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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.
_____/

No. C 10-5467 RS

ORDER DENYING MOTIONS TO DISMISS

I. INTRODUCTION

This suit involves a dispute between a branded drug manufacturer and two potential competitors seeking FDA approval to market generic versions of the patented product. Plaintiffs Shire LLC; Supernus Pharmaceuticals, Inc.; Amy F.T. Arnsten, Ph.D.; Pasko Rakic, M.D.; and Robert D. Hunt, M.D. (collectively, "plaintiffs") filed suit for patent infringement and declaratory judgment of patent infringement against defendants Impax Laboratories; Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.-Florida; Watson Pharma, Inc.; and Anda, Inc. (The latter four defendants are collectively referred to as "Watson.") Defendants answered and asserted affirmative

defenses and counterclaims. Plaintiffs move to dismiss all of defendants' counterclaims under Rule 12(b)(6) and to strike all their affirmative defenses under Rule 12(f). Impax counters with a motion to dismiss plaintiffs' first amended complaint (FAC) on the grounds that the FAC is pleaded in the same fashion as its Answer and if the Court dismisses one, it should dismiss the other as well. Watson joins in Impax's motion to dismiss. For the reasons stated below, plaintiffs' motions to dismiss defendant's counterclaims and to strike their affirmative defenses and defendants' motion to dismiss the FAC are each denied.

II. BACKGROUND

Plaintiffs are the owners/exclusive licensee of three patents covering the manufacture of guanfacine hydrochloride extended release tablets, which are marketed under the name INTUNIV for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The three patents-in-suit are United States Patents Nos. 5,854,290 (the '290 patent), 6,287,599 (the '599 patent), and 6,811,794 (the '794 patent). Impax and Watson seek FDA approval to manufacture and sell generic versions of guanfacine hydrochloride. To that end, each filed an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA). As part of an ANDA, a generic-drug applicant must inform the FDA of its position with respect to any patents that have been identified by the owner of a previously approved (or "listed") drug as covering the product.

In this case, both Impax and Watson filed a "paragraph IV certification," indicating that each of the listed drug's patents "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." If an ANDA contains a paragraph IV certification, then the applicant must provide a so-called "notice letter" to the patent holders and manufacturer of the listed drug including a detailed basis for any allegation of noninfringement, invalidity, or unenforceability. *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II). In order to encourage the early resolution of patent disputes involving the potential market entrance of generic drugs, the filing of a paragraph IV certification is considered "an act of infringement," such that the patent holder may bring suit in federal court. *See* 35 U.S.C. § 271(e)(2)(A). After receiving a notice letter, the patent holder has 45 days to file an infringement suit in order to stay FDA approval of the ANDA pending the outcome of the suit, expiration of the patent, or the running of 30 months.

In this case, plaintiffs received notice letters from defendants and filed suit in this Court in December 2010. Their FAC alleges claims for direct infringement, declaratory judgment of direct infringement, declaratory judgment of inducement of infringement, and declaratory judgment of contributory infringement for each of the three patents-in-suit. Each of the claims for direct infringement is based on the ANDA filing and includes an assertion that the case is "exceptional" pursuant to 35 U.S.C. § 285 (providing for award of attorney's fees). The same twelve claims are asserted against both defendants. A sample claim is Claim 3: "Impax has declared its intent to actively induce others to manufacture, use, offer to sell, or to sell in the U.S. or to import into the U.S., the Impax Proposed Products in the event that the FDA approves the Amended Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax's infringement under 35 U.S.C. § 271(b) of the '290 patent."

Impax answered the FAC and asserted seven counterclaims seeking declaration of noninfringement and declaration of invalidity for each of the three patents plus a claim that the case is "exceptional." A typical claim for noninfringement is Counterclaim One: "Impax does not and will not directly infringe, indirectly infringe, contribute to, or induce infringement of any valid and enforceable claim of the '290 patent by the commercial manufacture, use, sale, offer for sale, and/or importation of the proposed drug product described in Impax's ANDA No. 202238." Its affirmative defenses repeat the same six allegations of noninfringement and invalidity, the seventh defense alleges failure to state a claim, and the eighth defense reserves the right to raise any other defenses or counterclaims that might arise as a result of discovery.

Watson also answered the FAC. It does not assert separate counterclaims for noninfringement versus invalidity, but instead asserts three counterclaims for "non-infringement of any valid and enforceable claim" for each of the three patents. It separately asserts one counterclaim that the '290 patent is unenforceable due to inequitable conduct. Its fifth counterclaim states that the case is exceptional. Watson pleads four affirmative defenses: failure to state a claim; that they have not infringed any valid, enforceable claim of any of the three patents; unenforceability of the '290 patent due to inequitable conduct; and lack of subject matter

jurisdiction for three of the four Watson defendants (Watson Pharmaceuticals, Watson Pharma, and Anda).

