NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	:	**OPINION**
Plaintiffs,	:	
v.	:	16-cv-02290 (WHW)(CLW)
LUITPOLD PHARMACEUTICALS, INC., DAIICHI SANKYO, INC., and DAIICHI SANKYO COMPANY, LTD.,	:	
Defendants.	:	

Walls, Senior District Judge

Defendant Luitpold Pharmaceuticals moves for judgment against Plaintiffs Par Pharmaceutical, Par Sterile Products, and Endo Par Innovation Company under Fed. R. Civ. P. 12(c). ECF No. 41. The Court decides this motion without oral argument under Fed. R. Civ. P. 78. Defendant's motion is granted.

FACTUAL AND PROCEDURAL BACKGROUND

This case arises out of a patent dispute between Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par"), and Defendants Luitpold Pharmaceuticals, Inc., Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd. The Par plaintiffs consist of a corporation and two limited liability companies—the corporation existing under the laws of New York and the LLCs under the laws of Delaware—with principal places of business in New York. Am. Compl., ECF No. 70 ¶¶ 2–4. Defendant Luitpold Pharmaceuticals, Inc., is a New York corporation with its principal place of business in New

York; defendant Daiichi Sankyo, Inc., is a Delaware corporation located in New Jersey; and defendant Daiichi Sankyo Co., Ltd., is a Japanese company located in Tokyo and doing business in New Jersey. *Id.* ¶¶ 5–7. Par is the assignee of several patents for Adrenalin®, a product containing 1 mg of the active ingredient epinephrine, which is used primarily to treat allergic reactions. *Id.* ¶¶ 34–39. In early 2016, Defendant Luitpold filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), which sought approval to market a generic version of Par's Adrenalin® product. *Id.* ¶ 46. By letters dated March 9, 2016 and July 7, 2016, Luitpold submitted to Par notices of certification under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) regarding its proposed generic epinephrine product as specified in its ANDA. *Id.* ¶ 47–50. Par then initiated this suit under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act), asserting that Luitpold's ANDA submission constituted an act of infringement of their patents. *Id.* ¶¶ 65–80.

I. The Patents-in-Suit

There are two patents at issue in this case. The first patent, United States Patent No. 9,119,876 (the "'876 patent"), was duly and legally issued to Par Pharmaceutical, Inc. by the United States Patent and Trademark Office ("PTO") on September 1, 2015. *Id.* ¶ 34. The '876 patent is directed to certain pharmaceutical compositions comprising epinephrine, a medication that has been used for decades for a variety of treatments. *Id.* ¶¶ 36, 42; *see also id.*, Ex. A. The second patent, Patent No. 9,295,657 (the "'657 patent"), which is a continuation of the '876 patent, was duly and legally issued by the PTO on March 29, 2016. *Id.* ¶ 37; *see also id.*, Ex. B. The '657 patent is directed to methods of treating various conditions, such as anaphylaxis and the induction maintenance of mydriasis during intraocular surgery, by administering pharmaceutical compositions comprising epinephrine. *Id.* ¶ 38.

Drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act are identified by the publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Under 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '876 and '657 patents are listed in the Orange Book with respect to Par's FDA approved epinephrine injection product Adrenalin®. *Id.* ¶ 45. Adrenalin® "is the first FDA-approved epinephrine injection product for use in a clinical setting available in the United States." *Id.* "The prescribing information for Adrenalin® instructs physicians to administer Adrenalin® to patients to treat anaphylaxis." *Id.* ¶ 40.

II. The Development of Par's Adrenalin® Product

The development of Par's Adrenalin® product provides important background for understanding Par's charges against Luitpold. Before obtaining the Patents-in-Suit, Par's predecessor, JHP Pharmaceuticals ("JHP"), applied for FDA approval of an epinephrine formulation it had marketed for over 100 years. *Id.* ¶ 42. Specifically, JHP filed New Drug Applications ("NDAs") with the FDA for two Adrenalin® products. *Id.* ¶ 43. The FDA approved NDA No. 204200 for Adrenalin® 1 mg base/mL in December 2012 and NDA No. 20460 for Adrenalin® 30 mg base/30mL in December 2013. *Id.* During the FDA approval process, the FDA required JHP to meet strict impurity level requirements for Adrenalin® to ensure that patients suffering from emergency anaphylaxis received a medication potent enough to save their lives. *Id.* ¶ 42. Initial FDA approval was therefore conditioned on JHP conducting post-marketing studies and committing to further reduce the impurity levels of Adrenalin®. *Id.*

Par Sterile undertook the post-marketing commitment and successfully developed a new formulation of Adrenalin® with significantly fewer impurities. *Id.* ¶ 44. Based on the research it conducted, Par Sterile obtained the Patents-in-Suit, which, as previously discussed, cover the

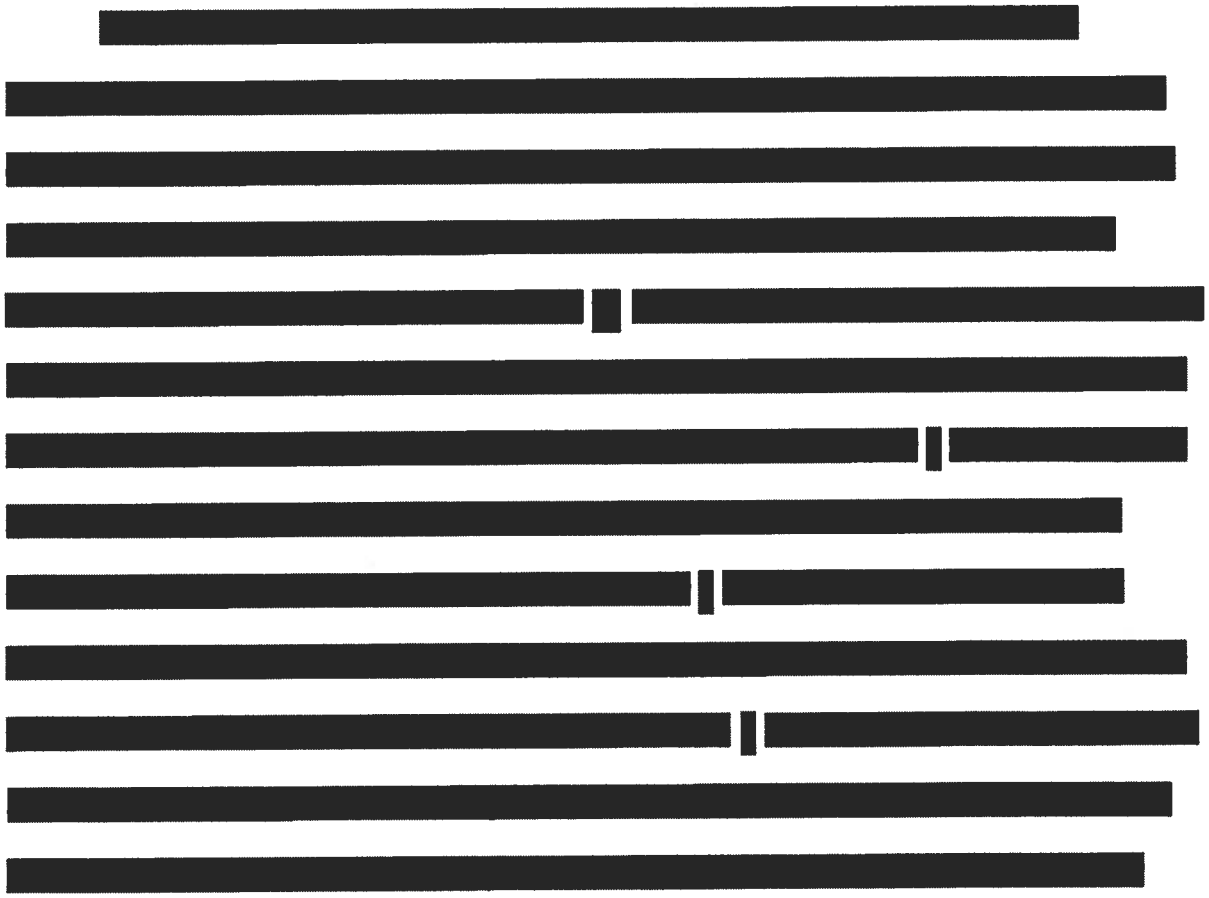
new epinephrine formulation as well as the methods of using the formulation to treat conditions such as anaphylaxis and maintenance of mydriasis during intraocular surgery. *Id.*

[redacted] Par Sterile submitted supplemental NDAs reflecting this new formulation to the FDA. ECF No. 70 ¶ 44. In December 2015, FDA approved Par Sterile's supplemental NDA for NDA No. 204640 (30 mg base/30 mL) covering the new formulation. *Id.* In September 2016, FDA approved Par Sterile's supplemental NDA for NDA No. 204200 (1 mg base/mL) covering the new formulation. *Id.*

III. Luitpold's ANDA

According to the Complaint, prior to the FDA's approval of Par's NDA for Adrenalin®, a subsidiary of Luitpold sold an unapproved version of epinephrine, which was recalled due to "discoloration" and "small visible particles." *Id.* ¶ 40 [redacted] Luitpold submitted ANDA No. 207-568 to the FDA under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic version of Par's Adrenalin®

product, which contains 1 mg of the active ingredient epinephrine.[1] ECF No. 70 ¶ 46; ECF No. 41-1 at 3. In accordance with 21 U.S.C. 355(j)(2)(B), Luitpold informed Par of its intent to seek approval to market a generic version of Adrenalin® in two notice letters (the "Notice Letters"). The first letter, dated March 9, 2016 ("First Notice Letter"), stated that Luitpold had submitted ANDA No. 207-568 and intended to manufacture a generic version of Adrenalin® before the expiration of the '876 patent. ECF No. 70 ¶¶ 47–48. The second letter, dated July 6, 2016 ("Second Notice Letter"), relayed the same information with regard to the '657 patent. *Id.* ¶¶ 49–50.



[1] Par alleges that before the FDA's approval of Par's NDA for Adrenalin®, Luitpold's subsidiary sold an unapproved version of epinephrine, which contained higher impurity levels than Adrenalin® and was eventually recalled. ECF No. 1 ¶¶ 39–42.

[redacted]

IV. The Complaint and Counterclaim

When a company files an ANDA, it must certify under the Hatch-Waxman Act that its proposed generic drug will not infringe a current listed drug patent. 21 U.S.C. § 355(j)(2)(A)(vii). Luitpold certified non-infringement of its generic epinephrine product under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV"). ECF No. 64 at 3. Paragraph IV states that the patent for the listed version of the proposed generic drug "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* Luitpold's Notice Letters informed Par that it had filed a Paragraph IV Certification asserting both the invalidity and Luitpold's non-infringement of the Patents-in-Suit. ECF No. 70 ¶¶ 48–50.

In response to Luitpold's Paragraph IV Certification, Par filed the present action on April 22, 2016, alleging that Luitpold's Generic Product will infringe the Patents-in-Suit. ECF No. 1 ¶¶ 62–77. After a majority of the briefing on this motion was completed, Par filed an Amended Complaint on October 14, 2016. ECF No. 70. The amendments include small factual updates and the addition of EPIC as a party, but they do not change the substance of the legal claims. ECF No. 70. Par alleges that Luitpold's Generic Product "will have the same active ingredient as Adrenalin®, the same or equivalent inactive ingredients as Adrenalin®, [] the same route of administration as Adrenalin®," "will be the bioequivalent to Adrenalin®," and "will have the same indication as Adrenalin®." ECF No. 70 ¶ 52. Though Par admits that Luitpold's ANDA formulation of generic epinephrine does contain the same or equivalent ingredients as the formulation specified in the Patents-in-Suit, ECF No. 37 ¶¶ 108–09, the Complaint alleges that

the product proposed in Luitpold's ANDA "is not the product Luitpold will market." ECF No. 64 at 4. The claim is therefore based on Par's allegation that "the product Luitpold will market infringes the Patents-in-Suit." *Id.*

The Complaint contains four counts of patent infringement against all defendants. Count One asserts that Defendants' submission of ANDA No. 207-568 constitutes infringement of Par's '876 patent under 35 U.S.C. § 271(e)(2) and that Defendant will infringe the '876 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g). ECF No. 70 ¶¶ 65–68. Count Two seeks a declaration under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, that Defendants would infringe the '876 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g) if they commercially manufacture, use, offer for sale, sell, or import Luitpold's Generic Product, or induce or contribute to such conduct. *Id.* ¶¶ 69–72. Counts Three and Four repeat the charges of Counts One and Two for the '657 patent. *Id.* ¶¶ 73–80. Plaintiffs seek injunctive, declarative, and monetary relief as well as an award of costs and expenses. *Id.* at 19–20.

On July 1, 2016, Luitpold answered Par's Complaint and asserted four counterclaims. Answer, ECF No. 13. Luitpold's primary argument is that its Generic Product does not literally infringe the Patents-in-Suit because it is "lacking multiple claim limitations of all claims of each patent." *Id.* ¶ 113. [redacted] Luitpold's First Counterclaim seeks a declaratory judgment that it has not and is not infringing "any valid and enforceable claim of the '876 and '657 patents." Id. ¶ 115. Luitpold's Second Counterclaim asks for declaratory relief on the basis that the Patents-in-Suit are invalid "for failure to meet the conditions of patentability of 35 U.S.C. § 101 *et seq.* *Id.* ¶ 117. Counterclaim Three asks for a declaration that Luitpold is entitled to a defense to infringement based on prior commercial use under 35 U.S.C. § 273.

Counterclaim Four seeks a declaration that the case against Luitpold is exceptional under 35 U.S.C. § 285. Plaintiffs answered Luitpold's counterclaims on August 8, 2016. Plaintiffs' [redacted] stated that the FDA will require, and Luipold will likely market, a generic product with a formulation that infringes the Patents-in-Suit. ECF No. 37 ¶¶ 108–09.

V. Luitpold's Motion for Judgment on the Pleadings

Defendant Luitpold filed the current motion for judgment on the pleadings on September 9, 2016. ECF No. 41. Luitpold argues that its "ANDA formulation does not infringe the Patents-in-Suit," and that Par's Complaint relies impermissibly on speculation that at some future time the FDA will require Luitpold to modify its ANDA formulation of generic epinephrine in such a way that it will infringe Par's patents. *Id.* at 1. Luitpold argues that "such a claim provides no basis for relief" and seeks judgment on the pleadings under Fed. R. Civ. P. 12(c) regarding all claims asserted against it by Par and on Luitpold's First and Second Counterclaims.[2] *Id.*

Par responds that the "case is focused solely on the product Luitpold intends to market" not the formulation of Luitpold's product as specified by its current ANDA. ECF No. 64 at 1–2. Par further contends that Luitpold "will have to amend its ANDA in order to obtain FDA approval." *Id.* at 1. Par insists that once discovery it complete, it will be clear that "the product Luitpold will ultimately market will be required to have 'the same or equivalent ingredients and, therefore, the same or equivalent formulation' as Par's patented product." *Id.* (quoting Compl.

[2] Luitpold also argues that it is entitled to judgment with respect to Par's allegation that it is "making or selling unapproved forms of epinephrine" because a private litigant cannot bring a claim based on the selling or marketing of unapproved drugs. ECF No. 41-1 at 2. Par notes that judgment is inappropriate because it did not attempt to bring a claim based on this allegation. ECF No. 64 at 2. The Court does not address this portion of the dispute any further because Par has removed the allegation from its Amended Complaint. ECF No. 70.

