IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

ROXANE LABORATORIES, INC.,

Plaintiff,

vs. **Civil Action 2:12-cv-312**
Judge Watson
Magistrate Judge King

ABBOTT LABORATORIES, *et al*.

Defendants.

OPINION AND ORDER

This matter is before the Court on the motion to compel production of documents filed on behalf of defendants Abbott Laboratories and AbbVie Inc. ("*Defendants' Motion to Compel*"), Doc. No. 82, and memorandum in support ("*Defendants' Memorandum*"), Doc. No. 83, plaintiff Roxane Laboratories, Inc.'s *Opposition to Defendants' Motion to Compel Production of Documents* ("*Plaintiff's Response*"), Doc. No. 89, and defendants' reply, *Reply in Support of Defendants'/Counter-Plaintiffs' Motion to Compel Production of Documents* ("*Defendants' Reply*"), Doc. No. 96. For the reasons that follow, *Defendants' Motion to Compel* is **GRANTED**.

I. Background

AbbVie is the holder of approved New Drug Application ("NDA") No. 22-417 for ritonavir tablets, 100 mg, which defendants market and sell under the tradename Norvir®. *Defendants' Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Amended Complaint* ("*Defendants' Answer*"), Doc. No. 58, ¶ 13. AbbVie also holds the

regulatory exclusivities associated with that NDA. *Id*. Plaintiff has submitted Abbreviated New Drug Application No. 202573 ("ANDA 202573") to the United States Food and Drug Administration in order "to obtain regulatory approval to engage in the commercial manufacture, use, or sale of generic oral ritonavir tablets, 100 mg," which are the "bioequivalent" to Norvir®, "before the expiration of the Listed Patents." *Amended Complaint*, ¶ 16.

Plaintiff instituted this action seeking a declaration of invalidity and noninfringement in connection with Patent Nos. 7,148,359 (the "'359 patent") and 7,364,752 (the "'752 patent") held by defendants and relating to the drug Norvir®. *See id*. at ¶¶ 1, 11-13. Plaintiff alleges, *inter alia*, that the asserted claims of the '359 and '752 patents are obvious over certain prior art references. *Id*. at ¶¶ 22, 27. Defendants have responded by asserting counterclaims for patent infringement, alleging that plaintiff's ANDA filing infringed the '359 and '752 patents under 35 U.S.C. § 271(e)(2)(A). *Defendants' Answer*, pp. 6, 14.

Defendants now seek to compel production of documents related to plaintiff's "investigation of and/or decision not to pursue: (1) a ritonavir oral solution and/or capsule formulation and (2) a non-solid dispersion tablet formulation of ritonavir, which fall within the scope of Defendants' Document Request Nos. 8-13, 15-19, 21-28, 30-31, 34-46, 48-57, 82-87, and 91."[1] *Defendants' Memorandum*, p. 2. "Those document requests sought, *inter alia*, documents pertaining to

[1] Defendants' current request is narrower in scope than the actual requests made in Defendants' Document Request Nos. 8-13, 15-19, 21-28, 30-31, 34-46, 48-57, 82-87, and 91. *See Defendants' Memorandum*, pp. 4-5.

ritonavir formulations other than the formulation Roxane disclosed in its [ANDA] 202573, which Roxane filed with the FDA to seek approval to sell a generic version of Defendants' Norvir® solid-dispersion tablets." *Defendants' Memorandum*, p. 3.

II. Standard

Rule 37 of the Federal Rules of Civil Procedure authorizes a motion to compel discovery when a party fails to provide a proper response to requests for production of documents under Rule 34. Fed. R. Civ. Pro. 37(a)(3)(B). "The proponent of a motion to compel discovery bears the initial burden of proving that the information sought is relevant." *Martin v. Select Portfolio Serving Holding Corp.*, No. 1:05–cv–273, 2006 U.S. Dist. LEXIS 68779, at *2 (S.D. Ohio Sept. 25, 2006) (citing *Alexander v. Fed. Bureau of Investigation*, 186 F.R.D. 154, 159 (D.D.C. 1999)).

Rule 26(b) provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). Relevance for discovery purposes is extremely broad. *Lewis v. ACB Bus. Servs., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998). "The scope of examination permitted under Rule 26(b) is broader than that permitted at trial. The test is whether the line of interrogation is reasonably calculated to lead to the discovery of admissible evidence." *Mellon v. Cooper-Jarrett, Inc.*, 424 F.2d 499, 500-01 (6th Cir. 1970). However, "district courts have discretion to limit the scope of discovery where the information sought is overly broad or would prove unduly burdensome to produce." *Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 305

(6th Cir. 2007) (citing Fed. R. Civ. P. 26(b)(2)). *See also Lewis*, 135 F.3d at 402 (determining the proper scope of discovery falls within the broad discretion of the trial court). In determining the proper scope of discovery, a district court balances a party's "right to discovery with the need to prevent 'fishing expeditions.'" *Conti v. Am. Axle & Mfg. Inc.*, 326 F. App'x 900, 907 (6th Cir. 2009) (quoting *Bush v. Dictaphone Corp.*, 161 F.3d 363, 367 (6th Cir. 1998)).

Finally, the party moving to compel discovery must certify that it "has in good faith conferred or attempted to confer with the person or party failing to make disclosure or discovery in an effort to obtain it without court action." Fed. R. Civ. P. 37(a)(1). *See also* S.D. Ohio Civ. R. 37.2. This prerequisite has been met in this case.

III. Discussion

The parties disagree whether documents related to ritonavir formulations other than those disclosed in ANDA 202573 are relevant in this action. Defendants argue that "the requested documents are directly relevant to objective evidence of nonobviousness of the inventions claimed in the [patents-in-suit], including the secondary considerations of copying, commercial success, and benefits of the claimed invention." *Defendants' Memorandum*, p. 2. Plaintiff argues that documents relating to ritonavir formulations other than those in ANDA 202573 "are not relevant to secondary considerations of non-obviousness of the patents-in-suit, and could not reasonably be used to establish copying, commercial success, or benefits of the claimed invention," because defendants have "not articulated any nexus between any other ritonavir formulation and the patents-in-suit." *Plaintiff's*

Response, *PAGEID* 2909. Plaintiff also argues that the document requests are "cumulative, duplicative, [] wholly unnecessary," and "unduly burdensome." *Id*. at *PAGEID* 2909, 2914.

A patent is invalid for obviousness "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Obviousness is a question of law with several underlying factual inquiries, including "(1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others." *In re Antor Media Corp.*, 689 F.3d 1282, 1293 (Fed. Cir. 2012) (citing *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966)). The party asserting invalidity of a patent based on obviousness must demonstrate by clear and convincing evidence that the claimed patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. *See Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000).

Defendants argue, first, that copying is relevant to secondary considerations of nonobviousness in an ANDA action. *Defendants' Memorandum*, pp. 6-7. Defendants, they argue, "should be entitled to obtain documents relevant to Roxane's investigation of these

alternative formulations, as they are relevant to the secondary consideration of copying." *Id*. at p. 7.

Defendants' argument fails to persuasively explain how the requested documents, *i.e*, documents related to formulations other than those in ANDA 202573, are relevant to whether the claimed invention was copied. A showing of bioequivalency is required for FDA approval of an Abbreviated New Drug Application, *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, Nos. 2012-1397, 2012-1398, 2012-1400, 2012-1424, 2013 WL 1606014, at *7 (Fed. Cir. Apr. 16, 2013) ("Such evidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval."); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 377 F. App'x 978, 983 (Fed. Cir. 2010), and plaintiff concedes that its ritonavir product is the bioequivalent to Norvir®. *Amended Complaint*, ¶ 16. It is the formulation in the ANDA that must be a bioequivalent and it is the ANDA formulation that is relevant in determining whether plaintiff copied the claimed invention. Plaintiff's other formulations are simply not relevant to whether the claimed invention was copied by plaintiff or any other entity. Defendants are not precluded from offering evidence of copying; plaintiff apparently concedes that evidence of copying has some relevance in ANDA litigation. *See Plaintiff's Response*, *PAGEID* 2913 (arguing that copying is "minimally relevant" and of "limited relevance" in ANDA litigation because courts have not found it to be "compelling"). However, the documents related to plaintiff's "investigation of and/or decision not to pursue" other

ritonivar formulations are not likely to lead to the discovery of evidence of copying.

Defendants next argue that the requested documents are relevant to the issue of commercial success, another secondary consideration. *Defendants' Memorandum*, p. 9. Specifically, defendants argue that the requested documents concern plaintiff's "investigation into alternative formulations, including market analyses, financial models or surveys into the relevant market and sales of the alternative ritonavir formulations." *Id*. Plaintiff respond that the requested documents are not relevant to the issue of commercial success because defendants have not established a nexus between other ritonavir formulations and the patents-in-suit. *Plaintiff's Response*, *PAGEID* 2909, 2911-12. Defendants reply that such a nexus is not a necessary predicate to the discovery of otherwise discoverable information; defendants insist that they are "seeking the requested documents to further support the nexus between Norvir® tablets and the claimed inventions of the '359 and '752 patents." *Defendants' Reply*, p. 4.

"Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). "The term 'nexus' is used, in this context, to designate a legally and factually sufficient connection between the proven success and the patented invention, such that the objective evidence should be considered in the determination of nonobviousness." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994) (quotations omitted) (quoting *Demaco Corp v. F.*

Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988)). The patentee bears the burden of proving the existence of that nexus. *See, e.g., Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010). Nevertheless, a patentee need not prove the existence of a nexus in order to discover otherwise relevant information; the information sought to be discovered need only be relevant to a party's claim or defense. *See* Fed. R. Civ. P. 26(b)(1).

Defendants contend that the information sought is relevant to the issue of commercial success. *Defendants' Memorandum*, p. 9. Commercial success is based on the conduct of consumers relative to the success of competitors. In this case, the commercial success of defendants' ritonavir tablets is considered in relation to the success of competing formulations of ritonavir, presumably other oral solutions or capsules or non-solid dispersion tablets. *See Ormco Corp.*, 463 F.3d at 1311-12 (commercial success is usually shown by significant sales in a relevant market). If plaintiff investigated and decided not to pursue other formulations of ritonavir, then it likely developed or obtained market analyses, financial models, or surveys into the relevant market and, in doing so, compiled sales data of the alternative ritonavir formulations. This information is directly relevant to whether the claimed invention is, or is not, commercially successful because, as noted *supra*, the commercial success of a claimed invention is to be measured relative to the commercial success of its competition.

Having determined that the information defendants seek is relevant, and thus discoverable, the Court must now consider

plaintiff's argument that the document requests are "cumulative, duplicative, [] wholly unnecessary," and "unduly burdensome." *Plaintiff's Response*, *PAGEID* 2909-11, 2914. Plaintiff's argument that the document requests seek cumulative, duplicative, and wholly unnecessary information is premised on its argument that the documents are not relevant. *See id*. This argument is without merit because, as discussed *supra*, defendants' document requests seek relevant information.

Plaintiff next argues that the requests are unduly burdensome because "Roxane does not have a centralized electronic document system," it "would have to ask hundreds of employees to search their electronic documents," and it would "require significant effort to review and produce." *Id*. at *PAGEID* 2909, 2914. Plaintiff also suggests that a Rule 30(b)(6) deposition "would be a far less burdensome method of obtaining [this] discovery." *Id*. at *PAGEID* 2914.

Plaintiff has not demonstrated that the requested discovery would be unduly burdensome. Specifically, plaintiff has provided no information regarding the number of documents that might fall within the scope of the challenged document requests, the time and expenses that would be required to compile response to those requests, or the potential disruption of plaintiff's business operations caused by its efforts to respond to defendants' document requests. The mere fact that a party may not have a centralized electronic document system does not insulate that party from all discovery efforts and does not itself establish that the current discovery requests are unduly burdensome. Although plaintiff asserts that a Rule 30(b)(6)

deposition would be less burdensome, absent a demonstration that defendants' document requests in this regard pose unreasonable burden, defendants will be permitted to pursue the particular method of discovery preferred by them.

Accordingly, *Defendants' Motion to Compel*, Doc. No. 82, is **GRANTED**.

Plaintiff is **ORDERED** to produce documents in its possession, custody, or control that relate to its investigation of and/or decision not to pursue: (1) a ritonavir oral solution and/or capsule formulation and (2) a non-solid dispersion tablet formulation of ritonavir.

April 30, 2013

s/Norah McCann King
Norah McCann King
United States Magistrate Judge