IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CELLTRION HEALTHCARE CO., LTD. and CELLTRION, INC.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 14-11613-MLW**
JANSSEN BIOTECH, INC.,	)	
Defendant.	)	

MEMORANDUM IN SUPPORT OF JANSSEN'S MOTION TO DISMISS CELLTRION'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION OR, IN THE ALTERNATIVE, TO DECLINE TO EXERCISE DECLARATORY JUDGMENT JURISDICTION

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I. INTRODUCTION

Celltrion Healthcare Co., Ltd and Celltrion, Inc. ("Celltrion") are seeking declaratory judgment that three Janssen Biotech, Inc. ("Janssen") patents relating to therapeutic antibodies are invalid. The case should be dismissed for lack of subject matter jurisdiction. Even accepting the facts alleged in Celltrion's Complaint as true, the Complaint fails to demonstrate that there is the type of real and immediate dispute needed to establish declaratory judgment jurisdiction.

Celltrion alleges that it "intends" to seek FDA approval to sell Remsima, a "biosimilar" – a drug that is highly similar – to Janssen's blockbuster drug Remicade® (referred to as the reference product). Although Celltrion has not yet even filed an application for FDA approval, Celltrion alleges that it "expects" to have FDA approval for Remsima in 2015. But the FDA has not yet approved any "biosimilar" drug for sale in the United States. Whether and when Remsima will be approved, and, if so, for what medical indications, is entirely speculative. Moreover Celltrion claims the harm it suffers is a "fear" of suit based on unrelated, and mostly foreign, litigations involving patents that are *not* the subject of this case. These allegations cannot form the basis for an objectively reasonable fear of suit under the three Janssen U.S. patents that *are* the subject matter of this case. Stated simply, Celltrion's alleged "facts" are too speculative to meet its burden of proving that there is a controversy of sufficient immediacy and reality to establish declaratory judgment jurisdiction.

But even if Celltrion's alleged dispute was real and immediate – which it is not – the Court should nonetheless decline to exercise declaratory judgment jurisdiction because allowing this case to proceed now would be wholly inconsistent with the recently enacted Biologics Price Competition and Innovation Act (BPCIA). In the BPCIA, Congress developed a detailed and specific mechanism for companies, like Celltrion, which are seeking approval of a biosimilar drug, to resolve patent disputes with the owner of the reference product—in this case Janssen.

The BPCIA provides a special pathway for manufacturers of biosimilar drugs to apply for FDA approval without conducting their own extensive clinical trials; instead they may rely on the clinical trials and other data of the reference product. But as part of the Act, Congress also provided mandatory procedures for resolving patent disputes relating to prospective biosimilar drugs – including a requirement that the biosimilar applicant undertake a series of specific steps before any patent action is filed. Under the law, if Celltrion had already filed its biosimilar application it would be statutorily barred from bringing the instant declaratory judgment action. Instead, Celltrion filed this suit prematurely – before filing its biosimilar application – in an attempt to avoid the patent resolution procedures of the BPCIA. There is no justification for permitting Celltrion to avail itself of the biosimilar approval pathway in the BPCIA while at the same time skirting the patent resolution procedures.

II. BACKGROUND

A. Pharmaceuticals, Biosimilars, and the BPCIA

Most well-known pharmaceutical products – like aspirin – are "small molecule drugs." *See* Declaration of Jay Siegel, M.D. at ¶ 7 ("Siegel Decl.") (Ex. 1).[1] These drugs contain active ingredients having well-defined, precise chemical structures. Scientists can synthesize these molecules in a laboratory using well-understood chemical reactions (*id.*).

A party may not sell a new small molecule drug in the United States until the FDA approves a New Drug Application (NDA) for that drug. The new drug applicant must support its NDA with extensive data from clinical trials that demonstrate the drug's safety and efficacy (*id.* at ¶ 10). *See* 21 U.S.C. § 355(b)(1), (d)(1)-(7). A party wishing to sell a drug with a small molecule that is identical to an already approved drug does not have to repeat the extensive

[1] "Ex. __" herein refers to exhibits to the Declaration of Jason Weil, filed herewith.

clinical trials or submit an NDA. Instead, that party may submit an Abbreviated New Drug Application (ANDA) seeking approval to sell a generic version of the drug. Because the generic drug uses an active ingredient identical to that of the approved drug, the ANDA applicant can rely on the data presented in the relevant NDA and need only present data showing that the proposed generic drug has the same active ingredient, strength, dosage form, and route of administration as the approved product, and that the generic drug is bioequivalent to that approved product (Siegel Decl. at ¶ 11). 21 U.S.C. § 355(j)(2).

Over the past few decades, in addition to new small molecule drugs, innovative companies have developed and commercialized new biologic therapeutics ("biologics") (Siegel Decl. at ¶ 9). Unlike small molecule drugs, biologics are not chemically synthesized in a laboratory, they are grown in genetically engineered, living cells. A new biologic drug manufacturer must file a Biologics License Application (BLA) and support that application with extensive data from clinical trials that demonstrate the drug's safety and efficacy to the FDA (*id.* at ¶ 10). 42 U.S.C. § 262(a)(2), (g).

The products at issue in Celltrion's Complaint – Remicade and Remsima – are biologic drugs, specifically, monoclonal antibodies. Monoclonal antibodies are among the most complex biologics the FDA has ever approved. Because the biologic manufacturing process is complex and uses living organisms, the structural features of a biologic drug can vary based on the precise manner in which a party creates the drug (Siegel Decl. at ¶ 12; Compl. at ¶¶ 20-22). These drugs contain large, complex molecules that have multiple domains that affect their function and persistence within the human body (Siegel Decl. at ¶ 9). These molecules generally cannot be completely characterized (*id.* at ¶ 12). Thus, although it is possible to show that the active ingredient in a generic small molecule drug is identical to an already approved small molecule

drug, it is not possible to prove that a proposed follow-on biologic is identical to an innovator's biologic. A potential biosimilar manufacturer can only hope to prove that its biologic is "highly similar" to an already approved product (*id.*).

Congress recognized this dilemma and, in 2010, passed the BPCIA. The BPCIA authorized the FDA to implement a less expensive drug approval pathway for biologics that are "biosimilar to a reference product." 42 U.S.C. § 262(i), (k). When a party files a biosimilars application under 42 U.S.C. § 262(k) (a "262(k) application"), the FDA may approve the applicant's biologic product as biosimilar to a reference product if there are "no clinically meaningful differences . . . in terms of the safety, purity and potency" between the previously approved "reference product" and the "biosimilar." § 262(i), (k)(3).[2]

Although this pathway allows a follow-on manufacturer to rely on the innovator's safety and efficacy data, applicants must still perform testing of their own, including some clinical testing, to show that a potential biosimilar is "highly similar" to the approved reference product (Siegel Decl. at ¶ 13). Nonetheless, by virtue of the 262(k) approval pathway in the BPCIA, a biosimilars manufacturer may bring its drug to market at a fraction of the cost of the pioneering molecule. *See* John R. Thomas, Cong. Research Serv. R41483, Follow-On Biologics: The Law and Intellectual Property Issues 3, 19 (Jan. 15, 2014) ("Thomas") (Ex. 2) (estimating cost of developing an innovative biologic at $1.2 billion and a follow-on biologic at $100-200 million); *see also,* Krista H. Carver et al., An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009, 65 Food & Drug L. J. 671, 789 (2010) ("Carver") (Ex. 3) ("[B]iosimilar-to-brand competition would differ from brand-to-brand competition because

[2] The BPCIA amended § 351 of the Public Health Service Act to create the § 351(k) biosimilar approval pathway. That provision is codified at 42 U.S.C. § 262(k). Thus, although this motion refers to the biosimilar application as a 262(k) application, and the applicant as a 262(k) applicant, they are sometimes referred to in other forums as a 351(k) application and a 351(k) applicant respectively.

biosimilar manufacturers would face 'about a tenth of the [development] cost[s] . . . .'" (citation omitted)). As part of the bargain for this less expensive approval pathway, the BPCIA provides a statutory exclusivity period for reference products and defines specific procedures for resolving patent disputes between biosimilar applicants and reference product sponsors. *See*, § IV, *infra*.

B. Janssen Biotech, Inc. and Remicade

Janssen is a pioneer and leader in the development of biologic drugs. Janssen received FDA approval to sell its biologic drug Remicade® infliximab, one of the first biologics of its kind sold in the United States for treatment of a chronic disease. Remicade is a monoclonal antibody that binds to and neutralizes a substance in our bodies called TNFα. TNFα is an important player in our immune systems but, if it is over-produced, it can lead to chronic disease.

Janssen invested hundreds of millions of dollars to develop Remicade and to run the clinical trials necessary to demonstrate Remicade's safety and efficacy. The FDA approved Remicade for treatment of Crohn's Disease – a debilitating disease of the digestive tract – in 1998. In the following years, the FDA approved Remicade for treatment of rheumatoid arthritis, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. In the fifteen-plus years since its introduction, doctors have used Remicade worldwide to safely and effectively treat, and improve the lives of, hundreds of thousands of patients.

Reflecting the innovation underlying Remicade's development, the United States Patent and Trademark Office has issued numerous patents related to Remicade and its use. Celltrion challenges three of those patents in this declaratory judgment action: U.S. Patent No. 5,919,452 ("452 Patent") (Ex. 4) covers a method of treating TNFα-mediated disease with a specific antibody; U.S. Patent No. 6,284,471 ("471 Patent") (Ex. 5) covers the composition of a specific anti-TNFα antibody; and U.S. Patent No. 7,223,396 ("396 Patent") (Ex. 6) covers a specific method of treatment of a specific type of Crohn's disease with an anti-TNFα antibody.

C. Celltrion and Its Complaint

Celltrion is a biosimilars manufacturer (Compl. at ¶¶ 1-3). It does not invent and develop new biologic drugs. Rather, Celltrion markets biologics that it alleges are highly similar to the reference product biologics that innovators invented and developed.

Celltrion alleges that its proposed drug Remsima is biosimilar to Janssen's Remicade. Celltrion states that it "intends" to apply for FDA approval to sell Remsima "during the first half of 2014" (*id.* at ¶ 6), and explains that its license application will rely on the safety and efficacy data developed by Janssen for Remicade (*id.* at ¶ 30 ("[C]linical trials . . . established that Remsima® was comparable in safety and efficacy to Remicade® . . . . Celltrion will use these same clinical trial results to support its application for approval in the United States."). Celltrion also claims that, even though it has not yet filed its license application, it "expects" to receive FDA approval to sell Remsima by "early 2015" (*id.* at ¶ 6).[3]

Based on its "intent" to submit a 262(k) application, its "expectation" the FDA will approve that application in short order, and its assumption that Janssen will sue Celltrion on the three patents-in-suit if Celltrion tries to sell Remsima, Celltrion seeks a declaration that Janssen's 452, 471, and 396 Patents are invalid and/or unenforceable (*id.* at ¶ 12). Celltrion does not seek declaratory judgment that Remsima does not infringe Janssen's patents. Nor does it aver in what way Remsima, or its intended uses, are allegedly covered by Janssen's patents. Instead, Celltrion contends that the Court has jurisdiction to opine on the validity of the three patents in suit because Celltrion intends to seek approval of Remsima as a "biosimilar" of Remicade and because Janssen has allegedly aggressively sought to protect its Remicade® monopoly.

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[3] Although Celltrion never expressly states that it will file a 262(k) application, it clearly intends to seek approval of Remsima as a biosimilar of Remicade (Compl. at ¶¶ 4, 20-25, 30, 32, and 36).

III. CELLTRION HAS NOT ESTABLISHED A REAL AND IMMEDIATE INJURY OR THREAT OF INJURY

A. The Declaratory Judgment Standard

The Declaratory Judgment Act provides that:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201.

The Supreme Court has explained that an actual controversy exists where "under all the circumstances . . . there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118, 127 (2007) (citation omitted). Both the patentee's conduct showing its position on whether the patents-in-suit cover the potentially infringing product, as well as the potential infringer's reasonable preparation to infringe those patents, are important factors in the totality of circumstances test. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879-80 (Fed. Cir. 2008). The Federal Circuit has viewed this inquiry through the lens of standing and has given examples of the types of harm that satisfy this requirement. *Prasco, LLC v. Medicis Pharm. Corp.,* 537 F.3d 1329, 1338, 1339 (Fed. Cir. 2008).

Celltrion, as plaintiff, bears the burden of proving subject-matter jurisdiction. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007). Celltrion must demonstrate subject-matter jurisdiction as of the date it filed its Complaint; later events cannot cure a subject-matter jurisdiction defect in the Complaint. *Prasco*, 537 F.3d at 1337. "The proper vehicle for challenging a court's subject-matter jurisdiction is Federal Rule of Civil Procedure 12(b)(1)." *Valentin v. Hospital Bella Vista*, 254 F.3d 358, 362 (1st Cir. 2001).

B. Celltrion Has Not Yet Engaged in Meaningful Preparation to Conduct Potentially Infringing Activity

Celltrion has not met, and cannot meet, its burden of proving the existence of a substantial controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. Celltrion failed to allege facts showing that it has engaged in meaningful preparation to conduct potentially infringing activity.

"[T]he issue of whether there has been meaningful preparation to conduct potentially infringing activity remains an important element in the totality of the circumstances [inquiry]." *Cat Tech*, 528 F.3d at 880. The Federal Circuit has affirmed dismissal of declaratory judgment complaints filed by parties, like Celltrion, who only expect to file applications with the FDA, and where there is no evidence that a party's potential product would ever be used in an infringing way. *See, e.g.*, *Telectronics Pacing Sys., Inc. v. Ventritex, Inc*., 982 F.2d 1520, 1527 (Fed. Cir. 1992) (holding dispute not real or immediate where medical device was years away from marketing approval and device might change during clinical trials); *see also Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328-29 (Fed. Cir. 2012) (no evidence that the accused device would ever be used according to the claimed method). Indeed, the Federal Circuit has never found declaratory judgment jurisdiction for a small molecule or biologic drug where, as here, a party had not yet filed the requisite FDA application and there was no other infringing activity. *See, e.g.*, *Benitec*, 495 F.3d at 1346-47 (jurisdiction lacking where no FDA application contemplated for years, if ever). There are good reasons for this.

First, before a party's application is actually complete and ready for filing with the FDA, it is impossible to know when it will be ready for filing. *See Benitec*, 495 F.3d at 1346-47. Celltrion has admitted this, by indicating that it is still in negotiations over the content of its application and that the FDA has already required additional clinical testing of Remsima (Compl.

at ¶¶ 35-37). These facts undermine Celltrion's claim that its FDA filing is imminent. Moreover, the FDA has only recently issued, and is still in the process of providing, guidance documents for the development of biosimilars (Siegel Decl. at ¶ 21). Celltrion did not have the benefit of some or all of those documents as it designed its development program (*id.*). It is entirely possible that the FDA will require Celltrion to do additional clinical testing or submit additional data before filing its application. If that is the case, it is unknown whether Celltrion will be able to clear those hurdles. In short, it is impossible to know whether Celltrion will be allowed to file its application and, if so, when.

Second, once the application is filed, there is no way to know whether and when the FDA will approve such an application. Celltrion suggests that the FDA will grant its application in the "ordinary course" (Compl. at ¶ 37). But, as Celltrion acknowledges, Remsima, if approved, "will become the *first* biosimilar of an antibody drug ever approved in the United States" (*id.* at ¶ 6 (emphasis added)). There can be no "ordinary course" for approval of biosimilar drugs because the FDA has not yet approved a single one. Further, the FDA review here is likely to take *longer* than it otherwise might because the FDA knows that the industry will scrutinize its precedent-setting decision to approve the first ever biosimilar product under the 262(k) pathway. Senior FDA officials will likely review the primary reviewer's decision on many levels (Siegel Decl. at ¶ 18). It is impossible to predict when and if Celltrion's application will be approved.

Third, at this early date, and without the benefit of Celltrion's 262(k) application or any information from the FDA on which medical indication(s) the FDA will grant approval, it is not possible to assess whether there will be a dispute under any particular Janssen patent. *See Matthews*, 695 F.3d at 1328 (The parties' dispute lacked immediacy because there was "no evidence as to when, if ever, the Bio Cremation equipment w[ould] be used in a manner that

could potentially infringe the Method Patents."); *cf. Telectronics*, 982 F.2d at 1527 (product could change during trials before approval).

The 396 Patent exemplifies the problem. That patent claims a method for treating a specific type of Crohn's disease by using a specific treatment regimen. There is no way to know now whether Celltrion will seek, or be granted, a license to sell Remsima for this treatment. The relevant regulatory agency in Canada, Health Canada, refused to approve Remsima for treatment of Crohn's disease (Siegel Decl. at ¶ 23). *See* Health Canada, Summary Basis of Decision (SBD): Remsima (Ex. 7). There is no way to know when, if ever, Remsima will be approved in the U.S. for a use that could potentially infringe the 396 Patent. *See Matthews*, 695 F.3d at 1328.

Finally, although Celltrion insists that its product is "fixed and definite" because other countries have approved Remsima (Compl. at ¶ 62), the FDA not only assesses the composition of a potential drug, it also regulates the manufacturing conditions and the indications for which the drug can be sold. The U.S. FDA reviews more information than some other countries' regulatory agencies (Siegel Decl. at ¶ 22). And some of these other countries ultimately approved Remsima for less than all uses Celltrion sought (*id.* at ¶ 23). Thus, Celltrion's "product" already differs from country to country. The product Celltrion will market in the U.S. is *not* fixed and definite.

Celltrion's allegations that it "intends" to file an application for FDA approval and "expects" to get such approval in 2015 are not the type of facts from which the Court can infer that an immediate and real controversy exists. Indeed they are not *facts* at all. They are a hope, a wish, or an aspiration, at most. And Celltrion does not even allege in its Complaint that it is seeking approval for the method of treating fistula Crohn's disease that is the subject of the 396

patent, much less that Celltrion will receive such approval. Celltrion has not met, and cannot meet, its burden of proving the existence of a real and immediate dispute.

C. Janssen Has Not Taken a Position That Would Threaten Harm to Celltrion

The specific harm Celltrion alleges – a "fear" of suit under the three Janssen patents – is not realistically based on any of Janssen's actions. Instead, Celltrion alleges that it fears suit because Celltrion will file for approval of Remsima as a biosimilar of Janssen's Remicade and Janssen has allegedly indicated, through its statements, conduct, and other litigations, that it will enforce its patent rights (Compl. at ¶¶ 10-12, 52, 60). But a party's own statements describing its product to the FDA are not sufficient to confer declaratory judgment jurisdiction, even if the patentee knows of those statements. *See Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1380 (Fed. Cir. 2010). Nor do Janssen's statements and conduct – largely unrelated to Remsima and the patents-in-suit – even approach the affirmative position needed to confer jurisdiction. "[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007); *see also Prasco*, 537 F.3d at 1339. "[T]he existence of a patent is not sufficient to establish declaratory judgment jurisdiction." *Prasco*, 537 F.3d at 1338.

1. Janssen's Unrelated Litigation and Statements About Its Patent Portfolio Do Not Create an Actual Controversy

Although "[p]rior litigious conduct is one circumstance to be considered" in a declaratory judgment jurisdictional inquiry, the prior litigation must indicate the patentee's position with respect to infringement of the challenged patents. *Id.* at 1341; *see also Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1331 (Fed. Cir. 2014) ("Novozymes has never withdrawn its

allegation that Danisco's α-amylase variant is encompassed by and would infringe the claim that issued in Novozyme's '573 patent."). *Compare Prasco*, 537 F.3d at 1341 ("[O]ne prior suit [between the same parties but] concerning different products covered by unrelated patents is not the type of pattern of prior conduct [supporting jurisdiction]") *with Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897, 899-902 (Fed. Cir. 2008) (MOSAID's statements, demand letters, and systematic suits against every other manufacturer provided jurisdiction). Celltrion's allegations of Janssen's purportedly "aggressive" legal challenges do not evidence a pattern of conduct by Janssen with respect to the three patents that are the subject of this case.

With respect to litigation in the United States (Compl. at ¶ 52), the two infringement actions in Texas, both identified in the Complaint as *Centocor Ortho Biotech, Inc., et al. v. Abbott Laboratories, et al.*, were infringement actions seeking monetary damages under a different patent against a different company based on a different product – Abbott's Humira antibody. *See Centocor Ortho Biotech, Inc. v. Abbott Labs.*, No. 09-cv-00389 (E.D. Tex. Dec. 28, 2009) (Complaint) (Ex. 8); *Centocor, Inc. v. Abbott Labs.*, No. 07-cv-00139 (E.D. Tex. Apr. 16, 2007) (Complaint) (Ex. 9). The suit against Genentech was a declaratory judgment action seeking a declaration of invalidity and non-infringement of a *Genentech* patent under which Janssen had a license. *See Centocor, Inc. v. Genentech, Inc.*, No. 08-cv-03573 (C.D. Cal. May 30, 2008) (Complaint) (Ex. 10). In the *Rockefeller University* suit, Janssen was *defending against* charges of infringement of a third party patent. *See Rockefeller Univ. v. Centocor, Inc.*, No. 04-cv-00168 (E.D. Tex. Apr. 28, 2004) (Complaint) (Ex. 11).[4]

Janssen's pursuit of an infringement action under a different patent against an infringer making a different product, its pursuit of declaratory judgments of noninfringement and

[4] In December 2008, "Centocor, Inc." became "Centocor Ortho Biotech, Inc." On June 22, 2011, the name of "Centocor Ortho Biotech, Inc." was changed to "Janssen Biotech, Inc."

invalidity of patents under which Janssen was licensed, or its *defense* against infringement allegations of third party patents, cannot possibly constitute evidence of Janssen's position on asserting the subject patents against Celltrion. *See SanDisk*, 480 F.3d at 1381 ("Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do."); *see also Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1357-59 (Fed. Cir. 2013) (Honeywell's suit on method claims in Germany made its position clear for purposes of U.S. conduct; there was no use that did not at least arguably infringe the U.S. patent's method claims). The differences between these prior lawsuits and Celltrion's causes of action cannot create an objective fear of harm in Celltrion with respect to the three challenged patents. *See Prasco*, 537 F.3d at 1338-39 (jurisdiction turns on "the *reality* of the threat . . . not the plaintiff's subjective apprehensions" (internal quotations and citation omitted)).

Indeed, even if Janssen has made statements about having patents enforceable until 2018 that it *may* assert against infringers (Compl. at ¶ 60), that is not sufficient to create an objectively reasonable threat of suit against Celltrion under specific U.S. patents, based on a product for which Celltrion has not yet sought FDA approval, and where Celltrion has not established that it is an infringer. *See MOSAID*, 518 F.3d at 899-902. In sum, Celltrion's alleged "facts" do not support jurisdiction. *See Prasco*, 537 F.3d at 1338, 1338-39.

2. Janssen's Activities Unrelated to the Challenged Patents Cannot Establish an Actual Controversy

Nor could Janssen's conduct in other venues with respect to Celltrion's foreign products constitute an objective threat of harm under the subject patents. Janssen's actions in these matters are either unrelated to any of Janssen's patents, or wholly unrelated even to patent law (Compl. at ¶¶ 53-59).

Janssen successfully challenged approval of Remsima in Mexico because Janssen still enjoyed data exclusivity under Mexican law (*id.* at ¶ 56). Janssen also successfully petitioned to have approval of Remsima suspended in Peru because Celltrion's application raised serious health concerns (*id.* at ¶ 57). Besides having a concern for public safety, Janssen obviously does not want an unsafe product on the market, where that unsafe product has a name designed to mimic the name of Janssen's product. These foreign challenges have nothing to do with Janssen's patents, inside or outside of the United States.

Similarly, by opposing registration of Celltrion's "Remsima" trademark for its Remicade-biosimilar, Janssen seeks only to prevent Celltrion's use of a trademark that is intentionally confusingly similar to the name of Janssen's own successful product. The name Celltrion chose – Remsima – could lead to confusion among pharmacists, doctors and patients and make it difficult to monitor patient safety (*id.* at ¶¶ 55, 59). These trademark actions have nothing to do with keeping Remsima off the market. As with each of the other actions recounted in Celltrion's Complaint, these actions are not evidence of Janssen taking a position with respect to the challenged patents or potential infringement by future sales of Remsima.

Janssen's participation in a lawsuit brought against Celltrion by a third party, The Kennedy Trust for Rheumatology Research, alleging that Remsima infringes the Kennedy Trust's *Canadian* patent for methods of treating rheumatoid arthritis is similarly not related to the patents cited in Celltrion's Complaint (*id.* at ¶ 53). Janssen is a participant in the lawsuit because it is a licensee of the Kennedy Trust patent. Participation as a third-party in the Canadian lawsuit is not evidence of *Janssen* taking a position with respect to Janssen's U.S. patents.

Celltrion's allegation that it is "informed" that, as part of *Canadian* proceedings brought by Celltrion's marketing partner Hospira against the Kennedy Trust, *third-party Janssen* refused

to grant a license under Janssen's *U.S. patents* (*id.* at ¶¶ 53-54), is unsupported. But even assuming that Janssen was not willing to discuss licensing its U.S. patents in settlement discussions for a Canadian litigation where Janssen was a third party, that is too tenuous to the issues here to support an allegation of an objective threat of harm under the subject patents.

Nor is Janssen's participation in the lawsuit *initiated* by *Celltrion's* marketing partner in the United Kingdom to revoke the *Kennedy Trust's* British patent (*id.* at ¶ 58), evidence of Janssen taking a position with respect to any of its own patents or, specifically, the three patents in Celltrion's Complaint.

Rather than point to any of Janssen's conduct based on similar patent claims in foreign venues (because there is none), Celltrion points to Janssen's unrelated conduct in those venues. Celltrion's focus on Janssen's irrelevant conduct outside of the United States (OUS) only highlights the fact that there is not yet a real and immediate dispute in the United States. Janssen's conduct has not forced Celltrion to "either pursu[e] arguably illegal behavior or abandon[] that which [it] claims a right to do." *SanDisk*, 480 F.3d at 1381.

3. Janssen Has Not Taken Any Relevant Position Against Celltrion On The Patents-In-Suit.

Celltrion's allegations that Janssen's aggressive strategy creates a threat of harm are particularly tenuous when considered in light of the three patents that Celltrion challenges in its Complaint. There is, for example, no certainty that Celltrion will seek or obtain FDA approval to market Remsima for the treatment of Crohn's Disease before the 396 Patent expires in 2016. And the fact that Health Canada refused to grant approval of Remsima to treat Crohn's disease reflects this lack of certainty. *See Matthews*, 695 F.3d at 1328 (holding that the court lacked jurisdiction where there was no evidence the product would ever be used in an infringing way).

The second patent challenged by Celltrion, the 452 Patent, expires in August 2014 – a date well before Celltrion's overly optimistic expected approval date. There simply cannot be a real dispute over the validity of a patent that will expire before the FDA could approve Remsima.

Finally, the status of the third patent included in Celltrion's Complaint, the 471 Patent, is also uncertain. All claims of the 471 Patent are currently rejected in a reexamination proceeding at the PTO. *See* USPTO Non-final Office Action, Reexamination No. 90/012,851 (Sept. 6, 2013) (Rejecting all claims of 471 Patent) (Ex. 12). Courts routinely stay pending litigation when a patent is accepted for reexamination. *See Gould v. Control Laser Corp.*, 705 F.2d 1340 (Fed. Cir. 1983). It would be particularly odd to *initiate* a *discretionary* declaratory judgment action while all claims *currently stand* rejected. Although Janssen believes the claims are patentable and that the PTO will confirm their patentability, there is no reason to initiate a declaratory judgment litigation on the 471 Patent at this time, before Celltrion has even filed its 262(k) application with the FDA.

D. No Legal Authority Supports Celltrion's Claim to Declaratory Judgment Jurisdiction

Janssen is aware of only one case that has addressed the question of declaratory judgment jurisdiction on facts similar to those here. That case – *Sandoz Inc. v. Amgen Inc*. – supports this motion to dismiss. *See Sandoz Inc. v. Amgen Inc*., No. 13-cv-2904 (N.D. Cal. Nov. 12, 2013) (Order Granting Motion to Dismiss) (Ex. 13).

There, Sandoz filed a declaratory judgment action alleging that once it completed clinical trials, it intended to seek FDA approval to sell a drug biosimilar to Amgen's biologic drug Enbrel. Sandoz sought a declaration that its biosimilar drug did not infringe certain Amgen patents and/or that the Amgen patents were invalid. But, just like Celltrion here, Sandoz sought declaratory judgment prior to filing its biosimilar application. And, like Janssen here, Amgen

had never indicated that it intended to sue Sandoz, nor was it in a position to consider such an action until Sandoz filed its license application with the FDA.[5] The district court dismissed Sandoz's Complaint for lack of subject matter jurisdiction.[6] The reasoning of the *Sandoz* case is directly applicable here, and counsels for dismissal of Celltrion's Complaint. Janssen is unaware of any legal authority supporting declaratory judgment jurisdiction before a party filed its biosimilar application.

IV. THE COURT SHOULD EXERCISE ITS DISCRETION AND DECLINE JURISDICTION

The facts do not evidence a substantial, real and immediate controversy between the parties. But even if an actual controversy did exist, this Court could, and should, decline to hear Celltrion's case. *Telectronics*, 982 F.2d at 1526 ("Even assuming an actual controversy, the exercise of a court's jurisdiction over a declaratory judgment action is discretionary.").

A court must determine whether resolving a case serves the objectives of the Declaratory Judgment Act. *See Cat Tech*, 528 F.3d 883. If not, the court should decline to hear the case. The present circumstances are not the type of conduct that the Declaratory Judgment Act exists to protect. Rather, the statutory scheme set forth by Congress in the BPCIA is the appropriate way to resolve any future patent disputes between Janssen and Celltrion.

A. The Patent Dispute Resolution Procedures of the BPCIA Control

Once Celltrion files its application for approval to market Remsima, the BPCIA will control procedures for resolving any disputes that might exist between Janssen and Celltrion. The BPCIA has three components: 1) it provides the less expensive 262(k) route for approval of

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[5] The court also held that it lacked statutory authority to hear the suit under the BPCIA, 42 U.S.C. § 262(l). This is discussed in Section IV, *infra*.

[6] Sandoz's appeal from the district court is currently pending at the Court of Appeals for the Federal Circuit. *Sandoz Inc. v. Amgen Inc.*, No. 2014-1693. If the Federal Circuit affirms because Sandoz sought declaratory judgment prior to filing a 262(k) application, this Court would be compelled to dismiss Celltrion's Complaint.

a drug as biosimilar; 2) it provides a period of statutory exclusivity to the reference product sponsor during which the FDA may not grant a biosimilar application; and 3) it provides a mechanism for resolving patent disputes over relevant patents still in force after the period of statutory exclusivity expires (Ex. 2, at 1).

Under the BPCIA's patent resolution procedures, 42 U.S.C. § 262(l), Celltrion would have to provide a copy of its 262(k) application to Janssen within twenty days of filing the application. § 262(l)(2). Janssen could then use that information to determine "whether a claim of patent infringement could reasonably be asserted" under any of its patents. § 262(l)(1)(D). If that were the case, then Janssen and Celltrion would identify a patent or patents for "immediate" litigation. Celltrion would also be obliged to provide notice of commercial marketing no later than 180 days before it intends to market its biosimilar drug so Janssen would have the option to seek a preliminary injunction or declaratory judgment. § 262(l)(8)(B), (l)(9)(A).

There is no provision in the BPCIA that would provide for Celltrion to file the current declaratory judgment action after filing its 262(k) application but before giving notice of commercial marketing. Janssen, could file such an action, but only if Celltrion failed to provide the application to Janssen or provided the application but then failed to follow a subsequent statutory provision. § 262(l)(9)(B), (l)(9)(C). Assuming Celltrion timely provided its application to Janssen, then *neither party* could bring a declaratory judgment action on any relevant patent until Celltrion gave notice of commercial marketing. § 262(l)(9)(A).

Janssen does not dispute Celltrion's right to seek approval of its product pursuant to § 262(k) if Celltrion can meet the statutory and regulatory requirements. Janssen does, however, object to Celltrion's attempt to avail itself of the benefits of the § 262(k) route to approval

without also following the statutory patent resolution provisions implemented to protect both the reference product sponsor and the 262(k) applicant.

B. Celltrion's Declaratory Judgment Action Contravenes the Patent Dispute Procedures of the BPCIA

The patent dispute resolution procedures of the BPCIA do not allow a 262(k) applicant to file a declaratory judgment action between the time it files its application and the time it gives notice of commercial marketing. That is, apparently, why Celltrion filed the instant declaratory judgment Complaint prior to filing its 262(k) application. This Court should not permit Celltrion to claim there is jurisdiction for this suit based on Celltrion's status as a *future* 262(k) applicant just so Celltrion can skirt the express limits on declaratory judgment actions Congress deemed appropriate for 262(k) applicants. If Celltrion is allowed to side-step the patent dispute procedures of the BPCIA, then every prospective biosimilar applicant will be able to evade the statutory regime by filing a declaratory judgment action immediately before filing its biosimilar application with the FDA. This would clearly frustrate the intent of the BPCIA provisions.

Celltrion alleges that its declaratory judgment action is necessary to "remove . . . uncertainties and clear the way for Celltrion's introduction of Remsima" (Compl. at ¶ 67). But Congress settled on the details of the 262(k) pathway, the statutory exclusivity, *and* the patent dispute procedures of the BPCIA based on the views of innovator companies, generic companies, and regulators (Ex. 3; *id.* at 816-17). If Celltrion feels that Congress's plan does not allow it to timely resolve its concerns, its remedy lies with Congress, not this Court.

V. JANSSEN SHOULD BE PERMITTED TO TAKE JURISDICTIONAL DISCOVERY

If the Court is not prepared to dismiss Celltrion's Complaint for the reasons set forth above, Janssen requests leave to take jurisdictional discovery from Celltrion before a decision on this Motion to Dismiss is rendered. Celltrion's Complaint alleges that Celltrion will file its

application during the first half of 2014 – in just over a month from now. Thus, Celltrion will allegedly trigger the BPCIA statutory scheme described in § IV before briefing on this motion is even complete, and the parties should proceed under that statutory framework. But if Celltrion does not file, and the Court is otherwise unwilling to dismiss this case, the Court should permit Janssen to take discovery relating to the allegations in Celltrion's Complaint about the purported immediacy and scope of its intended FDA filing, Celltrion's alleged clinical trials, its alleged meetings with the FDA, and its alleged preparation to "immediately" introduce Remsima upon receiving FDA approval. Janssen also requests the opportunity to supplement this memorandum based on the information uncovered through discovery, before a ruling on this motion is issued.

VI. CONCLUSION

Celltrion's Complaint fails to allege facts evidencing a real and immediate controversy between the parties. Celltrion's wish-and-hope that it will file for, and obtain, FDA approval to introduce Remsima to the U.S. market in early 2015 is purely hypothetical, and its fear of suit under Janssen's patents is purely subjective and not reasonably based on any of Janssen's actions. In addition, Celltrion's declaratory judgment Complaint flies in the face of the patent dispute procedures mandated by the BPCIA. Celltrion's Complaint should be dismissed.

In the event that the Court does not see fit to dismiss the Complaint, the Court should permit Janssen to take discovery into the jurisdictional allegations in Celltrion's Complaint to further develop the record for the Court's consideration before it rules on this motion.

Date: May 23, 2014

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing

MEMORANDUM IN SUPPORT OF JANSSEN'S MOTION TO DISMISS CELLTRION'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION OR, IN THE ALTERNATIVE, TO DECLINE TO EXERCISE DECLARATORY JUDGMENT JURISDICTION

was electronically mailed to counsel of record on May 23, 2014 through the Court's ECF notification system.

/s/ Jason Weil