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 are the parties' submissions regarding the declaratory judgment claims under 35 U.S.C. § 271(a), (b), and (c), Dkt. Nos. 405 and 406, and regarding the request of plaintiff Allergan, Inc., for notice before any at-risk launch by any defendant, Dkt. Nos. 407 and 408. After consideration of the briefs filed by the parties, the Court will not at this time order the defendants to give Allergan seven days' advance notice of any at-risk launch. As for the declaratory judgment claims, the Court will not dismiss or sever those claims, but will retain them as part of the case to be tried.

Also before the Court is the defendants' Notice of Stipulation of Infringement and Motion to Modify the Order of Proof at Trial, Dkt. No. 415, and Allergan's Brief in Response to Defendants' Notice of Stipulation of Infringement and Motion to Modify the Order of Proof at Trial, Dkt. No. 433. While the defendants are free to concede or not contest any particular issue at trial, the proposed stipulation does not, in the Court's view, take the issue of infringement out of the case and does not warrant changing the order of proof at trial. The motion to modify the Order of Proof at Trial is therefore DENIED.

1. Advance Notice of At-Risk Launch.

Arguing that it would face irreparable harm if any of the defendants launch a generic version of Allergan's Restasis product during the pendency of this litigation, Allergan requests that the Court order the defendants to provide Allergan with seven days' advance notice of any plan to launch such a product. The defendants object, arguing that the Court lacks authority to issue such an order, that Allergan's request for such an order is unripe, that Allergan has not made a showing of irreparable harm that would justify such an order, and that such an order would harm them competitively.

None of the defendants is free at this point to launch their generic versions of Restasis, because the federal Food and Drug Administration has not yet approved any of their Abbreviated New Drug Applications ("ANDAs"). However, the parties have advised the Court that the FDA is expected to act on at least some of the defendants' ANDAs shortly. Allergan notes that it is at least open to question whether the 30-month stay that normally applies to generic manufacturers in Hatch-Waxman litigation would apply to several of the defendants in this case. Therefore, according to Allergan, there is a substantial risk that those defendants might conduct an at-risk launch before the expiration of the 30-month period.

Four of the five defendants—Akorn, InnoPharma, Mylan, and Teva—have advised the Court that they have agreed not to launch before the trial is complete. The remaining defendant, Famy Care Ltd., is subject to a 30-month stay of approval and therefore is not free to launch before the time that this Court is likely to enter its judgment in this case. See Dkt. No. 407, at 2 & n.1.

The defendants argue that the Court lacks the authority to enter an order requiring them to provide Allergan with seven days' notice of their intent to launch. There is very little

authority on this point, and what authority there is shows up mainly in the form of terse observations by district courts without extended analysis. A few courts have issued such orders, often when they are agreed to, at least in part. See, e.g., Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. v. Actavis S. Atl. LLC, No. 1:12-cv-1061, Dkt. No. 21 (D. Del. Jan. 9, 2013); Medeva Pharma Suisee A.G. v. Roxane Labs, Inc., No. 3:07-cv-5165, Dkt. No. 119, at 1 (D.N.J. Nov. 30, 2009); Eli Lilly & Co. v. Sicor Pharms., Inc., Case No. 1:06-cv-238, Dkt. No. 171 (S.D. Ind. June 20, 2008).

