IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	)	Civ. No. 18-1121- MSG

M. GOLDBERG, J. **NOVEMBER 27, 2018**

MEMORANDUM OPINION

Defendant Eli Lilly and Company ("Lilly") has filed a motion to stay this antitrust action until after resolution of a related patent infringement action it brought against Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle").[1] For the reasons set forth below, Lilly's motion to stay will be granted.

I. BACKGROUND

Currently pending before me are two cases involving the same parties and patent (the '209 patent as defined below). The first is a patent infringement action captioned Eli Lilly and Company v. Eagle Pharmaceuticals, Inc., C.A. No. 17-1293-MSG. In that case, Eagle submitted a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") with a Paragraph IV certification stating that U.S. Patent No. 7,772,209 (the "'209 patent") will not be infringed by the

[1] On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

manufacture, use, offer for sale, sale, or importation of Eagle's NDA product, or alternatively, that the '209 patent is invalid. (C.A. No. 17-1293, D.I. 7 at ¶ 28). Lilly is the assignee of the '209 patent which is listed in the FDA's Orange Book as covering the drug product ALIMTA®. (C.A. No. 17-1293, D.I. 1 at ¶ 22). In September 2017, Lilly sued Eagle, pursuant to 35 U.S.C. § 271(e)(2), alleging that the use of Eagle's proposed NDA Product will infringe the '209 patent either literally or under the doctrine of equivalents and that Eagle will induce and contribute to that infringement. (Id. at ¶ 24-34). In October 2017, Eagle asserted a counterclaim, pursuant to 21 U.S.C. § 355G)(5)(c)(ii)(I), seeking the correction or removal of Lilly's "use code" for the branded drug ALIMTA®.[2] (C.A. No. 17-1293, D.I. 7 at ¶¶ 189, 204-207). Eagle claims that a use code Lilly submitted for ALIMTA® misrepresents the approved method of use covered by the claims of the '209 Patent. (Id. at ¶¶ 204-207). Discovery in the patent case is ongoing and trial is currently set for September 9, 2019. (Id. at ¶ 17).

The second case before me is the above-captioned antitrust action. In August 2017, Eagle filed a complaint in the U.S. District Court for the District of New Jersey alleging that Lilly violated antitrust laws by submitting for inclusion in the FDA's Orange Book an "incorrect and overbroad" use code for ALIMTA®, thereby preventing Eagle's entry into the relevant market. In response, Lilly filed a motion to transfer the antitrust action to this court or, in the alternative, stay the antitrust action until after resolution of the patent action. In July 2018, the Honorable John M. Vazquez granted the motion to transfer and denied the motion to stay as moot. After transfer to

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[2] Under FDA regulations, branded drug manufacturers like Lilly must submit a "use code" for publication in the FDA's Orange Book that describes the "method(s) of use claimed by a patent for which a claim of patent infringement could reasonably be asserted" if a manufacturer were to make, use, or sell a generic copy of the drug. 21 C.F.R. § 314.53(b)(1), (c)(2)(ii)(P)(3); Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404–06 (2012) (explaining FDA use codes).

the District of Delaware, Lilly renewed its motion to stay. A schedule has not yet been set in this antitrust matter, although the parties have proposed a jury trial sometime in the second half of 2020.

II. DISCUSSION

A court has broad discretion to grant or deny a motion to stay. Apotex, Inc. v. Senju Pharma. Co., 921 F. Supp. 2d 308, 313 (D. Del. 2013). In exercising that discretion, the court considers: (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage. Id.