ECF No. 1 ¶¶ 53–54.). Finally, Par argues that Luitpold's argument is nothing more than a ripeness challenge, which should have been brought under Fed. R. Civ. P. 12(b)(1) as a motion to dismiss for lack of subject matter jurisdiction. *Id.* at 5–20. Based on this argument Par requests that if Luitpold's motion is granted, the case be dismissed without prejudice. *Id.* at 16.

In its reply brief, Luitpold reasserts its grounds for judgment on the pleadings under Fed. R. Civ. P. 12(c) rather than a motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). ECF No 78. Luitpold argues that the Par's claims should be adjudicated on the merits because Par can only sue based on the drug Luitpold has proposed to manufacture under the actual ANDA, which Par admits does not infringe the Patents-in-Suit. *Id.* at 3.[3]

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(c) provides that "after the pleadings are closed – but early enough not to delay trial – a party may move for judgment on the pleadings." The movant must clearly show that there is "no material issue of fact and that he is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290–91 (3d Cir. 1988)) (internal quotation marks and citations omitted). A motion under Rule 12(c) is reviewed under the same standard as a motion to dismiss under Rule 12(b)(6). *Turbe v. Government of the Virgin Islands*, 938 F.2d 427, 427 (3d Cir. 1991). The court is required to "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." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007).

[3] On January 5, 2017 Defendant Luitpold Pharmaceuticals, Inc., requested leave to supplement the record of this motion with new, previously unavailable authority. ECF Nos. 88–89. Because the Court concludes that this action should be dismissed without reliance on the new authority in support of this conclusion, it is unnecessary to address Defendant's new authority herein.

Beyond the face of the pleadings, the court may consider exhibits attached to the complaint, matters of public record, and undisputedly authentic documents attached in a defendant's motion if the plaintiff's claims are based upon it. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.3d 1192, 1196 (3d Cir. 1993). "A 'document integral to or explicitly relied on in the complaint' may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" *Mele v. Federal Reserve Bank of N.Y.*, 359 F.3d 251, 256 n.5 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). In a Hatch-Waxman action such as this, the Court may consider the file histories of the Patents-in-Suit. *See In re Bendamustine Consolidated Cases*, Civ. No. 13-206, 2015 WL 1951399, at *1–2 (D. Del. Apr. 29, 2015) (noting that it is permissible to consider patent file histories and a moving defendant's ANDA filings without converting a motion for judgment on the pleadings to a motion for summary judgment). Where the factual allegations in a complaint contradict a document attached to the pleadings, the document controls. *See ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994).

DISCUSSION

I. Par's Patent Infringement Claims

Par alleges that Luitpold's Generic Product infringes the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) and § 271 (a), (b), (c), and (g). ECF No. 70 ¶¶ 65–80. Plaintiffs seek a judgment of infringement and a declaration that Luitpold will infringe the Patents-in-Suit if, before the patents' expiry, it attempts to commercially manufacture, use, offer for sale, or sell its Generic Product within the United States. *Id.* at 18–19. Defendant Luitpold moves for judgment on the pleadings as to each of Par's claims, arguing that its ANDA does not infringe Par's patents and that Par's Complaint is based entirely on conjecture that the FDA will force it to modify its

ANDA formulation to an infringing formulation. ECF No. 41-1 at 8. Because the product that can be manufactured under Luitpold's ANDA does not infringe Par's patents, Defendant's motion is granted.

"Under the Hatch-Waxman framework, the filing of an ANDA constitutes an artificial act of infringement for purposes of creating case or controversy jurisdiction." *Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (citing 35 U.S.C. § 271(e)(2)(A)) (collecting cases) (internal quotation marks omitted). The ANDA filing only constitutes "a technical act of infringement for jurisdictional purposes." *Id.* Once jurisdiction is established, courts determine whether an ANDA will infringe an existing patent by comparing "the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles." *Id.* (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003); *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed Cir. 1995)). The patentee has the burden of proving infringement by a preponderance of the evidence. *Id.*

Luitpold argues that its ANDA will not infringe the Patents-in-Suit because the generic drug formulation proposed in the ANDA lacks components essential to the Patents-in-Suit, [redacted] ECF No. 41-1 at 3. Par argues that the drug formulation in Luitpold's current ANDA "has nothing to do with this case" because the relevant inquiry focuses "solely on the product Luitpold intends to market." ECF No. 64 at 2. Par contends that there are many material facts in dispute regarding the final formulation of the drug Luitpold intends to sell, which makes judgment on the pleadings inappropriate. *Id.* at 1.

Par's argument that the Court patent infringement analysis must look beyond the drug

formulation specified in Luitpold's ANDA is based primarily on the Federal Circuit's language in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), that the relevant inquiry in a patent infringement case under 35 U.S.C. § 271(e)(2) is the product "likely to be sold following FDA approval." *Id.* 1568. But once this quotation is read in context, it is clear that it does not support Par's proposition that courts may determine patent infringement based on potential future drug formulations not specified in the operative ANDA.

"[T]he ANDA itself dominates the [patent infringement] analysis" under § 271(e)(2). *Ferring*, 764 F.3d at 1408. As the *Glaxo* Court explained: "Under § 271(e)(2)(A), a court must determine whether, if the drug were approved *based upon the ANDA*, the manufacture, use or sale of that drug would infringe the patent in the conventional sense." *Glaxo*, 110 F.3d at 1569 (emphasis added). "Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement [] control[s] the infringement inquiry." *Abbott*, 300 F.3d at 1373.

In many cases, such as this one, "the ANDA specification directly resolves the infringement question because it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such claim." *Ferring*, 764 F.3d at 1408; see also *Abbott*, 300 F.3d at 1373 ("If an ANDA specification defines a property of a compound such that it must meet a limitation of an asserted claim, then there will almost never be a genuine dispute of material fact that the claim is infringed with respect to that limitation."). For example, in *Sunovion Pharm. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, the court determined that the defendant's proposed generic product infringed the plaintiff's patent because the ANDA described an amount of stereoisomer within the scope of the asserted patent

claim. *Id.* at 1279–80. Similarly, in *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 the court found no infringement when the ANDA specification required a surface area outside the range claimed by the asserted patent. *Id.* at 1248–50.

The Federal Circuit has distinguished between cases where the ANDA specification resolves the question of infringement and those where it does not. *See Ferring*, 764 F.3d at 1408–09. But even in cases that cannot be resolved simply by looking at the face of the ANDA, the relevant inquiry focuses on the final product likely to be sold based on the ANDA specifications. *See id.* at 1409 ("The infringement evaluation is concerned only with the final, coated commercial tranexamic acid tablets for which Watson sought and was granted FDA approval to market as a generic version of a treatment of menorrhagia. Watson cannot sell the uncoated cores alone because it would not comply with its ANDA specification; to do so would be to sell both an unapproved and adulterated drug in violation of the law."). None of the cases cited by Par suggests otherwise.

Here Luitpold's ANDA formulation directly addresses the question of infringement and the Parties even agree that the current formulation of Luitpold's generic epinephrine product, as described in the relevant ANDA, does not infringe the Patents-in-Suit Opp. Br., ECF No. 64 at 1–2, 20; ECF No. 41-1 at 3–5. Par's argument against the entry of judgment for Luitpold at this stage is based entirely on speculation that the FDA will require Luitpold to adjust its product formulation in a way that will infringe the Patents-in-Suit. ECF No. 64 at 6–16. Par claims that because the FDA has not approved Luitpold's ANDA, ECF No. 57-2, it is more than speculative that the FDA will require the changes Par alleges. ECF No. 64 at 6–7. This argument misses the mark because it is premised on the mistaken belief that the Court can and should determine patent infringement by looking to drug formulations and ANDAs not yet in existence.

While 35 U.S.C. § 271(e)(2) creates an "artificial" controversy, it "does not encompass speculative claims of infringement." *Warner-Lambert*, 316 F.3d at 1364. As the Federal Circuit makes clear: "The statute [§ 271(e)(2)] explicitly defines the act of infringement as the filing of the ANDA. The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Id.* This limitation caused the *Warner-Lambert* Court to find no infringement when the permissible uses specified in a defendant's ANDA did not induce infringing behavior despite the plaintiff's insistence that the defendant would actively encourage patent infringement once its ANDA was approved. *Id.* at 1364. The Circuit made clear that future efforts by the defendant to infringe the plaintiff's patent would form the basis for a cause of action, but that "§ 271(e)(2) was not designed to cover such future acts." *Id.* at 1365. Luitpold's ANDA does not infringe the Patents-in-Suit as its formulation falls outside the independent claims of the '876 and '657 patents [redacted] *See* ECF Nos. 41-2–41-4. Because Par's claim is entirely premised on speculation that future, uncertain amendments to Luitpold's ANDA will infringe Par's patents, and there is no question that the drug specified in Luitpold's ANDA does not infringe the Patents-in-Suit, judgment in favor of Luitpold is warranted.[4]

[4] Federal law and FDA regulations reinforce the conclusion that judgment on the current ANDA formulation is warranted and future formulations are not ripe for dispute at this time. Luitpold is bound by the specifications of its ANDA and upon approval can only produce a drug that does not literally infringe the Patents-in-Suit. *See Bayer AG*, 212 F.3d at 1250. If Luitpold changes its ANDA, it must file the changes with the FDA, *see* 21 C.F.R. §§ 314.97, 314.70(a), and if the changes are to the drug's specification, Luitpold must obtain approval for the changes before they can be made, *see* 21 C.F.R. §§ 314.97, 314.70(b)(1). As Luitpold acknowledges in its Reply Brief, these changes would require it to file a second Paragraph IV certification, giving Par the opportunity to commence a separate infringement suit. ECF No. 71 at 12; *see also Ben Venue Labs, Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 580–81 (D.N.J. 2001). Finally, if Luitpold introduces a drug into interstate commerce without complying with the approval requirements of 21 U.S.C. § 355, it is subject to various additional penalties, *see* 21 U.S.C. § 331(d), including an injunction, *see* 21 U.S.C. § 332(a), criminal sanctions, *see* 21 U.S.C. § 333(a), seizure of the unapproved drug, *see* 21 U.S.C. § 334(a)(1), and debarment of its corporation and individual officials from submitting or assisting in the submission of an ANDA in the future, *see* 21 U.S.C. § 335a. Par is therefore protected from the future infringement it fears.

II. Luitpold's First Counterclaim

Luitpold's First Counterclaim seeks a declaratory judgment that the actual proposed formulation in its ANDA does not infringe the Patents-in-Suit. ECF No. 13 ¶¶ 114–15. Par admits that the drug formulation asserted in Luitpold's operative ANDA does not infringe its patents. ECF No. 64 at 20 ("Luitpold's Old Formulation[5] [is] not in dispute because Luitpold [will] have to change that formulation."). Though Par argues that the Court must deny Luitpold's motion so that it can develop the factual record as to what the FDA will require to approve Luitpold's ANDA, for the reasons stated above, claims related to unspecified new formulations in speculative ANDAs are not ripe for adjudication. It follows that judgment is granted in favor of Luitpold on its First Counterclaim.[6]

CONCLUSION

Defendants' motion for judgment on the pleadings is granted. An appropriate order follows.

DATE: 1 Dec 2017

William H. Walls
Senior United States District Court Judge

[5] Par's opposition brief defines Old Formulation as Luitpold's present ANDA formulation. ECF No. 64 at 1.
[6] Luitpold's Motion for Judgment on the Pleadings seeks "the entry of an Order under Luitpold's First and Second Counterclaims that Luitpold's ANDA formulation does not and will not infringe U.S. Patent Nos. 9,119,876 and 9,295,657." ECF No. 41 at 1. Counterclaim One seeks a declaratory judgment of non-infringement as to both Patents-in-Suit, ECF No. 13 ¶¶ 114–15, but Counterclaim Two seeks a declaratory judgment that the Patents-in-Suit are invalid. *Id.* ¶¶ 116–18. The invalidity of the Patents-in-Suit was not briefed and the Court does not address Counterclaim Two at this time.