IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SHIRE LLC; SUPERNUS PHARMACEUTICALS, INC.; AMY F.T. ARNSTEN, PH.D.; PASKO RAKIC, M.D.; and ROBERT D. HUNT, M.D.,

Plaintiffs,

v.

IMPAX LABORATORIES, INC.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.−FLORIDA; WATSON PHARMA, INC.; and ANDA, INC.,

Defendants.
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No. C 10-05467 RS

ORDER GRANTING DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND GRANTING PLAINTIFFS' MOTION FOR LEAVE TO AMEND

I. INTRODUCTION

This case tests whether various proposed generic versions of Intuniv, a drug prescribed for pediatric Attention Deficit Disorder (ADD), infringe the intellectual property of plaintiff Shire LLC, a brand-name drug supplier. Defendants are generic drug manufacturers who seek a judgment of patent invalidity or non-infringement, in order to advance the United States Food and Drug Administration's (FDA) approval of their generic versions of the drug under the Hatch-Waxman Act. The dispute posed by the instant set of motions arises from Shire's dedication of one of the patents-in-suit, U.S. Patent No. 5,854,290 ("the '290 patent"), to the public domain, and the consequences that flow from that disclaimer under the Hatch-Waxman Act.

First, Shire moves for leave to amend the operative First Amended Complaint (FAC) in order to: (1) withdraw their infringement claims pertaining to the '290 patent, (2) omit the named

inventors of the'290 patent as plaintiffs, and (3) address an unrelated, recent regulatory filing with the FDA by defendant Watson Laboratories. Defendants do not oppose the motion with respect to the latter purpose, but jointly oppose the request to the extent it relates to the '290 patent on the theory that it could potentially frustrate their attempt to obtain effective relief on their counterclaims under the Hatch-Waxman Act. Second, and relatedly, defendants move for summary judgment on their counterclaim of non-infringement of the '290 patent. Plaintiffs oppose the motion, arguing that the Court no longer possesses jurisdiction to adjudicate that claim, or alternatively, should elect to decline jurisdiction under the Declaratory Judgment Act. The motions are appropriate for disposition without oral argument pursuant to Civil Local Rule 7-1(b), and in consideration of the briefs, and for all the reasons set forth below, both motions must be granted.

II. BACKGROUND

Under the Hatch-Waxman Act, the statutory framework governing the regulatory process underlying this case, a brand-name drug company seeking the FDA's approval of a newly developed drug must file a New Drug Application (NDA) that includes information about patents "with respect to which a claim of patent infringement could reasonably be asserted." *See* 21 U.S.C. § 355(b)(1); *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1159-60 (Fed. Cir. 2012). That information is published in the FDA's Approved Drug Products with Therapeutic Equivalent Evaluations, colloquially known as "the Orange Book." A generic drug company may seek FDA approval for a generic equivalent of a brand-name drug using an Abbreviated New Drug Application (ANDA), which includes, in appropriate cases, a certification pursuant to § 355(j)(2)(A)(vii) that "such patent is invalid or will not be infringed."

In such circumstances, the FDA may approve the ANDA unless the brand-name NDA holder sues the generic ANDA filer for patent infringement within 45 days. *Id.* § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2) (filing of the ANDA is treated as an act of infringement). The first generic drug company to file such an ANDA receives 180 days of marketing exclusivity, from the date of its "first commercial marketing," before other generic companies enter the market. 21 U.S.C. § 355(j)(5)(B)(iv). Under 2003 amendments to the Hatch-Waxman Act, the first ANDA filer may forfeit its period of marketing exclusivity under certain circumstances, including if it fails to launch

the product after a final court judgment of noninfringement or invalidity. Thus, for instance, if a second ANDA filer is awarded a final judgment that the relevant patents are invalid or not infringed, the first ANDA filer forfeits its 180-day exclusivity period unless it begins marketing the drug within 75 days. *See* 21 U.S.C. § 355(j)(5)(D).

Here, Shire holds an exclusive license to three patents, including the '290 patent, which are listed in the Orange Book in connection with Shire's drug Intuniv, which is used to treat pediatric ADD. A Shire subsidiary also holds a NDA covering Intuniv from the FDA. In October of 2010, defendants Impax and Watson filed ANDAs, seeking authorization from the FDA to market generic versions of the 4 mg dosage form of Intuniv before Shire's patents expire. Their ANDAs certified, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that none of Shire's three patents would be infringed and that each was invalid or unenforceable. Neither Impax nor Watson were the ANDA first filer.[1]

Shire responded with this litigation, asserting infringement of all three patents, on December 2, 2010. Approximately a week later, defendant Impax filed an amended ANDA, and shortly thereafter Shire filed the operative FAC to address those amendments, per 21 U.S.C. § 355(j)(5)(B)(iii). Defendants answered and counterclaimed in late January of 2011. On February 2, 2012, Impax amended its pleadings to add an affirmative defense and counterclaim of unenforceability as to the '290 patent. The deadline for amendments to the pleadings passed on March 16, 2012, per the scheduling order entered in this case. Defendants have served their invalidity and infringement contentions, and Impax has amended them once, per the stipulation of the parties. Apparently, defendants have represented to Shire an intention to seek leave from the Court for further amendments, but have not yet formally done so.

