IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ZYDUS PHARMACEUTICALS USA and CADILA HEALTHCARE LIMITED, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. TORRENT PHARMACEUTICALS LIMITED, INC., TORRENT PHARMA INC., and HETERO LABS LIMITED, Defendants.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.
OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. ZYDUS PHARMACEUTICALS USA and CADILA HEALTHCARE LIMITED, Defendants.

HONORABLE JEROME B. SIMANDLE

Civil Action Nos.
14-3168 (JBS/KMW)
14-4671 (JBS/KMW)
14-5878 (JBS/KMW)
14-6398 (JBS/KMW)
14-7252 (JBS/KMW)

MEMORANDUM OPINION REGARDING MOTIONS TO DISMISS OTSUKA'S INFRINGEMENT CLAIMS UNDER THE '350 PATENT

SIMANDLE, Chief Judge:

These related patent infringement actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 281, generally concern Plaintiff Otsuka Pharmaceutical Co, Ltd.'s (hereinafter, "Otsuka") position that various generic defendants' abbreviated new drug applications (hereinafter, "ANDAs") infringe the various patents covering Otsuka's brand name aripiprazole product, Abilify®.[1]

[1] The patents asserted in these related actions specifically include: U.S. Patent Nos. 5,006,528 ("the '528 patent"),

Following the Court's decision upon Otsuka's motions for a preliminary injunction and to amend its Complaints,[2] and in advance of the Court's October 19, 2015 Markman hearing, Defendants Zydus Pharmaceuticals USA and Cadila Healthcare Limited (collectively, "Zydus"), Torrent Pharmaceuticals Limited, Inc., Torrent Pharma Inc., and Hetero Labs Limited (collectively, "Torrent"), and Teva Pharmaceuticals USA, Inc. (hereinafter, "Teva," and together, "Defendants") move to dismiss Otsuka's direct, induced, and contributory infringement

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7,053,092 ("the '092 patent"), 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), 8,642,600 ("the '600 patent"), 8,642,760 ("the '760 patent"), and 8,759,350 ("the '350 patent" or the "Patent"). The pending motions to dismiss, however, only concern Otsuka's infringement claims under the '350 Patent.

[2] As the lengthy exclusivity period of the patent covering the primary aripiprazole compound came to a close, Otsuka moved to enjoin the defendants from launching competing generic aripiprazole products, on the grounds that the package inserts or labels for the proposed generic products in all of the related infringement actions would induce infringement of Claim 1 of the '350 Patent. See generally Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, 2015 WL 1782653, at *3-*4 (hereinafter, the "TRO Opinion"). Nevertheless, Otsuka had never asserted the '350 Patent against Zydus, Torrent, and Teva, and so, three days after the logistics conference concerning Otsuka's anticipated injunctive motion practice (at which time counsel for Otsuka made no mention of its intent to assert the '350 Patent), Otsuka moved to amend its Complaints in order to assert the '350 Patent, for the first time, against Zydus, Torrent, and Teva. See id. On April 16, 2015, the Court, as explained in greater below, granted Otsuka's motions to amend, principally in light of the liberal standard for amendment under Federal Rule of Civil Procedure 15(a). See id. at *4-*6.

claims under the '350 Patent.[3] [See Docket Item 113 in Civil Action No. 14-3168; Docket Item 125 in Civil Action No. 14-4671; Docket Item 115 in Civil Action No. 14-5878; Docket Item 111 in Civil Action No. 14-6398; and Docket Item 72 in Civil Action No. 14-7252.]

As to claims of direct infringement, the Defendants argue, in particular, that their proposed ANDA products cannot, as a matter of law, directly infringe any claim of the '350 Patent, because their proposed aripiprazole products contain only a single active ingredient, aripiprazole, and not the multi-component pharmaceutical composition (consisting of aripiprazole in addition to either citalopram and/or escitalopram) purportedly disclosed by the '350 Patent. (See Zydus' Br. at 8-9; Torrent's & Teva's Br. at 1-4, 13-16.) In addition, the Defendants submit that Otsuka's induced and/or contributory infringement claims lack essential allegations, namely, that these Defendants' proposed labels actively and intentionally

[3] Although Zydus briefed the issue of Otsuka's '350 claims separately from Torrent and Teva, the Court will address the plausibility of the '350 infringement claims in a single decision, based upon the nearly-identical nature of the material allegations, and because the Defendants have briefed identical issues in relation to their substantially similar proposed aripiprazole products. See FED. R. CIV. P. 42(a) (discussing district courts' discretion to consolidate "common question[s] of law or fact"); see also ACR Energy Partners, LLC v. Polo N. Country Club, Inc., ___ F.R.D. ____, 2015 WL 4993588, at *2 (D.N.J. Aug. 21, 2015) (finding the issuance of a "single, consolidated decision" appropriate on a common issue across actions).

encourage and instruct the use of their generics in an infringing manner, i.e., as products for the "Adjunctive Treatment of Major Depressive Disorder," the primary indication of the '350 Patent. (See Zydus' Br. at 10-14; Torrent's & Teva's Br. at 17-22.)

Otsuka, for its part, does not oppose dismissal of its claims for direct and contributory infringement of the '350 Patents.[4] (See Otsuka's Opp'n at 5 n.6.) Otsuka does, however, submit that dismissal of its claims for induced infringement of the '350 Patent would be premature before claim construction, and prior to the resolution of certain "factual issues" regarding whether Defendants' proposed labels actively instruct and/or encourage infringement of the '350 Patent (despite having "'carved out'" the patented indication). (Otsuka's Opp'n at 4-11.)

For the reasons that follow, Defendants' motions will be granted in part and denied in part. Specifically, Otsuka's claims for direct and contributory infringement of the '350 Patent will be dismissed with prejudice, but its claims for induced infringement of the '350 Patent will be dismissed without prejudice and with leave to amend, to the extent such an

[4] As a result, Otsuka's direct and contributory infringements claims under the '350 Patent will be dismissed with prejudice.

amendment can be made consistent with counsel for Otsuka's obligations under Federal Rule of Civil Procedure 11(b).

The Court finds as follows:[5]

1. Otsuka, a pharmaceutical company primarily organized and existing under the laws of Japan, holds New Drug Application (hereinafter, "NDA") No. 21-436, approved by the Food and Drug Administration (hereinafter, the "FDA"), for aripiprazole tablets, which Otsuka markets under the trade name Abilify®. (Zydus Am. Compl. at ¶¶ 1, 17-18, 25-27.) In connection with Abilify's® listing in the Orange Book, the FDA's book of drug products approved under the Food, Drug, and Cosmetic Act (hereinafter, the "Orange Book"), 21 U.S.C. § 355(j), Otsuka identifies the '350 patent, which issued on June 24, 2014, and discloses a "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." (Zydus Am. Compl. at ¶¶ 77-81.)

[5] For purposes of the pending motions, the Court accepts as true the facts set forth in Otsuka's Amended Complaints, together with the exhibits attached to the Amended Complaints, and matters of public record. See Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014) (discussing district courts' treatment of motions to dismiss for failure to state a claim). Here, the material portions of each Amended Complaint are substantively identical, and so the Court will, in the interests of simplicity, refer to the Amended Complaint filed in the oldest of the related actions involved in the pending motions, Otsuka Pharm. Co., Ltd. v. Zydus Pham. USA Inc., Civil Action No. 14-3168 (JBS/KMW), unless otherwise indicated.

2. The Patent, which contains eighteen claims directed at the disclosed composition and specified methods of use, specifically describes "pharmaceutical compositions" consisting of "carbostyril derivatives ... in combination with serotonin reuptake inhibitors in a pharmaceutically acceptable carrier" for the treatment of "mood disorders such as depression and major depressive disorder." ('350 Patent at 1:18-24.) Independent claims 1-3, in turn, teach: a pharmaceutical composition comprising (a) aripiprazole in combination with (b) at least one serotonin reuptake inhibitor selected from citalopram, escitalopram and salts thereof. (See '350 Patent at 28:64-29:6.) The remaining independent claims 9-11 then describe methods of treating specific mood disorders by administering an "effective amount" of the combination "pharmaceutical composition" disclosed in claims 1-3. (Id. at 29:26-30:20.)

3. Between April and August of 2014, each Defendant filed an ANDA with the FDA, seeking approval to market generic aripiprazole tablets and/or orally disintegrating aripiprazole tablets, prior to the expiration of the '350 Patent. (See Zydus Am. Compl. at ¶ 18; Torrent Am. Compl. at ¶ 20; Teva Am. Compl. at ¶ 14.) Each Defendants' ANDA, however, included a "section viii" statement, certifying that the applicant would not seek approval for any indications or uses asserted to be covered by

the ’350 Patent. See Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, 2015 WL 1782653, at *15 (D.N.J. Apr. 16, 2015). In other words, each Defendant (and indeed all generic defendants in these related infringement actions) purport to have “carved-out” the pertinent indication (e.g., “adjunctive treatment for major depressive disorder”) from their respective generic Ability® labels. See id.

4. Despite these assertions, Otsuka alleges that the label for each Defendant’s generic aripiprazole product “recommend[s], suggest[s], encourage[s] and/or instruct[s] others to use [the proposed generic aripiprazole product] in a manner that infringes at least one claim of the ’350 Patent.” (See Zydus Am. Compl. at ¶ 84; Torrent Am. Compl. at ¶ 34; Teva Am. Compl. at ¶ 36.) As a result, Otsuka filed Amended Complaints in this District on April 14, 2015, alleging, as relevant here, that Defendants’ “manufacture, use, offer for sale, sale and/or importation” of generic aripiprazole products will constitute “direct infringement, contributory infringement and/or active inducement of infringement of the ’350 Patent,” among other patents covering Otsuka’s Abilify® product, pursuant to 35 U.S.C. §§ 271(a)-(c). (See Zydus Am. Compl. at ¶ 105; Torrent Am. Compl. at ¶ 44; Teva Am. Compl. at ¶ 48.) The pending Rule 12(b)(6) motions followed.

5. Under Federal Rule of Civil Procedure 12(b)(6), the Court must "'accept all factual allegations as true, construe the Complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the Complaint, the plaintiff may be entitled to relief.'" Fleisher v. Standard Ins. Co., 679 F.3d 116, 120 (3d Cir. 2012) (citations omitted). However, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action" fails to suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, the "well-pled factual allegations" must be sufficient to demonstrate a plausible "entitlement to relief." Iqbal, 556 U.S. at 678 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Umland v. PLANCO Fin. Serv., Inc., 542 F.3d 59, 64 (3d Cir. 2008) (same).

6. The Court rejects, at the outset, the parties' positions that the Court's decision on Otsuka's motions to amend in order to assert the '350 Patent and/or on Otsuka's motions for a temporary restraining order govern the disposition of the pending motions to dismiss. (See, e.g., Torrent's and Teva's Br. at 16-20 (relying upon the TRO Opinion to argue that Otsuka's induced infringement claims must fail as a matter of law); Otsuka's Opp'n at 1-2, 5-6 (arguing, based upon the decision on the motion to amend, that the Court has already found that the '350 Patent infringement claims satisfy federal

pleading requirements).) Indeed, because the Court specifically declined to robustly address futility "in expedited motion practice" on the motion to amend, Otsuka, ___ F. Supp. 3d ____, 2015 WL 1722653, at *5, the Court finds no support for Otsuka's position that the Court has already resolved the pleading sufficiency of the '350 claims in favor of Otsuka. (See generally Otsuka's Opp'n at 1-2.) Rather, the Court's decision to permit amendment hinged upon the absence of any "undu[e] delay" and/or "unfair prejudice," and particularly because of the "elaborate record" already developed on "the contours of the '350 Patent" by the other generic defendants in connection with the injunctive motion practice. Otsuka, ___ F. Supp. 3d ____, 2015 WL 1722653, at *5 (emphasis in original).

7. The Court finds Defendants' reliance upon the Court's findings in its TRO decision equally unpersuasive as a basis to dismiss Otsuka's '350 claims for failure to state a claim. Simply put, the Court's TRO Opinion relied upon a factual record far in excess of that which can be considered in the context of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Indeed, the focus of the inquiry on the pending motions concerns the pleading sufficiency of Otsuka's induced infringement claims, not whether the voluminous record amassed by the parties on the injunctive motion practice suggests that Otsuka's recovery on these claims is improbable. See Skinner v.

Switzer, 562 U.S. 521, 530-31 (2011) (noting that the inquiry on a motion to dismiss concerns whether a complaint suffices "to cross the federal court's threshold," not whether the plaintiff "'will ultimately prevail'" on the merits) (citations omitted); see also Twombly, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.") (internal quotation marks and citation omitted).

8. The Court therefore turns to the standard for induced infringement, and to the issue of whether Otsuka's Amended Complaints suffice to state plausible claims of induced infringement of the '350 Patent.

9. 35 U.S.C. § 271(b) states that, "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[6] See also Commil USA, LLC v. Cisco Sys., Inc., ___ U.S. ____, 135 S.Ct 1920, 1928 (2015) (discussing the standard for induced infringement, in particular the scienter

[6] Otsuka's claims for induced infringement equally rest upon 35 U.S.C. § 272(e)(2)(A), which provides that an ANDA filer can only be liable for infringement if it submits an ANDA seeking approval "for a drug claimed in a patent or the use of which is claimed in a patent" prior to the patent's expiration. "In order to prevail on a claim of induced infringement under section 271(e)(2)," however, "a patent holder must establish the traditional elements of a claim of induced infringement." Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1336 (Fed. Cir. 2003) (Schall and Clevenger, J., concurring); see also Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263, 1272 (Fed. Cir. 2007) (same). The statutory basis for the claim therefore has no impact on the pending motions.

requirement). In order to state a claim for inducement, the patent owner must therefore allege "direct infringement, and that the alleged infringer 'knowingly induced infringement and possessed specific intent to encourage another's infringement.'" i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010) (citation omitted). In other words, Otsuka's theory of induced infringement will be plausible "if, but only if," Otsuka alleges "direct infringement," Limelight Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111, 2117 (2014) (citation omitted), and presents plausible facts that Defendants knowingly induced infringing acts and possessed a specific intent to encourage another to infringe the '350 patent. See Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1328 (Fed. Cir. 2009); DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1305-06 (Fed. Cir. 2006) (en banc in relevant part); Warner–Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003).

10. The Amended Complaints in this instance, however, contain no such allegations.[7] Rather, the Amended Complaints, even read generously in favor of Otsuka and accepted as true, allege only that Defendants' have "actual knowledge" of the '350 Patent, and that "the label[s] for [Defendants'] generic

[7] The Court disregards, as it must, Otsuka's opposition briefing to the extent it references Defendants' websites and marketing materials in order to establish facts beyond those pled in the Amended Complaints (or attached as exhibits). (See generally Otsuka's Opp'n at 10-12.)

products will recommend, suggest, encourage and/or instruct others to use [Defendants'] generic products in a manner that infringes at least one claim of the '350 [P]atent." (Zydus Am. Compl. at ¶ 84; Torrent Am. Compl. at ¶ 34; Teva Am. Compl. at ¶ 36.) Based upon these minimal allegations, Otsuka submits that Defendants' actions will constitute "active inducement of infringement of the '350 Patent." (Zydus Am. Compl. at ¶¶ 108, 116; Torrent Am. Compl. at ¶¶ 44, 47; Teva Am. Compl. at ¶¶ 45, 48.)

11. The Amended Complaints therefore contain no allegations regarding Defendants' specific intent or any specific acts taken to encourage such infringement, much less any attendant factual support to render these allegations plausible. Rather, Otsuka provides little more than a formulaic and incomplete recitation of the standard for induced infringement. See 35 U.S.C. § 271(b). Otsuka's simple reiteration of the legal conclusion that Defendants induced infringement fails to plead the "'factual content'" necessary for the Court to draw the "'reasonable inference'" of culpable conduct intended to induce infringement. Addiction & Detoxification Inst. LLC v. Carpenter, ___ F. App'x ____, 2015 WL 4430128 (Fed. Cir. July 21, 2015) (citation omitted) (affirming a district court's dismissal of a claim for induced infringement for failure to plead allegations regarding intent

or any specific acts caused by Defendants). Instead, the allegations offer unsupported conclusions, without any allegations directed at intentionality and/or any specific actions.[8] See Bonutti Skeletal Innovations, LLC v. Globus Med. Inc., No. 14-6650, 2015 WL 3755223, at *4 (E.D. Pa. June 15, 2015) (dismissing induced infringement claims without prejudice for failure to plead adequate facts regarding "specific intent," among other elements); Avocet Sports Tech., Inc. v. Garmin Int'l, Inc., No. 11-4049, 2012 WL 2343163, at *4 (N.D. Cal. June 5, 2012) (same); Eagle Harbor Holdings LLC v. Ford Motor Co., No. 11-5503, 2012 WL 398688, at *2 (W.D. Wash. Feb. 7, 2012) (same); Skipprint, LLC v. Rastar, Inc., No. 13-039, 2013 WL 4430873, at *5-*6 (D. Utah Aug. 16, 2013) (same).

12. For these reasons, Otsuka's claims against Defendants for induced infringement of the '350 Patent will be dismissed without prejudice and with leave to amend within seven (7) days, to the extent such amendment can be made consistent with counsel for Otsuka's obligations under Federal Rule of Civil Procedure 11(b).[9]

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[8] Nor does the alleged existence of unresolved factual issues and/or the presence of ongoing discovery change whether the Amended Complaints presently state plausible claims for induced infringement.

[9] In that respect, the Court directs counsel for Otsuka's attention to the litany of evidentiary deficiencies identified in the Court's TRO Opinion. See, e.g., Otsuka, ___ F. Supp. 3d ____, 2015 WL 1782653, at *7-*25.

13. An accompanying Order will be entered.

October 13, 2015
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
Chief U.S. District Judge