UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

APOTEX INC.,

Plaintiff,

v.

GILEAD SCIENCES, INC., et al.,

Defendants.

Case No. 18-cv-06475-JCS

ORDER GRANTING MOTION TO DISMISS

Re: Dkt. No. 28

REDACTED

United States District Court
Northern District of California

I. INTRODUCTION

Plaintiff Apotex Inc. ("Apotex") brings an action seeking a declaratory judgment of non-infringement as to United States Patent Nos. 8,106,183 (" '183 Patent") and 9,085,601 (" '601 Patent") (collectively, the "patents-in-suit") in connection with its Abbreviated New Drug Application ("ANDA") for a Proposed Regadenoson Product (ANDA No. 207604). Apotex named as Defendants Gilead Sciences, Inc. ("Gilead"), which owns the patents-in-suit, and Astellas Pharma US, Inc. ("Astellas Pharma"), the holder of the New Drug Application ("NDA") for Lexiscan, the product that Apotex seeks to market in generic form. Lexiscan is listed in the Food and Drug Administration's official publication of approved drugs ("Orange Book") together with the patents-in-suit.

Gilead and Astellas Pharma bring a Motion to Dismiss ("Motion") in which they assert that: 1) the claims against Astellas Pharma should be dismissed because this Court does not have personal jurisdiction over it and venue here is improper; and 2) all of Apotex's claims must be dismissed because it has failed to join Astellas US LLC ("Astellas LLC"), which is a required party, and Astellas LLC cannot be joined in this action because, like Astellas Pharma, Astellas LLC is not subject personal jurisdiction in this Court. In its Opposition, Apotex does not dispute

that there is no personal jurisdiction as to Astellas Pharma and stipulates to the dismissal of that entity without prejudice.[1] Apotex also does not dispute that the Court does not have personal jurisdiction over Astellas LLC. Therefore, the only remaining issue is whether the Motion should be granted and the action dismissed on the basis that Apotex failed to join (and cannot join) a necessary party. The Court finds that the Motion is suitable for determination without oral argument and therefore vacates the hearing set for Friday, February 8, 2019 at 9:30 a.m. pursuant to Civil Local Rule 7-1(b). For the reasons stated below, the Motion is GRANTED.[2]

II. BACKGROUND

A. Factual Background

Astellas Pharma markets a product called "Lexiscan® and is the NDA holder for that product." Complaint ¶ 34. Lexiscan is a "single-dose prefilled syringe" filled with a "clear, colorless solution containing regadenoson 0.4 mg/5 mL (0.08 mg/mL)." Opposition, Ex. I. The patents-in-suit, which are owned by Gilead, are listed in the Orange Book as covering Lexiscan. Complaint ¶¶ 35-36, 39 & Exs. A & B (listing Gilead as assignee on patents-in-suit).

[REDACTED], Astellas LLC's predecessor, Fujisawa Healthcare, Inc. ("FHI"), entered into a Collaboration and License Agreement ("CLA") with Gilead's predecessor, CV Therapeutics, Inc. ("CVT"), [REDACTED]

Johnston Decl. ¶ 5 ("Astellas US LLC is the successor-in-interest to Fujisawa Healthcare Inc.") [REDACTED]

; *see also* Reply, Ex. 4 (Gilead Form 10-K for fiscal year ending December 31, 2009) at 2 (stating that Gilead acquired CVT in 2009). [REDACTED]

[1] Because the Court finds that the entire action is subject to dismissal, it need not reach the question of whether it is appropriate to dismiss Astellas Pharma pursuant to Rule 21 of the Federal Rules of Civil Procedure based on misjoinder.

[2] The parties have consented to the jurisdiction of the undersigned magistrate judge pursuant to 28 U.S.C. § 636(c).

[REDACTED]

B. Statutory Framework Under the Hatch-Waxman Act

When a company or individual files an NDA with the Food and Drug Administration ("FDA"), it must, *inter alia*, identify those patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). After an NDA is approved, the FDA publishes the enumerated patents in the Orange Book. *Id.*

The Hatch-Waxman Act allows a generic drug manufacturer to seek expedited approval to market a generic version of an already-approved drug by submitting an ANDA. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *see also* 21 U.S.C. § 355(j)(1) ("Any person may file with the Secretary an abbreviated application for the approval of a new drug."). As part of the application process, the applicant is required to certify that the proposed product will not infringe any patents listed for the drug in the Orange Book, or that those patents are invalid. 21 U.S.C. § 355(j)(2)(A)(vii). The applicant also must send what is referred to as a "Paragraph IV Notice Letter" to the owner of the patent and to the NDA holder of the approved drug informing them that the ANDA applicant seeks to manufacture that drug in generic form and certifying that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 U.S.C. § 355(j)(2)(B)(iii) (specifying that notice must be given to "each owner that is the subject of the certification" and "the holder of the approved application . . . for the drug that is claimed by a patent or a use of which is claimed by the patent . . . .").

Under the Hatch-Waxman framework, the ANDA applicant must wait at least 45 days after the Paragraph IV Notice Letters have been received before bringing an action for a declaratory judgment against the patent owner or holder for a declaration of noninfringement or invalidity. 21 U.S.C. § 355(j)(5)(C)(i)(I). During that period, the recipient of a Paragraph IV Notice Letter may bring an infringement action against the ANDA applicant, resulting in a 30-month stay of the FDA approval process. 21 U.S.C. § 355(j)(5)(B)(iii). On the other hand, if no recipient of the

Paragraph IV Notice brings an infringement action within the 45-day period, the ANDA applicant may bring a declaratory judgment action against the patent owner or the holder of the NDA seeking a declaration of noninfringement and/or invalidity under 28 U.S.C. § 2201. 21 U.S.C. § 355(j)(5)(C)(i)(II). This subsection of the Hatch-Waxman Amendments further provides that "[a] civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business." *Id.*

C. Procedural Background and Related Litigation

On August 31, 2018, Apotex sent Paragraph IV Notice Letters to Astellas Pharma and Gilead; the letters were received on September 4, 2018. Opposition, Exs. B (Paragraph IV Notice Letter, C (Gilead Receipt) & D (Astellas Pharma Receipt). Neither Gilead nor Astellas Pharma brought an infringement action within 45 days of receiving Apotex's notice, which expired on October 19, 2018. On October 23, 2018, Apotex filed the instant action, filing a complaint seeking a declaratory judgment of non-infringement against Gilead and Astellas Pharma with respect to the patents-in-suit (the '183 and '601 patents).

On October 25, 2018, Astellas Pharma, Astellas LLC, and Gilead jointly filed a complaint for patent infringement in the District of Delaware against Apotex asserting that Apotex's generic drug will infringe the '183 and '601 patents. *See* United States District Court for the District of Delaware, Civil Action No. 18-cv-1675 ("the Delaware Action"). On the same day, Gilead and the two Astellas entities filed actions against Sandoz, Inc. (Civil Action No. 18-cv-1676), Sun Pharma Global FZE (Civil Action No. 18-cv-1677) and Wockhardt Bio AG and Wockhardt USA LLC (Civil Action No. 18-cv-1678) based on ANDAs filed by those companies to manufacture generics of Lexiscan. All of these cases have been related by the Delaware District Court.

D. Contentions of the Parties

In the Motion, Defendants argue that this case must be dismissed pursuant to Rules 12(b)(7) and 19 of the Federal Rules of Civil Procedure for failure to join a required party, namely, Astellas LLC. Motion at 12. Because questions of joinder are not unique to patent law, they assert, Ninth Circuit law governs this question rather than the law of the Federal Circuit. *Id.* In the Ninth Circuit, a case must be dismissed under Rule 19 where: 1) the absent party is

required; 2) joinder of that party is not feasible; and 3) the party is indispensable. *Id*. at 12 (citing *EEOC v. Peabody W. Coal Co.*, 400 F.3d 774, 779-80 (9th Cir. 2005)).

