

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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PURDUE PHARMA L.P.,	:	10 Civ. 3734 (SHS)
THE P.F. LABORATORIES, INC.,	:	
PURDUE PHARMACEUTICALS L.P.,	:	<u>OPINION & ORDER</u>
AND RHODES TECHNOLOGIES,	:	

Plaintiffs and Counterclaim Defendants,

-against-

RANBAXY INC.,	:
RANBAXY PHARMACEUTICALS INC.,	:
RANBAXY LABORATORIES LTD.,	:
ACTAVIS ELIZABETH LLC,	:
MYLAN PHARMACEUTICALS INC.,	:
and MYLAN INC.,	:

Defendants and Counterclaim Plaintiffs.

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SIDNEY H. STEIN, U.S. District Judge.

Actavis Elizabeth LLC has moved for leave to amend its Answer and Counterclaims to include the affirmative defense of collateral estoppel. Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue") oppose Actavis's motion principally on the grounds that Actavis's collateral estoppel theory is meritless and therefore any amendment would be futile. Purdue additionally contends that Actavis's request should be denied as untimely. Because Actavis's defense appears plausible on its face and because Actavis's delay causes no prejudice to Purdue, the Court grants Actavis leave to amend its Answer and Counterclaims.

I. Background

This Hatch-Waxman action is one of many in which Purdue has sued to stop other drug manufacturers from producing generic equivalents of Purdue's OxyContin pain reliever. Here, Purdue claims Actavis, Ranbaxy, and Mylan have infringed three of Purdue's patents: Patent No. 7,683,072 ("072"); Patent No. 7,674,799 ("799"); and Patent No. 7,674,800 ("800"). These patents resulted from Purdue's multi-year effort to

reduce the amount of a chemical impurity present in oxycodone tablets and patent its work. *Chapman v. Casner*, 315 F. App'x 294, 295 (Fed. Cir. 2009).

Purdue believed that it had invented a novel way to reduce this impurity, 14-hydroxycodone ("14-hydroxy"), and in 2005 applied for U.S. Patent No. 7,129,248. ('248 Patent, Ex. D. to Decl. of Sona De dated May 21, 2012.) That patent was "directed to a process for preparing [oxycodone] having less than 25 ppm of 14-hydroxycodone." (*Id.*) Purdue subsequently filed a continuing application, No. 11/391,897 ("897"), that claimed a process for reducing 14-hydroxy by converting a chemical intermediate 8, 14-dihydroxy-7, 8-dihydrocodeinone ("8, 14-dihydroxy") into 14-hydroxy, and then converting 14-hydroxy into oxycodone. *Chapman*, 315 F. App'x at 295 (discussing claim 96).

During an interference proceeding before the U.S. Patent Trade Office Board of Patent Appeals and Interferences, the PTO considered whether Purdue could patent the process it described.¹ The PTO rejected Purdue's claim as obvious. *Id.* at 297-98. The Federal Circuit affirmed, concluding that the prior art disclosed "conditions suitable to promote reaction of 8, 14-dihydroxy to 14-hydroxy" because it was known that the 8 β form of 8, 14-dihydroxy "will under certain reaction conditions form 14-hydroxy." *Id.* In other words, scientists working with oxycodone had already discovered that 8 β , 14-dihydroxy could be transformed into 14-hydroxy, so it was not novel to propose that 8, 14-dihydroxy (whether 8 α or 8 β) could be transformed into 14-hydroxy and, in turn, transformed into oxycodone. *Id.* at 297-98.

The patents in this action each continue from the '897 application. Like the '897 application, the '799 patent, '800 patent, and the '072 patent are each "directed to a process for preparing an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodone." (Patent No. 7,674,799, Ex. A to De Decl.; Patent No. 7,683,072, Ex. B. to De Decl.; Patent No. 7,674,800, Ex. C to De Decl.)

Actavis now seeks to amend its Answer and Counterclaims to state that "Plaintiff is barred from asserting claims of the '799, '800 and '072 patents by the doctrine of collateral estoppel" as a Fourth Affirmative Defense.² (Proposed Amended Answer at 7, Ex. A to Decl. of Gregory K. Sobolski dated May 2, 2012.) According to Actavis, certain of Purdue's patent claims have been foreclosed by the Federal Circuit's determination in *Chapman v. Casner*. Actavis disclosed its collateral estoppel defense to

¹ As discussed below, the parties dispute whether the PTO also considered other claims made in the '897 application.

² Similar motions have been filed by defendants in four other OxyContin patent actions: No. 11 Civ. 2037 (Teva Pharmaceuticals USA, Inc.), No. 11 Civ. 2038 (Actavis), No. 11 Civ. 2400 (Impax Laboratories, Inc.), and No. 11 Civ. 8153 (Amneal Pharmaceuticals, LLC). The Court has today resolved those motions by separate Orders, relying on the reasoning of this Opinion & Order.

Purdue on March 2, 2012 (Actavis Supp. Responses & Objections to Pls.' Interrogatory No. 7 dated March 2, 2012, Exhibit B to Sobolski Decl), formally requested Purdue's consent to an amendment on April 12, 2012 (Email from K. Schuler to P. Hendler dated April 12, 2012, Exhibit E to Sobolski Decl), and filed this motion for leave to amend on May 2, 2012 (Dkt. No. 139). Actavis had previously proposed October 14, 2011, and Purdue had previously proposed March 1, 2011, as the deadline to amend the pleadings. (Rule 26(f) Report, Dkt. No. 101.) Actavis attributes its delay to facts discovered during the February 16, 2012 deposition of Oleg Ioselevich. (Actavis Mem. in Support of Motion for Leave to Amend 7.)

II. Discussion

Federal Rule of Civil Procedure 15(a)(2) instructs this Court to “freely give leave [to amend] when justice so requires.” But the Court may deny leave to amend for “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.” *Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008) (quotation marks and citation omitted).

Purdue urges the Court to reject Actavis's proposed amendment as futile and also as untimely. The Court accepts neither argument.

A. Actavis's proposed amendment is not futile.

1. *Standard*

Ordinarily a proposed amendment would be futile if it could not withstand a Rule 12(b)(6) motion to dismiss. *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 339 (2d Cir. 2000). Where the proposed amendment concerns an affirmative defense, however, “futility ought technically turn on the proposed defense's legal sufficiency and whether it is subject to a motion to strike under Fed. R. Civ. P. 12(f).” *Credit Suisse First Boston, LLC v. Intershop Commc'ns AG*, 407 F. Supp. 2d 541, 546 (S.D.N.Y. 2006). Rule 8(c)(1) casts estoppel as an affirmative defense; therefore, the futility of Actavis's proposed amendment turns on whether the Court would strike that defense as “insufficient” pursuant to Rule 12(f).

Insufficiency has three hallmarks: “(1) there must be no question of fact that might allow the defense to succeed; (2) there must be no substantial question of law that might allow the defense to succeed; and (3) the plaintiff must be prejudiced by the inclusion of the defense.” *Coach Inc. v. Kmart Corps.*, 756 F. Supp. 2d 421, 425 (S.D.N.Y. 2010). This exacting standard reflects the courts' disfavor of motions to strike. *See William Z. Salcer*,

Panfild, Edelman v. Envicon Equities Corp., 744 F.2d 935, 939 (2d Cir. 1984), *vac'd on other grounds* by 478 U.S. 1015 (1986).

After *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), courts in this circuit have differed in the doctrinal standard they use to assess whether any question of law or fact exists so as to make a defense legally insufficient. Before *Twombly* and *Iqbal*, courts struck affirmative defenses only when “it appear[ed] to a certainty that plaintiffs would succeed despite *any state of the facts* which could be proved in support of the defense.” *Salcer*, 744 F.2d at 939 (emphasis added). Some district judges in this circuit have reasoned that *Twombly* concerned only Rule 8(a) claims for relief, not Rule 8(c) affirmative defenses, and thus did not change the standard for assessing a motion to strike. *E.g.*, *Aros v. United Rentals, Inc.*, No. 10 Civ. 73, 2011 WL 5238829, at *1-3 (D. Conn. Oct. 31, 2011). Others have concluded that the pleading standard articulated in *Twombly* and *Iqbal* applies to motions to strike as well. *E.g.*, *E.E.O.C. v. Kelley Drye & Warren, LLP*, No. 10 Civ. 655, 2011 WL 3163443, at *2 (S.D.N.Y. July 25, 2011); *Coach, Inc. v. Kmart Corps.*, 756 F. Supp. 2d 421, 425 (S.D.N.Y. 2010); *Aspex Eyewear, Inc. v. Clariti Eyewear, Inc.*, 531 F. Supp. 2d 620, 622-23 (S.D.N.Y. 2008); *Burck v. Mars, Inc.*, 571 F. Supp. 2d 446, 456 (S.D.N.Y. 2008). The Court need not enter this debate because Actavis's defense satisfies the higher standard of *Twombly*.

2. *Actavis's collateral estoppel defense is plausible.*

Considering the proposed amendment alongside the *Chapman* opinion, the Court concludes that Actavis has proposed the legally sufficient defense that Purdue has previously litigated and lost some of the patent claims at issue here.

a) *Collateral estoppel forecloses patent claims that are “patentably indistinct” from rejected claims.*

“A judgment in an action precludes relitigation of claims or issues that were or could have been raised in that proceeding.” *In re Deckler*, 977 F.2d 1449, 1452 (Fed. Cir. 1992). The Federal Circuit “has applied interference estoppel to bar the assertion of claims for inventions that are patentably indistinct from those in an interference that the applicant had lost.” *Id.* Importantly, the Federal Circuit assesses estoppel by considering “whether the issue of invalidity common to each action is substantially identical,” not whether the “specific claims around which the issues were framed” are the same. *Westwood Chem., Inc. v. United States*, 525 F.2d 1367, 1372 (Ct. Cl. 1975).

b) *Actavis states a plausible theory of collateral estoppel.*

The pleadings and public documents on which Actavis relies plausibly suggest that Purdue has previously litigated the patentability of at least certain of the claims here. Purdue previously defended the patentability of low-impurity oxycodone:

- Purdue previously sought to patent the process of producing low impurity oxycodone. *Chapman*, 315 F. App'x at 295.
- Purdue explicitly claimed a process that transformed 8, 14-dihydroxy into 14-hydroxy, whether from the 8 α or 8 β stereoisomer. *Id.* at 297.
- The Federal Circuit concluded that Purdue's method was obvious in light of prior knowledge that 8 β ,14-dihydroxy could be converted into 14-hydroxy. *Id.*
- The dissent to the Federal Circuit opinion makes many of the points Purdue advances here, including that Purdue discovered 8 α and that its method to reduce 14-hydroxy by manipulating 8 α was new and useful. *Id.* at 298, 300.

Purdue's arguments in this action echo its prior presentation in the interference proceeding. As in the interference, the claims here concern a process for producing low-impurity oxycodone. As in the interference, Purdue argues that it has created low-impurity oxycodone by manipulating 8, 14-dihydroxy. As in the interference, Purdue attaches significance to its work in identifying the 8 α stereoisomer and recognizing its importance. These similarities make Actavis's collateral estoppel argument plausible for the purposes of this motion.

In response, Purdue contends that Actavis's theory will fail as a matter of law because the specific patent claims in this action were not litigated in *Chapman*. Specifically, Purdue asserts that *Chapman* did not consider (1) an oxycodone product with a specified level of 14-hydroxy or (2) a product containing oxycodone derived from a specified chemical intermediate. (Purdue's Opp. 12.) Purdue may be correct, but neither of Purdue's points of contrast precludes Actavis's defense at this stage.

First, as to the impurity limitation, the *Chapman* panel stated that it "affirm[ed] the Board's decision to reject claims 96-118 of the '897 application." *Chapman*, 315 F. App'x at 298. Claims 115, 116, 117, and 118 each reference a 14-hydroxy limit. ('897 Application App'x 1, Ex. E to Reply Decl. of Gregory K. Sobolski dated May 31, 2012.) Based on the *Chapman* decision, Actavis has grounds to argue that Purdue has previously litigated the patentability of a process to reduce 14-hydroxy product to a specified purity level.

Second, as to the source limitation, unpatentable products may not be made patentable by imposing a process limitation on them. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006). After all, "[t]he patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985); *Amgen, Inc. v. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 1366

(Fed. Cir. 2009) (citing *Thorpe*). Applying that rule, if low-impurity oxycodone made by manipulating 8 α is indistinguishable from low-impurity oxycodone made by manipulating 8 β , as Actavis contends, then Purdue's process limitation has no legal significance. Purdue merely developed a different process for making an existing product. *Cf. Thorpe*, 580 F.3d at 1340. As a result, the claims rejected as obvious in the '897 application may estop the claims here, notwithstanding a difference in the chemical source of the oxycodone. *See In re Deckler*, 877 F.2d 1449, 1452 (Fed. Cir. 1992).

Third, the presence of disputed facts and law suggest that Actavis's defense should not be precluded as futile. As noted above, motions to strike—and by extension assessments of futility—are improper vehicles for fact finding. *Coach Inc. v. Kmart Corps.*, 756 F. Supp. 2d 421, 425 (S.D.N.Y. 2010). Here the parties behave as though the legal sufficiency of the collateral estoppel defense cannot be assessed without resort to evidence: Actavis attaches various documents to its motion, including interrogatories, expert opinions, and emails. (*See* Exs. B, E, F, & G to Sobolski Decl.; Ex. D to Sobolski Reply Decl.) Purdue attaches correspondence, interrogatories, and a deposition transcript. (*See* Exs. J-N to De Decl.) And the parties cite to, and rely on, these documents and others in their arguments. Most sharply, the parties dispute the novelty and import of Purdue's 8 α work, whether 8 α is process limitation, and, if so, the extent to which the Federal Circuit considered it. But a motion for leave to amend does not present an appropriate vehicle for the Court to weigh the significance of 8 α or its discovery, examine the factual record before the Federal Circuit, or consider deposition testimony. These factual disputes are appropriate for resolution only on a fuller record.

B. Actavis's delay does not justify denying it leave to amend.

1. Standard

Delay may justify denial of leave to amend if the party seeking to amend acted in bad faith, if the amendment would prejudice the opposing party, or if the amendment would effect an unjustified amendment to a Rule 16(b) scheduling order. *See Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 339 (2d Cir. 2000); *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993). In assessing prejudice, courts consider whether the amendment would "(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction." *Block*, 988 F.2d at 350. "[T]he longer the period of an unexplained delay, the less will be required of the nonmoving party in terms of a showing of prejudice." *Id.*

2. ***Actavis has explained its delay and Purdue faces insignificant prejudice.***

Weighing Actavis's delay, its excuse, the likely prejudice, and consequences for this action, the Court concludes that allowing the amendment will promote justice.

First, Actavis has explained its delay. Actavis contends that it timely moved to amend its answer once it discovered facts to support the collateral estoppel defense during the February 16, 2012 deposition of Oleg Ioselevich and subsequent interrogatories. (Actavis Mem. 7.) Indeed, Actavis proposed its amended answer less than one month later. (Actavis Supp. Responses & Objections to Pls.' Interrogatory No. 7 dated March 2, 2012, Exhibit B to Sobolski Decl.) Purdue responds that the public record would have allowed Actavis to "easily assess[] this defense back when it pleaded this case." (Purdue's Opp. to Motion to Amend 16.) The Court agrees. But the Court also recognizes that the strategic significance of collateral estoppel became undeniable after Purdue began to focus on the 8 α limitation at the same time that its witness disclaimed a meaningful difference between 8 α and 8 β . The Court accepts that these events prompted Actavis to seek to amend its Answer and Counterclaims.

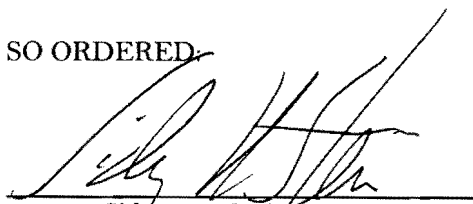
Second, Purdue faces insignificant prejudice. Purdue states that it "will likely need to consider retaining its own such expert to prepare a responsive opinion." (Purdue Opp. 17.) But if Purdue retains an expert it will do so because Actavis has asserted a collateral estoppel defense, not because Actavis delayed in asserting the defense. Purdue has not articulated a cost that might have been avoided had Actavis acted sooner. *E.g.*, *Evans v. Syracuse City Sch. Dist.*, 704 F.2d 44, 48 (2d Cir. 1983). Nor does Purdue show that it has forfeited some legal right because of Actavis's delay. *E.g.*, *Strauss v. Douglas Aircraft Co.*, 404 F.2d 1152, 1157-58 (2d Cir. 1968). Nor will the amendment delay the resolution of the parties' dispute. *Cf. Block*, 988 F.2d at 350. In fact, defendants in other actions have timely sought to amend their answers to include an estoppel defense. As Purdue has opposed those motions on the futility grounds rejected above, Purdue will have to litigate this defense in other actions concerning the '072, '799, and '800 patents. Purdue loses little by litigating this issue in this action, too.

III. Conclusion

Because Actavis's proposed Fourth Affirmative Defense appears plausible on its face and because Actavis's delay caused no prejudice to Purdue, the Court grants Actavis leave to amend its Answer and Counterclaims in the form attached to the Affidavit of Gregory K. Sobolski, Esq., dated May 2, 2012 as Exhibit A. Actavis is directed to file that document within five business days of the date of this Opinion and Order.

Dated: New York, New York
September 5, 2012

SO ORDERED



Sidney H. Stein, U.S.D.J.