IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING INTERNATIONAL CENTER S.A., and FERRING B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-894-RGA-MPT
NOVEL LABORATORIES, INC. and GAVIS PHARMACEUTICALS,LLC.,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

This matter arises from plaintiffs Ferring Pharmaceuticals Inc., Ferring International Center S.A., and Ferring B. V.'s (collectively, "Plaintiffs") complaint against defendants Novel Laboratories, Inc. and Gavis Pharmaceuticals, LLC (collectively, "Defendants") filed on July 5, 2017. The complaint alleges that Novel infringed or will infringe Plaintiffs' patents, by filing Abbreviated New Drug Application No. 210306 (the "ANDA") seeking approval to commercially manufacture, use, or sell a generic version of Plaintiffs' Prepopik® prior to the expiration of certain of their patents. On August 15, 2017, Defendants filed a motion to dismiss pursuant to FED. R. CIV. P. 12(c) to those portions of Counts I and II of the Complaint that seek declaratory judgment,[1] and the entirety of Count III[2] for lack of subject matter jurisdiction over the Declaratory Judgment

[1] D.I.16.
[2] *Id.*

Act claims set forth therein.

Pending before the court is Novel's motion to dismiss. This Report and Recommendation addresses whether Plaintiffs sufficiently established subject matter jurisdiction, specifically, whether there is an actual immediate case or controversy to be decided, and whether there is a dispute of material fact. For the reasons stated below, it is recommended that the Defendants' motion be denied with respect to Counts I, II, and III.

II. BACKGROUND

A. Parties

Plaintiff Ferring Pharmaceuticals Inc. is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054. Plaintiff Ferring International Center, S.A. is a Swiss private limited liability company having its offices at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland. Plaintiff Ferring B.V. is a Dutch private limited liability company having its offices at Polaris Avenue 144, Hoofddorp, 2132 JX, Netherlands.

Defendant Novel Laboratories, Inc. is a private Delaware corporation with its principal place of business at 400 Campus Drive, Somerset, New Jersey 08873. Defendant Gavis Pharmaceuticals, LLC is a private Delaware limited liability company also with its principal place of business at 400 Campus Drive, Somerset, New Jersey 08873.

B. Patents-in-Suit

The parties agree that Plaintiffs are the owner of the following United States

Patents: 8,450,338 ("the '338 patent"), 8,481,083 ("the '083 patent") and 9,669,110 ("the '110 patent").[3] The parties further agree that in accordance with 21 U.S.C. §355(b)(1) and 21 C.F.R. § 314.53, the '338 patent and the '083 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book").[4] The parties also agree that the '110 patent is not an Orange Book patent for Prepopik®.[5]

C. Background

Defendants sent a letter to Plaintiffs on May 19, 2017 notifying that their ANDA was filed with the Food and Drug Administration ("FDA") seeking regulatory approval to commercially manufacture, use, or sell a generic version of Plaintiffs' Prepopik® product prior to the expiration of the '338 and the '083 patents, both listed in the Orange Book for Prepopik®.[6] The letter provided information to Plaintiffs consistent with the Federal Food, Drug and Cosmetic Act and 21 C.F.R §§314.94 and 314.95, and certified that, in Defendants' opinion, the '338 and '083 patents are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Defendants' ANDA Product.[7]

On July 5, 2017, Plaintiffs filed their action for infringement of the '338 patent, the '083 patent, and the '110 patent.[8] Counts I and II assert respective infringement of the '338 patent and the '083 patent, and Count III asserts infringement of the '110 patent.[9]

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[3] D.I.1 at 5.
[4] *Id*. at 6.
[5] D.I. 17 at 5, D.I. 25 at 5.
[6] D.I. 1 at 6.
[7] *Id.*
[8] D.I. 1.
[9] D.I. 1 at 7-9.

In Counts I and II, Plaintiffs allege that Defendants' ANDA infringes on the Orange Book patents, and once the ANDA is approved, Defendants will infringe those patents.[10] Count I, in part, seeks a declaratory judgment pursuant to 35 U.S.C. § 271(g) that, once approved, the process used to make Defendants' ANDA product will constitute infringement of the process claims in the '338 patent.[11] Count III refers in its entirety to declaratory judgment of infringement of the '110 patent.[12] Since the '110 patent is for an off-label dosing instruction of Prepopik®, it is not listed in the Orange Book.[13] Plaintiffs allege that the dosing instructions for Defendants' ANDA drug overlaps with those of the '110 patent, thereby inducing infringement of this patent.[14] Plaintiffs further allege that Defendants knew of the '110 patent and, by marketing their ANDA product with an FDA approved product insert, will actively and intentionally aid, abet, encourage, participate and induce others to perform acts that Defendants know will directly infringe one or more claims of the '110 patent.[15] Plaintiffs claim there is an actual case or controversy between the parties regarding (1) whether the process to make Defendants' ANDA product infringes the '338 patent, (2) whether the use of Defendants' ANDA product in accordance with FDA approved product insert will infringe the '110 patent, and (3) whether Defendants will induce others to infringe the '110 patent.[16]

On July 27, 2017, Defendants answered the Complaint, denying Plaintiffs'

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[10] *Id.*
[11] D.I. 1 at 8.
[12] D.I. 1 at 9-10.
[13] D.I. 25 at 5.
[14] D.I. 25 at 10.
[15] D.I. 1 at 9-10.
[16] D.I. 1 at 7, 10.

claims, and asserting an affirmative defense for lack of subject matter jurisdiction over the 35 U.S.C. §§271(a), (b), and (g) infringement claims.[17] Defendants also raised counterclaims for declaratory judgment of invalidity and/or non-infringement of the '338 and the '083 patents.[18]

On August 15, 2017, Defendants brought the instant motion to dismiss pursuant to Fed. R. Civ. P. 12(c).[19] Defendants contend that this Court lacks subject matter jurisdiction over the claims.[20]

On August 17, 2017, Plaintiffs filed their Answer to the Counterclaims.[21] On August, 21, 2017, the Court entered a scheduling order, setting a trial date of February 25, 2019.[22] Discovery, to date, has been limited.

III. STANDARD OF REVIEW

A. Motion For Judgment on the Pleadings

Pursuant to Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "after pleadings are closed—but early enough not to delay trial." When evaluating a motion for judgment on the pleadings, the Court must accept all factual allegations in a complaint as true and view them in the light most favorable to the non-moving party.[23] However, the court is "not compelled to accept unsupported conclusions and unwarranted inferences, or a legal conclusion couched as a factual

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[17] D.I. 8 at 10-11.
[18] D.I. 8 at 12.
[19] D.I. 16.
[20] *Id.*
[21] D.I. 19.
[22] D.I. 21.
[23] See *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008); *see also Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000).

allegation."[24] A Rule 12(c) motion will not be granted "unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law."[25] This is the same standard as a Rule 12(b)(6) motion to dismiss.[26] "The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference."[27]

B. Subject Matter Jurisdiction

When jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence.[28] Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially, that is, based on the legal sufficiency of the claim, or factually, based on the sufficiency of jurisdictional facts.[29] Where there is a facial attack on jurisdiction, the court must accept as true the allegations contained in the complaint.[30] Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.'"[31]

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[24] *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007).

[25] *Rosenau*, 539 F.3d at 221.

[26] See *Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir.1991).

[27] *Venetec Int'l, Inc. v. Nexus Med., LLC,* 541 F. Supp.2d 612, 617 (D. Del. 2008); *see also In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1426 (3d Cir.1997). (explaining that any documents integral to pleadings may be considered in connection with Rule 12(c) motion); *buySAFE, Inc. v. Google Inc.*, 964 F. Supp.2d 331, 334 (D. Del. 2013).

[28] *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000).

[29] *Moore's Federal Practice - Civil,* § 12.30[4] (2018).

[30] *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

[31] *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

When there is a factual attack, the court is not "confine[d] to the allegations in the . . . complaint, but [may] consider affidavits, depositions and testimony to resolve factual issues bearing on jurisdiction."[32] Under this circumstance, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of the jurisdictional claims."[33]

In addition, the district court is limited in its discretion to dismiss the case.[34] When there is an actual controversy and a declaratory judgment would decide the legal relations between the parties, a declaratory judgment claim is usually not subject to dismissal.[35] Moreover, if the court decides to dismiss an actual controversy, then it must provide support for the dismissal.[36]

C. Declaratory Judgment

"The Declaratory Judgment Act creates a remedy by which federal courts 'may declare the rights and other legal relations of any interested party seeking such declaration' when there is a 'case of actual controversy.'"[37] Prior to *MedImmune, Inc. v. Genentech, Inc.*,[38] declaratory judgment actions required "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity

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[32] *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *see also Mortenson v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977).

[33] *Mortenson*, 549 F.3d at 891.

[34] *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995).

[35] *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993).

[36] *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005).

[37] *Principal Life Ins. Co. v. Lawrence Rucker 2007 Ins. Trust*, 674 F. Supp. 2d 562, 565 (D. Del. 2009) (quoting 28 U.S.C. § 2201).

[38] 549 U.S. 118 (2007).

which could constitute infringement or concrete steps taken with the intent to conduct such activity."[39] In *MedImmune*, however, the Supreme Court rejected the reasonable apprehension of suit test as the sole way to bring a declaratory judgment action.[40] The Court held that jurisdiction over a declaratory judgment action requires:

> [T]he dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it 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. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.[41]

The difference between a hypothetical and actual controversy is difficult to determine, and, therefore, the court must utilize a fact-based analysis.[42] To satisfy immediacy and reality, a plaintiff must show (1) an injury-in-fact (2) that is "fairly traceable" to defendant's conduct, and (3) redressable.[43] An adverse legal interest requires the parties to have a dispute over legal rights, i.e., "an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring."[44] Without adverse legal rights, an adverse economic interest alone is an insufficient basis

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[39] *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

[40] *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008) (citing *Caraco Pharms. Labs. Ltd. v. Forest Labs.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008)).

[41] *MedImmune*, 549 U.S. at 127 (internal quotations omitted) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)).

[42] *Prasco*, 537 F.3d at 1336 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) and *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008)).

[43] *Id*. at 1338.

[44] *Arris Group, Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1374-75 (Fed. Cir. 2011).

for a declaratory judgment claim.[45]

IV. ANALYSIS

A. Request for Declaratory Judgment Pursuant to Counts I and II of The Complaint

Defendants assert that the declaratory judgment claims under 35 U.S.C. §§271 (a), (b), and (g) with respect to infringement of the '338 and '083 patents lack sufficient immediacy and reality to warrant subject matter jurisdiction, as they are based on FDA approval of the ANDA and Defendants' intention to market a generic drug pursuant to the approved ANDA, both of which, Defendants claim, are uncertain to occur.[46] Plaintiffs assert that Defendants do not set forth any specific facts indicating that FDA approval or future generic product launch is speculative,[47] and Defendants have made, and will continue to make substantial preparation to import and sell their ANDA product in the United States prior to the expiration of the '338 and '083 patents.[48] Further, Plaintiffs contend both Counts I and II fall under 35 U.S.C. § 271(e)(2), with 35 U.S.C. § 271(a) providing the background and underlying basis for the infringement analysis; thus Defendants' motion with respect to 35 U.S.C. § 271 (a) is moot.

As Plaintiffs suggest, Defendant offers no facts about uncertainty of either its ANDA approval or their intentions to manufacture, import, market and sell a generic version of Prepopik® pursuant to the approved ANDA and prior to the expiration of the '338 and '083 patents. Rather, Defendants assert that no declaratory judgment

[45] *Id*.
[46] D.I. 17 at 8-9.
[47] D.I. 25 at 7.
[48] D.I. 1 at 8.

jurisdiction can exist prior to FDA approval of an ANDA due to the uncertainty of approval.[49] Plaintiffs have adequately demonstrated the contrary by pointing out that this court has already exercised jurisdiction over a claim for infringement of the '338 AND '083 patents in another case.[50] In that case, which went to trial, subject matter jurisdiction was not specifically analyzed, but there does not appear to be challenges to it from any party.[51]

Further, Defendants effectively concede subject matter jurisdiction in their counterclaim filed in conjunction with their answer to the complaint on July 27, 2017. Defendants allege:

> [T]here is an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court between [Defendants] and [Plaintiffs] as to whether [Defendants'] ANDA [p]roduct would infringe any or all of the claims of the '338 and '083 patents as to whether the claims of the '338 and '083 patents are invalid.[52]

Therefore, with respect to Counts I and II, Plaintiffs have sufficiently established this court's subject matter jurisdiction.

B. Request for Declaratory Judgment Pursuant to Count III of The Complaint

Defendants assert that Count III, which seeks a declaratory judgment that Defendants' ANDA products may indirectly infringe the '110 patent, not only looks far into the future, but also impermissibly speculates about prescribing practices that

[49] D.I. 17 at 8-9.

[50] D.I. 25 at 3, *Ferring Pharm., Inc. v. Par Pharm., Inc.,* 267 F. Supp 3d 501 (D. Del. 2017). (No. 15-173-RGA).

[51] *Ferring Pharm., Inc. v. Par Pharm., Inc.,* 267 F. Supp 3d 501 (D. Del. 2017). *No. 15-173-RGA.*

[52] D.I. 8 at 14.

cannot possibly be known today.[53] Further, Defendants assert that Count III is an end run around the protections of the Hatch-Waxman Act, and allowing Plaintiffs to proceed would eviscerate protections granted by the statutory scheme.[54]

As noted, the '110 patent is not listed in the Orange Book for Prepopik®.[55] The '110 patent contains off-label dosing instructions for Prepopik®.[56] These instructions detail a split dosing regimen.[57] Under such regimen, the patient is to take one dose the evening before the colonoscopy, and a second dose about three hours to about 1 hour before the colonoscopy procedure.[58] Defendants' ANDA product proposed labeling, specifically the "Dosing and Administration" section, instructs the patient to take the first dose the evening before the colonoscopy, and the second dose during the morning prior to the colonoscopy, with no specific time limitations.[59] The ANDA product's Full Prescribing Instructions provide more detail about the second dose. These instructions, in the "Dosing and Administration" section, indicate the second dose should be taken approximately five hours before the colonoscopy.[60]

Plaintiffs assert the language in Defendants' proposed package labeling may be read to instruct an infringing use of the '110 patent, since the broad instructions, without a timing limitation for the second dose, may reasonably be relied on by healthcare providers and patients because the proposed label is featured more

[53] D.I. 17 at 11.
[54] *Id*. at 12.
[55] D.I. 17 at 5; D.I. 25 at 5.
[56] D.I. 25 at 5.
[57] *Id.*
[58] *Id.*
[59] D.I. 17 at Appendix 3, p.2.
[60] *Id*. at Appendix 3, pp.7-9.

prominently than dosing time limitations in the "Full Prescribing Information" instructions.[61] As such, Plaintiffs assert that users of the ANDA product could reasonably take the second dose within the three hours to 1 hour before the colonoscopy, and in doing so, infringe the '110 patent.[62]

Here, material facts are disputed by the parties. There is a substantial controversy between the parties as to whether the ANDA product's proposed package labeling would cause users to take the product within the time frame in the '110 patent. Defendants claim the ANDA product dosing instructions as a whole (both the proposed labeling instructions and the Full Prescribing Information instructions), steer clear of the '110 patent instructions. Plaintiffs claim that the ANDA products' proposed labeling instructions are featured more prominently than the Full Prescribing Information instructions, and may reasonably cause users to follow only the proposed labeling instructions, with the result that some users will take the ANDA drug during the time frame protected by the '110 patent. Declaratory judgment, in this instance, would affect the legal relations of the parties. Since an issue of material fact exists, Count III is not subject to dismissal at this time.

Therefore, with respect to Count III, Plaintiffs sufficiently established this court's subject matter jurisdiction.

V. RECOMMENDATION DISPOSITION

Consistent with the findings herein, it is recommended that:

Defendants' motion for judgment on the pleadings for lack of subject matter

[61] D.I. 25 at 17.
[62] *Id.*

jurisdiction (D.I. 16) be denied with respects to Counts I, II and III.

This Report and Recommendation is filed pursuant to 28 U.S.C. §636(b)(1)(B), FED. R. CIV. P. 72(b)(1), and D.Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served a copy of this Report and Recommendation.[63] These objections and response to the objections are limited to ten (10) pages each.

The parties are directed to the Court's standing Order in Non-*Pro Se* matters for Objections Filed under FED. R. CIV. P. 72, dated October 9, 2013, a copy of which is available on the Court's website, www.ded.uscourts.gov.

Date: April 2, 2018

/s/ Mary Pat Thynge
Chief U.S. Magistrate Judge

[63]FED. R. CIV. P. 72(b)(2).