III. DISCUSSION

First, plaintiffs move to dismiss defendants' counterclaims for failure to state a claim. Under Federal Rule of Civil Procedure 8(a)(2), a complaint must present "a short and plain statement of the claim" demonstrating that the plaintiff is entitled to relief. Fed. R. Civ. P. 8(a)(2). If this standard is not met, the opposing party may move to dismiss for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Under Rule 12(b)(6), dismissal is appropriate if the claimant either does not raise a cognizable legal theory or otherwise fails to allege sufficient facts to support a cognizable claim. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). In this case, plaintiffs bring their motions to dismiss for the latter reason, i.e., that defendants' counterclaims are not supported by sufficient factual allegations.

Defendants' oppose plaintiffs' motion on two grounds: (1) that their counterclaims are pleaded at the same level of detail as defendants' claims; and (2) that, under the circumstances of this case, they have met the objective of Rule 8, which is to place the opposing party on fair notice such that they may defend against their counterclaims. With the exception of Watsons' Counterclaim Two for unenforceability, which is discussed separately below, both plaintiffs' claims for declaratory judgment of infringement and defendants' counterclaims for declaratory judgment of noninfringement and/or invalidity are governed by the same pleading standard. In this case, defendants contend that plaintiffs seek to have the Court hold them to a higher standard than demonstrated in the FAC.

Defendants respond that they have met their Rule 8 pleading standard by alleging facts sufficient to state a claim for infringement under 35 U.S.C. § 271(e)(2). Under that provision, it is an "act of infringement" to submit an ANDA application with a paragraph IV notification where the drug or its use is claimed in a patent. Thus, in Claim 1, plaintiffs allege that Impax's filing of ANDA no. 202238 infringes the '290 patent under section 271(e)(2)(a). Plaintiffs assert corresponding section 271(e) claims for violation of the '599 patent and the '794 patent against Impax and for violation of all three patents by Watson based on the filing of its ANDA application.

As defendants characterize the filing of the ANDA as an "act of infringement" pursuant to statute, they insist they have identified a reason why the minimal factual allegations necessary to state this claim should not be compared to defendants' burden to state their claims. Plaintiffs, however, also assert additional claims under each patent against defendants for declaratory judgment of direct infringement, inducement of infringement, and contributory infringement. Since defendants deny that the parties' pleadings incorporate information contained in the ANDA filing or notice letters, it is unclear why the mere filing of an ANDA has any impact on the pleading of their claims for declaratory relief under sections 271(a), 271(b), and 271(c) of the Patent Act. Yet plaintiffs plead these claims by reference to the language of the statute, without additional factual allegations. At the same time, plaintiffs suggest that defendants fail to state claims for declaratory judgment of noninfringement and invalidity because they have not identified which claims are not infringed and what prior art applies to specific claims. As the FAC does not refer to specific claims that defendants purportedly infringe, it is hard to accept plaintiffs' assertion that they have pleaded everything necessary, i.e., the filing of the ANDAs, yet defendants' counterclaims must be dismissed for failure to state a claim. In short, with respect to the claims and counterclaims involving declaratory judgment, as well as the allegations that the case is "exceptional," all are pleaded in essentially the same barebones fashion.

While the fact that an opponent's claims may be insufficiently pleaded does not excuse a party from its own burden to meet the requirements of Rule 8, the brevity of the claims and counterclaims in this case must be judged in context. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009) ("Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense."). The context here includes the fact that this case was initiated after defendants filed their respective ANDAs and notice letters. Thus, as a practical matter, plaintiffs have more information regarding the issues in this suit than litigants in other types of suits frequently have. Moreover, the Patent Local Rules place further obligations on the parties to state their specific and binding positions regarding infringement and invalidity. *See*, *e.g.*, Patent Local Rule 6-3 (providing that the amendment of infringement or invalidity contentions may be made only by Order of the Court on a

timely showing of good cause). Thus, requiring parties to replead their claims and counterclaims with additional factual allegation represents a burden with little benefit. Accordingly, plaintiffs' motions and defendants' motion to dismiss the claims and counterclaims respectively for failure to state a claim are all denied.

Plaintiffs also move to strike defendants' affirmative defenses under Federal Rule of Civil Procedure 12(f). Granting or denying a motion to strike lies within the discretion of the court. *See Federal Sav. & Loan Ins. Corp. v. Gemini Mgmt*, 921 F.2d 241, 244 (9th Cir. 1990). In the context of this suit, plaintiffs have adequately stated their counterclaims. Thus, defendants' motions to strike affirmative defenses based on noninfringement and invalidity of the asserted patents must also be denied. With respect to defendants' defense of failure to state a claim, the Court likewise has denied their motion to dismiss the FAC. Accordingly, plaintiffs' motion to strike the Rule 12(b)(6) defense is denied as moot. Impax asserts one final "defense," which merely states a reservation of rights to assert other defenses or counterclaims. In its Opposition, Impax admits that this language does nothing to alter its burden under Rule 15, should it seek later to amend its pleading. Therefore, the motion to strike this statement is also denied as moot.

Watson asserts two remaining defenses. Of these, its defense based on inequitable conduct will be discussed below with its counterclaim for unenforceability of the '290 patent. In its Fourth Defense, Watson asserts that subject matter jurisdiction is absent with respect to the claims asserted against Watson Pharmaceuticals, Watson Pharma, and Anda. Its Answer fails to include factual allegations that provide the basis for this asserted defense. Based on its Opposition and plaintiffs' Reply, however, it is apparent that both sides understand that Watson contends subject matter jurisdiction is proper only with respect to the entity that filed the ANDA, specifically Watson Laboratories, Inc.-Florida. Plaintiffs argue that the defense must be dismissed for failure to meet the standards of *Iqbal* and *Twombly*. *See* 129 S. Ct. 1937 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). In the case on which plaintiffs rely, the court maintains that one of the reasons to hold defenses to this standard is to "weed out the boilerplate listing of affirmative defenses which is commonplace in most defendants' pleadings where many of the defenses alleged are irrelevant to the claims asserted." *Barnes v. AT&T Pension Benefit Plan*, 718 F. Supp. 2d 1167, 1172 (N.D. Cal.

2010). As Watson pleaded four affirmative defenses and defendants appear to understand the relationship of its subject matter jurisdiction defense to this ANDA action, the concern expressed by the court in *Barnes* simply is not present here. Instead, striking this one defense, of which plaintiffs have fair notice, and requiring Watson to restate it would waste resources better spent on advancing this case on the merits. Accordingly, plaintiffs' motion to strike the subject matter jurisdiction defense is denied.

The remaining issue is whether Watson has adequately pleaded its counterclaim and defense that the '290 patent is unenforceable due to inequitable conduct. As a fraud-based claim, an allegation of inequitable conduct must meet the heighted pleading standard of Rule 9(b). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). In other words, a claimant "must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* In addition, plaintiffs urge the Court to consider whether Watson meets this pleading standard in light of the Federal Circuit's recent en banc decision. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 2011 U.S. App. LEXIS 10590 (Fed. Cir. May 25, 2011). In that case, the Federal Circuit tightened the standards for finding both intent and materiality. *Id.* at *32. In cases involving nondisclosure of information, the party asserting inequitable conduct must show by clear and convincing evidence that the patentee deliberately withheld a reference that he or she knew was material. *Id.* With respect to materiality, the Federal Circuit held that it must be shown that the patent would not have granted but, for the undisclosed reference. *Id.* at *37. As the case establishes what is necessary to prevail on a claim, it is informative. In this case, however, it does not provide guidance as to whether Watson pleaded sufficient facts to state a claim.

Here, Watson makes more than conclusory allegations that the patentees failed to disclose material prior art. Instead, its Answer describes two specific pieces of prior art: a poster co-authored by defendants Hunt and Arnsten on the use of guanfacine in the treatment of ADHD (the "Hunt poster"); and a poster describing work by a different research group on the same topic (the "Chappell poster"). The Answer describes the conference at which both posters were allegedly displayed and the dates of the event. The Answer alleges that Hunt and Arnsten failed to disclose

the Hunt poster and that Arnsten asserted a later publication date for the Chappell poster in a declaration submitted to the Patent and Trademark Office during prosecution of the '290 patent. These details are sufficient to plead the circumstances of the alleged inequitable conduct. Accordingly, plaintiffs' motion to dismiss the inequitable conduct claim and defense is denied.

IV. CONCLUSION

Plaintiffs' motions to dismiss the counterclaims and to strike the affirmative defenses of defendants Impax and Watson are denied. Defendant's motion to dismiss plaintiffs' FAC also is denied.

IT IS SO ORDERED.

Dated: 8/29/11

RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE