IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	
v.	)	CA. No. 1:13-cv-01674 (RGA)
WATSON LABORATORIES, INC.,	)	
Defendant.	)	

WATSON LABORATORIES, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNTS II AND IV UNDER RULE 12(b)(1)

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INTRODUCTION

For liability to arise under §§ 271(a)-(c) in this action, two things must occur: FDA has to approve Watson's ANDA; and Watson must launch its generic Suboxone® sublingual film drug product ***before*** the Court adjudicates the patent infringement and validity issues of this case. Plaintiffs have failed to show that either of these events are sufficiently "real and immediate" for subject matter jurisdiction to attach. In fact, they are not. Watson's motion should be granted and Counts II and IV should be dismissed.

Here are the facts: FDA approval of Watson's ANDA is stayed for 30 months, until February 28, 2016. Even then, FDA might not approve the application (if, for instance, Watson's ANDA does not meet the requirements for approval). But if FDA approves, Watson would have to make a decision to launch at risk—assuming that this Court has not yet adjudicated the infringement and invalidity issues in the case. This contingent-filled scenario is not "real and immediate"; in fact, it is exceedingly unlikely. Trial in this action is set to begin August 31, 2015—six months before the 30-month stay expires. What's more, Plaintiffs can always seek an injunction to prevent launch of an FDA-approved generic product pending this Court's decision on the merits.

Plaintiffs' brief barely scratches the surface of these issues, papering them over with bald, unsupported assertions. Plaintiffs reference Watson's activities directed toward preparing and submitting the ANDA, which is legally irrelevant—such activity is not an act of infringement by virtue of the "safe harbor" of 35 U.S.C. § 271(e)(1). Such activity could give rise to an infringement claim under § 271(e)(2), but not under §§ 271(a)-(c). However, Plaintiffs have not alleged that Watson has engaged in commercialization activity that might give rise to a separate claim. Nor can they: there are no facts to support such an allegation, as Watson does not even have tentative approval from FDA.

Plaintiffs emphasize that Watson is currently selling a generic Suboxone® tablet—a completely different product not at issue here—but they fail to explain how this fact demonstrates that infringing sales of Watson's generic Suboxone® sublingual film product are anything more than hypothetical. Finally, Plaintiffs point to Watson's status as a "first filer," but the value of that status does not depend on Watson selling its generic product while infringement and invalidity issues are still unresolved. That is, Watson does not need to violate §§ 271(a)-(c) to capitalize on its first-filer status. The argument is a red herring.

In short, Plaintiffs' §§ 271(a)-(c) claims are based solely on (i) Watson's noninfringing research and development activities, (ii) Watson's submission of the ANDA, and (iii) hypothetical future events that may never occur. This is the very definition of a speculative controversy over which the Court does not have jurisdiction. Counts II and IV should be dismissed.

ARGUMENT

As an initial matter, Watson's motion does ***not*** present a factual challenge to this Court's jurisdiction. (*See* D.I. 25, Opp. 6.) Watson made clear in its opening brief that "Watson accepts Plaintiffs' allegations as true." (D.I. 13, Opening Br. 1 n.2; *see also id.* at 6.) Accordingly, Watson presents a ***facial*** challenge to jurisdiction. *In re Schering Plough Corp.*, 678 F.3d 235, 243 (3d Cir. 2012) (attack was facial in nature "because [defendants] contend[ed] that the Amended Complaints lack sufficient factual allegations to establish standing"). Plaintiffs may not rely on materials outside their Complaint. It is not their prerogative to reframe Watson's motion.

In adjudicating a facial challenge, "the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Id.* Doing so here establishes that subject-matter jurisdiction is wholly lacking.

I. Any Purported Controversy Is Too Remote And Speculative To Support Jurisdiction.

Counts II and IV are based on sheer speculation that either of the necessary predicates to the §§ 271(a)-(c) counts—FDA approval followed by commercial sale before a decision on the merits of the case—will ever occur. Plaintiffs do not allege that these predicates are "real and immediate," and their brief does not cure these deficiencies.

Plaintiffs do not dispute that a statutory 30-month stay precludes FDA from approving Watson's ANDA until February 2016. (The only way it will occur earlier is if Watson defeats the patents, in which case there is no infringement issue at all.) Because the stay prevents the approval (and thus the sale) of Watson's product, there is no real and immediate §§ 271(a)-(c) controversy to support declaratory judgment jurisdiction. In addition, the Court has set a trial date for August 31, 2015. Accordingly, it is very unlikely that there will ***ever*** be a controversy under §§ 271(a)-(c).

Another court in this district has reached this same result in a materially identical case. In *In re Rosuvastatin Calcium Patent Litigation*, the court emphasized that the 30-month stay would not expire until 19 months after the decision. MDL No. 08–1949, 2008 WL 5046424, *12 (D. Del. Nov. 24, 2008). As a result, "there [was] simply no sufficient immediacy to the controversy." *Id.* Thus the court dismissed the claim under § 271(a). Other courts are in accord. *See, e.g., Eisai Co. v. Mutual Pharm. Co.*, Civ. A. No. 06-3613, 2007 WL 4556958, *18 (D.N.J. Dec. 20, 2007). Plaintiffs barely mention the 30-month stay in their brief, but their ploy to avoid the holdings of *Rosuvastatin* and *Eisai* is ineffective.

According to Plaintiffs, *Eisai* is distinguishable because it did not involve a § 271(e)(2) claim. But that is irrelevant. The existence (or absence) of a justiciable controversy under § 271(e)(2) has no effect on whether a justiciable controversy exists under §§ 271(a)-(c). These

provisions are triggered by entirely separate acts: filing an ANDA, on the one hand, and manufacture or sale, on the other. Accordingly, each separate controversy must be supported independently. *See Rosuvastatin*, 2008 WL 5046424, at *13 (holding that defendant's counterclaims under § 271(e)(2) did not establish a controversy under § 271(a)); *City of Los Angeles v. Lyons*, 461 U.S. 95, 102-04 (1983) (holding that plaintiff who had been choked by police had standing to sue for damages, but did not have standing to sue for a declaratory judgment without a showing he was likely to be choked in the future). For precisely the same reasons, Watson's counterclaims do not establish an immediate controversy under §§ 271(a)-(c). *Rosuvastatin*, 2008 WL 5046424, at *13. ***Of course*** there is a controversy under § 271(e)(2), which supports Watson's counterclaims—Watson filed an ANDA and did not move to dismiss Counts I and III. But that does not create an immediate controversy under §§ 271(a)-(c).

In an attempt to avoid the persuasive force of *Rosuvastatin*, Plaintiffs make two attempts to distinguish it. Neither holds water. ***First***, Plaintiffs try in vain to downplay the significance of the 30-month stay, citing two distinguishable cases that, upon closer examination, either do not involve Paragraph IV certifications or do not involve a stay at all.

In Plaintiffs' first case, *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.*, 329 F. Supp. 2d 394 (S.D.N.Y. 2004), defendant's ANDA contained Paragraph IV certifications as to composition claims in two patents, and section viii statements as to claims, in a handful of patents, directed to methods of using the composition in combination with another drug (the "combination use claims").[1] *Id.* at 399. Because defendant's ANDA contained only section viii

[1] A statement under 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii statement"), also referred to as a "carve out," is one where the "ANDA applicant indicates that [an Orange Book listed] patent poses no bar to approval of its ANDA because it seeks to market the drug for a use other than the one encompassed by the patent." *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.*, 329 F. Supp. 2d 394, 398 (S.D.N.Y. 2004). "Paragraph IV certifications and Section viii Statements

statements as to the combination use claims, a claim under § 271(e) was not possible, *see Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002) ("An applicant proceeding by means of a section viii statement . . . does not face an infringement action under 35 U.S.C. § 271(e)(2)(A) . . ."); plaintiff could adjudicate these claims only by seeking declaratory judgment. Moreover, unlike here, actual infringement could occur in the near future: though a key blocking patent did not expire for several years, two other litigants were challenging that patent and, if successful, they would clear the way for defendant to begin marketing immediately. *Takeda*, 392 F. Supp. 2d at 402-03. Because the section viii statements did not preclude FDA approval or result in a 30-month stay, and because the already-advanced challenge to blocking patents could otherwise clear the way for ANDA approval and drug marketing, future infringement was sufficiently real and immediate to support declaratory relief. Here, by contrast, Watson's product will not reach the market in the near future. In all likelihood, Watson's product will not hit the market ***until after Plaintiffs' patent rights have been adjudicated against Watson*** under § 271(e)(2).

Plaintiffs' second case, *Glaxo Group, Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1009 n.4 (N.D. Ill. 2001), involved a patent that was not listed in the Orange Book. Because the procedure to trigger § 271(e)(2) requires a certification to an Orange Book listing, a claim under § 271(e)(2) was not possible. Having no other mechanism to be heard, the court allowed the case to proceed under the declaratory judgment count. Nevertheless, as a prerequisite, the court specifically noted that "the ANDA [was] likely to be approved . . . before the patent expires." *Id.* at 1009. Here, because of the 30-month stay and the § 271(e)(2) claim, the ANDA is ***not*** likely

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have quite different consequences. Applicants submitting Section viii Statements have no obligation to provide notice, nor must the FDA wait thirty months to approve the application." *Id.* at n.3.

to be approved before the patent expires, unless this Court finds that the patent is invalid and Watson does not infringe.

Second, Plaintiffs offer two facts that allegedly distinguish *Rosuvastatin*—namely, that Watson is a "first filer," and that Watson currently markets a Suboxone® tablet. But these facts are not alleged in the Complaint and should be disregarded. In the Complaint, Plaintiffs pleaded ***only*** that "[o]n information and belief," Watson "intend[s] to infringe" by manufacture or otherwise "immediately following approval of [the] ANDA." (*See, e.g.*, D.I. 1, Compl. ¶ 33.) Plaintiffs' additional facts add nothing to their basic allegation. Even if Watson is the "first applicant," that does not mean Watson is entitled to quicker FDA approval, a higher likelihood of FDA approval, or a lifting of the 30-month stay.[2] Nor is a seller of generic Suboxone® tablets (which are a different product that is not accused of infringement) entitled to any of those things. Moreover, none of the cited press releases, or any other fact, demonstrate that Watson would launch prior to patent adjudication and thus run the risk of damages for patent infringement. Without such facts, Plaintiffs' allegation that Watson would launch "immediately" upon FDA approval is nothing more than rank speculation and bald, unsupported assertion, insufficient to support jurisdiction.

Ultimately, Plaintiffs have only an allegation that Watson intends to infringe immediately upon approval of its ANDA. Even if that allegation is accepted as true, the ANDA is not likely to be approved for over two years—after Plaintiffs' patent rights have been fully adjudicated under § 271(e)(2). Such a speculative controversy cannot support declaratory judgment jurisdiction.

[2] In addition, ***every*** ANDA case has a "first applicant." To distinguish any case on that ground would create an exception that swallows the rule.

II. Plaintiffs' Cited Authority Is Either Distinguishable Or Poorly Reasoned.

In an attempt to avoid the persuasive power of *Rosuvastatin*, Plaintiffs cite four decisions—three of them by the same Judge—that neither cite *Rosuvastatin* nor discuss the issue extensively. All of those decisions are flawed.

The only non-Delaware case in the batch, *Bayer Healthcare, LLC v. Norbrook Labs., Ltd*., Nos. 08-C-953, 09-C-108, 2009 WL 6337911 (E.D. Wis. Sept. 24, 2009), is strikingly unpersuasive for three reasons. ***First***, the court never considered the significance of the 30-month stay. ***Second***, the court concluded, with no analysis, that a § 271(e)(2) claim created an immediate controversy on §§ 271(a)-(c) claims. *See* 2009 WL 6337911 at *14 (distinguishing *Eisai* on the ground that "the court determined that there was no § 271(e)(2) claim"). This is wrong. *See supra* at 4; *Rosuvastatin*, 2008 WL 5046424, at *13; *Lyons*, 461 U.S. at 102-104. ***Third***, the decision relies almost entirely on an inapposite Federal Circuit decision, *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007). There, the court found a live controversy over a declaratory judgment action brought by *the ANDA applicant* under § 271(e)(5)[3] based on the patentee's commencement of a § 271(e)(2) action. That is the exact opposite of what occurred here: a declaratory judgment action under §§ 271(a)-(c) brought by *the patentee/NDA holder*, *against* the ANDA applicant, based on the mere filing of an ANDA. Indeed, Plaintiffs know *Teva* is inapposite—they do not once cite it directly.

The three Delaware decisions, all by Judge Robinson, do not control either, for three similar reasons.[4] ***First***, none of these decisions even considered the importance of the thirty-

[3] 35 U.S.C. § 271(e)(5) gives a cause of action to an ANDA applicant who has not been sued, and who desires a full adjudication of rights as to Orange-Book-listed patents prior to FDA approval.

[4] *Cephalon, Inc. v. Sandoz, Inc.* is also distinguishable because it concerned a declaratory judgment action over later-filed patents that were not listed in the Orange Book. The primary

month stay. ***Second***, they misconstrue § 271(e)(2) claims as involving "a forward-looking analysis of what defendants will do upon ANDA approval." *Cephalon v. Watson*, 629 F. Supp. 2d 338, 351 (D. Del. 2009). But there is nothing "forward-looking" about § 271(e)(2) here. That section creates an artificial act of patent infringement: filing an ANDA. That has already happened. ***Third***, as described above, a § 271(e)(2) controversy does not create a §§ 271(a)-(c) controversy. Respectfully, the Court here should follow *Rosuvastatin* and *Eisai* as the better-reasoned decisions.

III. Counts II And IV Are Unnecessary And Contrary To The Hatch-Waxman Scheme.

The Hatch-Waxman Act enacted an elaborate scheme that covers the exact circumstances present here. When a proposed generic drug has not yet gone to market and the ANDA has not been approved, no claim under §§ 271(a)-(c) is possible. Thus, to allow patentees to protect their rights, Congress created a new, artificial act of infringement under § 271(e)(2), i.e., the filing of an ANDA. (*See* D.I. 13, Opening Br. 4-5.)

Now, Plaintiffs essentially argue that Congress's creation was unnecessary, because the mere filing of an ANDA can trigger declaratory judgment jurisdiction under §§ 271(a)-(c). But § 271(e)(2) should not be interpreted as a useless creation. It is not, as Plaintiffs submit, a remedy that will be available "at a later time." (Opp. 13.) It is a ***present*** remedy that is predicated on Watson's ***completed conduct***, and was created ***for the purpose*** of giving the patentee access to court in just this situation. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

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holding of the case was that jurisdiction existed under § 271(e)(2). No. 11–821, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012). In the alternative, the court found declaratory judgment jurisdiction in order to prevent the defendant from "market[ing] its generic as soon as its ANDA [was] approved by the FDA without responsibly resolving all the patent issues related to said product." *Id.* at *6. Here, the claims under Section 271(e)—which Watson has not moved to dismiss—will resolve all patent issues related to Suboxone® sublingual film.

Moreover, there is a substantial difference in remedies afforded under these provisions. For successful § 271(e) claims, "the court shall order the effective date of any approval" of the ANDA to be after "the expiration of the patent." 35 U.S.C. § 271(e)(4). But under §§ 271(a)-(c), Plaintiffs' remedy is enjoining future sales until patent expiration, as well as damages for past sales. *See, e.g.*, 35 U.S.C. § 284. The point of distinction is that, in the Hatch-Waxman context, an injunction against the patentee and damages are discretionary and only apply to the actual act of infringement where there has been "***commercial*** manufacture, use, offer to sell, or sale within the United States." *Compare* 35 U.S.C. § 271(e)(4)(B) ("may be granted"); § 271(e)(4)(C) ("may be awarded") (emphasis added); *with* 35 U.S.C. § 271(a) (infringement for "whoever without authority makes, uses, offers to sell, or sells any patented invention").

Although Plaintiffs cite two cases that purport to address the Hatch-Waxman scheme, neither case permitted a patentee to bring a declaratory judgment claim after the applicant filed a Paragraph IV certification. In fact, neither case dealt with a Paragraph IV certification at all. In *Takeda v. Watson*, the defendants instead filed a section viii statement. The defendants argued that because a section viii statement was not an act of infringement under Hatch-Waxman, there could be no claim under Section 271(e). 329 F. Supp. 2d at 403. In *Cephalon v. Sandoz*, Sandoz did not, and was not required to, make a Paragraph IV certification as to two patents listed in the Orange Book after the litigation commenced. 2012 WL 682045, at *1. Plaintiffs also mischaracterize the *Sandoz* case; the court discussed the declaratory judgment issue only in the alternative event that there was no jurisdiction under § 271(e)(2). *See* 2012 WL 682045, at *5. In any event, the argument presented in both cases was that Congress did not create a cause of action to cover those facts.

This case is the opposite. Congress did create a cause of action to cover these facts—and that is powerful evidence that no such cause of action previously existed. *See Rosuvastatin*, 2008 WL 5046424, at *12-13 (declining to allow plaintiff to "pursue an ordinary § 271(a) patent infringement action on the same patent and based on all the same facts" as their § 271(e)(2) claim). And the remedy created by Congress will fully adjudicate Plaintiffs' patent rights. This case has been set for trial beginning on August 31, 2015, six months before the expiration of the 30-month stay. This will allow the Court to determine the parties' rights before the stay's expiration. If Plaintiffs' action is successful, § 271(e)(2) will prevent the ANDA from being approved and will prevent Watson from entering the market until the patents expire. If not, the ANDA will be approved and Watson will be able to sell its product free of liability. There is no more to this case.

Plaintiffs assert that Watson could infringe in a way "not associated with Watson's ANDA." (D.I. 25, Opp. 12.) They do not say how this could possibly occur, and so it is nothing but conjecture. Indeed, the plaintiff in *Rosuvastatin* made the same argument. The court rejected it. *See* 2008 WL 5046424, at *13 n.12 (ruling that "there is no basis at this time to believe that any of the Defendants have any intention to engage in any conduct that could even arguably constitute infringement other than in connection with the pending ANDAs"). In short, Section 271(e)(2) is entirely adequate for this case.

CONCLUSION

There is no immediate controversy over traditional infringement claims. Alternatively, if there is jurisdiction, this Court should decline to exercise it. The § 271(e)(2) claims will fully adjudicate Plaintiffs' patent rights. For these reasons, and those set forth in Watson's Opening Brief, Counts II and IV should be dismissed.

Dated: December 23, 2013

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