IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:13-CV-760-BO

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	
v.	)	ORDER
BIODELIVERY SCIENCES INTERNATIONAL, INC.,	)	
Defendant.	)	

This cause comes before the Court on defendant's motions to dismiss and to stay. A hearing was held on these matters before the undersigned on April 25, 2014, at Raleigh, North Carolina. For the reasons discussed below, defendant's motion to dismiss is granted.

BACKGROUND

Plaintiff RB Pharmaceuticals, a UK company, owns patent no. 8,475,832 (the '832 patent) which relates to sublingual and buccal film compositions and was issued on July 2, 2013. The inventors to whom the '832 patent was originally issued assigned their rights to MonoSol, who later assigned its rights to RB Pharmaceuticals Limited, or RBP UK. Plaintiff Reckitt Benckiser Pharmaceuticals (RBP), a Virginia company, is the owner of New Drug Application No. 22-410 with the Food and Drug Administration (FDA) for a drug used to treat opioid dependence called Suboxone. Suboxone is administered sublingually through a film. The New Drug Application (NDA) for Suboxone sublingual film was approved by the FDA on August 30, 2010. RBP also owns NDA No. 20-733 for Suboxone sublingual tablet, which contains the same

active ingredients as Suboxone sublingual film but is administered in tablet as opposed to film form.

Defendant submitted an NDA to the FDA on July 31, 2013, and is seeking approval to manufacture and sell a drug called Bunavail, which contains the same active ingredients and is intended to treat the same medical conditions as Suboxone. Bunavail is believed to be administered by a mucoadhesive applied orally. Plaintiffs contend that defendant's submission of its NDA to the FDA constitutes patent infringement and that its application was specifically drafted to circumvent the Hatch-Waxman Act, 21 U.S.C. § 355. In count one, plaintiffs seek a declaratory judgment that defendant's Bunavail product is covered by one or more claims of the '832 patent. Plaintiffs allege that, unless enjoined by this Court, defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States of Bunavail upon approval of its pending NDA and that such actions would infringe plaintiffs' '832 patent. In count two, plaintiffs allege that defendant's submission of its NDA is an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2)(A). Plaintiffs seek an order requiring that the FDA set the effective date of approval for defendant's NDA to be not earlier than the expiration date of the '832 patent, pursuant to 35 U.S.C. § 271(e)(4).

DISCUSSION

Defendant contends that the Court lacks subject matter jurisdiction over count one as there is no case or controversy to be decided. Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a claim for lack of subject matter jurisdiction. When subject matter jurisdiction is challenged, the plaintiff has the burden of proving jurisdiction to survive the motion. *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647-50 (4th Cir. 1999). "In determining whether jurisdiction exists, the district court is to regard the pleadings' allegations as mere

evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Richmond, Fredericksburg & Potomac R.R Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991). To this end, "the nonmoving party must set forth specific facts beyond the pleadings to show that a genuine issue of material fact exists." *Id.* (citing *Trentacosta v. Frontier Pacific Aircraft Indus.*, 813 F.2d 1553, 1558-59 (9th Cir. 1987)). The movant's motion to dismiss should be granted if the material jurisdictional facts are not in dispute and the movant is entitled to prevail as a matter of law. *Id.*

The Declaratory Judgment Act provides that in a case of actual controversy within its jurisdiction, a court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a). The Declaratory Judgment Act does not, however, create an independent basis for subject matter jurisdiction. *Gibraltar, P.R., Inc. v. Otoki Grp., Inc.* 104 F.3d 616, 619 (4th Cir. 1997). Plaintiffs allege that this Court has jurisdiction over their declaratory judgment claim in light of its jurisdiction over patent disputes and specifically under 35 U.S.C. § 271(a)-(c). In patent matters, a dispute presents an actual case or controversy if it is one that is "definite and concrete, touching the legal relations of parties having adverse legal interests; and [it must] be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotations, alterations, and citations omitted). The basis of a court's jurisdiction over a declaratory judgment action is measured at the time of the filing of the complaint, and "a claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation and citation omitted).

The complaint in this matter was filed on October 29, 2013. Defendant filed its NDA with the FDA in July 2013, and at the time of filing of this order, the Court is unaware that the FDA has acted on defendant's application. Although plaintiffs allege that defendant has announced its intent to market Bunavail once it obtains FDA approval, any actual future alleged infringement of plaintiffs' patent "depends on two contingent future events: FDA approval of [defendant's] []NDA, and [defendant's] decision to market [Bunavail] pursuant to that []NDA. At least until the []NDA is approved. . . the controversy is not sufficiently immediate." *Eisai Co., Ltd. v. Mut. Pharm. Co., Inc.*, CIV.A. 06-3613(HAA), 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *see also Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A.05-590 GMS, 2006 WL 2375035 (D. Del. Aug. 16, 2006) (dismissing declaratory judgment claim based on potential future infringement and noting that "[a]t the time Abbott filed its complaint, the FDA had not approved DexCom's product and Abbott could not predict when, or if, the FDA would approve the product."). Any actions taken to date regarding defendant's research or development of Bunavail appear to fall under the safe harbor provision enacted in order to encourage ongoing research and development and cannot be used to support plaintiffs' claim for future infringement. 35 U.S.C. § 271(e)(1). Additionally, a court may consider whether an alleged future infringer has engaged in marketing or solicited orders for an accused product when determining whether a justiciable controversy exists, but plaintiffs have not alleged that defendant has advertised or taken orders for its Bunavail product. *See Interdigital Tech. Corp. v. OKI America, Inc.*, 845 F. Supp. 276, 284 (E.D.Pa. 1994). Although plaintiffs contend that defendant has included information about its Bunavail product in its annual report and issued press releases regarding its Bunavail application, the Court does not find these actions to be sufficient to demonstrate any immediacy of potential infringement.

For these reasons, the Court finds that plaintiffs' claim for declaratory judgment based on contingent future events is premature and that the Court therefore lacks subject matter jurisdiction to consider it.[1]

Defendant next contends that count two of plaintiffs' complaint fails to state a claim upon which relief can be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure. When acting on a motion to dismiss under Rule 12(b)(6), "the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir.1993). A complaint must allege enough facts to state a claim for relief that is facially plausible, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007), which requires that the facts pled "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"; mere recitals of the elements of a cause of action supported by conclusory statements do not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). If the factual allegations do not nudge the plaintiff's claims "across the line from conceivable to plausible," the "complaint must be dismissed." *Twombly*, 550 U.S. at 570.

Once an NDA is approved, the drug manufacturer must submit the patent number and expiration date of any patent that claims the drug or method for inclusion in the FDA's "Orange Book." 21 U.S.C. § 355(b)(1). An applicant submitting an NDA to the FDA may under certain circumstances rely on the FDA's prior findings regarding safety and efficacy of an allegedly bioequivalent listed drug product, instead of having to repeat the testing necessary for a new drug application. *See* 21 U.S.C. §§ 355(j) (abbreviated NDA for generic drugs); 355(b)(2) (505(b)(2) NDA where listed drug is similar to new drug). Defendant has filed a 505(b)(2) NDA regarding Bunavail, which means that it has relied in its application on investigations it did not conduct and

[1] Because the Court finds that plaintiffs' claim is not ripe, it declines to consider defendant's argument regarding standing.

for which it has not obtained a right of reference. Unlike an applicant for a generic drug, a 505(b)(2) applicant is permitted to choose the most appropriate listed drug for reference and is not required to choose the most similar listed drug. 21 U.S.C. § 355(b)(2); Cmp. Ex. E at 7 ("An applicant choosing to rely on FDA's finding of safety and/or effectiveness for a listed drug very similar to the proposed product . . . would generally need to submit less additional data . . . [but] this suggested approach does not reflect a statutory or regulatory requirement.").

Both a generic drug applicant and a 505(b)(2) applicant must make one of four certifications in its NDA regarding each patent that is listed in the FDA's Orange Book for the referenced drug: "(1) that no patent information has been filed (a "Paragraph I" certification), (2) that the patent has expired (a "Paragraph II" certification), (3) that the patent will expire on a specific date (a "Paragraph III" certification), or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted" (a "Paragraph IV" certification)." *Eisai Co.*, 2007 WL 4556958 *1 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV)). Where an applicant files a Paragraph IV certification, the applicant must give notice to the patent owner with the basis on which it contends that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). Such notice provides the patent owner with forty-five days to file an infringement action, which if filed will trigger a thirty month stay of the FDA's consideration of the NDA. 21 U.S.C. § 355(j)(5)(B)(iii). In such instance, the patent owner's infringement action is considered an "artificial" infringement action and is filed under 25 U.S.C. § 271(e)(2). *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, (1990) (§ 271(e)(2) creates a "a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications.").

Plaintiffs' count two is a § 271(e)(2) artificial infringement claim regarding plaintiffs' '832 patent on sublingual and buccal film compositions. Defendant has indicated in its 505(b)(2) NDA that plaintiffs' Suboxone sublingual tablet, not sublingual film, is its reference drug; defendant did not file a Paragraph IV certification regarding the '832 patent, and thus plaintiffs' '832 patent has not been implicated in defendant's 505(b)(2) application.

Absent a Paragraph IV certification referencing plaintiffs' '832 patent, plaintiffs' § 271 artificial infringement claim is beyond the scope of defendant's 505(b)(2) application and therefore fails to state a claim upon which relief can be granted. *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012) ("When considering allegations that an ANDA filing infringes a patented method, § 271(e)(2) directs our analysis to the scope of approval sought in the ANDA—the statute defines the infringing act as filing an ANDA for 'a drug claimed in a patent or the use of which is claimed in a patent.'"). Although the application at issue in *AstraZeneca* was a generic drug application, the Federal Circuit's holding remains applicable in the 505(b)(2) context. As the court in *AstraZeneca* recognized, "the Act allows generic manufacturers to limit the scope of regulatory approval they seek – and thereby forego Paragraph IV certification and a § 271(e)(2) infringement suit – by excluding patented indications from their ANDAs." *Id.* The Court finds the *AstraZeneca* holding to be both instructive and persuasive in this context, and that its application requires dismissal of plaintiffs' § 271(e)(2) claim. *See also Novartis Pharm., Corp. v. Wockhardt USA LLC*, 12-CV-3967, 2013 WL 5770539 (D.N.J. Oct. 23, 2013) ("According to the Federal Circuit in *Warner–Lambert* and *AstraZeneca*, a claim for infringement under § 271(e)(2) must involve filing an ANDA seeking approval for a patented use."); *Eisai Co., Ltd.*, 2007 WL 4556958 *12 (" this Court holds that to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV

certification against a patent listed in the Orange Book for the drug in question."); *Novo Nordisk Inc. v. Mylan Pharm Inc.*, Civ. Action No. 09-2445(FLW), 2010 WL 1372437 *10 (D.N.J. March 31, 2010) (noting *Eisai* court's thorough analysis and adopting holding that where no Paragraph IV certification has been filed an act of infringement under § 271(e)(2) cannot be established).

For these reasons, plaintiffs have failed to state a claim upon which relief can be granted in count two of their complaint.

CONCLUSION

Accordingly, defendant's motion to dismiss [DE 18] is GRANTED and plaintiffs' complaint is DISMISSED in its entirety. Defendant's motion to stay [DE 33] is therefore DENIED AS MOOT. For good cause shown, the motions to seal [DE 30 & 42] are GRANTED.

SO ORDERED, this 20 day of May, 2014.

Terrence W. Boyle

TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE