IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., *Plaintiff*, v. TEVA PHARMACEUTICALS USA, INC., et al., *Defendants*.	§ § § § § § § § § §	Case No. 2:15-cv-1455-WCB

MEMORANDUM OPINION AND ORDER

Before the Court is plaintiff Allergan, Inc.'s Motion to Compel Compliance with Subpoena, Dkt. No. 291, which seeks to compel third party Alcon Laboratories, Inc., to produce a set of previously identified documents.[1] In its response, Alcon has opposed the motion but requested that, in the event the Court grants the motion, the Court also order that Allergan pay Alcon's expenses regarding the subpoena, including attorneys' fees. Allergan's motion is GRANTED, and Alcon's conditional cross-motion is DENIED without prejudice.

BACKGROUND

The defendant pharmaceutical companies are seeking approval by the Food and Drug Administration ("FDA") to sell a generic version of Restasis, an ophthalmic product sold by Allergan. Allergan initiated the present Hatch-Waxman action, alleging that the defendants' generic versions infringe several of Allergan's patents related to Restasis. In response, the

[1] The Court does not address Alcon's argument that Allergan's motion should be denied as to any documents outside the Identified Set, see Dkt. No. 304, at 11, because the Court construes Allergan's motion as requesting production of only the Identified Set of documents, see Dkt. No. 291, at 3 ("A limited set of documents directly relevant to Allergan's nonobviousness defense were selected for production.").

defendants have asserted, among other things, that Allergan's patents are invalid for obviousness.

Allergan intends to offer evidence of the failure of others to develop a treatment for dry eye as part of its nonobviousness defense. In an effort to obtain evidentiary support for that argument, Allergan has served third party Alcon with a subpoena for the production of documents. Dkt. No. 291-1 (subpoena); Dkt. No. 291-2 (proof of service). As relevant here, Allergan asked for information regarding the development of Alcon's products Rejena, Zyclorin, Cilomilast, Durezol, and Hydroxypropyl Guar Galactomannan ("HPGG") (referred to as AL43536 in the subpoena). Dkt. No. 291-1, at 11. Alcon objected to all the requests in the subpoena and refused to produce any documents. Dkt. No. 291-4.

After Allergan and Alcon met and conferred, Allergan agreed to narrow the scope of the subpoena to the new drug application ("NDA") file and investigational new drug application ("INDA") file for Durezol, and the INDA files for Rejena, Zyclorin, Cilomilast, and HPGG. See id.; Dkt. No. 304-1, at 2. Alcon agreed to make that narrowed set of documents available for inspection. Dkt. No. 291-6. Allergan sent two attorneys to inspect those documents, and the attorneys selected a subset of those documents for production. The subset, referred to herein as the Identified Set, consists of several thousand pages of material. See Dkt. No. 291, at 3; Dkt. No. 304, at 3. The attorneys were not permitted to make copies of the documents or to take notes with them regarding the documents' contents. See Dkt. No. 291, at 3.

After the inspection, Alcon objected to production of the Identified Set of documents on various grounds, but it offered to provide a declaration from an undisclosed individual regarding some of the contents of the documents. Dkt. No. 291, at 3-4. Allergan offered to pay for the reproduction of the Identified Set of documents in electronic form using a vendor chosen by

Alcon. Dkt. No. 308, at 3. Nonetheless, Alcon maintained its objections. See generally Dkt. No. 312.

DISCUSSION

The Court has broad discretion in resolving disputes over motions to compel discovery of documents. Imperial Ethiopian Gov't v. Baruch-Foster Corp., 535 F.2d 334, 337 n.8 (5th Cir. 1976). The scope of discovery is limited by Fed. R. Civ. P. 26(b)(1), which allows:

> discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

1. Alcon objects to Allergan's subpoena primarily on the basis of relevance. Alcon argues that the product information at issue would not support Allergan's theory that others failed to develop a treatment for dry eye disease and that the failure of others is evidence that Allergan's invention would not have been obvious.

Alcon does not dispute that the failure of others to solve the problem addressed by the patents-in-suit may be relevant. But Alcon contends that "the problem" is narrowly defined as "a need for emulsions comprising a reduced amount of cyclosporin which are therapeutically effective, but which reduce side effects." Dkt. No. 304, at 6. In support of that argument, Alcon points to language in the specification of U.S. Patent No. 8,629,111 ("the '111 patent")—the same language that appears in the specification of the other patents in suit—that "there was a need, as of the date of the inventions[,] for 'enhanced methods of treating ophthalmic or ocular conditions with cyclosporin-containing emulsions' with a 'reduced' amount of cyclosporin[] to[,] among other things, reduce 'eye irritation.'" Dkt. No. 304, at 6 (quoting '111 patent, col. 2, ll. 7-

9, 48-51; id., col. 5, ll. 3-8). And Alcon points out that four of the five products Allergan has identified (Durezol, Rejena, Cilomilast, and HPGG) do not contain cyclosporin.

Alcon's argument is not persuasive. First, the probative value of the failure of others to solve the problem addressed by Allergan's patents is not limited to failures associated with cyclosporin products. It is true that the failure of others must be directed to the problem solved by the patents. See Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1578-79 (Fed. Cir. 1991) ("the failure of others to find a solution to the problem which the patent[s] in question purport[] to solve . . . shows indirectly the presence of a significant defect [in the prior art], while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.") (alterations in original) (internal quotation marks omitted). But it is not just the failure of others to identify the exact product claimed by the patents that is relevant. In fact, evidence that others were "going in different ways" is considered "strong evidence that the [inventor's] way would not have been obvious." In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1082 (Fed. Cir. 2012); see also Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263, 1267, 1269 (Fed. Cir. 2007) (obviousness findings were not clearly erroneous as based on, inter alia, the "failure of the inventors and others to resolve citalopram without undue experimentation and the testimony of Forest's experts" that one of skill "would have been motivated to develop new compounds rather than undertake the difficult and unpredictable task of resolving a known racemate").

The problem addressed by the patents-in-suit was that emulsions containing therapeutically effective amounts of cyclosporin had undesirable side effects. The fact that others may have tried to solve that problem by "going in [a] different way" and using different compounds, rather than changing the amounts of the cyclosporin and hydrophobic components

in the composition, supports the inference that others did not believe the latter approach would work. See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d at 1082.

All of the identified Alcon products, whether cyclosporin-based or not, fit within that rationale for the probative value of evidence of the failure of others. All five of the Alcon products at issue "are products for which Alcon pursued an indication for the treatment of dry eye disease during development and through clinical trials, yet none of them made it to market with an indication to treat dry eye disease." Dkt. No. 308, at 1; see also Dkt. No. 304-9, at 3 (September 2009 proposed package insert for Rejena included an indication for "treatment of the signs and symptoms of dry eye disease"); Dkt. No. 304-3, at 1 (Durezol package insert states that it is "indicated for the treatment of inflammation and pain associated with ocular surgery"); Dkt. No. 304-7, at 5 (Cilomilast "is indicated for the maintenance of lung function . . . in patients with obstructive pulmonary disease"); Dkt. No. 304-8, at 2 (describing purpose of clinical study as "observ[ing] lacrimal fluid condition (tear film break-up time) chronologically after a single dose of [HPGG] ophthalmic products" and "lacrimal fluid retention time"). Failure to obtain FDA approval may be used to show the failure of others. See Knoll Pharm. Co. v. Teva Pharms. USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004); Pfizer Inc. v. Teva Pharms. USA, Inc., 460 F. Supp. 2d 659, 662 (D.N.J. 2006).[2]

Alcon also maintains that others' failed efforts must predate or be contemporaneous with the date of Allergan's invention. The pertinent date, according to Alcon, is either December

[2] Alcon points out that Restasis is indicated "to increase tear production" in patients with keratoconjunctivitis sicca ("KCS"), but not to treat "the condition known as dry eye *per se*." Dkt. No. 304, at 2 n.2. The patents, however, claim the emulsion present in Restasis as a treatment for dry eye and KCS, see, e.g., '111 patent, col. 16, ll. 35-40, so Alcon's failures to develop a treatment for dry eye are relevant to the patents in suit, regardless of whether Allergan's commercial embodiment has been administratively approved for that purpose.

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