 (D. Del. June 29, 2012) (attached as Exhibit 5 to D.I. 39).

12. Defendants' proposed regulatory bar would prevent a party receiving Defendant's confidential information from engaging in "any communication with any U.S. or foreign regulatory agency," including "the preparation or filing of Citizen Petitions or Suitability Petitions with the United States Food and Drug Administration, relating to colchicine oral

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[3] Courts engage in a balancing test to weigh the seven *Pansy* factors: "(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 v. Borough of Stroudsburg*, 23 F.3d 772, 787-88 (3d Cir. 1994)).

solution and drug products." (D.I. 36, Ex. A at ¶¶ 5, 17) Unlike the prosecution bar, which protects against inadvertent disclosure of confidential information, the regulatory bar proposed by Defendant is intended to prevent individuals with access to confidential information from intentionally submitting citizen petitions to the FDA regarding the accused product. *See id.*

13. Here, Defendant suggests that Romeg could "ask the FDA to withhold approval of Granules's affordable generic product based on non-public information." (D.I. 36 at 2) But the language of paragraph 5 of the proposed protective order expressly prohibits Romeg from using confidential information for any other purpose outside of "prosecuting, defending, or settling this action." (*Id.*, Ex. A at ¶ 5) 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. Submitting such a petition would require an intentional act on Romeg's part, and it is therefore not comparable to circumstances requiring a prosecution bar. *Compare Mayne Pharma*, C.A. No. 15-438-LPS, D.I. 47 at 13:15-14:16; *Alza*, C.A. No. 13-1104-RGA, D.I. 78 at 26:7-15; *Cephalon*, C.A. No. 11-1152-SLR, D.I. 56 *with In re Deutsche Bank*, 605 F.3d 1373, 1378 (Fed. Cir. 2010) (recognizing, in the context of a prosecution bar, the "difficult[y] for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so.").

14. Conclusion. In view of the foregoing analysis, Defendant's letter request (D.I. 36) is GRANTED-IN-PART with respect to the prosecution bar and DENIED with respect to the regulatory bar. In accordance with the court's rulings in this Memorandum Order, the parties shall submit a revised joint proposed protective order to the court on or before May 12, 2021.

15. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to three (3) pages each.

16. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge