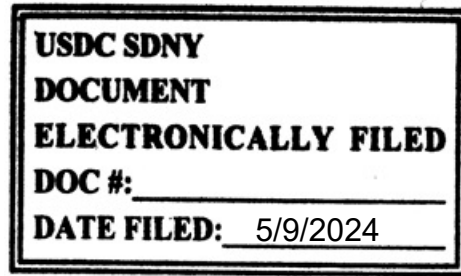


May 8, 2024

BY ECF



The Hon. Robert W. Lehrburger
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, New York 10007

NORTON ROSE FULBRIGHT

Norton Rose Fulbright US LLP
1301 Avenue of the Americas
New York, New York 10019-6022
United States of America

Direct line +1 212 318 3108
robin.adelstein@nortonrosefulbright.com

Tel +1 212 318 3000
Fax +1 212 318 3400

Re: Lupin Ltd. v. Salix Pharma., Inc., et al., No. 1:22-cv-07656-JHR-RWL

Dear Judge Lehrburger:

We represent Defendant and Counterclaim-Plaintiff Salix Pharmaceuticals, Inc. and Defendant Bausch Health US, LLC (“Defendants”) in the above-referenced action and submit this letter-motion pursuant to Rule III(G) and the Appendix of Your Honor’s Individual Practices in Civil Cases to request that the Court permit Defendants to maintain the confidentiality of Defendants’ trade secret information within the document filed at Dkt. 82-1. Consistent with Your Honor’s Individual Practices, and contemporaneously with this letter-motion, Defendants are (1) publicly filing a copy of Dkt. 82-1 in redacted form; and (2) filing under seal a copy of Dkt. 82-1 with their proposed redactions highlighted in yellow.

Plaintiff Lupin Ltd. does not object to Defendants’ proposed redactions of Dkt. 82-1.

The Proposed Redactions Protect Confidential, Trade Secret Information.

Defendants seek to maintain confidential trade secret information, which is “broadly defined” as “any formula, pattern, device or compilation of information which is used in one’s business, and which gives the owner an opportunity to obtain an advantage over competitors who do not know or use it.” *Town & Country Linen Corp. v. Ingenious Designs LLC*, No. 18-CV-5075 (LJL), 2022 WL 2757643, at *14 (S.D.N.Y. July 14, 2022). Dkt. 82-1, Exhibit 1 to the Declaration of Benjamin Bloodstein (the “Exhibit”), is a proposed Letter of Request seeking international judicial assistance from Italy under the Hague Evidence Convention. Two Zach Zambon Chemicals reports (the “Zach Reports”) are attached to the proposed Letter of Request to help orient the Italian authorities and the foreign corporate recipient of the document request to the documents sought by Defendants.¹ The Exhibit reveals Defendants’ confidential, trade secret information relating to manufacturing specifications for rifaximin active pharmaceutical ingredient (“API”) and flow sheets that identify the proprietary process for production of purified rifaximin. The U.S. Food and Drug Administration considers such information trade secrets and has protected it from disclosure under a Freedom of Information Act request. *See Appleton v. Food & Drug Admin.*, 451 F. Supp. 2d 129, 141 (D.D.C. 2006) (drug specifications and manufacturing processes

¹ Defendants understand that the documents sought by the Letters of Request are located at a processing plant that was sold in 2017 by Zach Zambon Chemicals to a new owner. Defendants attached the Zach Reports to aid the new owner in determining the location of the requested files. *See* Dkt. 82, ¶ 2. The Exhibit is maintained in confidence by the Italian authorities.

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comprise trade secrets exempt from FOIA disclosure).

Further, Defendants have safeguarded these trade secrets. The Zach Reports and other documents that contain rifaximin API specifications were produced in discovery by Defendants and properly designated to maintain their confidentiality pursuant to the terms of the Protective Order (Dkt. 114).

The Confidential, Trade Secret Information Should Be Protected From Disclosure.

The Second Circuit has set out a three-part test to determine whether to protect the confidentiality of documents submitted to a court: (1) determine whether the documents are “judicial documents” entitled to the presumption of public access; (2) determine the applicable weight of the presumption that may apply; and (3) balance “countervailing factors” against such weight of the presumption, including the “privacy interests” of the interested parties. *See Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119-20, 124 (2d Cir. 2006) (holding that documents may be kept under seal if “countervailing factors” warrant confidentiality). Under this test, Defendants are appropriately seeking to seal only those portions of the Exhibit that comprise trade secret information.

First, the Exhibit is not a “judicial document” entitled to a presumption of public access. The Exhibit is discovery material produced to aid the Italian authorities and foreign corporate recipient of the document request. *See United States v. Smith*, 985 F. Supp. 2d 506, 520 (S.D.N.Y. 2013) (“discovery materials filed with the court in connection with discovery-related disputes are not covered by the qualified right of access”). Further, the content of the redacted trade secret information is not necessary to the Court’s review of Defendants’ Letters of Request. The Court in *Lugosch* explained that “the mere filing” of a document does not afford it the presumption of access and that it “must be relevant to the performance of the judicial function and useful in the judicial process” to constitute a “judicial document.” *Lugosch*, 435 F.3d at 115, 119. Given the nature of the Exhibit, it is not a “judicial document” and therefore the presumption of public access should not apply.

Second, even if the presumption of access were to apply, it should be afforded little weight because the documents at issue are discovery documents submitted only to assist in determining the location of relevant information. *See Alexander Interactive, Inc. v. Adorama, Inc.*, No. 12 CIV. 6608 PKC JCF, 2014 WL 4346174, at *2 (S.D.N.Y. Sept. 2, 2014) (“the weight of the presumption is not particularly great” in connection with “a motion to compel further discovery from a party”). Here, the Exhibit was filed in furtherance of foreign discovery and not a dispositive motion; accordingly, “the presumption in favor of public access is weak.” *Id.*

Third, Defendants’ interest in protecting their confidential, trade secret information ***strongly outweighs*** the public’s right to access the trade secrets contained within the documents. *See Fed. R. Civ. P. 26(c)(1)(G)* (permitting protective orders for “trade secret or other confidential information”); *see also W.J. Deutsch & Sons Ltd. v. Diego Zamora, S.A.*, No. 1:21-CV-11003-LTS, 2022 WL 890184, at *3 (S.D.N.Y. Mar. 25, 2022) (granting motion to redact “categories of confidential business information that . . . have been previously recognized by courts in this circuit

to be either confidential information worthy of sealing, or trade secrets.”). Disclosure of the Exhibit would provide Defendants’ competitors with confidential, competitively-sensitive information relating to the manufacturing specifications for rifaximin API and the proprietary process for production of purified rifaximin. “Release of this information would,” in whole or in part, “reveal how the drug being discussed in the document is formulated, chemically composed, manufactured, and quality controlled[.]” *See Appleton*, 451 F. Supp. at 141 (citation and quotations omitted) (drug specifications and manufacturing processes comprise trade secrets). Courts routinely permit parties to seal or redact materials that, if disclosed, may similarly result in competitive harm. *See, e.g., id.* (“documents contain[ing] information consisting of drug product manufacturing information, including *manufacturing processes* or drug chemical composition and *specifications*” were “*properly withheld . . . as trade secret information*”) (emphasis added); *GoSMiLE, Inc. v. Dr. Johnathan Levine, D.M.D. P.C.*, 769 F. Supp. 2d 630, 649-50 (S.D.N.Y. 2011) (granting motion to seal “highly proprietary material” because privacy interests “outweigh the presumption of public access”); *Andrx Pharms., LLC v. GlaxoSmithKline, PLC*, 236 F.R.D. 583, 586 (S.D. Fla. 2006), *aff’d*, No. 05-23264CV, 2006 WL 2403942 (S.D. Fla. Aug. 14, 2006) (citation omitted) (““Courts dress technical information with a heavy cloak of judicial protection because of the threat of serious economic injury to the discloser of scientific information.””).

The Proposed Redactions are Necessary and Narrowly Tailored.

The requested relief is necessary and narrowly tailored to protect the confidentiality of Defendants’ trade secret information. *See Lugosch*, 435 F.3d at 124 (sealing is “justified” if “that sealing is necessary to preserve higher values and only if the sealing order is narrowly tailored to achieve that aim”); *see also Order, Presidio, Inc. v. Driven Acquisition, Inc.*, No. 1:23-cv-6235 (S.D.N.Y. Jan. 17, 2024) (Lehrburger, J.) (granting request to maintain trade secrets under seal and with redactions). Redacting the API specifications and information identifying the proprietary process for production of purified rifaximin will not deprive the public of critical information.

For these reasons, Defendants respectfully request that the Court permit Defendants to maintain the confidentiality of their trade secret information under seal and filed with proposed redactions.

Thank you for your consideration of this request.

Respectfully submitted,



Robin D. Adelstein

Granted.

SO ORDERED:

5/9/2024



HON. ROBERT W. LEHRBURGER
UNITED STATES MAGISTRATE JUDGE

cc: All Counsel of Record by ECF