

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEYDRAFT NOT FOR PUBLICATION

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Civil Action No.:
2:10-CV-06108-ES-JAD**OPINION ON
DEFENDANT'S MOTION
TO AMEND ITS ANSWER****[ECF No. 218]****I. INTRODUCTION**

The instant action is a patent-infringement case in which Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") is suing Defendant Roxane Laboratories, Inc. ("Roxane") for infringing various patents after Roxane's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking the FDA's approval to market and sell a generic version of Jazz's Xyrem[®] drug.

Pending before this Court is Defendant Roxane Laboratories, Inc.'s ("Roxane") Motion to Amend its Answer to include two (2) additional affirmative defenses: prosecution laches and unclean hands; Jazz has opposed the instant motion. The Court has considered the parties' submissions and for the reasons set forth below defendant's motion to amend is hereby **Granted**.

II. RELEVANT FACTUAL AND PROCEDURAL HISTORY

On or about July 8, 2010, Roxane filed an ANDA with the FDA seeking approval to market and distribute a generic sodium oxybate product stated to be the bioequivalent to Jazz's XYREM[®] product. (ECF No. 219, Roxane's Brief In Support of Motion to Amend, at p. 6; see also ECF No. 222, Jazz's Opposition Brief, at p. 11). In response to Roxane's ANDA application, Jazz initiated five (5) separate actions which were ultimately consolidated into the above captioned matter. (See ECF No. 222, at p. 11; see also ECF No. 214, April 12, 2013 Opinion and Order Granting Jazz's Motion to Consolidate). The instant action was filed on November 22, 2010 (see ECF No. 1, Jazz's Complaint ("Cmplt.")). The aforementioned five (5) actions were consolidated under the above-captioned docket number on April 12, 2013. (See ECF No. 214¹).

On February 7, 2011, an initial scheduling conference was held in the instant matter. (ECF No. 12, Letter Order); (Minute Entry from February 7, 2011). During that conference, the Court reserved on setting a pretrial scheduling order to permit Jazz

¹ The Court's Order and Opinion dated April 12, 2013 [ECF No. 214], consolidated the suits docketed under Civil Action Nos. 10-6108; 12-6761 and 12-7459 under the earliest filed action, Civil Action No. 10-6108. It also should be noted that prior to the Court's April 12, 2013 Opinion and Order, two prior actions (Civil Action Nos. 11-660 and 11-2523 had already been consolidated with the 10-6108 action, thereby accounting for the five (5) actions that are substantively contained in the 10-6108 action. (See ECF No. 222 at. p. 6, FN 3).

to obtain information from a third party it needed in order to submit its Infringement Contentions. Due to disputes between the parties, a formal scheduling order was not entered until September 1, 2011. (ECF No. 60, Pretrial Scheduling Order ("PSO")). This initial PSO set a deadline of December 5, 2011, as the deadline for the parties to amend the pleadings and/or add parties. (Id.). On July 28, 2011, this case was reassigned to the Hon. Cathy L. Waldor, U.S.M.J. Opening Markman briefs were filed on December 5, 2011, expert discovery regarding Markman issues closed on January 5, 2012, and Markman briefing closed on February 3, 2012 with the filing of responsive Markman papers. (PSO at ¶¶ 7, 9, and 10).

After engaging in extensive motion practice regarding various discovery related issues on December 10, 2012, the instant action was transferred to the Hon. Steven C. Mannion, U.S.M.J. On April 15, 2013, after granting Jazz's motion to consolidate, the Court entered an Amended Scheduling Order that included a briefing schedule for the instant motion to amend. (ECF No. 215, Scheduling Order, at ¶ 7). Pursuant to the April 15, 2013 Scheduling Order, Roxane timely filed the instant motion on April 26, 2013. (See ECF No. 218, Roxane's Motion to Amend). Jazz filed a timely Opposition [See ECF No. 222] and Roxane filed a timely Reply. (See ECF No. 224, Roxane's Reply

Brief). On September 9, 2013, the instant matter was reassigned to the undersigned Magistrate Judge.

III. DISCUSSION

B. Rule 15(a)

Rule 15(a) of the Federal Rules of Civil Procedure, which governs amendments to pleadings, provides, in relevant part:

(1) Amending as a Matter of Course. A party may amend its pleading once as a matter of course within:

(A) 21 days after serving it, or

(B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.

(2) Other Amendments. In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.

Fed. R. Civ. P. 15(a). The federal rules liberally allow for amendments in light of the "principle that the purpose of

pleading is to facilitate a proper decision on the merits," and provide that if the underlying facts relied upon by a party might be a proper subject of relief, that party should have the opportunity to test its claims on the merits. Foman v. Davis, 371 U.S. 178, 182 (1962) (internal quotations marks omitted).

Under Rule 15, the decision to permit an amendment rests in the sound discretion of the Court. See id.; Heyl & Paterson Int'l Inc. v. F.D. Rich Housing of V.I., Inc., 663 F.2d 419, 425 (3d Cir. 1981). The United States Supreme Court has stated that leave to amend under Rule 15 may be denied in cases of: (1) undue delay; (2) bad faith or dilatory motive; (3) undue prejudice; or (4) futility of amendment. See Foman, 371 U.S. at 182; see also Arthur v. Maersk, Inc., 434 F.3d 196, 204 (3d Cir. 2006) (stating that "[l]eave to amend must generally be granted unless equitable considerations render it otherwise unjust"). Stated differently, absent substantial prejudice, an amendment should be allowed under Rule 15 unless denial can be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiencies by amendments previously allowed, or futility of the proposed amendment(s). Long v. Wilson, 393 F.3d 390, 400 (3d Cir. 2004).

Jazz opposes Roxane's motion to amend primarily on the basis of the futility of the two defenses that Roxane seeks to add stating that "the legal theories it asserts have no basis in

law and directly contradict the rights accorded to an inventor under United States patent law" (ECF No. 222, Jazz's Opposition Brief, at p. 6). Jazz also argues, less vigorously, that because Roxane could have asserted the two defenses years ago, the instant motion to amend is untimely. (Id.).

a. Undue Delay & Prejudice

Regarding undue delay, the Court of Appeals for the Third Circuit has stated:

The passage of time, without more, does not require that a motion to amend a complaint be denied; however, at some point, the delay will become "undue," placing an unwarranted burden on the court, or will become "prejudicial," placing an unfair burden on the opposing party. The question of undue delay, as well as the question of bad faith, requires that we focus on the plaintiffs' motives for not amending their complaint to assert this claim earlier; the issue of prejudice requires that we focus on the effect on the defendants.

Adams v. Gould, Inc., 739 F.2d 858, 868 (3d Cir.1984) (internal citations omitted). See also Cureton v. NCAA, 252 F.3d 267, 273 (3d Cir. 2001) (stating that "the question of undue delay requires that we focus on the movant's reasons for not amending sooner"). Furthermore, under Rule 15, leave to amend is generally granted where, during the course of discovery, a party discovers "new evidence." See, e.g., Slade v. Fauver, No. CIV.A.90-1417, 1990 WL 153960, at *4 (D.N.J. Sept. 24, 1990)

(granting leave to amend where new claims were discovered and "proposed amendments had no dilatory purpose and no significant discovery or pretrial preparation had taken place . . ."); Kronfeld v. First Jersey Nat'l Bank, 638 F. Supp. 1454, 1460 (D.N.J. 1986) (granting motion to amend upon discovery of new evidence where it did "not appear that the incidental prejudice is an insufficient ground on which to deny leave to amend, undue delay or undue prejudice support denial).

To determine if a party would be unduly prejudiced, the Court considers whether the amendment will result in additional discovery or costs, or the need to defend against new facts or theories, Cureton, 252 F.3d at 273, or an inability to obtain and present evidence that the non-movant would have offered had the amendment been timely. Bechtel v. Robinson, 886 F.2d 644, 652 (3d Cir. 1989). As the Long court observed, to establish undue prejudice, the non-moving party must show that the proposed pleading 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 [non-movant] from bringing a timely action in another jurisdiction." Long, 393 F.3d at 400 (adopting the standard of Block v. First Blood Assocs., 988 F.2d 344 (2d Cir. 1993)) (internal quotation marks omitted).

As an initial point, this Court rejects Jazz's contention that Roxane's filing of the instant motion to amend is untimely. The operative Scheduling Order in this case set the deadline for Roxane to file its motion to amend its Answer for April 26, 2013. (See ECF No. 215, at ¶ 7). Roxane filed the instant motion on April 26, 2013 in compliance with the operative Scheduling Order, thereby making its motion timely.

To the extent that Jazz has also argued that Roxane's motion to amend should be denied due to undue delay, the Court also rejects this contention. As Jazz asserts in its Opposition Brief, "Roxane filed its Answers to the Complaints concerning the '650 and '275 patent actions on November 9, 2012 and January 4, 2013 respectively." Given the fact that Roxane's proposed equitable defenses only pertain to the allegations of infringement of the '650 and '275 patent claims, the Court does not view the 4-6 month between Roxane filing its Answers and Roxane seeking leave to amend its Answers as constituting undue delay. This view is especially true considering: 1) there was minimal discovery that occurred during this relatively short time period; 2) the parties were awaiting hearing and decision by the Court on Roxane's Order to Show Cause concerning Jazz's alleged violation of the discovery confidentiality order- a decision that may have obviated the need for Roxane to pursue the two proposed affirmative defenses; and 3) the fact that the

Court had not yet granted Jazz's motion to consolidate and issued the related amended scheduling order. All of these facts and circumstances lean heavily in favor of not finding that Roxane unreasonably delayed in seeking to amend its Answers to include the prosecution laches and unclean hands defenses. Jazz's argument that it will be unduly prejudiced if Roxane is allowed to add these defenses is also unavailing. Given the fact that the parties remain engaged in extensive discovery related motion practice and the fact that Jazz is primarily responsible- due to it filing multiple actions against Roxane- for the magnitude and protracted nature of this litigation, the Court is not persuaded that Jazz will be unreasonably prejudiced by any additional discovery that may need to be taken by the parties pertaining to Roxane's two proposed equitable defenses. Therefore, given the weakness of Jazz's undue delay & prejudice arguments, the Court rejects these arguments and turns its attention to the issue of futility.

b. Futility

A court will consider an amendment futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." Harrison Beverage Co. v. Dribeck, 133 F.R.D. 462, 468 (D.N.J. 1990) (internal citations and quotations marks omitted). In determining whether an amendment

is "insufficient on its face," the Court employs the same standard that is applied under a Rule 12(b)(6) motion to dismiss. Burlington, 114 F.3d at 1434. Under a Rule 12(b)(6) analysis, the question before the Court is not whether the movant will ultimately prevail, but whether the complaint sets forth "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). Detailed factual allegations are not necessary to survive a Rule 12(b)(6) motion, but "a [pleader's] obligation to provide the grounds of his entitlement to relief requires more than labels[,] . . . conclusions, and a formulaic recitation of the elements of a cause of action" and demands that the "[f]actual allegations . . . be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the [pleading] are true (even if doubtful in fact)." Id. at 555 (internal quotation marks omitted).

A two-part analysis determines whether this standard is met. Fowler, 578 F.3d at 210 (interpreting Ashcroft v. Iqbal, 556 U.S. 662, 667, 129 S. Ct. 1949). First, a court separates the factual and legal elements of a claim. Fowler, 578 F.3d at 210. All well-pleaded facts set forth in the pleading and the contents of the documents incorporated therein must be accepted as true, but the Court may disregard any legal conclusions. Id. at 210; Iqbal, 556 U.S. at 667 (noting that a complaint is

insufficient if it offers "labels and conclusions," a "formulaic recitation of the elements of a cause of action," or "naked assertions devoid of further factual enhancement") (internal quotations marks and alterations omitted).

Second, a court must determine whether the plaintiff's complaint articulates "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; accord Fowler, 578 F.3d at 211. As the Supreme Court instructed in Iqbal, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 667. Although this is not a "probability requirement," the well-pleaded facts must do more than demonstrate that the conduct is "merely consistent" with liability so as to "permit the court to infer more than the mere possibility of misconduct" to make a showing of entitlement to relief. Id. at 1949-50 (internal quotation marks omitted). This "context-specific task . . . requires the reviewing court to draw on its judicial experience and common sense." Fowler, 578 F.3d at 211 (quoting Iqbal, 556 U.S. at 679).

Federal Rule of Civil Procedure 8 creates a liberal pleading standard that does not require detailed factual allegations. Regarding defenses, Rule 8(b) requires the pleader to "state in short and plain terms its defenses to each claim

asserted against it." Fed.R.Civ.P. 8(b)(A). Accordingly, to satisfy the Rule 8(a), a pleading must contain facts- facts that the Court must accept as true at this stage- that are consistent with a legal theory that would entitle the pleading party to relief. Thus, in determining whether Roxane's proposed amendments are futile, the Court must turn its attention to Roxane's proposed Amended Answer. More specifically, the Court must evaluate whether Roxane's proposed defenses of prosecution laches and unclean hands, as pled, satisfy the pleading requirements of Rule 8(b). After carefully reviewing Roxane's proposed Amended Answer, the Court concludes that Roxane has sufficiently pleaded facts that support both the defense of prosecution laches and unclean hands. (See ECF No. 218-3, Roxane's Proposed Amended Answer, at ¶¶ 5-47). Also, in arguing the futility of Roxane's defenses, Jazz's arguments have proven far too much. By attacking the factual strength of the Roxane's proposed prosecution laches and unclean hands defenses instead of the legal sufficiency of Roxane's pleading of those defenses, Jazz's arguments go far beyond what the Court may properly consider at this stage.

Regarding the prosecution laches defense, to establish a *prima facie* defense, the pleading must aver facts that support the following three (3) elements: 1) an unreasonable and unexplained delay by the patentee; 2) that results in prejudice

to the accused infringer; and 3) the prejudice is evidenced by intervening rights. See Cancer Research Tech. Ltd. v. Barr Labs., Inc. 625 F.3d 724, 729 (Fed. Cir. 2010). On the first element, Roxane has alleged that Jazz delayed the filing of its patents applications for no other purpose but to prolong litigation (based on information gleaned during the course of this litigation about Roxane's proposed product) and thereby effectively prevent Roxane from introducing a competing product into the market. (See ECF No. 224, at p. 9; ECF No. 218-3 at ¶¶ 16, 36-38). Jazz's challenge to this element is its assertion that since the 1994 amendments to the patent law changed the life of a patent from beginning to run from the date of filing to the date of issuance, delay by the patentee in filing patent applications cannot extend the life of a patent. (See ECF No. 222 at pp. 16-17). While this argument may be true in and of itself, the Court is agreement with Roxane that this point does nothing to render the prosecution laches defense futile in this case because, as Roxane has articulated in its moving brief and reply, it is not arguing that Jazz's delay in filing its patent applications has effectively extended the life of its patents. Roxane's argument is that Jazz's unexplained delays have had the effect of prolonging this litigation which has the practical effect of preventing Roxane from launching its product. Jazz's opposition is devoid of any argument and/or legal authority that

the prosecution laches defense may not be applied under the facts and circumstances that Roxane has alleged. Jazz's other argument on this element is an improper merits based argument in which Jazz argues that it did not unreasonably delay in filing its patent applications. (See ECF No. 222 at p. 23). Therefore, the Court concludes that this element has been sufficiently pled.

Regarding the second element (prejudice), Roxane has alleged that it has been prejudiced by Jazz's delay in filing its patent applications, as Jazz's delays has prevented timely resolution of Roxane's legal rights, which, in turn, would effectively prevent Roxane from launching its product. (See ECF No. 224, at p. 11; ECF No. 218-3 at ¶ 16). Jazz's main argument (also merits based) is that Roxane has not received FDA approval for its generic product and therefore, Jazz argues, Roxane has not been prejudiced. (See ECF No. 222 at p. 29). This argument is unpersuasive as it does not address the fact that taking its allegations as true, Roxane has been and continues to be prejudiced by having to remain embroiled in the instant litigation longer than it otherwise would be if Jazz had not delayed the filing of its patent applications for the alleged purpose of keeping Roxane entangled in litigation, thereby undermining the goals of the Hatch-Waxman Act.

On the third element (intervening rights), Roxane has alleged that its intervening rights are derived from its reliance on its good-faith belief that its product did not infringe of Jazz's intellectual property rights as represented in Jazz's originally filed patents and/or that those patents were invalid when Roxane endeavored to develop its product. (See ECF No. 224, at p. 11; ECF No. 218-3 at ¶ 39). Once again, Jazz's challenge to this element goes too far as Jazz argues that Roxane has no intervening rights because Roxane's product infringes on Jazz original patent claims. (See ECF No. 222 at p. 25). Jazz's argument, if believed, would prove patent infringement, the underlying issue in this action. However, at this stage, the Court is only concerned with whether Roxane *may* intervening rights, not whether it actually did have intervening rights. Stated differently, the Court's inquiry at this the pleading stage is not whether Roxane actually infringed on Jazz's original patent claims but whether Roxane has adequately alleged facts consistent with the theory that it did not believe it was infringing on Jazz original patent claims and therefore had acquired rights via its reliance based on its non-infringement of Jazz's patents. On its face, Roxane's proposed pleading satisfies the pleading standard with respect to the third element of its prosecution laches defense. Therefore,

because it has pled sufficient facts relative to each element, Roxane has adequately pled the defense of prosecution laches.

The Court is likewise convinced that Roxane has adequately pled its proposed unclean hands defense. In order for the defense of unclean hands doctrine to apply, three (3) basic elements must be pled: First, there must be an unconscionable act alleged; Secondly, the unconscionable act must affect the equitable relations between the parties; and finally the alleged unconscionable act must concern an issue that is before the Court. See In Re Valley Corp., 181 F.3d 517, 524 (3d Cir. 1999). In its proposed Amended Answer, Roxane has alleges that Jazz used confidential information that it acquired during the course of the instant litigation regarding Roxane's sodium oxybate product and its method of dosing/distributing said product for the purpose of filing and prosecuting continuation patents, not based on what the inventors thought they invented, but for the purpose of prolonging the instant litigation in order to effectively prevent Roxane from launching its generic product. (See ECF No. 224, at p. 13; ECF No. 218-3 at ¶¶ 43-47). Again, in challenging this proposed defense, Jazz does not attack the legal sufficiency of Roxane's proposed pleading of its unclean hands defense, but instead Jazz argues the merits of Roxane's proposed defense. (See ECF No. 222 at p. 30-31). Therefore, because Roxane's Proposed Amended Answer makes out a *prima facie*

showing of an unclean hands defense, as Roxane has asserted facts that support the required elements, and because Jazz has failed to show how Roxane's pleading of this defense is legally insufficient, the Court finds that Roxane's unclean hand defense, as pled, passes the futility test.

IV. CONCLUSION

For the reasons articulated in this opinion, Defendant Roxane Laboratories, Inc.'s Motion to Amend its Answers to include the defenses of prosecution laches and unclean hands is hereby **Granted**.

The Court shall issue an Order consistent with this opinion.



Joseph A. Dickson, U.S.M.J.

Date: December 30, 2013

Cc: Hon. Esther Salas, U.S.D.J.