I find that a stay of this antitrust action until after the patent infringement action is resolved will simplify the issues, primarily because Eagle's antitrust claims involve questions of patent law. To prevail on its antitrust claim, Eagle will have to show, among other things, that the use code Lilly submitted is not one "with respect to which a claim of patent infringement could reasonably be asserted." 21 C.F.R. § 314.53(b)(1). If Eagle loses the pending patent infringement action, it is doubtful Eagle could make such a showing. In addition, if Eagle's product infringes a valid claim of the '209 patent, then Eagle may not have an antitrust claim, because Eagle's product was lawfully prohibited from going on the market before the '209 patent expires, regardless of the propriety of Lilly's use code. See In re Wellbutrin XL Antitrust Litig., 868 F.3d 132, 151–52, 165 (3d Cir. 2017) (finding no antitrust injury by delay of generic competition where patent lawfully

blocked market entry). Thus, the issues in the antitrust case will at least be narrowed, if not disposed of entirely, by the resolution of the patent case.[3]

Eagle argues that a stay would be wasteful, because it would not be able to proceed with discovery on overlapping issues. (D.I. 55 at 7). I disagree. Eagle can pursue discovery relevant to the patent infringement counterclaims based on Lilly's use code and will not be prohibited from seeking this discovery simply because it overlaps with the antitrust claims in this action. Moreover, a delay of antitrust specific discovery—which courts have recognized can be "voluminous, time-consuming, and expensive" (see, e.g., D.I. 40 at 13)—will avoid potential waste if the claims in the antitrust action are narrowed or mooted by the resolution of the patent infringement action.

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[3] For this very reason, it is common practice for courts to stay an antitrust case until after resolution of a related patent case. See, e.g., Apotex, 921 F. Supp. 2d at 314 (staying antitrust litigation pending outcome of patent litigation because "there was a possibility that the resolution of underlying patent claims could moot, narrow, or otherwise simplify antitrust claims"); Monsanto Co. v. Syngenta Seeds, Inc., 2006 WL 7204491, at *1 (D. Del. Nov. 8, 2006) (staying antitrust action that had "at least a minimal overlap" with the pending patent action because the patent appeal would "necessarily … affect the complexion of the antitrust case to some extent"). It is equally common for a court in a patent infringement action to bifurcate and stay the antitrust counterclaims. Intellectual Ventures I LLC v. Toshiba Corp., 2015 WL 1476708, at *2 (D. Del. Mar. 20, 2015) (explaining that it "makes sense" to stay antitrust counterclaims because "they are based in large measure on the efficacy of the patent litigation itself; e.g., if the patents are deemed valid by the fact-finder, there is no basis for … antitrust remedies"); Masimo Corp. v. Philips Elecs. N. Am. Corp., 2010 WL 925864, at *3 (D. Del. Mar. 11, 2010) (stating that the bifurcation of patent and antitrust claims followed by a stay of those antitrust claims "is not mandatory, but it is common"); Eurand Inc. v. Mylan Pharm. Inc., 2009 WL 3172197, at *2 (D. Del. Oct. 1, 2009) (staying discovery on antitrust counterclaims because those claims "may be rendered moot by resolution of the patent infringement issues"); see also D.I. 40 at 12-13 (J. Vasquez transfer order collecting New Jersey cases).

Lilly has not asked for a bifurcation and stay of Eagle's antitrust counterclaim. But the cases cited above are particularly noteworthy after Eagle argued that Lilly's motion is "basically equivalent to a motion to bifurcate" now that both cases are in the same forum. (D.I. 55 at 8).

Finally, discovery in the patent action is ongoing and a trial is currently scheduled for September 2019. No schedule has been entered yet in the antitrust action, and the parties are requesting a jury trial sometime in late 2020. Thus, resolving the patent action before the antitrust action makes sense, and will also "avoid possible inconsistent results by different fact-finders." SanDisk Corporation v. Round Rock Research, LLC, 2014 WL 12768216, at *2 (D. Del. July 1, 2014) (staying antitrust litigation until the verdict in the patent jury trial to avoid inconsistent results by different fact-finders).

For the foregoing reasons, Lilly's motion for a stay (D.I. 49) is granted. This action is stayed at least until the conclusion of trial in the patent action. An appropriate order will be entered.