On March 22, 2012, days after the deadline for amendments passed, the '290 inventor plaintiffs filed a statutory disclaimer with the Patent & Trademark Office (PTO) pursuant to 235 U.S.C. § 253 and 37 C.F.R. 1.321(a), dedicating the claims of the '290 patent to the public domain. Although it is not entirely clear why Shire chose to disclaim the '290 patent, defendants suggest it did so after it came to light that plaintiffs had improperly concealed and misrepresented publication

[1] The record does not reveal the identity of the ANDA first filer, but presumably it is another third-party generic drug manufacturer.

dates of prior art during prosecution of the patent. *See* Defs.' Opp'n at 1:10-14. In any case, plaintiffs also requested that the FDA delist the '290 patent from the Orange Book, although that has not occurred to date. They then requested defendants stipulate to their request to dismiss the related infringement claims and counterclaims, as well as the '290 inventor plaintiffs, from this action. It is undisputed that since the '290 patent was dedicated to the public, defendants cannot infringe its claims, and defendants do not oppose the motion to the extent it eliminates plaintiff's direct infringement contentions. Defendants oppose the motion, however, to the extent it has any affect on the Court's jurisdiction over their counterclaims. They assert that the absence of a final judgment may deprive them of effective relief under the Hatch-Waxman Act because the '290 patent remains listed in the Orange Book. Defendants have therefore filed a motion for summary judgment of non-infringement of the '290 patent.[2]

Finally, on May 31, 2012, defendant Watson notified Shire that it had amended its ANDA to include 1, 2, and 3 dosage forms of its proposed generic version of Intuniv. Shire also seeks leave to amend the FAC to address those amendments, per § 355(j)(5)(B)(iii), which provides 45 days for the patentee to file suit on patents certified as not infringed, invalid, or unenforceable.

III. LEGAL STANDARD

A. Summary judgment

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Here, because there are no disputed facts, and defendants' motion seeks a ruling on a pure question of law, the motion is appropriate for adjudication. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

B. Leave to amend

[2] The parties also note that the District Court of Delaware held the '290 patent invalid under 35 U.S.C. § 102(c) as "abandoned," after notification of Shire's disclaimer. Although the parties here debate the significance of that judgment, that question need not be addressed in light of the result reached below.

Under Federal Rule of Civil Procedure 15(a)(2), the court should freely grant leave to amend "when justice so requires." The standard is one of "extreme liberality." *DCD Programs v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987). In determining whether leave to amend is warranted, courts consider five factors: (1) undue delay; (2) bad faith; (3) prejudice to the opposing party; (4) futility of the amendment; and (5) whether previously allowed amendments have failed to cure deficiencies. *See Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). "Prejudice is the 'touchstone of the inquiry under rule 15(a).'" *Id.* (citing *Lone Star Ladies Inv. Club v. Schlotzky's Inc.*, 238 F.3d 363, 368 (5th Cir. 2001)).

IV. DISCUSSION

A. Summary judgment

Defendants move for summary judgment on their counterclaim of non-infringement of the '290 patent over plaintiffs' opposition. As noted, there are no disputed factual issues, rather, the dispute concerns the legal result. Defendants argue that a judgment of non-infringement is a foregone conclusion now that plaintiffs have disclaimed all of the '290 patent's claims and even admitted that "[d]efendants cannot infringe." Pls.' Mot. for Leave to Amend, at 2:11. Plaintiffs, by contrast, maintain that the Court lacks jurisdiction under Article III to enter judgment because the controversy is now moot. Alternatively, if there is jurisdiction, defendants nonetheless urge the Court to decline to exercise its discretionary jurisdiction under the Declaratory Judgment Act.

It is, of course, a bedrock principle of law that "[t]o qualify as a case fit for federal-court adjudication, 'an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.'" *Arizonan for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (quoting *Preiser v. Newirk*, 422 U.S. 395, 401 (1975)). That principle flows from Article III, § 2 of the Constitution, *see id.* at 64, and is incorporated into the Declaratory Judgment Act's provision that, "[i]n a case of actual controversy within its jurisdiction, … any court of the United States … may declare the rights of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). By the same token, Article III does not permit the issuance of advisory opinions, where no actual controversy exists. *Preiser*, 422 U.S. at 402. Rather, if the

dispute is extinguished, or mooted, the Constitution requires dismissal for lack of jurisdiction. *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000).

Although plaintiffs argue that the controversy is moot because the '290 patent now belongs to the public, in so doing they ignore the true nature of the controversy at issue.[3] In the context of Hatch-Waxman litigation, the Federal Circuit has repeatedly found that the elimination of the threat of an infringement suit does not necessarily defeat jurisdiction under the Declaratory Judgment Act where barriers to market entry remain for generic drug companies. *Caraco Pharm. Labs. v. Forest Labs., Inc.*, 527 F.3d 1278, 1296-97 (Fed. Cir. 2008). As the Court explained in *Caraco*:

> In sum, Caraco's declaratory judgment action presents an Article III controversy as to whether the drug described in Caraco's ANDA infringes Forest's Orange-Booklisted '941 patent. This controversy is not premised only upon a threat of an infringement suit. A controversy also exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market. Forest's covenant not to sue does not eliminate the controversy with Caraco, because the controversy can only be resolved by a judgment that determines whether Forest's '941 patent is infringed by the drug described in Caraco's ANDA. Accordingly, we hold that this action presents an ongoing Article III case and controversy.

Id. at 1297. Other, recent opinions from the Federal Circuit support this line of reasoning. *See Teva Pharms., USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1348 n.3 (Fed. Cir. 2010) (vacated on other grounds); *Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158, 1164 (Fed. Cir. 2012) ("Sunovion does not attempt to argue that its covenant not to sue Dey over the '289 patent moots this case, as that argument is foreclosed by our contrary holding in *Caraco.*"). *See also Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317-18 (D.C. Cir. 2010) (patentee's voluntary request to de-list patent from Orange Book does not trigger first ANDA filer's exclusivity period).

Although defendants attempt to distinguish *Teva* and *Dey Pharma* on procedural grounds, and rely instead on a slightly older case, *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), the former cases represent good law and the latter is of no assistance to them. In *Janssen*, there was no jurisdiction because the subsequent ANDA filer stipulated to the validity, infringement, and enforceability of another Orange Book listed patent, which effectively barred

[3] Because the controversy is not moot, there is no need to discuss the various exceptions to the mootness doctrine, as defendants do in their opposition brief.

market entry regardless of any judicial declaration as to the patents-in-suit. *See Dey Pharma*, 677 F.3d at 1163 (citing *Janssen*, 540 F.3d at 1360). That unusual factual circumstance is not present here, and consequently, *Janssen* does not control this case. To say that the straightforward rule adopted in *Teva*, *Dey Pharma*, and *Caraco* applies here is not to imply, however, that there is any inconsistency between those cases and *Janssen*, as defendants suggest.

In *Teva*, for example, the brand-name drug manufacturer, Eisai, filed statutory disclaimers on two of its patents listed in the Orange Book in connection with the drug donepezil. In a declaratory judgment action later filed by Teva, the generic drug company, Eisai moved to dismiss Teva's claim seeking a judgment of non-infringement, for lack of subject matter jurisdiction. While the motion was pending, Eisai negotiated a covenant-not-to-sue on two other patents also listed in the Orange Book. The District Court granted the motion to dismiss Teva's claims, but the Federal Circuit reversed. Recognizing that Eisai's disclaimers and promises not to sue dispatched the threat of enforcement, the Court nonetheless noted that "[w]hat matters for our purposes is that all four of the DJ patents remain listed in the Orange Book." *Teva Pharms.*, 620 F.3d at 1345. "Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework such an injury[-in-fact] occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs." *Id.* at 1347 (emphasis added). In *Teva*, as in *Caraco* and *Janssen*, "the alleged action taken (giving rise to the injury-in-fact) was listing particular patents in the Orange Book." *Id.* As a consequence, *Teva* held that "[n]either the statutory disclaimers nor Eisai's covenant-not-to-sue render this declaratory judgment action moot because the DJ patents remain listed in the Orange Book." *Id.* at 1348 n.3.