A greater number of courts have refused to issue such orders, often expressing doubt as to their authority to do so. See Otsuka Pharm. Co. v. Torrent Pharms. Ltd., 99 F. Supp. 3d 461, 471-72 (D.N.J. 2015) (recognizing "the principle that the generic defendants would not be required to provide notice of intent to launch at risk"); Hoffman-LaRoche, Inc. v. Teva Pharms. USA, Inc., No. 2:11-cv-3635, Dkt. No. 124 (Feb. 5, 2013) ("[T]he Court is not persuaded by Roche's arguments that the Court has the authority to order advance notice of its intent to launch in the absence of an agreement by Teva."); Teva Pharms. USA, Inc. v. Sandoz, Inc., No. 08 Civ. 7611, 2010 WL 8760315, at *1 (S.D.N.Y. Oct. 12, 2010) ("Plaintiff's request amounts, in essence, for the Court to order Defendants to provide Plaintiffs with confidential business information, which for all intent and purposes, would function as an injunction by prohibiting Defendants from launching their product even if they have FDA approval and the thirty-month statutory stay period has expired."); Astrazeneca LP v. Breath Ltd., No. 08-cv-1512, Dkt. No. 86, at 2 (D.N.J. Sept. 8, 2009) (request for order to provide advance notice of launch "is denied for the reasons set forth in the record of these proceedings, including because the Court does not believe it has legal authority to grant such relief."); Novartis Pharms. Corp. v. Mylan Pharms., No. 3:06-cv-2885, Dkt. No. 98, at 6 (D.N.J. Sept. 22, 2008) ("I've been reluctant and have

refused to require that Mylan state when they would launch . . . [b]ecause frankly I am not comfortable in determining that that is within my power to do.").

Allergan asserts that entering such an order is within the Court's discretionary power to manage its docket. The Court is not persuaded that the matter is that simple. Imposing an obligation on four of the five the defendants to provide advance notice to Allergan as to when they will launch their competing products goes well beyond a mere matter of docket control; as recognized by Judge Jones in the Teva v. Sandoz case cited above, it constitutes an injunction that can be justified if and only if (1) the court has jurisdiction to issue the injunction and (2) the court has made the requisite findings to warrant imposing such relief.

As to the first, the Court is satisfied that, under the proper circumstances, an order to provide advance notice of a planned launch would not lie beyond the Court's jurisdiction. The Court's equitable powers in a case such as this one extend to ancillary orders that may be necessary to protect the protect the plaintiff against the risk that the defendants will take action that will effectively defeat the plaintiff's right to relief.

While recognizing that the Court's jurisdiction may extend to matters such as orders for advance notice of launch plans, the Court is cognizant of the prudential limitations on the exercise of that jurisdiction. Launch dates are highly confidential and important commercial information. The Court should not lightly order parties to disclose such information to their competitors. Moreover, before entering such a mandatory injunction, the Court would have to be confident that the equitable considerations that govern the issuance of injunctions require the grant of the requested relief. At this point, the Court is not satisfied that those equitable considerations justify the entry of the requested injunction, for several reasons.

First, the Court is not currently prepared to conclude that Allergan has shown a likelihood of success on the merits that would warrant the requested relief. The Court is aware at this point only of the outlines of the parties' cases. After sitting through the trial, the Court will have a much better sense of Allergan's likelihood of success, which will bear importantly on how the Court will adjudicate Allergan's various claims to temporary and permanent relief thereafter.

Second, the defendants have agreed not to launch their generic versions of Restasis during the trial. There is therefore no urgency for the Court to act prior to trial. Instead, the Court will be able to reassess the need, if any, for the requested injunctive relief after hearing the evidence in the case.

Third, Allergan's claim of irreparable harm is predicated on an affidavit by one of its employees and some citations to court decisions. Dkt. No. 408-1. Allergan's claim is disputed by the defendants, who contend that Allergan's assertions regarding the damage that any at-risk launch would cause to Allergan is greatly exaggerated. Dkt. No. 407, at 5-6. If Allergan continues to desire some form of interim relief, it can move for a preliminary injunction and, in support of that motion, can offer evidence regarding the injury that would be caused by an at-risk launch. The defendants will be free at that point to offer contrary evidence if they choose. The parties can also present evidence and argument regarding whether the harm to Allergan from an at-risk launch would be compensable in damages, assuming Allergan were ultimately to prevail in the lawsuit. That procedure will likely provide the Court with a much sounder evidentiary basis for making a determination as to whether Allergan has shown irreparable harm.

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