IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CLARUS THERAPEUTICS, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 15-1004-RGA-MPT
LIPOCINE INC.,	)	
Defendant	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

On November 2, 2015, Clarus Therapeutics, Inc. ("plaintiff") filed this action against Lipocine Inc. ("defendant"), alleging infringement of U.S. Patent No. 8,828,428 ("the '428 patent") arising from defendant's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA"). Plaintiff seeks declaratory judgment of defendant's willful and deliberate infringement of the '428 patent.

Pending before the court is defendant's motion to dismiss for lack of subject matter jurisdiction under FED. R. CIV. P. 12(b)(1) on the basis of no actual controversy and lack of ripeness. This Report and Recommendation addresses whether there is an actual case or controversy within the meaning of the Declaratory Judgment Act, 28 U.S.C. § 2201(a). For the reasons stated below, it is recommended that the defendant's motion be denied.

II. BACKGROUND

A. Parties

Plaintiff is a company organized and existing under the laws of the State of Delaware, with its principal place of business in Northbrook, Illinois.[1] Defendant is a company organized and existing under the laws of the State of Delaware, with a principal place of business in Salt Lake City, Utah.[2]

B. Patent-in-suit

Plaintiff asserts it currently holds and has held all rights to the patent-in-suit by assignment from inventors Robert E. Dudley and Panayiotis P. Constantinides since the issuance of the '428 patent from the United States Patent and Trademark Office ("USPTO") on September 9, 2014.[3] The '428 patent expires on April 14, 2026.[4] The '428 patent, entitled "Pharmaceutical Delivery Systems for Hydrophobic Drugs and Compositions Comprising Same" claims:

> an oral formulation comprising a testosterone ester (e.g., testosterone undecanoate), a lipophilic surfactant (i.e., a mono- or di-glyceride of a fatty acid), a hydrophilic surfactant, (i.e., Cremophor RH40 (polyoxyl 40 hydrogenated castor oil)) and optional cosolvents (i.e., about 200 to about 10,000 g/mol average molecular weight polyethylene glycol) that is free of ethanol.[5]

Defendant has several patent applications pending, including U.S. Patent Application No. 14/713,692 ("the '692 patent application").[6] In support of this patent

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[1] D.I. 1 at 1.
[2] *Id.* at 2.
[3] D.I. 14 at 1; D.I. 1, Ex. A.
[4] D.I. 1 at 7.
[5] D.I. 14 at 1-2.
[6] D.I. 8 at 3.

application, defendant filed a Suggestion of Interference related to plaintiff's '428 patent on May 15, 2015.[7] The USPTO accepted the Suggestion of Interference on December 4, 2015.[8] A Declaration of Interference was consequently issued between the '428 patent and the '692 patent application, in which defendant is the senior party.[9] The Interference concerns claims 1-4 of the '428 patent and claims 21 and 22 of the '692 patent application.[10] The Patent Trial and Appeal Board ("PTAB") will determine the priority of the patent claims and questions of patentability for the patent-in-suit "that could result in the cancellation of claims in the patent-in-suit."[11] Oral arguments for the first "motions phase" of the Interference will commence on September 9, 2016 and the Interference will likely conclude in the latter part of 2017.[12]

C. NDA Procedural Framework and Relevant NDAs

Drug companies must submit an NDA with the FDA prior to releasing and selling a new drug.[13] The FDA has 60 days after the application is submitted to conduct a preliminary review to determine whether the NDA is sufficiently complete to allow for a substantive review.[14] If the FDA finds the application acceptable, it decides whether the NDA needs standard or accelerated review.[15] In accordance with the Prescription Drug User Fee Act ("PDUFA"), the FDA relays its choice of review and acceptance of the

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[7] *Id.*
[8] *Id.*
[9] *Id.* at 3-4.
[10] D.I. 14 at 8.
[11] D.I. 8 at 4 (citing 35 U.S.C. § 135(a)).
[12] D.I. 14 at 8.
[13] D.I. 8 at 2.
[14] *Id.*
[15] *Id.*

application in what is commonly referred to as the "74-day letter."[16] Included in this 74-day letter is the "PDUFA goal date," which indicates the date by which the FDA must review, but not necessarily approve, an NDA.[17]

Plaintiff presently has an NDA before the FDA for its testosterone undecanoate product, Rextoro™ ("Rextoro").[18] This NDA was accepted by the FDA on January 3, 2014 and the FDA assigned a PDUFA goal date of November 3, 2014.[19] During Rextoro's FDA review period, both the FDA's Bone, Reproductive, and Urologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee found there was insufficient evidence to prove effectiveness of the drug and the overall benefit/risk profile of the product was not acceptable to support approval.[20] Plaintiff's NDA was pending before the FDA at the time its complaint was filed and has not been approved to date.[21]

Defendant filed an NDA with the FDA for its oral testosterone undecanoate formula, LPCN 1021 ("LPCN 1021" or "Lipocine's NDA product"), on August 27, 2015.[22] It received a 74-day letter from the FDA on November 12, 2015, which assigned a PDUFA goal date of June 28, 2016.[23] At the end of this review period, defendant may be informed as to whether its product has been approved.[24] Defendant's NDA is

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[16] *Id.*
[17] *Id.*
[18] *Id.* at 3.
[19] *Id.*
[20] *Id.* D.I. 15, Ex. 9.
[21] D.I. 8 at 3.
[22] *Id.* at 2.
[23] *Id.* at 2-3.
[24] *Id.* at 3.

currently pending and has not yet been approved.[25]

III. STANDARD OF REVIEW

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction under Rule 12(b)(1)

When jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence.[26] 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.[27] Where there is a facial attack on jurisdiction, the court must accept as true the allegations contained in the complaint. 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.'"[28]

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."[29] Under that 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."[30]

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[25] *Id.*

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

[27] *Moore's Federal Practice* § 12.30[4] (3d ed. 1997).

[28] *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)).

[29] *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).

[30] *Carpet Group*, 227 F.3d at 69 (quoting *Mortenson*, 549 F.3d at 891).

B. Declaratory Judgment Jurisdiction

"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.'"[31] "A party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving the facts alleged, 'under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'"[32] Prior to *MedImmune, Inc. v. Genentech, Inc.*, declaratory judgment actions required that there be "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 which could constitute infringement or concrete steps taken with the intent to conduct such activity."[33] However, "[t]he Supreme Court's opinion in *MedImmune* represents a rejection of [the] reasonable apprehension of suit test"[34] Jurisdiction over a declaratory judgment action requires:

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[31] *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).

[32] *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007) (quoting *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 771 (2007)).

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

[34] *SanDisk Corp. v. STMicroelectronics, Inc*., 480 F.3d 1372, 1380 (Fed. Cir. 2007), "We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the application of the principles of declaratory judgment jurisdiction to the facts and circumstances of each case. We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights." *Id.* at 1381.

> the 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.[35]

Evidence of marketing products or services and entering into licensing agreements supports an actual controversy as they are "directed toward making, selling or using subject to an infringement charge or making meaningful preparation for such activities."[36] In addition, "[i]f. . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction" at that time.[37] The burden is on the party claiming declaratory judgment jurisdiction to establish jurisdiction existed when the action was filed and has since continued.[38] Once the initial burden has been met, absent contrary facts, jurisdiction remains.[39]

C. Ripeness

"The conflict between the parties must be ripe for judicial intervention; it cannot be 'nebulous or contingent,' but 'must have taken on a fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the

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[35] *MedImmune*, 127 S.Ct. at 771 (internal citation and quotations omitted).

[36] *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 286 (E.D. Pa. 1994).

[37] *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993) (emphasis in original).

[38] *Benitec*, 495 F.3d at 1344.

[39] *Cardinal*, 508 U.S. at 98.

adversaries, and some useful purpose to be achieved in deciding them.'"[40] Ripeness is determined by "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration."[41] An issue is fit for judicial review when "further factual development would not 'significantly advance [a court's] ability to deal with the legal issues presented.'"[42] Withholding court consideration "causes hardship to the plaintiff where the complained-of conduct has an 'immediate and substantial impact' on the plaintiff."[43]

IV. ANALYSIS

A. Declaratory Judgment Jurisdiction

To succeed in its motion to dismiss, defendant must show there is a lack of substantial controversy and plaintiff does not have an adverse legal interest of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[44]

For immediacy, "a party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement[;] there must be a showing of 'meaningful preparation' for making or using that product."[45] "A declaratory judgment plaintiff must allege 'significant, concrete steps

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[40] *Principal Life,* 674 F. Supp. 2d at 565 (quoting *Public Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 244 (1952)).

[41] *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

[42] *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1295 (Fed. Cir. 2008) (quoting *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 812 (2003)).

[43] *Id.* (quoting *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 171 (1967)).

[44] *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 771 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273). *See also Interdigital*, 845 F. Supp. at 286.

[45] *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008) (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988);

to conduct infringing activity.'"[46] Defendant not only has a working product, but also has an NDA before the FDA for review.[47] Additionally, plaintiff notes defendant's market research, hiring of new sales and marketing personnel, saving for manufacture of commercial quantities of its product, manufacture of launch supplies, and anticipation of the manufacturing agreements.[48] Defendant contends the prerequisite FDA approval for commercialization and entry into the market is uncertain and, if approval is eventually given, commercial launch will not be immediate.[49] While this may be accurate, defendant's conduct is still indicative of meaningful preparation for the making, launch, and use of LPCN 1021 that satisfies the immediacy requirement for declaratory judgment jurisdiction.

Reality in patent infringement cases is determined by how "substantially fixed" rather than "fluid and indeterminate" the technology or product in question is at the time declaratory relief is sought.[50] Defendant's NDA product has successfully progressed through clinical trials and currently awaits review and approval of the FDA.[51] While

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citing *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401 (Fed. Cir. 1995)). *See also Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004).

[46] *Organic Seed Growers and Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1359 (Fed. Cir. 2013) (citing *id.*)

[47] *Contra Benitec*, 495 F.3d at 1346-1350 (Fed. Cir. 2007) (dismissing declaratory judgment action where party had not yet filed NDA with the FDA for its product) and *Sierra*, 363 F.3d at 1378-1381 (immediacy not met when no evidence of a built prototype existed).

[48] D.I. 14 at 7-8, 15; D.I. 16, Ex. 40 (King Decl.) at ¶ 12-25. *See also* D.I. 15, Ex. 24; D.I. 16, Ex. 30.

[49] D.I. 8 at 8.

[50] *Cat Tech*, 528 F.3d at 882 (citing *Sierra*, 363 F.3d at 1379).

[51] D.I. 15, Ex. 18, Ex. 21, Ex. 25. *Contra Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992) (dismissal of declaratory judgment action where clinical trials had just begun).

plaintiff's expert, Dr. Susan S. Allen, has argued the FDA could still claim deficiencies in the application, LPCN 1021 can, in all likelihood, be produced without significant change to its composition or design.[52] Consequently, defendant's product is substantially fixed to meet the reality prong for declaratory judgment jurisdiction.

Finally, the Declaratory Judgment Act articulates, "the sole requirement for jurisdiction . . . is that the conflict be real and immediate, i.e., that there be a true, actual 'controversy'. . . ."[53] However, "[i]f. . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction."[54] Defendant has been charged with patent infringement and both immediacy and reality are satisfied. Therefore, there is a substantial controversy with adequate reality and immediacy to support jurisdiction of the complaint under the Declaratory Judgment Act. Thus, subject matter jurisdiction exists.

B. Ripeness

Ripeness is determined by "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration."[55] The first prong exists when "further factual development would not 'significantly advance [a court's] ability to deal with the legal issues presented.'"[56] The second prong is satisfied when "the

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[52] D.I. 16, Ex. 39 (Allen Decl.) at ¶ 27 (citing 21 C.F.R. § 314.110).

[53] *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993) (quoting *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-735 (CA Fed. 1988) (citations omitted)).

[54] *Id.* (emphasis in original).

[55] *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

[56] *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1295 (Fed. Cir. 2008) (quoting *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 812 (2003)).

complained-of conduct has an 'immediate and substantial impact' on the plaintiff."[57]

Here, the first prong of ripeness is met because factual developments would not significantly advance the court's ability to deal with the legal issues presented in this case and declaratory judgment would not be based on merely hypothetical facts.[58] Defendant argues this prong is not satisfied because its NDA product has not been approved by the FDA and, despite progress in the FDA's procedural framework for NDAs, there is no guarantee it will be approved.[59] However, based on its progress, the apparent finality of the product's design and composition, and preliminary activities readying for LPCN 1021's launch, there are no additional facts needed to determine whether LPCN 1021 infringes on the '824 patent. Defendant further contends the upcoming Interference involving the '824 patent proves the issues are not fit for judicial decision because the PTAB will determine issues of patentability and priority. Yet, the PTAB's decision in the upcoming Interference will not determine the issue of infringement central to plaintiff's complaint. Due to the lack of further factual development needed and the PTAB's inability to hear plaintiff's infringement claim in the forthcoming Interference, the issue is fit for judicial decision.

The second prong of ripeness is also met because the complained-of conduct has an immediate and substantial impact on plaintiff.[60] Defendant has not been given FDA approval, nor commercialized.[61] However, defendant has commenced activities

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[57] *Id.* (quoting *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 171 (1967)).

[58] *Id. See also Principal Life Ins. Co. v. Lawrence Rucker 2007 Ins. Trust*, 674 F. Supp. 2d 562 (D. Del. 2009).

[59] D.I. 8 at 5-6.

[60] *Caraco*, 527 F.3d at 1295.

[61] D.I. 8 at 1, 8.

connected to the preparation and launch of LPCN 1021 that indicate immediate harm to plaintiff should court consideration be withheld.[62] Plaintiff asserts it will be harmed both monetarily and irreparably if the FDA approves defendant's NDA product because it will be the first to market and capture exclusivity.[63] Defendant's NDA product is potentially infringing on the '824 patent and the potential liability will increase upon FDA approval and consequent commercialization. Defendant cites *Cedars-Sinai Medical Center v. Watkins* to assert the existence of a pending Interference disproves the immediate harm necessary for ripeness.[64] Defendant claims the Interference proves further factual development is needed and immediate harm is lacking because the future Interference could render the action moot.[65] However, the court in *Minnesota Mining* stated:

> "[i]t surely would serve a 'useful purpose' for [plaintiff and defendant] to have a court decide whether [the product] infringes a patent. . . . Moreover, a resolution of that question will 'afford relief from the uncertainty, insecurity, and controversy' which the conflict between the parties has engendered. Failure to do so may cause significant harm to [plaintiff]."[66]

Further, the court in *Minnesota Mining* determined the possibility of mootness due to an Interference is an inappropriate reason to decline to find ripeness and declaratory judgment jurisdiction.[67]

Defendant additionally contends the FDA's approval is uncertain, and such

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[62] D.I. 15, Ex. 12, Ex. 19; D.I. 16, Ex. 40 (King Decl.) at ¶ 12-25.

[63] D.I. 14 at 17-18.

[64] D.I. 8 at 6. *See also Cedars-Sinai Center v. Watkins*, 11 F.3d 1573, 1581 (Fed. Cir. 1993).

[65] *Id.* at 4, 8.

[66] *Minnesota Min. and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 674 (Fed. Cir. 1991).

[67] *Id.* at 676-677.

approval does not necessarily result in a commercial launch - much less an immediate one.[68] Though the FDA's approval is a prerequisite to commercialization and entry into the market, defendant has meaningfully prepared for the making and selling of LPCN 1021.[69] Such meaningful preparation supports the finding of immediacy necessary for ripeness.[70] Thus, the issue of patent infringement in this case is both fit for judicial decision and withholding court consideration would inflict hardship on plaintiff.

C. Safe Harbor Provision of Patent Act

Under the Safe Harbor Provision of the Patent Act, competitors are immunized from infringement when making, using, offering to sell, or selling a "*patented* invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[71] The intent behind this provision was to allow competitors to begin regulatory approval processes during development, including post-submission activities related to the continued approval of the NDA or ANDA and to maintain the ability to market the drug.[72] While defendant has not yet received FDA approval and has not conducted any actions that deviate from those reasonably related to the development of its product, defendant does not currently hold a patent for its

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[68] D.I. 8 at 8.

[69] D.I. 14 at 7-8, 15; D.I. 16, Ex. 40 (King Decl.) at ¶ 12-25. *See also Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008); *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 284-286 (E.D. Pa. 1994)

[70] *Id.*

[71] 35 U.S.C.A. § 271(e)(1) (emphasis added).

[72] *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1524-1525 (Fed. Cir. 1992).

invention.[73] Defendant instead has a patent application - the '692 patent application.[74] Therefore, the Safe Harbor Provision does not apply to defendant and the '692 patent application.

D. Discretion in Exercising Jurisdiction in the Alternative

Abuse of a court's discretion to exercise jurisdiction is found when (1) it is clearly unreasonable, arbitrary, or fanciful, (2) it is based on an erroneous conclusion of law, (3) the court's findings are clearly erroneous, or (4) the record contains no evidence upon which the court rationally can base its decision.[75] Defendant proposes the court, in its discretion, decline to exercise jurisdiction over the declaratory judgment action.[76] Defendant maintains declining to exercise jurisdiction over this action would be in the interest of the judicial economy.[77] Although defendant further claims the pending Interference is relevant when deciding whether to exercise jurisdiction, this Interference does not provide grounds for the court to dismiss this action. The Interference proceeding will not determine the issue of infringement but only the issues of priority and patentability.[78] In *Minnesota Mining*, the court found dismissing a declaratory judgment action based on a pending Interference when said Interference would not decide (or would even moot) the infringement issues raised in the action is an abuse of

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[73] D.I. 8 at 3.
[74] *Id.*
[75] *Minnesota Min.*, 929 F.2d at 673 (citing *Western Elec. Co. v. Piezo Technology Inc.*, 860 F.2d 428, 430-431 (Fed. Cir. 1988); *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1022 (Fed. Cir. 1986)).
[76] *Id.* at 10.
[77] *Id.*
[78] *See Id*. at 674.

discretion.[79] Here, the court will not dismiss this declaratory judgment action because it has found subject matter jurisdiction exists, the Interference will not decide the infringement issues raised by plaintiff, and it is in the interest of justice for it to proceed.

V. ORDER AND RECOMMENDED DISPOSITION

Consistent with the findings herein, it is recommended that plaintiff's motion to dismiss defendant's counterclaim for lack of subject matter jurisdiction under FED. R. CIV. P. 12(b)(1) (D.I. 7) be denied.

Pursuant to 28 U.S.C. § 636(b)(1)(A) and (B), FED. R. CIV. P. 72(b) and D. DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to ten (10) pages after being served with the same. Any response is limited to ten (10) pages.

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: June 23, 2016

/s/ Mary Pat Thynge
Chief United States Magistrate Judge

[79] *Id.* at 674-675.