According to Defendants, Astellas LLC is required because it is an exclusive licensee of the patents-in-suit. *Id*. at 13 (citing *Aspex Eyewear v. Miracle Optics, Inc*., 434 F.3d 1336, 1344 (Fed. Cir. 2006)). Defendants further assert that Astellas LLC cannot be joined because this Court does not have personal jurisdiction over that entity. *Id*. at 13-14. Finally, Defendants argue that Astellas LLC is indispensable because: 1) any adverse judgment by this Court will prejudices Astellas LLC; 2) there is no way to avoid such prejudice as any judgment in this action will impact the scope of Astellas LLC's patent rights; 3) judgment in this action will be inadequate because it will not afford complete relief and raises the risk of multiple lawsuits with inconsistent outcomes; and 4) Apotex will not be prejudiced by dismissal of this action because all necessary parties have already consented to venue in the Delaware Action, where Apotex can bring counterclaims for noninfringement and invalidity. *Id*. at 13-16.

In its Opposition, Apotex rejects Defendants' assertion that dismissal is required under Rule 19. First, it argues that the Hatch-Waxman provision that authorizes a civil action for declaratory relief, 21 U.S.C. § 355(j)(5)(C)(II), is the "controlling statute" and that it is undisputed that Apotex has met the requirements of that section for bringing a civil action against Gilead; it further contends the provision is clear that Astellas Pharma is *not* a required party and therefore can be dropped from the case (as Apotex seeks to do). *Id.* at 7-8. Finally, Apotex argues that the Hatch-Waxman Act does *not* require ANDA applicants to give notice to exclusive licensees or make them defendants in a civil action brought under 21 U.S.C. § 355(j)(5)(C)(II). *Id*. at 16.

Second, Apotex contends the cases upon which Defendants rely for the proposition that an exclusive licensee is a required party is not on point because they do not involve actions seeking declaratory judgment. *Id*. at 16-18. It further contends that Defendants' reliance on Rule 19 is misplaced because Rule 19 cannot be used to modify the substantive rights afforded under the Hatch-Waxman Amendments. *Id*. at 18-19. In support of this argument, Apotex cites to 28 U.S.C. § 2072 (providing that the Federal Rules of Civil Procedure "shall not abridge, enlarge or modify any substantive rights") and Rule 82 of the Federal Rules of Civil Procedure (providing

that the Federal Rules of Civil Procedure "do not extend or limit the jurisdiction of the district courts or the venue of actions in those courts"). *Id*. at 18. Apotex also argues that Astellas LLC cannot be "indispensable" for the same reason it cannot be a required party, namely, because a licensee is not a required party under Hatch-Waxman and Defendants cannot rely on Rule 19 to modify Apotex's substantive right to maintain an action for declaratory relief under Hatch-Waxman against Gilead alone. *Id*. at 19.

Apotex also argues that where courts have reached the question of whether an exclusive licensee is an indispensable party in an action for declaratory judgment they have found that they are not. *Id*. at 20.

Finally, Apotex questions whether Astellas LLC is, in fact, an exclusive licensee of Gilead. *Id*. at 21. It asserts that the patents claim a *crystalline* form of regadenoson, whereas Lexiscan is a solution, and further argues that "there is no chain of evidence in the limited record provided by Defendants connecting the dots between the original licensing agreement, the Gilead ['183] and ['601] Patents, any Astellas LLC use of those patents, and, ultimately, Astellas Pharma's marketed product in the United States (LEXISCAN®)." *Id*. Even if such a connection were established, Apotex asserts, Defendants have not shown that there is any conflict of interest between Gilead and Astellas LLC that could justify dismissal of this action. *Id*.

III. ANALYSIS

A. Legal Standards Under Rule 12(b)(7) and Rule 19

Pursuant to Rule 12(b)(7) of the Federal Rules of Civil Procedure, a court may dismiss an action for failure to join a required party under Rule 19. Rule 19, in turn, permits a court to dismiss an action where a party is "required," joinder of that party is not feasible, and the court concludes "in equity and good conscience" that the action should not proceed between the existing parties, that is, that the party is indispensable.

B. Whether Rule 19 Applies to Declaratory Judgment Actions Under Hatch-Waxman

Apotex contends Rule 19 of the Federal Rules of Civil Procedure does not apply to a declaratory judgment brought under 28 U.S.C. § 2201 (the Declaratory Judgment Act) and the

Hatch-Waxman Act. The Court disagrees.

First, the Hatch-Waxman Act places certain limitations on an ANDA applicant's ability to bring an action for declaratory judgment but does not create an independent cause of action; rather, it simply permits ANDA applicants to bring an action under the Declaratory Judgment Act when the requirements of Hatch-Waxman have been satisfied. *See* 21 U.S.C. § 355(j)(5)(C). Moreover, it is well-established that "the operation of the Declaratory Judgment Act is procedural only." *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 240 (1937). In other words, neither the Hatch-Waxman provision that permits an ANDA applicant to bring a declaratory judgment action nor the Declaratory Judgment Act itself creates any independent substantive right or expands federal jurisdiction. Consequently, neither 28 U.S.C. § 2702 (which provides that the Federal Rules of Civil Procedure "shall not abridge, enlarge or modify any substantive right") nor Rule 82 of the Federal Rules of Civil Procedure (which provides that federal jurisdiction may not be limited or extended by the Federal Rules of Civil Procedure) supports Apotex's argument that Rule 19 is not applicable in this case.

The Court also rejects Apotex's reliance on the language of Section 355(j)(5)(C)(i)(II) in support of its assertion that Rule 19 cannot be applied in this case. While that section permits an ANDA applicant to bring a civil action for a declaratory judgment against the patent owner *or* the NDA holder, nothing in that section suggests that Congress intended to limit the normal procedural rules governing joinder of required parties with respect to such actions or to modify the jurisdictional requirements under substantive patent law. To the contrary, such a reading of this section would be at odds with the doctrine of prudential standing that generally applies in patent cases. For example, even though this provision may authorize an ANDA applicant to seek a declaratory judgment only as to an NDA holder (because of the "owner or holder" language in it), there is no reason to conclude that Congress intended to abrogate the established rule that a party that challenges a patent must include the proper parties as defendants. *See, e.g., A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1217 (Fed. Cir. 2010) (noting that "[u]nder long-standing prudential standing precedent" applicable in infringement actions, "an accused infringer must likewise join both the exclusive licensee and the patentee in a declaratory action"); *see also Enzo*

APA & Son, Inc. v. Geapag A.G., 134 F.3d 1090, 1094 (Fed. Cir. 1998) (finding that "the court lacks jurisdiction over [accused infringer's] declaratory judgment claims under Fed. R. Civ. P. 19 for nonjoinder" where patentee was not joined as defendant); *Abraxis Bioscience, Inc. v. Navinta LLC,* 625 F.3d 1359, 1367 (Fed. Cir. 2010) (dismissing infringement action brought by NDA holder under the Hatch-Waxman Act where NDA holder "lacked standing on the day it filed the action").

Likewise, the fact that Section 355(j)(5)(C)(i)(II) does not expressly require that exclusive licensees must be joined in an action under that section is of no moment; to the extent an exclusive licensee is a required party under the rules of standing that apply in patent cases, the Court concludes that those apply regardless of whether they are expressly incorporated into the Hatch-Waxman Act. Similarly, while Section 355(j)(5)(C)(i)(II) provides that "[a] civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business," the Court interprets that provision only as establishing venue as to the "the owner or holder [of the NDA]" named as a defendant and not as abrogating the joinder rules set forth in Rule 19 or any other requirements of the Federal Rules of Civil Procedure.

Accordingly, the Court concludes that Rule 19 applies in this case.

C. Whether Rule 19 Requires Dismissal of the Action

1. Whether Astellas LLC is an exclusive licensee

As a preliminary matter, Apotex suggests that Astellas LLC is not an exclusive licensee for the purposes of determining whether it is a required party. Among other things, it suggests that the CLA may not make Astellas LLC an exclusive licensee under the patents-in-suit because Lexiscan is a solution rather than a crystal and therefore, is not covered by the patents-in-suit. The Court rejects this argument. The evidence in the record, summarized above, shows that Astellas LLC holds an exclusive license [REDACTED] . Regadenoson is the solution used in Lexiscan, and Lexiscan is listed in the Orange Book along with the patents-in-suit. Apotex's argument that Lexiscan falls outside of the scope of the claims of the patents-in-suit goes to the merits of the case, not to whether Astellas LLC is an exclusive licensee.

2. Whether Astellas LLC is a required party

In an action in which a patent is challenged, an exclusive licensee is a necessary party and therefore must be joined. *Aspex Eyewear, Inc. v. Miracle Optics, Inc*., 434 F.3d 1336, 1344 (Fed. Cir. 2006) (citing *Independent Wireless Tel. Co. v. Radio Corp*., 269 U.S. 459, 466 (1926) (both the owner and the exclusive licensee are generally necessary parties in an action in equity)); *see also Alfred E. Mann Found. For Sci. Research v. Cochlear Corp*., 604 F.3d 1354, 1360 (Fed. Cir. 2010) (explaining that under *Aspex*, "[w]hen there is an exclusive license agreement, as opposed to a nonexclusive license agreement, but the exclusive license does not transfer enough rights to make the licensee the patent owner, either the licensee or the licensor may sue, but both of them generally must be joined as parties to the litigation."). This rule applies in declaratory judgment actions as well as in actions for patent infringement. *See A123 Sys., Inc*., 626 F.3d at 1217 ("an accused infringer must likewise join both the exclusive licensee and the patentee in a declaratory action") (citing *Enzo APA & Son, Inc. v. Geapag A*.G., 134 F.3d 1090, 1094 (Fed.Cir.1998)). Under this authority, the Court finds that because Astellas LLC is an exclusive licensee, it is a required party in Apotex's declaratory judgment action.

3. Whether Astellas LLC can be joined

Apotex does not dispute that Astellas LLC is not subject to this Court's jurisdiction. Therefore, the Court finds that it is not feasible to join Astellas LLC in this action.

4. Whether Astellas LLC is an indispensable party

In determining whether Astellas LLC is an indispensable party, courts consider the following nonexclusive factors: (1) "to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties;" (2) "the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided;" (3) "whether a judgment rendered in the person's absence will be adequate;" and (4) "whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder." Fed. R. Civ. P. 19(b). The Court concludes that all of these factors point towards dismissal of this action.

First, the Court finds that an adverse judgment declaring that Apotex's regadenoson

product does not infringe the patents-in-suit would severely prejudice Astellas LLC. [REDACTED]

If Apotex markets a competing product before the patents-in-suit expire, those sales are likely to have a substantial negative impact [REDACTED] . Further, Astellas LLC's interests are not identical to Gilead's as [REDACTED] ; the risk posed by a competing generic product will therefore have a disproportionately negative impact on Astellas LLC as compared to Gilead. It is likely because the interests of Astellas LLC and Gilead are not identical that [REDACTED] . Therefore, the Court concludes Astellas LLC will be prejudiced if it is not joined in this action.

Second, the Court is not aware of any measures that might be taken to eliminate or reduce this prejudice as Astellas LLC would be deprived of its ability to protect its interest in defending the patents-in-suit if this case were to go forward.

Third, because Astellas LLC is a required party, any judgment entered in this action is likely to be inadequate because it will not sufficiently address Astellas LLC's interests. Because Astellas LLC has standing as an exclusive licensee to pursue its own action (at least if the patentee is also joined), the result is likely to be piecemeal litigation. Indeed, there is already a parallel case in Delaware in which Astellas LLC *is* a party (along with the patentee and the NDA holder), involving the same patents and product. Because all of the required parties are before the District Court of Delaware, the Court concludes that the challenges raised by Apotex in this action can only be fully resolved in the Delaware Action. For the same reason, the Court finds that Apotex will have an adequate remedy if this action is dismissed for failure to join a required party.

For these reasons, the Court concludes that Astellas LLC is an indispensable party under Rule 19. The Court further concludes that under Rule 19, this action should not proceed among the existing parties.

IV. CONCLUSION

For the reasons stated above, the Court GRANTS the Motion and dismisses this action without prejudice for failure to join Astellas LLC, which is a required party. The Clerk is instructed to close the file.

IT IS SO ORDERED.

Dated: January 31, 2019

JOSEPH C. SPERO
Chief Magistrate Judge

United States District Court
Northern District of California