UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CELLTRION HEALTHCARE CO., LTD. and CELLTRION, INC., Plaintiffs, v. KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH, Defendant.	:	Civil Action No.: 14-cv-2256 (PAC)

DEFENDANT KENNEDY TRUST'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF CELLTRION'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION PURSUANT TO FED.R.CIV.P. 12(b)(1), OR TO STAY THE ACTION

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I. INTRODUCTION

Celltrion Healthcare Co., Ltd and Celltrion, Inc. (collectively, "Celltrion") are seeking a declaratory judgment that three patents owned by Kennedy Trust for Rheumatology Research ("Kennedy") are invalid. The case should be dismissed for lack of subject matter jurisdiction pursuant to Fed.R.Civ.P. 12(b)(1). There is no case or controversy at this time between Kennedy and Celltrion and, indeed, there may never be one. Even if the facts alleged in Celltrion's Complaint were true, the Complaint fails to demonstrate that there is the type of real and immediate dispute needed to establish declaratory judgment jurisdiction.

Celltrion alleges in its Complaint filed on March 31, 2014 that it "intends" to seek U.S. Food and Drug Administration ("FDA") approval to sell Remsima, a "biosimilar" – a drug that is highly similar but not necessarily identical – to blockbuster drug Remicade, which is marketed by Janssen Biotech, Inc. ("Janssen" formerly Centocor), a licensee of Kennedy. Janssen's Remicade contains cA2, but Celltrion does not allege that its own product contains cA2. Celltrion did not actually file an application for FDA approval until August 8, 2014. Celltrion alleges that it "expects" to have FDA approval to market Remsima in 2015. But the FDA has never approved any "biosimilar" drug for sale in the United States, and according to an announcement by another company, has only very recently accepted the first application for approval. Whether and when Celltrion's filed application will be accepted, and whether and when Remsima will be approved, and, if so, for use in treating what medical conditions and with what labeling, is entirely speculative. Specifically, it is unknown at this time whether Remsima, if approved, would need to be used together with methotrexate in the treatment of rheumatoid arthritis.

Celltrion claims that it will suffer harm because Kennedy owns the three patents that are the subject matter of this case. To the extent claims of all three patents are limited to cA2,

Celltrion's allegations cannot form the basis for an objectively reasonable fear of suit under these patents. The cA2 claims have never been litigated. Further, as acknowledged in the Complaint, Kennedy's patents are the subject of reissue and/or reexamination proceedings, the outcome of which are not known. Celltrion has no risk that any injunction will be sought by or granted to Kennedy. Its only risk is that sometime in the future it may need to take a license and pay royalties. The likelihood of that occurrence cannot be ascertained now. That Kennedy's foreign patents were the subject of litigation has no bearing on Celltrion's activities in the United States. Celltrion cannot meet its burden of proving that there is a controversy of sufficient immediacy and reality to establish declaratory judgment jurisdiction.

Allowing this case to proceed would be wholly inconsistent with the 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. 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 innovative product as to which they have a biosimilar. As part of the Act, Congress provided mandatory procedures for resolving patent disputes relating to prospective biosimilar drugs. These procedures require that the biosimilar applicant undertake a series of specific steps before any patent action is filed and give notice prior to commercial marketing. As a result, Celltrion is statutorily barred from bringing the instant declaratory judgment action. Celltrion has filed this premature action in an attempt to avoid the patent resolution procedures of the BPCIA. Celltrion could easily wait until it reaches the stage of the FDA process where a lawsuit could be brought. 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. *See Sandoz Inc. v. Amgen Inc.*, 2013 WL 6000069 (N.D. Cal. Nov.12, 2013) (granting motion to dismiss for lack of subject matter jurisdiction).

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.") (Zivin 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 containing 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 that is identical to an already approved drug does not have to repeat the extensive 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 contains an active ingredient identical to the active ingredient in the approved drug, the ANDA applicant can rely on the data in the relevant NDA and need only show that its proposed generic drug has the same active

[1] Celltrion also has brought a declaratory judgment action against Janssen in the District of Massachusetts seeking to invalidate three Janssen patents. Janssen has filed a motion to dismiss that action for lack of subject matter jurisdiction. In support of its motion, Janssen relied on a Declaration of Jay Siegel, M.D., dated May 21, 2014. In the opposition to Janssen's motion, Celltrion relied on a Declaration of JaeHwee Park, dated July 7, 2014 ("Park Decl.") (Zivin Decl., Ex. 2). Since the declarations are a public record, and since the witnesses are available for examination by Celltrion in Massachusetts and the witnesses are not available to Kennedy, Kennedy mentions the declarations as background. See *Carter-Wallace, Inc. v. Otte*, 474 F.2d 529, 536-37 (2d Cir. 1972) (patent infringement action where former testimony of experts was permitted to be used). The Court need not rely upon the declarations, or it can do so, and convert the motion to one for summary judgment. See *Global Network Comm., Inc. v. City of New York*, 458 F.3d 150 (2d Cir. 2006).

ingredient, strength, dosage form, and route of administration as the approved product, and thus 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 containing drugs, biologics are not chemically synthesized but are made 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 biologics, specifically, monoclonal antibodies. Monoclonal antibodies are among the most complex biologics the FDA has ever approved. Because the manufacturing process for biologics 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 ¶¶ 15, 16). 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)(2), (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).

Although this pathway allows a follow-on manufacturer to rely on the innovator's safety and efficacy data, applicants still must 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 obtain approval to market its biosimilar product at a fraction of the cost incurred by the innovator when developing the original biologic. 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 the innovators who developed the reference products. *See*, § IV, *infra*.

B. Kennedy and Anti-TNFα Co-Administration With Methotrexate

As the Court knows, Kennedy was the pioneer in the discovery of methods of treating patients with rheumatoid arthritis ("RA") and other auto-immune diseases. Kennedy's Professors Ravinder Maini and Marc Feldmann discovered the role of the protein tumor necrosis factor alpha ("TNFα"). They discovered that the monoclonal antibody cA2, which was produced as an experimental drug by Centocor (now Janssen) for other purposes, would bind to TNFα. Later, Professor Maini and Feldmann discovered that cA2 when co-administered with methotrexate was highly effective in treating RA. Kennedy has obtained several patents for its inventions in this field. Notably, Kennedy has no patents on the biologic itself, but only on methods of treatment of certain medical conditions.

In 2001, Kennedy obtained U.S. patent No. 6,270,766 ("the '766 patent"), which claimed, *inter alia*, a method of treating RA by co-administering methotrexate and an anti-TNFα antibody. That patent expired in October 2012. The patent was licensed by Kennedy to Centocor (later Janssen). In 2005 Centocor sublicensed Abbott (later AbbVie). Kennedy later licensed its patent portfolio to UCB and to Amgen/Wyeth/Pfizer. Thus, three of the largest selling drugs in the world – Janssen's Remicade, Abbott's Humira and Amgen/Wyeth's Enbrel – were licensed under the Kennedy patent portfolio.

Kennedy's Professors Maini and Feldmann discovered in 1995 that a further unexpected result in treatment of RA was achieved by co-administering methotrexate and an anti-TNFα antibody in the mode of adjunctive and/or concomitant therapy. These modes of therapy and other improvements are the subjects of the claims of the continuation patents Nos. 7,846,442 ("the '442 patent"); 8,383,120 ("the '120 patent"); and 8,298,537 ("the '537 patent").

Claims 1-7, 13-14 and 17-20 of the '442 patent were litigated before the Court in a declaratory judgment action brought by AbbVie, 11 Civ. 2541, and the Court held that those claims were invalid for obviousness –type double patenting over claims 8-14 of the '766 patent, in a judgment dated July 2, 2013. The Court's judgment was affirmed on appeal by the Court of Appeals for the Federal Circuit on August 21, 2014, No. 2013-1545. It should be noted that, pursuant to a stipulation and this Court's order, the remaining claims of the '442 patent which specifically relate to cA2 (Remicade) were not litigated by AbbVie (Dkt. No. 99, Order of September 6, 2012) (Zivin Decl., Ex. 3).

Claims 1-2, 6-8, 12-14 and 18-19 of the '120 patent also were litigated before the Court in a second declaratory judgment action brought by AbbVie, 13 Civ. 1358. The Court granted summary judgment on July 9, 2014 declaring that those claims are invalid under the doctrine of collateral

estoppel based on the judgment in the first AbbVie law suit. That judgment is the subject of a pending appeal in the Federal Circuit, No. 14-1672. Again, the remaining claims of the '120 patent which specifically relate to the cA2 antibody were not litigated in the second AbbVie case, pursuant to a stipulation and this Court's Order (Dkt. No. 26, Order of October 3, 2013) (Zivin Decl., Ex. 4).

The third patent attacked by Celltrion, the '537 patent, was briefly a subject of the second AbbVie action, but was withdrawn from suit and never litigated (Dkt. No. 26, Order of October 3, 2013). Further, the claims that relate specifically to cA2 were withdrawn from consideration in the same stipulation and order.

None of the claims of the '442, '120 and '537 patents which are specifically directed to cA2 have ever been the subject of a Court decision by this Court or the Federal Circuit.

Kennedy never has sought to affirmatively enforce the '442, '120 and '537 patents against anyone, including Celltrion.[2]

As stated in the Complaint, requests to reexamine the '442 and '120 patents were filed in the PTO by an unidentified requester. The requester in both cases is suspected to be Celltrion or its marketing partner. Kennedy filed a reissue patent application for the '442 patent, and the reissue has been merged with the reexamination. Kennedy also filed a reissue application for the '537 patent. All of the proceedings in the PTO are pending and none are final. It is not known at this time which claims if any will survive the current PTO proceedings and what will be their scope.

C. Janssen and Remicade

Janssen (formerly Centocor) is a subsidiary of Johnson & Johnson, the large pharmaceutical company. Janssen received FDA approval to sell its biologic drug infliximab under the trademark

[2] Celltrion and/or its marketing partner, Hospira, challenged Kennedy's patents in England, Finland and Hong Kong. Celltrion and Hospira eventually took a license under the Kennedy patents in those countries and elsewhere, rendering those cases moot. Celltrion and/or Hospira then brought a declaratory judgment action challenging Kennedy's Canadian Patent; Kennedy counterclaimed; those matters are pending. Of course, Kennedy's U.S. patents were not the subject of the foreign law suits.

Remicade. Remicade, containing the monoclonal antibody cA2, is one of the first biologics of its kind sold in the United States.

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.

D. 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 ¶ 5). However, Celltrion did not actually apply for FDA approval until August 8, 2014, more than four months after the Complaint was filed. That application has not yet been accepted.[3] Celltrion alleges in the Complaint that, even though it had not yet applied for a license, it "expects" to receive FDA approval to sell Remsima by "early 2015" (*id.* at ¶ 33).[4] The FDA has only recently accepted for filing the first biosimilar application filed by another company (Sandoz), and has never

[3] Even if an application is filed, it must be accepted for review by the FDA. That is not the same as approval for marketing.

[4] 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 ¶¶ 3, 5).

approved any biosimilar application. *See* visiongain blog dated July 25, 2014 (Zivin Decl., Ex. 5). Celltrion admits, in its own press release about its filing with the FDA, that approval will take about one year, that is, no earlier than August 2015. (Zivin Decl., Ex. 6). Independent commentators are not so sanguine. *See* Law360 article (Zivin Decl., Ex. 7). In any event, it is unlikely that Celltrion could receive marketing approval from the FDA any earlier than one year from now.

Based on an "intent" to submit a 262(k) application, an "expectation" the FDA will approve that application in short order, an assumption that sale of Remsima will infringe a Kennedy patent, and an assumption that Kennedy will sue Celltrion on the three patents-in-suit if Celltrion tries to sell Remsima, Celltrion seeks a declaration that Kennedy's patents are invalid (Compl. at ¶ 59). Celltrion does not seek a declaratory judgment that Remsima does not infringe Kennedy's patents. Nor does it aver in what way Remsima, or its intended uses, are allegedly covered by claims of Kennedy's patents, which claims are not fixed due to ongoing PTO proceedings. 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 Kennedy allegedly has aggressively sought to protect its patent rights.

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, 1338-39 (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 that subject-matter jurisdiction existed as of the date it filed its Complaint; later events cannot cure a subject-matter jurisdiction defect in the Complaint. *See 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). Thus, the operative date for testing jurisdiction is March 31, 2014, the date the complaint was filed.

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 who have provided 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 FDA application had not yet been filed). 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 what will be filed. Celltrion admitted this, by stating in the Complaint that it was still in negotiations over the content of its application and that the FDA had already required additional clinical testing of Remsima (Compl. at ¶¶ 31, 32). This is confirmed by the Park Declaration. Those facts undermined Celltrion's claim that its FDA filing was imminent. This lack of immediacy was borne out by subsequent events. It took more than four months for Celltrion to even file an application, which has not yet been accepted by the FDA, and is at least a year away from approval. 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 was entirely possible that the FDA would require Celltrion to do additional clinical testing or submit additional data before filing its application, and this apparently turned out to be the case. In short, it is impossible to know whether Celltrion's application will be accepted and, if so, when.

Second, once an application is filed and formally accepted for review, there is no way to know whether and when the FDA will approve the application. Celltrion suggests that the FDA will grant its application in the "ordinary course" (Compl. at ¶33). But, as Celltrion acknowledges, Remsima, if approved, "will become the *first* biosimilar of an antibody drug ever approved in the United States" (*id. a*t ¶ 5 (emphasis added)). There can be no "ordinary course" for approval of biosimilar drugs because the FDA has not yet approved a single one, and has only recently accepted for review one application filed by another company. 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 decisions to approve the first biosimilar products under the 262(k) pathway. Senior FDA officials will likely review the primary reviewer's decision on many levels (Siegel Decl. at ¶ 18). *See also* the Law360 article. It is impossible to predict when and if Celltrion's application will be approved even if it is filed.

Third, at this early date, and without the benefit of Celltrion's 262(k) application or any information from the FDA as to which medical condition or conditions the FDA will grant approval, it is not possible to assess whether there will be a dispute under the claims of any particular Kennedy 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 Cremationø⊕ 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).

Kennedy's patents claim only methods of treatment of RA. There is no way for Kennedy to know now whether Celltrion will seek, or be granted, a license to sell Remsima for that condition. For example, if Celltrion's Remsima is approved only for treatment of Crohn's Disease, then no Kennedy patent claims would be infringed and there will be no controversy. There is no way to know when, if ever, Remsima will be approved in the U.S. for a use that could potentially infringe Kennedy's patents. *See Matthews*, 695 F.3d at 1328.

Fourth, Kennedy's patents claim methods of treatment of RA using specific regimens of co-administration of the antibody with methotrexate. There is no way to know whether Celltrion's Remsima will be labeled in a manner which would require the use of methotrexate or the regimens or dosages which will be required.

Fifth, Kennedy's patent claims of interest to Celltrion all require the use of cA2. It is not known whether the active ingredient in Celltrion's Remsima is cA2, particularly since Celltrion's complaint does not allege that it is. Thus, it cannot be known whether any product approved for sale in the U.S. will infringe any of the cA2 claims of the Kennedy patents.

Finally, although Celltrion insists that its product is "fixed and definite" because other countries have approved Remsima (Compl. at ¶ 54), 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 FDA reviews more information than many 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 approved "product" already

differs from country to country. The product Celltrion will market in the U.S. is *not* fixed and definite.

Celltrion's allegations in the Complaint 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 existed as of the filing of the Complaint. Indeed, they are not *facts* at all. They are a hope, a wish, or an aspiration, at most. Celltrion has not met, and cannot meet, its burden of proving the existence of a real and immediate dispute.

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

The specific harm Celltrion alleges – a "fear" of suit under the three Kennedy patents – is not realistically based on any of Kennedy's actions. Celltrion alleges that it fears suit because Celltrion will file for approval of Remsima as a biosimilar of Janssen's Remicade and Kennedy allegedly has indicated, through its statements, conduct, and other litigations, that it will enforce its patent rights (Compl. at ¶¶ 34-52). In fact, Kennedy already has granted a license to Celltrion in Europe, Australia and Hong Kong and has told Celltrion's marketing partner Hospira that it would look favorably on a request for a license for the United States and Canada effective in 2015. Kennedy remains interested in licensing its patents on non-discriminatory terms. It does not wish to put Celltrion or any other manufacturer out of business. Nor do Kennedy'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.

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 a-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 Kennedy's purportedly "aggressive" legal challenges do not evidence a pattern of conduct with respect to the three patents that are the subject of this case.

With respect to litigation in the United States (Compl. at ¶ 45), the two infringement actions identified in the Complaint were infringement actions seeking monetary damages under a different patent, the '766 patent, against different companies based on different products – UCB's Cimzia product and Wyeth/Amgen's Enbrel product. Those two cases were immediately resolved by Kennedy's issuance of licenses. Indeed, as the Court knows, Kennedy did not sue or counterclaim against AbbVie for patent infringement despite the latter's two declaratory judgment actions seeking invalidity of other claims of the patents-in-suit.

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, all of which are

the subject of ongoing parallel PTO proceedings. *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)). Celltrion's alleged "facts" do not support jurisdiction. *See id*.

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

Kennedy is aware of only one decision that has addressed the question of declaratory judgment jurisdiction on facts similar to those here. That decision – *Sandoz Inc. v. Amgen Inc*. – supports this motion to dismiss. *See Sandoz Inc. v. Amgen Inc*., 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013) (order granting motion to dismiss).

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 anti-TNFα 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 Kennedy 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. Kennedy is unaware of any legal authority supporting declaratory judgment jurisdiction before a party filed its biosimilar application.

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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 order is currently pending in the Federal Circuit. *Sandoz Inc. v. Amgen Inc.*, No. 2014-1693. If the Federal Circuit affirms that there was no subject matter jurisdiction, this Court would be compelled to dismiss Celltrion's complaint. Federal Circuit law governs whether an action for a declaratory judgment of patent invalidity may be maintained. *Organic Seed Growers & Trade Association v. Monsanto Co.*, 851 F.Supp.2d 544, 550, fn. 4 (S.D.N.Y. 2012).

IV. THERE IS NO SUBJECT MATTER JURISDICTION BECAUSE CELLTRION HAS BY-PASSED THE BPCIA FRAMEWORK

The facts do not evidence a substantial, real and immediate controversy between the parties. But even if an actual controversy did exist, this Court should decline to hear Celltrion's case. *See 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 the case serves the objectives for which the Declaratory Judgment Act was created." *Cat Tech*, 528 F.3d at 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 Kennedy and Celltrion.

Once Celltrion filed its application for approval to market Remsima, the BPCIA controlled procedures for addressing any disputes that might exist between Kennedy and Celltrion. The BPCIA has three components: 1) it provides the less expensive 262(k) route for approval of 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 addressing patent disputes over relevant patents still in force after the period of statutory exclusivity expires.

Under the BPCIA's patent resolution procedures, 42 U.S.C. § 262(l), Celltrion could provide a copy of its 262(k) application to Kennedy, as well as to Janssen, within twenty days of filing the application. § 262(l)(2). Kennedy 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 Kennedy and Celltrion could 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 Kennedy 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 allows Celltrion to file a declaratory judgment in advance of the filing of a 262(k) application and without giving notice of commercial marketing. Kennedy could file such an action, but only if Celltrion failed to provide the application to Kennedy 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 Kennedy, then *neither party* could bring a declaratory judgment action on any relevant patent until Celltrion gave notice of commercial marketing. § 262(l)(9)(A).

Celltrion is attempting to avail itself of the benefits of the § 262(k) route to approval without following the statutory patent resolution provisions implemented to protect both the reference product patent owner and the 262(k) applicant. 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 before filing its FDA application. 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 launch of Remsima®" (Compl. at ¶ 59). 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. Celltrion should comply with BPCIA and try to resolve any potential patent dispute at the appropriate statutory opportunity. If Celltrion believes that Congress's framework does not allow it to timely resolve its concerns, its remedy lies with Congress, not this Court.

V. THE COURT SHOULD STAY THIS LATER-FILED ACTION UNTIL THE PTO'S EARLIER-FILED REEXAMINATION/REISSUE PROCEEDINGS ARE CONCLUDED

The ultimate fate of Kennedy's patents included in Celltrion's Complaint presently is uncertain. As stated in the Complaint (¶¶ 41, 42, 44), all claims of the patents already are the subject of reexamination/reissue proceedings at the PTO. Courts frequently stay pending litigation when a patent already is the subject of reexamination, *see Gould v. Control Laser Corp.*, 705 F.2d 1340 (Fed. Cir. 1983), especially where the reexamination was underway before the suit was filed, *see Aerotel, Ltd. v. IDT Corp.*, 2003 WL 23100263 (S.D.N.Y. 2003). It would be particularly odd to *initiate* a *discretionary* declaratory judgment action while all claims currently are under review. Although Kennedy believes at least some of the claims are patentable and that the PTO will confirm their patentability, there is no reason to initiate a declaratory judgment litigation on the patents at this time, when Celltrion has filed its 262(k) application with the FDA only a few days ago and is at least one year away from possible approval.

If the Court determines that jurisdiction is proper, the Court should stay this action pending final disposition of the reexamination/reissue proceedings. It is appropriate to stay proceedings in the early stages of litigation before the Court and the parties have invested substantial time and resources, particularly where the resolution of a reexamination may simplify or completely obviate the issues in the case. *See Luv N' Care, Ltd. v. Regent Baby Products Corp.*, 10-Civ. 9492, 2014 WL 572524, at *2 (S.D.N.Y. Feb. 13, 2014); *Lederer v. Newmatic Sound Sys., Inc.*, 10-CV-0271 (JS)(AKT), 2011 WL 31189, at *3 (E.D.N.Y. Jan. 4, 2011); *Softview Computer Products Corp. v. Haworth, Inc.*, 97 CIV. 8815 KMW HBP, 2000 WL 1134471, at *2-*4 (S.D.N.Y. Aug. 10, 2000).

In determining whether to grant a stay pending reexamination, courts consider the following factors: (1) whether discovery is complete and whether a trial date has been set; (2) whether a stay

will simplify the issues in question and trial of the case; and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. *Softview* at *2.

Because all three factors weigh heavily in favor of a stay, the Court should grant Kennedy's motion to stay the action pending resolution of the reexamination/reissue proceedings.

A. A Stay Is Favored Where There Has Been No Substantial Progress Towards Trial

"Cases are routinely stayed in the absence of substantial progress toward trial." *Lederer* at *3 (citation and internal quotation marks omitted). Here, an answer has not been filed, discovery has not begun, and a trial date has not been set. This factor weighs in favor of a stay.

B. A Stay Will Necessarily Simplify The Issues Before The Court

Courts long have recognized that a stay pending reexamination or reissue will necessarily pare down the issues in litigation.[7] *See Softview* at *2. For example, the reexamination proceeding may directly simplify the issues by invalidating or narrowing a claim or claims. *Id*. Furthermore, even if all claims were confirmed, the Court stands to benefit from the reexamination record and any analysis provided by the PTO's expert in regards to prior art that allegedly invalidates or limits the claims. *See id.* This factor also weighs in favor of a stay.

C. A Stay Neither Unduly Prejudices Nor Presents A Clear Tactical Disadvantage To Celltrion.

A stay would neither unduly prejudice nor present a clear tactical disadvantage to Celltrion. Celltrion could not be in position to market its product for at least one year. Indeed,

[7] Courts have found the following advantages to result from granting a stay during the pendency of reexamination: (1) all prior art presented to the Court will have been first considered by the PTO; (2) many discovery problems relating to prior art can be alleviated by the PTO examination; (3) in those cases resulting in effective invalidity of the claims, the suit will likely be dismissed; (4) the outcome of the reexamination may encourage a settlement; (5) the record of the reexamination would likely be entered at trial, thereby reducing the complexity and length of the litigation; (6) issues, defenses, and evidence will be more easily limited in pre-trial conferences after a reexamination; and (7) the cost will likely be reduced both for the parties and the Court. *Softview* at *2.

reexamination/reissue proceedings may be concluded by the PTO before Celltrion receives any 262(k) approval.

Kennedy is not a competitor of Celltrion who will achieve an undue advantage from a stay. *See e.g., Dorman Products, Inc. v. Paccar, Inc.*, 13-6383, 2014 WL 2725964, *2 (E.D. Pa. June 16, 2014) (parties competing in different markets suggests defendant would not be unduly prejudiced by stay); *Software Rights Archive, LLC v. Facebook, Inc.*, C-12-3970 RMW, 2013 WL 5225522, *6 (N.D. Cal. Sept. 17, 2013) (a stay would not present undue prejudice because parties were not competitors); *Neste Oil OYJ v. Dynamic Fuels, LLC*, 12-1744-GMS, 2013 WL 3353984, *3-*4 (D. Del. July 2, 2013) (parties' status as indirect competitors weighed against finding the stay unduly prejudiced plaintiff); *Rembrandt Gaming Technologies, LP v. Boyd Gaming Corp.*, 2:12-cv-00775-MMD-GWF, 2012 WL 6021339, *2-*3 (D. Nev. Dec. 3, 2012) (emphasizing that parties' relationship as non-direct competitors lessens the risk of prejudice to non-moving party).

Further, a stay would not present a clear tactical disadvantage to Celltrion given the timeliness of this request. *See, e.g., Synchronoss Technologies, Inc. v. Asurion Mobile Applications, Inc.*, 11-5811 (FLW), 2013 WL 1192266, *5 (D.N.J. Mar. 22, 2013) (finding no tactical disadvantage present where a stay was requested shortly after PTO's initial response to reexamination request); *Generac Power Sys. Inc. v. Kohler Co.*, 807 F.Supp.2d 791, 798 (E.D. Wis. 2011) (finding no tactical disadvantage present where stay and reexamination were requested early in litigation). Celltrion faces no risk of an injunction sought by Kennedy. Therefore, this factor weighs strongly in favor of a stay.

Because all factors weigh heavily in favor of a stay, the Court should grant Kennedy's motion to stay pending resolution of the reexamination/reissue proceedings, if the Court does not dismiss the action.

VI. CONCLUSION

Celltrion's Complaint fails to allege facts evidencing a real and immediate controversy between the parties. There was no subject matter jurisdiction when the case was filed, and that deficiency cannot be cured by later events. Celltrion's wish-and-hope that it will obtain FDA approval to introduce Remsima to the U.S. market in 2015 is hypothetical and speculative. There is no real impact on Celltrion if this suit does not proceed. Celltrion's fear of suit by Kennedy is subjective and unreasonable. Celltrion's declaratory judgment Complaint flies in the face of the patent dispute procedures mandated by the BPCIA, procedures which should be followed by Celltrion. Celltrion's Complaint should be dismissed.

In the event that the Court does not see fit to dismiss the Complaint, the Court should stay the action until the PTO's reexamination and reissue proceedings are concluded.

Respectfully submitted,

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Dated: August 28, 2014

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CERTIFICATE OF SERVICE

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

DEFENDANT KENNEDY TRUST'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF CELLTRION'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION PURSUANT TO FED.R.CIV.P. 12(b)(1), OR TO STAY THE ACTION

was electronically mailed to counsel of record on August 28, 2014 through the Court's ECF notification system.

/s/ Norman H. Zivin