Here, the same is true: while Shire represents that it has requested that the FDA de-list the '290 patent, apparently the agency has not yet complied with that request, and there is no indication in the record when, if ever, the de-listing might occur. Contrary to Shire's suggestion, the efficacy of the requested relief is not contingent on any future "hypothetical events" such that an order might be rendered advisory. *See* Pls.' Opp'n to Mot. for Summ. J. at 1:15-16. That is because, as *Teva* explains, the injury flows from Shire's election to list the '290 patent in the Orange Book, thereby creating a barrier-to-entry. Accordingly, it matters not that other, subsequent events – such as

actions taken by the ANDA first-filer – might effectively thwart defendants from ultimately gaining FDA approval for their generic versions of Intuniv. Here, it is enough to satisfy jurisdiction pursuant to the Declaratory Judgment Act that a declaration of non-infringement would remove the '290 patent as a stumbling block to market entry under the Hatch-Waxman framework. Of course, should the FDA finally de-list the '290 patent, then, under the logic of *Teva*, jurisdiction might be lost over defendants' relevant counterclaims.[4] At present, however, there is an injury-in-fact flowing from Shire's earlier decision to list the '290 patent in the Orange Book, sufficient to sustain jurisdiction under the Declaratory Judgment Act. *Dey Pharma*, 677 F.3d at 1164 ("[a]s we held under materially identical facts in *Caraco*, simply eliminating one barrier is sufficient for declaratory jurisdiction, so long as litigation is also pending that could eliminate the other barriers").

Although Shire alternatively asks the Court to exercise its discretion to decline jurisdiction under the Declaratory Judgment Act and withhold judgment, that result is not appropriate here. Shire maintains that defendants will not be prejudiced if the Court declines jurisdiction because it has already "withdrawn" the '290 patent from the Orange Book, within the meaning of 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), sufficient to trigger market exclusivity for the ANDA first-filer. In the first instance, Shire has neglected to identify any authority construing that particular subsection of Title 21, and consequently, its self-interested proposition of law cannot be accepted as true. Second, if that were actually true, then there would be no substantial reason for Shire to oppose entry of judgment. Third, to the extent Shire suggests that the Court cannot adjudicate infringement without first addressing validity and enforceability, again, it has furnished no authority to that effect.[5] Fourth, and most fundamentally, for all the reasons set forth above, declining jurisdiction would deny defendants effective relief under the Hatch-Waxman Act, and permit Shire to manipulate the

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[4] Noting that 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) addresses patents "withdrawn" from the Orange Book by the NDA filer, plaintiffs maintain they have done everything they can to withdraw the patent within the meaning of the law, but concede that the "[t]he final act of deleting this information from the Orange Book is performed by the FDA." Pls.' Opp'n to Mot. for Summ. J. at 4 n.1.

[5] Shire's reading of defendants' pleadings is overly formalistic. The wording of defendants' counterclaims does not preclude judgment. There also does not appear to be a doctrinal bar to entry of judgment as to non-infringement where the patentee has already admitted that infringement is impossible. *See Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983) ("Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity").

regulatory framework unfairly by creating a disclaimer "loophole." Fifth, to the extent Shire suggests defendants have failed to avail themselves of all administrative remedies before the FDA, there is no such requirement, and in any case, the availability of appropriate relief under the FDA's internal regulations is far from certain. Sixth and finally, Shire has already conceded that "[d]efendants cannot infringe [the '290 patent]." Pls.' Mot. for Leave to Amend, at 2:11. Accordingly, defendants are entitled to summary judgment in their favor on the issue of non-infringement.

B. Leave to amend

Shire also moves for leave to amend on the grounds that its disclaimer of the '290 patent has the effect of depriving the Court of subject matter jurisdiction over its direct infringement claims. Specifically, plaintiffs concede that they can never enforce the claims of the '290 patent against any other party, lack a legal interest in it, and hence do not have standing to sue. *See Teva*, 620 F.3d at 1348 n.3 (citing *Guinn v. Kopf,* 96 F.3d 1419, 1422 (Fed. Cir. 1996)) ("A statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently enforced."). As discussed above, the elimination of plaintiffs' claims predicated on the '290 patent has no impact on the Court's jurisdiction over defendants' counterclaims. In light of that conclusion, defendants have no basis for opposition to the motion, and plaintiffs are granted leave to amend for purposes of omitting its direct infringement claims and the inventor plaintiffs as named parties. Likewise, defendants do not oppose Shire's request for leave to amend the FAC for purposes of addressing Watson's amended ANDA. Given the liberal policy favoring amendment, and defendants' apparent non-opposition to that aspect of Shire's request, plaintiffs are granted leave to amend the pleadings to address the amendments made to Watson's ANDA.

V. CONCLUSION

For the stated reasons, defendants' motion for summary judgment is hereby granted: the '290 patent is not infringed. Plaintiffs' motion for leave to amend is also granted. The proposed Second Amended Complaint must be filed within ten days of the date of this Order.

IT IS SO ORDERED.

Dated: 8/20/12

RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE