IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC	:	
	:	
Plaintiff,	:	
	:	
v.	:	C. A. No. 18-960-LPS-CJB
	:	
INTERNATIONAL MEDICATION SYSTEMS, LIMITED,	:	
	:	
	:	
Defendant,	:	

Stephen B. Brauerman, BAYARD, P.A., Wilmington, DE

Stefan V. Stein, Cole Carlson, and William Stein, GrayRobinson, P.A., Tampa, FL

Attorneys for Plaintiff

Melanie K. Sharp, James L. Higgins, and Michelle M. Ovanesian, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE

Douglas H. Carsten, Joshua A. Mack, WILSON SONSINI GOODRICH & ROSATI, San Diego, CA

Attorneys for Defendant

MEMORANDUM OPINION

March 31, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiff Belcher Pharmaceuticals, LLC ("Plaintiff" or "Belcher") asserts in its June 28, 2018 Complaint that Defendant International Medication Systems, LLC ("Defendant" or "IMS") infringes Plaintiff's U.S. Patent No. 9,283,197 ("the '197 patent"). (D.I. 1) ("Complaint" or "Compl.") Defendant "filed a NDA [New Drug Application] under 21 U.S.C. § 355(b)(2) of the Hatch-Waxman Act (making it a '505(b)(2) application'), for 0.1 mg/mL epinephrine injections ('IMS's NDA')," which Plaintiff asserts is an artificial act of infringement under 35 U.S.C. § 271(e)(2). (D.I. 9 at 2) Pending before the Court is Defendant's motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). (D.I. 8) After considering the parties' briefing and supplemental briefing (D.I. 9, 15, 19, 27, 28), the Court will deny Defendant's motion.

I. BACKGROUND

U.S. Patent Application No. 14/460,845 was filed on August 15, 2014, and the '197 patent issued as a result on March 15, 2016. (D.I. 1-1 at 1) The '197 patent was issued to Jugal K. Taneja and assigned to Plaintiff. (D.I. 15 at 4) Of the three independent and four dependent claims, only Claims 6 and 7 are asserted, which the Complaint alleges are infringed by Defendant's NDA product.

IMS filed its paper NDA in February, 2018 for 0.1 mg/mL epinephrine injections. (D.I. 9 at 2) This filing was made pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), specifically 21 U.S.C. § 355(b)(2), which covers "drug[s] for which the investigations . . . relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were

conducted."[1] Pursuant to § 355(b)(2)(A)(iv) ("Paragraph IV"), a § 355(b)(2) applicant must submit to the U.S. Food and Drug Administration ("FDA") "a certification, in the opinion of the applicant . . . with respect to each patent which claims the drug for which such investigations were conducted . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Defendant submitted a Paragraph IV certification with respect to the '197 patent, a patent which is listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). (D.I. 9 at 2)

Plaintiff alleges Defendant's NDA filing was an act of infringement under 21 U.S.C. § 271(e)(2)(A), which provides: "It shall be an act of infringement to submit an application under . . . section 505(b)(2) of [the Food, Drug, and Cosmetic Act] for a drug claimed in a patent or the use of which is claimed in a patent." Defendant sent notice of its Paragraph IV certification to Plaintiff on May 16, 2018, which opened a 45-day window in which Plaintiff could, by filing suit, obtain an automatic 30-month stay of FDA approval of Defendant's NDA. *See* 21 C.F.R. § 314.107(b)(3)(i)(A). The parties negotiated an offer of confidential access ("OCA") by Plaintiff to IMS's NDA, pursuant to which Defendant produced a copy of its entire NDA submission to Plaintiff on June 7, 2018, three weeks prior to the 45-day deadline. (D.I. 9 at 3) Plaintiff filed its Complaint on June 28, 2018.

[1] This procedure, under § 355(b), is similar to but distinct from that governing Abbreviated New Drug Applications ("ANDA"), which are governed by 21 U.S.C. § 355(j). Drugs for which approval is sought via a "paper NDA" pursuant to § 355(b), as here, require additional safety and efficacy clinical studies. By contrast, drugs for which approval is sought via an ANDA pursuant to § 355(j) require a demonstration only of bioequivalence.

II. LEGAL STANDARDS

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of a complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

A well-pleaded complaint must contain more than mere labels and conclusions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff must plead facts sufficient to show that a claim has substantive plausibility. *See Johnson v. City of Shelby*, 135 S. Ct. 346, 347 (2014). A complaint may not be dismissed, however, for imperfect statements of the legal theory supporting the claim asserted. *See id.* at 346.

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). A claim is facially plausible "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 678. At bottom, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary

element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

III. DISCUSSION

The pertinent allegations of infringement in the Complaint are as follows:

> 17. IMS submitted NDA No. 21163 to the Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, or sale of the [IMS] NDA Product.
>
> 18. By letter dated May 16, 2018 ("Notice Letter"), . . . IMS notified Belcher that IMS had submitted NDA No. 211363 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the NDA Product before the expiration of the '197 Patent.
>
> 19. In the Notice Letter, Defendant notified Plaintiff that, as a part of IMS's NDA, they had filed a certification . . . ("Paragraph IV Certification") with respect to the '197 Patent.
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> 20. The manufacture of IMS's NDA Product is covered by Claims 6 and 7 of the '197 Patent.
>
> . . .
>
> 23. By submitting NDA No. 211363 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the NDA Product throughout the United States prior to the expiration of the '197 Patent, Defendant committed an act of infringement of the '197 Patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

(Compl.)[2]

Defendant argues that "Belcher's Complaint is fatally flawed" because it "merely states legal conclusions without alleging any facts that could make a plausible case for patent infringement against IMS." (D.I. 9 at 3) Defendant contends that the mere allegation that "[t]he manufacture of IMS's NDA Product is covered by Claims 6 and 7 of the '197 Patent" (Compl. at ¶ 20) is conclusory and provides insufficient notice of Plaintiff's claim. According to IMS, "'There needs to be some facts alleged that articulate why it is plausible that the other party's product infringes that patent claim -- not just the patentee asserting, in conclusory fashion, that it is so.'" (D.I. 9 at 6) (quoting *North Star Innovations, Inc. v. Micron Tech., Inc.*, 2017 WL 5501489, at *2 (D. Del. Nov. 16, 2017)) In Defendant's view, Plaintiff "fails to describe any facts regarding how IMS's NDA infringes the asserted claims." (*Id.* at 7) (citing *SIPCO, LLC v. Streetline, Inc.*, 230 F. Supp. 3d 351, 353 (D. Del. 2017)).

Underlying Defendant's contentions is the contention that Plaintiff's Complaint should be treated like any other complaint for patent infringement, and not given special treatment – even at the pleading stage – under § 271(e)(2). (*See* D.I. 9 at 7; D.I. 19 at 2, n.2) ("'Section 271(e)(2)(A) defines the filing of an ANDA as an act of infringement, but it does not alter the underlying patent infringement analysis.'") (quoting *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012)) In essence, Defendant's position is that while the Hatch-Waxman Act creates subject matter jurisdiction over the "artificial act of infringement" of filing a paper NDA (or ANDA), actual infringement still must be pled with particularity to survive a Rule 12(b)(6) motion. Further, meeting this requirement means complying with the "mandate[]"

[2] As Plaintiff points out, "none of the allegations are made based on 'information and belief.'" (D.I. 27 at 3) While the Complaint does not make this clear, evidently Plaintiff intends to allege both literal infringement and infringement under the doctrine of equivalents. (*See id.*)

of the Supreme Court in *Iqbal* and *Twombly* to include in a complaint "'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" (D.I. 19 at 3) (quoting *Iqbal*, 556 U.S. at 678) To Defendant, "Supreme Court precedent is clear, and given Belcher's full access to all the documents it needs to allege infringement, Belcher's fact-free Complaint should be dismissed." (*Id.* at 1)

Plaintiff responds that only the asserted claims and the artificial act of infringement need be pled, "because 'Congress defined infringement in a special way to create an 'artificial' act of infringement under § 271(e)(2): submitting an ANDA.'" (D.I. 15 at 5-6) (quoting *Bristol-Myers Squibb Company v. Mylan Pharm. Inc.*, 2017 WL 3980155, at *10 (D. Del. Sept. 11, 2017)) Plaintiff contends it provided Defendant with fair and sufficient notice of infringement by describing Defendant's NDA submission and alleging that the NDA product will infringe Claims 6 and 7. (*Id.* at 6) The Complaint also references Plaintiff's pre-Complaint review of Defendant's NDA and Paragraph IV notice letter, from which it may be reasonably inferred that Plaintiff's holds a good faith belief in its ability to prove actual infringement. (*Id.*) Fundamentally, in the view of Plaintiff, given all of this exchange of information, "Defendant should be well aware of the basis of the Complaint." (*Id.*)

The Court agrees with Plaintiff. In the Court's view, both the language and the purpose of the Hatch-Waxman Act establish that a plaintiff in receipt of a paragraph IV certification providing notice of the filing of an ANDA (or, as here, a paper NDA)[3] relating to one of the

[3] Defendant argues that its paper NDA should be treated differently than a typical ANDA application. "Belcher fails to take into account that IMS filed a 505(b)(2) application, which is an NDA not an ANDA. Unlike an ANDA [under 505(j)], a 505(b)(2) application is necessarily different by statute, and it requires additional clinical studies to confirm that the product is safe and effective." (D.I. 19 at 4) The Court disagrees, concluding instead that the same pleading standard applies to both 505(j) and 505(b)(2) suits. Both are statutorily-created artificial acts of infringement, and both serve the same purpose of facilitating the speedy and cost-effective

plaintiff's Orange Book-listed patents may state a claim for infringement by alleging its interest in the patent, its receipt of the paragraph IV certification, the filing of the ANDA or NDA, and its contention that the defendant's proposed product will infringe. Under the Act, filing an ANDA or paper NDA constitutes an artificial but justiciable act of patent infringement. *See* 21 U.S.C. § 271(e)(2)(A); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("Thus, § 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity."); *Bristol-Myers Squibb*, 2017 WL 3980155, at *7 ("What, then, does Hatch–Waxman define as an act of infringement? The submission of an ANDA to the FDA, if the ANDA seeks approval before the expiration of a patent.").

As the Supreme Court has described, the Act created a unique action to facilitate the speedy and cost-effective entrance of generic drug to the market:

> The function of the paragraphs in question is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications. As an additional means of eliminating the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly, § 101 of the 1984 Act amended § 505 of the FDCA, 21 U.S.C. § 355, to authorize abbreviated new drug applications (ANDA's), which would substantially shorten the time and effort needed to obtain marketing approval. . . . In addition, § 103 of the 1984 Act amended § 505(b) of the FDCA, § 355(b), to permit submission of a so-called paper new drug application (paper NDA), an application that relies on published literature to satisfy the requirement of animal and human studies demonstrating safety and effectiveness. *See* § 355(b)(2). Like ANDA's, paper NDA's permit an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug.

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market-entry of a generic drug, while at the same time protecting valuable patent rights, by providing a mechanism for relatively expeditious pre-launch resolution of patent disputes.

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990).

This purpose is advanced by allowing plaintiff's in this type of case to rely on the sufficiency of pleading the artificial act of infringement, allowing the particularized theory of infringement to be developed through discovery and other phases of the case. A plaintiff in receipt of a paragraph IV certification has an extremely limited time, just 45 days, in which to decide whether (and, if so, where and against whom), to file suit, if it is to obtain the benefit of the automatic stay of FDA approval.[4] It will not always be reasonable to expect a plaintiff in such a position to develop the level of specificity Defendant asks the Court to impose. Relatedly, although in this case the parties negotiated Plaintiff's pre-Complaint confidential access to Defendant's NDA filing, such an accommodation will not always occur, and it is not a requirement of the Hatch-Waxman Act. For this reason, as well, Plaintiff may not know much about the details of a proposed product and may, again, not be able to plead infringement with specificity. Nor, of course, may the plaintiff go out and purchase the accused product and test it for itself since, in these cases, the product does not yet actually exist (and if samples have been created, they cannot, by law, be available for purchase). Finally, because the defendant in these cases actually triggers the litigation – by giving notice to the plaintiff that defendant has applied for regulatory approval of a drug that is similar to a drug that the plaintiff listed in the Orange Book as being covered by the asserted patent – the defendant already knows at least some of the reason why the plaintiff may plausibly believe that its patent also covers defendant's proposed

[4] Almost without exception, the NDA or ANDA filings are quite lengthy – here, Defendant's ANDA was more than 4,000 pages. (*See* D.I. 15 at 6) Further, sometimes, as happened here, a sizeable portion of the 45-day window in which to file suit is devoted to attempting to negotiate the terms of an OCA. Additionally, it is not uncommon for multiple ANDAs to be filed on the same patent at the same time, putting a plaintiff in the position of having to make decisions about launching multiple litigations, all within the same (or substantially the same) 45-day window.

product. *See generally Bristol-Myers Squibb*, 2017 WL 3980155, at *7-8 ("Congress created this particularized framework in order to trigger expedited patent litigation between branded and generic drug manufacturers before the generic drug is launched into the market to compete with the branded drug. . . . Thus, an applicant submits an ANDA with full knowledge of the effect of its application and with the objective of marketing its drug product in the event that the application is approved."); *Par Pharm., Inc. v. Hospira, Inc.*, 2018 WL 3343238, at *4 (D. Del. May 11, 2018) ("[T]he court must accept as true the allegations of the complaint, which state that the Hospira ANDA Product meets each limitation of the patents-in-suit.").

In the Court's view, Plaintiff's pleading here complies with the requirements of *Iqbal* and *Twombly* as applied to the unique context of a Hatch-Waxman claim for patent infringement. In context, the Complaint ***does*** "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

This holding is not in conflict with "the patentee's burden of proving ultimate infringement," which "is not met by the filing of the ANDA" and "is the same as it is in any other infringement suit." *Glaxo, Inc.*, 110 F.3d at 1569-70. The parties have not drawn the Court's attention to any case (nor has the Court itself found one) that says that what is required for ***pleading*** infringement in the Hatch-Waxman context is also the same as in any other infringement suit. Hence, Plaintiff's allegations that Defendant committed an artificial act of infringement by filing its paper NDA, and that Defendant's proposed drug product will infringe Claims 6 and 7 of the'197 patent (an Orange Book-listed patent), are sufficient to survive Defendant's motion to dismiss.

Finally, the Court is unpersuaded by Defendant's suggestion that the reason for the lack of specificity in Plaintiff's Complaint – and the futility that would mar any amended complaint

the Court might contemplate permitting Plaintiff to file – is that Plaintiff knows and understands that "any theory of infringement would necessarily invalidate the '197 patent." (D.I. 9 at 1) Defendant asserts:

> If IMS's manufacture and sale of injectable epinephrine formulations would infringe the patent, then what Belcher claims to be its invention is simply not new. Any arguments that Belcher makes regarding how IMS's NDA products infringe the '197 patent would actually be admissions that the '197 patent is invalid in view of IMS's manufacture and sale of injectable epinephrine formulations since at least 2010, long before the 2014 patent filing date.

(*Id.*) The Court, of course, is not in a position to evaluate the merits of Defendant's invalidity defense at the motion to dismiss stage. As Plaintiff explains, many of the premises of Defendant's argument implicate factual disputes. For example:

> Defendant's 2010 epinephrine formulation documentation . . . has not been shown to be the formulation used in Defendant's NDA Product because Defendant's only evidence proffering such arguments includes a blank batch record as well as a package insert that does not show the manufacturing details of the formulation . . . .
>
> . . . [Nor] has [it] been shown that the 2010 Formulation was the subject of a commercial offer for sale or that it was ready for patenting.
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> . . .
>
> Lastly, Defendant has not shown by clear and convincing evidence that the 2010 Formulation would render the '197 Patent invalid as obvious [for reasons including secondary considerations of nonobviousness].

(D.I. 15 at 2-3)[5] Moreover, application of the Court's claim construction decision from a related case, *see Belcher Pharm., LLC v. Hospira Inc.*, C.A. No. 17-775-LPS D.I. 96, 97 (D. Del. Sept. 28, 2018), to the infringement and invalidity contentions here also presents factual disputes.

More fundamentally, the Court presumes (as it is permitted to do, on the record before it) that Plaintiff's counsel are well aware of their obligations, including under Federal Rule of Civil Procedure 11, and therefore presumes Plaintiff has a non-frivolous, good faith basis for its allegation of infringement. Should this turn out not to be correct, Defendant will have an opportunity to seek appropriate relief. But dismissal of the Complaint on the basis of the pending motion is not warranted.[6]

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[5] The defenses asserted here by IMS are different than those asserted in the cases to which IMS compares the instant case. (*See* D.I. 9 at 12) In *Amgen Inc. v. Coherus Biosciences Inc.*, 2018 WL 1517689 (D. Del. 2018) ("*Amgen*"), and *Cumberland Pharmaceuticals Inc. v. Sagent Agila LLC*, 2013 WL 5913742 (D. Del. 2013) ("*Cumberland*"), the Court granted motions to dismiss infringement claims brought pursuant to the Hatch-Waxman Act where it was clear from the face of the complaint and the other materials the Court was permitted to consider that, respectively, the plaintiff's claims lacked merit based on prosecution history estoppel, *see Amgen* at *4 & n.5 ("[T]he facts in the prosecution history here are undisputed. . . . [T]he Court has sufficient context in this case to make a decision of law that prosecution history estoppel applies. . . . [O]nly a legal dispute [is presented] that, in the Court's view, turns on the clear and unambiguous prosecution history."), or based on application of a claim construction the Court viewed as not reasonably disputable, *see Cumberland* at *2 (noting plaintiff admitted "EDTA is a chelating agent and that Sargent's product includes EDTA" and holding: "No claim construction is necessary in order to determine that [the claim term] 'free from a chelating agent' means that a claimed composition may not include a chelating agent"). The situation presented by the instant case, in which Defendants' asserted defenses (i.e., anticipation, obviousness) appear to involve disputed facts, is quite different.

[6] Nor does the Court find that the most reasonable exercise of its discretion is to convert the motion to dismiss into a summary judgment motion, as Defendant asks the Court to do as an alternative to granting its motion. (*See, e.g.*, D.I. 28 at 6) Should either party wish the Court to consider a summary judgment motion (early, or at the conclusion of all fact and expert discovery), it should include such a proposal in the forthcoming proposed scheduling order the Court will be directing the parties to submit.

IV. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' motion to dismiss. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC	:	
	:	
Plaintiff,	:	
	:	
v.	:	C. A. No. 18-960-LPS-CJB
	:	
INTERNATIONAL MEDICATION SYSTEMS, LIMITED,	:	
	:	
Defendant,	:	

ORDER

At Wilmington this **31st** day of **March, 2019**, consistent with the Memorandum Opinion issued this date, **IT IS HEREBY ORDERED** that Defendant International Medication Systems Limited's motion to dismiss for failure to state a claim (D.I. 8) is **DENIED**.

The parties shall meet and confer and, no later than April 8, 2019, submit a proposed scheduling order.

UNITED STATES DISTRICT COURT