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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Celltrion Healthcare Co., Ltd. and Celltrion, Inc.,

Plaintiffs,

-against-

Kennedy Trust for Rheumatology Research (formerly known as The Mathilda and Terence Kennedy Institute of Rheumatology Trust),

Defendant.

Case No.: 1:14-cv-02256 (PAC)

Oral Argument Requested

PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANT KENNEDY TRUST'S
MOTION TO DISMISS THE COMPLAINT OR TO STAY THE ACTION

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INTRODUCTION

Plaintiffs Celltrion Healthcare Co., Ltd. and Celltrion, Inc. ("Celltrion") spent years—and more than $100 million—developing Remsima, a biosimilar version of Remicade, which provides treatment for a variety of chronic and debilitating diseases. Thanks to Celltrion's hard work, Remsima has won approval over the past two years in more than *50* countries. These approvals followed careful review of Remsima by some of the world's most rigorous regulatory authorities, including those of Europe, Canada, and Japan.

The United States soon will join the countries that have approved Remsima. Celltrion recently filed its application with the U.S. Food & Drug Administration ("FDA") to market Remsima in the United States. But Celltrion's ability to distribute Remsima upon receiving FDA approval faces a significant obstacle: the Kennedy Trust for Rheumatology Research ("Kennedy") holds patents it has a history of asserting (as this Court has recognized), and Kennedy has repeatedly asserted this family of patents against Remsima in other jurisdictions. Kennedy also has rejected Celltrion's prior requests to license its patents in the United States and has failed to offer Celltrion a covenant not to sue. At the pre-motion conference, Kennedy's counsel made clear that his client intends to seek royalty damages from Celltrion when Remsima is approved.

The relevant Kennedy patents are invalid and unenforceable. Celltrion should not have to wait until Remsima is approved and Kennedy chooses to assert its patent rights. The circumstances here establish the type of "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) (citations omitted).

Kennedy's arguments to the contrary are wrong. Kennedy seeks to impose restrictive jurisdictional rules regarding the timing of an FDA application or approval. But these kinds of bright-line rules have no place in the analysis. *See Organic Seed Growers & Trade Ass'n v. Mon-*

santo Co., 718 F.3d 1350, 1355 (Fed. Cir. 2013). Kennedy also draws highly technical, non-material distinctions about its prior litigation in other countries—including its prior litigation involving Remsima. And Kennedy virtually ignores Celltrion's well-pleaded allegations about its substantial preparation to bring Remsima to market. All of this is sufficient to give this Court jurisdiction to decide the validity and scope of the patents at issue. In contrast, if this case is dismissed or delayed, Remsima's U.S. launch could be unnecessarily delayed for years.

Kennedy separately contends that this Court lacks jurisdiction because of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). But the BPCIA's prohibitions on declaratory-judgment actions are not jurisdictional and do not even apply to this case. Nor is Celltrion's suit an evasion of the BPCIA's patent information-exchange process, as Kennedy contends. That process ripens disputes between a holder of a marketing license for a biologic product and a biosimilar applicant so that they can litigate otherwise unripe patent claims during the first marketing license holder's 12-year term of marketing exclusivity. Here, however, Kennedy is not the holder of any marketing license—indeed, Kennedy does not make or sell any product—so it has no right to participate in the information exchange (and certainly has no right to force Celltrion to provide its application to Kennedy). In any event, Celltrion's patent claims against Kennedy are independently ripe. Dismissing this action would frustrate the BPCIA's purposes by delaying Celltrion's entry into the market.

Finally, Kennedy seeks a stay pending the resolution of reexamination and reissue proceedings before the U.S. Patent & Trademark Office. This request fails to recognize this Court's unique expertise concerning the patents at issue, inaccurately portrays courts' willingness to stay actions in similar circumstances, understates the limitations of the PTO's process, and fails to account for the time Celltrion will lose to market Remsima after it is approved.

STATEMENT OF FACTS

I. REGULATORY BACKGROUND—THE BPCIA.

Biological products like Remsima and Remicade cannot be sold without a license. *See* 42 U.S.C. § 262(a). To reduce the cost of obtaining a license and lower consumer prices, Congress enacted the BPCIA and created an accelerated licensing pathway. *See* H.R. 3590–686, 111th Cong. § 7001(b) (2009). A biologics manufacturer now may apply for a license by showing its product is a "biosimilar," *i.e.*, highly similar to an already licensed "reference product." 42 U.S.C. § 262(i)(2). A product cannot be licensed as a biosimilar until 12 years after its reference product was first licensed. *Id.* § 262(k)(7)(A).[1]

To help bring biosimilars to market as soon as the 12-year term expires, Congress allowed biosimilar manufacturers to apply for licenses up to 8 years before, leaving courts ample time to work through patent disputes that might arise. *Id.* § 262(k)(7)(B). Congress believed many patent disputes would be resolved during the 12-year term, but it was concerned that leaving any dispute unresolved until the end of the 12-year term would delay entry of biosimilars into the market and would effectively lengthen that term. The BPCIA thus provides a mechanism to ripen otherwise unripe patent disputes before the 12-year term expires and "ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 21, 9 (July 14, 2009) (statement of Rep. Eshoo).

Filing a biosimilar application is an act of (alleged) infringement of patents the applicant

[1] This term was the focus of intense deliberation; Congress rejected longer and shorter proposals. *See* Krista Carver, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 787–98, 805–06, 817 (2010).

and reference product sponsor identify in post-filing information exchanges. *See* 35 U.S.C. § 271(e)(2)(C)(i). Specifically, the applicant and reference product sponsor create and exchange "list[s] of patents" for which an infringement claim reasonably could be asserted. 42 U.S.C. § 262(l)(3). Then they negotiate over which patents "shall be the subject of an" infringement action that the reference product sponsor "shall bring." *Id.* §§ 262(l)(4), (l)(6). The BPCIA prohibits the applicant and reference product sponsor from maintaining patent lawsuits filed *during* this information-exchange process, *see id.* § 262(l)(9), but it does not prohibit suits, like Celltrion's, that are independently ripe and filed *before*. The BPCIA also does not encompass disputes between biosimilar applicants and entities like Kennedy. Rather, the only entities that participate in the BPCIA's patent-information-exchange process are the biosimilar applicant and the reference product sponsor. An entity that owns a patent the reference product sponsor exclusively licenses may receive a copy of the biosimilar application, but only if the parties want to provide it and the owner agrees to the statute's confidentiality requirements. *Id.* § 262(l)(1)(B)(iii).

II. FACTUAL BACKGROUND—CELLTRION'S EFFORTS TO DEVELOP REMSIMA AND KENNEDY'S EFFORTS TO OPPOSE IT.

Celltrion has spent more than $112 million developing Remsima. Compl. ¶ 19. Clinical trials have established Remsima's comparability to Remicade, in both safety and efficacy. *Id.* ¶ 26. Korea approved Remsima for sale in 2012; the European Medicines Agency approved it last fall. *Id.* ¶¶ 27, 28. Remsima now has been approved for marketing in more than 50 countries, with applications under review in another 26, and it is already being sold in over 20 countries. *See* Decl. of JaeHwee Park in Supp. of Celltrion's Opp. ("Park Decl.") ¶¶ 12-13. No country has required a change to Remsima's antibody amino acid sequence, structure, and manufacturing process, and the same product is being sold all over the world. *Id.* ¶ 14. All countries that have approved Remsima have approved its use in treating rheumatoid arthritis in combination with

methotrexate, and Celltrion is seeking FDA approval to market Remsima for the same use. *Id.* ¶¶ 14, 24; Decl. of Gordon Johnston in Supp. of Celltrion's Opp. ("Johnston Decl.") ¶¶ 38–39.

Celltrion has been focused on FDA approval since Congress enacted the BPCIA. Celltrion designed its manufacturing facilities to meet the FDA's standards. Park Decl. ¶ 27. Celltrion submitted an Investigational New Drug application in October 2013 and completed clinical testing in March 2014. Compl. ¶¶ 31–32. In April, Celltrion obtained detailed guidance from the FDA regarding the contents of its application. Park Decl. ¶ 19. Celltrion complied with that guidance and filed its application on August 8. *Id.* ¶ 21; *see* Compl. ¶ 33.

The FDA has committed to process biosimilar applications like Celltrion's in ten months or less. Johnston Decl. ¶¶ 23–24, 30. The FDA has substantially met its target dates for pre-application meetings with Celltrion regarding Remsima. *Id.* ¶ 29. Celltrion believes the FDA will keep its commitment and approve Remsima in 2015, because: (1) Celltrion's manufacturing facilities were designed to meet FDA standards; (2) Celltrion prepared its application in consultation with the FDA; (3) Celltrion's data has been reviewed and approved by regulatory agencies covering more than 50 countries, including the rigorous European, Canadian, and Japanese authorities; (4) Celltrion prepared and filed its U.S. application based on the experience it gained during this process; (5) the FDA has met its interim deadline goals already; and (6) the FDA has the necessary resources. *Id.* ¶¶ 18–19, 29–31, 32–33, 35–36; *see also* Park Decl. ¶¶ 12, 15–22, 27. Celltrion accordingly has increased its manufacturing capacity, established a domestic office, and invested in a marketing and distribution network to satisfy U.S. demand for Remsima. Park Decl. ¶¶ 26–28; Compl. ¶¶ 55–56.

Celltrion's success has been met by determined opposition from its competitors and their licensors, including Kennedy. Kennedy has garnered millions of dollars in royalties from its pa-

tents by licensing them to other companies, Compl. ¶ 43, and it has gone to great lengths to protect that income. Most importantly for this case, Kennedy has claimed that the Remsima antibody infringes its patent rights in both the United Kingdom and Canada. In the U.K., Kennedy filed a counterclaim against Celltrion's marketing partner, Hospira UK, Ltd., and contended that the Remsima antibody (which was approved under the brand name Inflectra) infringed the European counterpart patents to the '442, '537 and '120 patents. Compl. ¶ 46. Kennedy ultimately resolved that claim by negotiating a license to those patents, but it pointedly refused to grant Hospira or Celltrion a license in Canada or the United States. *Id.* ¶¶ 46–47. Unsurprisingly, Kennedy then proceeded to file claims for patent infringement in Canada against Celltrion and Hospira, contending that the Remsima antibody "infringes the Canadian counterpart to the '442 patent[.]" *Id.* ¶ 48. Most tellingly, Kennedy has repeatedly refused Celltrion's requests for a license to Kennedy's patents in the United States. *Id.* ¶ 49.

Kennedy's attempts to enforce its patent rights against Hospira and Celltrion are consistent with its pattern of litigating patent disputes. Kennedy brought infringement suits based upon the '766 patent (the parent patent of the '442, '537 and '120 patents at issue in this case) against UBC, Inc., Amgen and Wyeth. Compl. ¶ 45. More recently, Kennedy asserted counterclaims in litigation involving the patents at issue here (the claims at issue of the '442 patent and the '120 patent were eventually invalidated by this Court; the '537 patent was dropped from the cases based on Kennedy's covenant not to sue). *Id.* In rejecting Kennedy's challenge to declaratory-judgment jurisdiction in one of those cases, this Court noted Kennedy's "history of enforcing its patent rights against third parties." *Id.*; *see also AbbVie Inc. v. Mathilda & Terrence Kennedy Inst. of Rheumatology Trust*, No. 11 Civ. 2541, (S.D.N.Y. Oct. 14, 2011), ECF No. 25.

Indeed, Kennedy has publicly committed to "protect[ing] intellectual property created or

acquired by the Trust," and it has stockpiled millions of dollars for the designated purpose of "[d]efending the Trust's patent portfolio and associated royalty income." Compl. ¶¶ 50–51.

ARGUMENT

I. THIS CASE IS RIPE BECAUSE THE DISPUTE BETWEEN CELLTRION AND KENNEDY IS "DEFINITE AND CONCRETE," "REAL AND SUBSTANTIAL."

A. Ripeness Is Based On The Totality Of The Circumstances.

The Declaratory Judgment Act provides that "[i]n 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(a). The "case of actual controversy" requirement arises from the Constitution's limitation of federal jurisdiction to "[c]ases and [c]ontroversies." *MedImmune*, 549 U.S. at 127. A declaratory-judgment action is ripe if "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." *Id.* (emphasis added) (citation omitted).

As this Court recently noted, *MedImmune* "'lowered the threshold' for establishing the existence of an actual case or controversy in intellectual property-related declaratory judgment cases." *Gelmart Indus., Inc. v. Eveready Battery Co.*, No. 13 Civ. 6310 (PKC), 2014 WL 1512036, at *3 (S.D.N.Y. Apr. 15, 2014) (Castel, J.) (citation omitted)). The post-*MedImmune* test is a "more lenient legal standard" that "facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases." *Micron Tech., Inc. v. Mosaid Techs, Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008). *See also Gelmart*, 2014 WL 1512036, at *3.

Importantly, no bright-line rules govern. *See Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1331 (Fed. Cir. 2014) (noting the "Supreme Court's insistence on applying a flexible

totality of the circumstances test [and] its rejection of technical bright line rules"). For example, while the issue of whether a declaratory-judgment plaintiff has engaged in "meaningful preparation to conduct potentially infringing activity remains an important element in the totality of circumstances," the plaintiff "need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment . . . ." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880-81 (Fed. Cir. 2008). *See also Gelmart*, 2014 WL 1512036, at *5 (rejecting arguments that a "case is not ripe for adjudication because the Complaint sets forth insufficient detail concerning [plaintiff's] anticipated launch of the proposed [product] line"). Kennedy's claim that Celltrion must prove with absolute certainty the date its product will launch and the specifics of the FDA approval, *see* MTD at 11–13, contradicts *MedImmune*'s flexible standard.

In this case, all the circumstances weigh in favor of jurisdiction. Celltrion has engaged in substantial preparation to market Remsima in the United States. Remsima's formula is fixed and will not change in any way relevant to the three disputed patents. Kennedy has repeatedly asserted its patent rights to block the Remsima antibody in foreign jurisdictions. In resolving some of those matters, it expressly refused to grant Celltrion a license to its United States patents. Nor has Kennedy offered Celltrion any assurances that it will not assert the patents at issue and demand a royalty from Celltrion for its distribution of Remsima in the United States (even on the '537 patent, for which Kennedy gave AbbVie a covenant not to sue). For these and the other reasons provided below, the Complaint easily satisfies the *MedImmune* standard.

B. Celltrion's Substantial, Concrete Preparations To Bring Remsima To The U.S. Market Establish A Ripe Controversy.

1. Celltrion has substantially completed the process of seeking regulatory approval.

Celltrion's Complaint and the Declaration of JaeHwee Park establish that, contrary to

Kennedy's argument, Celltrion has engaged in the necessary "significant, concrete steps to conduct [potentially] infringing activity" that create an immediate and real dispute. *Cat Tech*, 528 F.3d at 880. Celltrion brings this action in the final stage of its extensive preparations to launch Remsima in the United States:

- Celltrion has invested more than 6 years and $112 million to research, develop, and clinically test Remsima. Compl. ¶ 19; Park Decl. ¶ 5.

- Celltrion has obtained approvals for Remsima in more than 50 countries and has launched (with its licensees) in over 20 countries. Compl. ¶¶ 27–29; Park Decl. ¶¶ 9–13.

- Celltrion has completed Phase I and Phase III global clinical trials, and the FDA has concluded that no further Phase III testing is necessary (it recommended only a bridging study, which Celltrion completed). Compl. ¶¶ 32; Park Decl. ¶¶ 7, 17–18.

- Celltrion worked closely with the FDA to prepare its application, and (consistent with the allegations in the Complaint) filed it on August 8, 2014. Park Decl. ¶¶ 15–21.

- Celltrion's manufacturing facilities already satisfy the FDA's standards, and Celltrion built the manufacturing capacity to have stockpiles of Remsima ready for sale as soon as the FDA approves it. Compl. ¶¶ 53–55; Park Decl. ¶¶ 27–28.

- Celltrion has established a marketing infrastructure in the United States. Compl. ¶¶ 55–56; Park Decl. ¶ 26.

Minimizing Celltrion's substantial preparations, Kennedy contends that this Court could *never* obtain jurisdiction before a biosimilar application is submitted (even when, as here, the filing of the BLA on August 8 was imminent) or approved by the FDA. *See* MTD at 10–12. But an actual controversy can exist before a declaratory-judgment plaintiff obtains regulatory approval. *Infinitech, Inc. v. Vitrophage, Inc.*, 842 F. Supp. 332, 337–38 (N.D. Ill. 1994). Embarking "upon a protracted and costly process of obtaining regulatory approval . . . evinces the kind of 'concrete steps' or 'meaningful preparation' needed to establish an actual controversy under

'all the circumstances.'" *Id.*[2] Likewise, on facts similar to those here, another court held that "[a]n approval date that is 20 to 24 months away can be considered sufficiently imminent by this Court" to constitute meaningful preparation, particularly where a party has engaged in "systematic attempts . . . to meet the regulatory requirement coupled with the acts of hiring key sales and managerial personnel and constructing a manufacturing facility[.]" *Amgen, Inc. v. F. Hoffman-LaRoche Ltd*., 456 F. Supp. 2d 267, 278 (D. Mass. 2006).[3]

Indeed, having completed its Phase III clinical testing and its application (which is now on file), Celltrion is miles ahead of the plaintiffs in the cases Kennedy relies upon. *See Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346–47 (Fed. Cir. 2007) (plaintiff did not even have data to determine when or whether it could *ever* file an FDA application); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992) (plaintiff "had only recently begun clinical trials, and was years away from potential FDA approval"); *see also Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1329–31 (Fed. Cir. 2012) (there was no evidence whether the product *ever* would be used in an infringing way).

Celltrion's progress and Remsima's established record of success also distinguishes this

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[2] *See Cat Tech*, 528 F.3d at 881 (a plaintiff "need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment"); *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1358-60 (Fed. Cir. 2013) (a "present intent" to supply an infringing product and concrete steps such as negotiating supply contracts constituted meaningful preparation when the predicted commercial launch of product was still a year away); *see also Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 396–97 (D. Mass. 1996) (Wolf, J.) (the plaintiff "had actually produced Avonex for sale in anticipation of receiving the FDA's approval and taken other concrete steps to market the drug promptly," including "invest[ing] more than $150 million in research and development concerning Avonex, and had spent another $24 million to stockpile and prepare to market the drug").

[3] In *Amgen*, the plaintiff amended its complaint after filing its application, although (consistent with *MedImmune*) the court did not identify that fact as dispositive. Celltrion believes no amendment is necessary here, as the filing of its application simply confirmed its well-pleaded allegations that it was about to do so, *see* Compl. ¶ 33. If, however, the Court believes that jurisdiction depends upon a specific allegation that its application is on file, Celltrion respectfully requests that it be permitted to amend its Complaint pursuant to Fed. R. Civ. P. 15.

case from *Sandoz Inc. v. Amgen Inc.*, No. 13-cv-2904, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013). Unlike Celltrion, Sandoz filed its declaratory-judgment complaint just after embarking upon Phase III clinical trials. It thus had not established the safety and efficacy of its product nor presented any related data to the FDA. Celltrion is much further along; it has successfully completed its Phase III trials more than a year ago, completed the short bridging study requested by the FDA before Celltrion filed its application, and has already obtained regulatory approval of its product in dozens of other jurisdictions.[4]

Kennedy's arguments that it is "impossible to know" the contents of an application before filing, MTD at 11, and that there is "no way to know whether and when the FDA will approve the application," *id.* at 12, amount to assertions that declaratory judgment is *never* appropriate pre-approval. This is precisely the kind of "bright line" rule that *MedImmune* and its progeny forbid. This Court itself has rejected similar arguments because "*Iqbal* and *MedImmune* do not require such a heightened level of particularity." *Gelmart*, 2014 WL 1512036, at *5.

Kennedy supports its arguments with references to a declaration submitted by an employee of the parent company of Janssen Biotech, Inc., Dr. Jay Siegel, in litigation between Janssen and Celltrion in Massachusetts. *See* Zivin Decl., Ex. 1 (the "Siegel Decl."). But Dr. Siegel has no personal knowledge whatsoever of Celltrion's dealings with the FDA, and his speculation cannot counter Celltrion's allegations and supporting evidence. For example, Dr. Siegel opines that the FDA "may change" its favorable response to Celltrion's data after receiving Celltrion's final application. Siegel Decl. ¶ 22. But the FDA's favorable response was based on a detailed review of Celltrion's methods and data on biosimilarity and safety, and Celltrion's application

[4] Given Celltrion's success in other countries and its progress with the FDA, Kennedy is incorrect to argue that if the Federal Circuit affirms the District Court's dismissal in *Sandoz*, this case must be dismissed. *See* MTD at 16 n.6. But if the Federal Circuit finds jurisdiction on the facts of *Sandoz*, Celltrion's much stronger posture would compel jurisdiction here.

now includes the same data. Park Decl. ¶¶ 15, 17, 23. Dr. Siegel also claims that the FDA might take longer to review Celltrion's application because it will be the first-ever under the BPCIA. Siegel Decl. ¶ 18. But the FDA has committed to issue a final response on most biosimilar applications within ten months and has met its interim deadline commitments with respect to the Remsima application. Johnston Decl. ¶¶ 24, 29–30; Park Decl. ¶ 20. Given the FDA's track record in meeting target dates for approval of biologics generally, there is no support for Dr. Siegel's speculation that delay is possible in this case.[5] Johnston Decl. ¶¶ 27–31. Moreover, the FDA carefully considered and negotiated its 10-month performance target with the industry, knowing that it will be accountable for meeting its target. *Id.* ¶¶ 21–26. If the FDA believed that the earliest-filed applications required enhanced scrutiny, as Dr. Siegel speculates, it would have implemented a longer initial review goal. *Id.* ¶ 26.

The well-pleaded allegations of Celltrion's complaint are thus more than sufficient to constitute the requisite meaningful preparation to conduct potentially infringing conduct.

2. Remsima is a substantially fixed product.

Kennedy contends that Remsima is not a "fixed and definite" product, MTD at 13, again speculating that the FDA *might* impose conditions on manufacturing or indications for which Remsima may be sold. But Kennedy fails to provide any basis for these supposed conditions that rebut the allegations in the Complaint, or explain how these conditions could affect the controversy over the three patents at issue here.[6]

[5] The same holds true for the speculative news article attached to Kennedy's motion to dismiss. *See* Zivin Decl., Ex. 7.

[6] The support Kennedy cites for its argument that Remsima "differs from country to country" is one paragraph of Dr. Siegel's declaration in the *Janssen* litigation. *See* MTD at 13-14; Siegel Decl. ¶ 23. That paragraph identifies only Health Canada's outlier decision declining to approve Remsima for the treatment of Crohn's disease and ulcerative colitis. *Id.* But Kennedy does not contend that this affects the controversy over Kennedy's patents; indeed, Kennedy

Kennedy first incorrectly contends there is no way of knowing whether Celltrion's product's active ingredient is the cA2 antibody, as required by Kennedy's patents. MTD at 13. But Celltrion's complaint alleges that Remsima's antibody sequence is identical to that of Remicade's antibody (also referred to as the cA2 antibody). *See* Compl. ¶¶ 3, 26, 40; Park Decl. ¶ 3.[7] Moreover, many of the claims in Kennedy's patents do not require use of the cA2 antibody, but are instead directed to use of *any* anti-TNF antibody.

Kennedy contends that there is no way of knowing whether Celltrion's product will be approved for use in treating rheumatoid arthritis in combination with methotrexate. MTD at 13.[8] But there is no dispute that *Remicade* is approved for treating rheumatoid arthritis "in combination with methotrexate." Johnston Decl. ¶ 39. As a biosimilar of Remicade, Remsima can only be approved for the same indication. *Id.* ¶ 38. Moreover, Celltrion's Phase III clinical trial tested the efficacy of Remsima in treating rheumatoid arthritis when co-administered with methotrexate. Park Decl. ¶ 8. And every country that has approved Remsima has permitted its use in treating rheumatoid arthritis in combination with methotrexate. *Id.* ¶¶ 11–12. There is no basis in the Complaint for Kennedy's suggestion that Remsima may be approved (only) for some other indication and not for treating rheumatoid arthritis in combination with methotrexate.

Kennedy's speculation that changes may be required to Remsima's formula is likewise baseless. To streamline production of Remsima for global sales, Celltrion developed manufacturing and purification processes to satisfy FDA standards. Park Decl. ¶ 27. The Remsima antibody formulation has been approved in the European Union, whose regulatory framework for

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has asserted infringement claims against Celltrion in Canada notwithstanding this limitation. *See* Compl. ¶ 48.

[7] Kennedy concedes Remicade "contain[s] the monoclonal antibody cA2[.]" MTD at 8.

[8] Kennedy asserts that its patents require certain doses, but many of the claims do not.

biologics was the model Congress used for the BPCIA. *See* Adler Declaration, Ex. 1 at 817–18. Celltrion will introduce the same formulation in the United States, and the testing results and data that will accompany its application were derived from that formulation. Park Decl. ¶ 23. Celltrion expects to receive purchase orders for Remsima before approval and is preparing to stockpile Remsima for immediate sale after approval. Compl. ¶¶ 55–56; Park Decl. ¶ 28. Celltrion's expectations thus are reasonable and support its right to a declaratory judgment. The mere (and unlikely) *possibility* that the FDA *could* request changes does not affect this Court's subject matter jurisdiction. *See Infinitech*, 842 F. Supp. at 338 n.4.

C. Kennedy's Prior Litigation Against the Remsima Antibody And Its Other Lawsuits To Protect Its Patents Demonstrate A Real And Substantial Dispute Between The Parties.

Contrary to Kennedy's assertions, Celltrion's case for jurisdiction is based upon much more than the "mere … existence" of Kennedy's patents. MTD at 14 (citing *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007)). It is based on Kennedy's specific assertion of infringement claims against Celltrion and its partner in marketing Remsima in Canada and the U.K., as well as its general commitment to enforcing its patents against third parties. "Prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 (Fed. Cir. 2008).[9] In this case, that circumstance weighs strongly in favor of finding jurisdiction.

Perhaps the most compelling evidence that Celltrion faces suit from Kennedy are the claims Kennedy already has asserted against Remsima's introduction in foreign jurisdictions. In the U.K., Kennedy filed a counterclaim against Hospira (Celltrion's marketing partner), arguing

[9] After *MedImmune*, proving a reasonable apprehension of suit is still sufficient, but no longer essential, to establish declaratory judgment jurisdiction. *Prasco,* 537 F.3d at 1336.

that the Remsima antibody infringed the European counterpart patents to the '442, '537 and '120 patents. Compl. ¶ 46. Kennedy has also asserted infringement claims against Celltrion and Hospira in Canada, based upon the Canadian counterpart to the '442 patent. *Id.* ¶ 48.

Kennedy attempts to minimize the significance of the claims it pursued against Remsima in other jurisdictions. It asserts, without support, that foreign litigation "has no bearing on Celltrion's activities in the United States," MTD at 2, and it implies that only domestic litigation involving the specific patents at issue can be considered, *id.* at 15. The law is not so myopic; "prior litigious conduct" is relevant even when it occurs outside the United States. Many courts have found ripeness based on overseas opposition to a competing product. *See Arkema*, 706 F.3d at 1358 (filing suit in Germany alleging infringement of a European patent was "a sufficient affirmative act on the part of the patentee for declaratory judgment purposes"); *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 822 (N.D. Ill. 2004) ("[F]oreign litigation, while not dispositive of a reasonable apprehension of suit in the United States, is one factor to be considered") (citations omitted); *Electro Med. Sys. S.A. v. Cooper Lasersonics, Inc.*, 617 F. Supp. 1036, 1038 (N.D. Ill. 1985) (holding that prior foreign infringement suits based on corresponding patents against plaintiff's products at issue satisfy jurisdictional requirements).

Contrary to Kennedy's suggestions, the infringement claims asserted by Kennedy in the U.K. and Canada were not unrelated lawsuits involving different products or technology than those at issue here. They involved the foreign counterparts to the three patents at issue in this case, and the same product (given the brand name Inflectra) that Celltrion is now seeking to launch in the United States. It is hard to imagine *any* litigation, in *any* forum, being more relevant to Kennedy's intent to enforce its patent rights here. The cases support this view. *Danisco*, 744 F.3d at 1331 ("[A] history of patent litigation between the same parties involving *related*

technologies, products, and patents . . . may weigh in favor of the existence of subject matter jurisdiction.") (emphasis added); *Electro Med*, 617 F. Supp. at 1038.

Were there any doubt, the resolution of the U.K. claims makes it clear that Celltrion faces an objectively reasonable threat of litigation when the FDA approves Remsima. As Kennedy itself notes, it resolved the U.K. litigation in part by granting a license to Celltrion in Europe, Australia, and Hong Kong.[10] MTD at 14. Kennedy elides the rest of the story set forth in the Complaint: that it *refused* to grant a license to Celltrion for the corresponding U.S. and Canadian patents. Compl. ¶¶ 47, 49. But Kennedy has reiterated its right to royalties in the United States before this Court, agreeing that if Celltrion's application is approved, "if we had to do it without a negotiated license, *we would seek the royalties* that they would otherwise have collected." Pre-Hearing Conference Tr., at 6–7 (emphasis added). It is thus crystal clear that upon FDA approval, Kennedy believes Celltrion will infringe and owe royalties in the United States. Celltrion is thus entitled to an invalidity and unenforceability determination now.

Kennedy's domestic litigation against other parties, seeking to enforce the same substantive patent rights as here, confirms Celltrion's objectively reasonable fear of suit. Kennedy brought infringement suits based upon the parent patent of the '442, '537 and '120 patents against UBC, Inc., Amgen and Wyeth. Compl. ¶ 45. More recently, Kennedy asserted counterclaims against AbbVie on all three of the patents-at-issue here (the '537 patent was voluntarily removed from the suits based on Kennedy's covenant not to sue).[11] *Id.* Indeed, Kennedy's ef-

[10] This agreement was an acceptable financial resolution of the U.K. dispute for Celltrion and Hospira, but does not in any way constitute a concession that Kennedy's patents are valid.

[11] Kennedy claims that it did not assert *infringement* counterclaims in the AbbVie actions before this Court, MTD at 15, but this is disingenuous. Kennedy sought a declaration that AbbVie's sales of Humira come within the scope of at least one valid claim of the '442 patent (Count III), and for breach of arbitration awards and related agreements governing royalties that

forts to protect its intellectual property led this Court to conclude in the *AbbVie* litigation that Kennedy's "history of enforcing its patent rights against third parties" supported declaratory judgment jurisdiction. *AbbVie*, No. 11 Civ. 2541, ECF No. 25. Kennedy's litigation in these similar cases is sufficient to demonstrate an actual controversy here. *See Alpharma, Inc. v. Purdue Pharma L.P.*, 634 F. Supp. 2d 626, 631 (W.D. Va. 2009) (noting a declaratory-judgment plaintiff's "uncertainty is all the more reasonable in light of the defendant's aggressive litigation strategy in similar cases"); *Micron*, 518 F.3d at 901 (finding an actual controversy where plaintiff "watched [the patentee] sue each of the other leading [market participants]," demonstrating an "aggressive litigation strategy"). This is so even when, unlike in this case, the precise patents or patent claims are not at issue in the other proceedings. *See, e.g., D2L Ltd. v. Blackboard, Inc.*, 671 F. Supp. 2d 768, 776–77 (D. Md. 2009) (holding that prior litigation over the technology covered by a patent was sufficient "even when the prior suit did not involve the patent in the declaratory judgment action and there had been no threat to enforce that patent by the defendant"). What matters for ripeness is whether prior litigation involved *Kennedy's related patents* because that demonstrates Kennedy's willingness to protect its intellectual property rights. There is no question that it does here; the litigation with AbbVie involved the same patents as the patents-in-suit, and the other litigation involved the parent patent to the patents-in-suit. All the asserted patents relate to the method of treatment of rheumatoid arthritis by a combination of a TNF-α antibody and methotrexate. Celltrion reasonably fears that similar assertions by Kennedy will delay Remsima's entry into the U.S. market.

Finally, Kennedy has the means and ample reserves dedicated to enforcing its patent rights. Kennedy maintains a "Legal Expense Fund" with a balance of more than £16.3 million,

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AbbVie allegedly owed for the use of Kennedy's patents (Counts IV and V). Kennedy thus asserted claims in that litigation directly related to the enforcement of its alleged patent rights.

and it spent £6.12 million on "Intellectual Property Protection" in fiscal year 2012. Compl. ¶ 51.

In sum, Kennedy's repeated claims of infringement against Remsima in other jurisdictions, its vigorous assertion of patent rights against third parties based on patents that are either the same as or related to the patents-in-suit, and its substantial means and intent to extract royalties from Celltrion when the FDA approves Remsima establish that Celltrion faces an imminent threat of suit with "sufficient immediacy and reality to warrant the issuance of a declaratory judgment" regarding the patents identified in its Complaint. *MedImmune*, 549 U.S. at 127.

II. THE BPCIA DOES NOT BAR THIS CASE.

Kennedy contends that this Court lacks subject-matter jurisdiction under the BPCIA, or alternatively that it should exercise its discretion to decline jurisdiction under the Declaratory Judgment Act. MTD at 16–18. Both contentions lack merit.

A. The BPCIA's Prohibitions On Declaratory-Judgment Actions Do Not Apply To This Case And Are Not Jurisdictional.

Citing *Sandoz v. Amgen*, Kennedy contends that this Court must dismiss because the BPCIA precludes the Court from exercising jurisdiction over Celltrion's claims against Kennedy. *See* MTD at 16 & n.6. The Court should not follow *Sandoz*'s flawed holding.

Kennedy's observation that nothing "in the BPCIA . . . allows Celltrion to file" this action, *id*. at 18, has it all backward. The Declaratory Judgment Act is what *allows* Celltrion to file this action. The proper question is whether something in the BPCIA *forbids* Celltrion to do what the Declaratory Judgment Act allows, and the answer is no. Subsection (l)(9) of the BPCIA forbids *some* declaratory judgment actions, but not this one.

By its terms, subsection (l)(9) applies only to actions between a "subsection (k) applicant" and a "reference product sponsor," and then only if the actions concern patents identified during the BPCIA's information-exchange process. 42 U.S.C. § 262(l)(9). At the time Celltrion

filed its complaint, it had not yet applied to have Remsima approved as a biosimilar of Remicade, so Celltrion was not a "subsection (k) applicant."[12] For its part, Kennedy is not a "reference product sponsor" because it is not the entity that obtained approval to market Remicade (that would be Janssen, not Kennedy). *See* 42 U.S.C. § 262(l)(1)(A) (defining "reference product sponsor"). Moreover, because Celltrion and Janssen still have not engaged in the information-exchange process, they have never identified the patents that subsection (l)(9) says cannot be the subject of a declaratory-judgment action.

The *Sandoz* court further mistook subsection (l)(9)'s limited prohibition on declaratory-judgment actions as affecting federal courts' subject-matter jurisdiction. The text of subsection (l)(9)(A) says that "neither the reference product sponsor nor the subsection (k) applicant may … bring" certain declaratory-judgment actions. The prohibition is not written like a jurisdictional rule. The Supreme Court and Second Circuit have held that practically identical statutory language does not create a jurisdictional rule because the words "may not bring" address the propriety of *parties* bringing actions, not the authority of *courts* adjudicating those actions. *See City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 127 (2d Cir. 2011); *see also Fauntleroy v. Lum*, 210 U.S. 230, 235 (1908) ("[N]o one would say that the words … 'An action shall not be brought …' go to the jurisdiction of the court.") (citation omitted).

The structure of the BPCIA's prohibitions confirms that they are not jurisdictional. Jurisdictional rules usually are absolute. But in subsections (l)(9)(B) and (C), Congress created exceptions to the BPCIA's primary prohibition on declaratory-judgment actions—for times when the subsection (k) applicant fails to fulfill certain obligations during the information-exchange

[12] Celltrion's subsequent application has no effect on this Court's subject-matter jurisdiction because "'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" *Grupo Dataflux v. Atlas Global Grp., L.P.*, 541 U.S. 567, 570 (2004) (quoting *Mollan v. Torrance*, 9 Wheat. 537, 539 (1824)).

process. "It would be at least unusual to ascribe jurisdictional significance to a condition subject to these sorts of exceptions." *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 165 (2010). Indeed, jurisdiction is not supposed to depend on the actions of litigants. *See United States v. Cotton*, 535 U.S. 625, 630 (2002) ("[J]urisdiction" refers to a court's power to hear a case, a matter that "can never be forfeited or waived" by the parties); *see also Jones v. Bock*, 549 U.S. 199, 211-12, 221 (2007) (holding that an administrative-exhaustion requirement is not jurisdictional).

Subsection (l)(9)'s mere reference to the Declaratory Judgment Act does not make the prohibition jurisdictional, either. That Act does not create or expand federal jurisdiction; instead, it creates a remedy for cases that otherwise satisfy federal jurisdictional requirements. *See Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239–40 (1937). Limitations on the availability of declaratory relief are not also limitations on federal jurisdiction.

B. Declining To Exercise Jurisdiction Would Be An Abuse of Discretion.

It is rarely in the public interest for a court to exercise discretion to dismiss a ripe patent dispute. *See Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352, 1357–58 (Fed. Cir. 2004). Yet Kennedy urges the Court to do just that because, in Kennedy's view, "the statutory scheme set forth by Congress in the BPCIA is the appropriate way to resolve any future patent disputes between Kennedy and Celltrion." MTD at 17. Kennedy could not be more wrong.

Kennedy proceeds from a false premise. The BPCIA's information-exchange process is not an alternative to litigation or a "dispute resolution" process that Celltrion is trying to avoid. It is a dispute *preparation* process designed culminate in litigation. *See* 42 U.S.C. §§ 262(l)(4)(A), (l)(6). Dismissing the case because Celltrion has not yet engaged in that process will not keep the dispute out of court; it will only delay the time when a court resolves it.

Kennedy also proceeds from a false policy premise. In drafting the subsection (l)(9), Congress addressed declaratory-judgment actions between biologics manufacturers and decided

to bar only a subset—those filed *after* the information-exchange process begins but before it ends. *See* 42 U.S.C. § 262(l)(9). Dissatisfied with Congress's policy choice, Kennedy asks the Court to bar declaratory-judgment actions filed *before* the information-exchange process even begins. This Court cannot use its discretion to reject Congress's deliberate policy choice.

Delaying this litigation until Celltrion completes the information exchange would serve no purpose. One of the purposes of the information-exchange process is to make biosimilar applicants aware of certain patents allegedly covering their products, but Celltrion already knows that the '442, '120, and '537 patents pose a risk to Celltrion's efforts to market Remsima. Those patents will not even be disclosed during the information-exchange process because they are neither owned nor exclusively licensed by the reference product for Remsima, Janssen. *See* 42 U.S.C. § 262(l)(3)(A). Despite Kennedy's assertions to the contrary, it is *not* a "reference product sponsor" that engages in the BPCIA's information exchange process. *See* MTD at 17–18; *id.* at 18 (using the neologism "reference product *patent owner*" instead of the statutory term "reference product sponsor").[13] Kennedy merely owns three patents Janssen uses non-exclusively. Congress understood that reference product sponsors might not own all the patents they use, but Congress did not include the owners of those patents in the information-exchange process. *See* 42 U.S.C. § 262(l)(3)(A) (distinguishing between "a reference product sponsor" and "a patent owner that has granted an exclusive license to the reference product sponsor"); *id.* § 262(l)(1)(B)(iii) (providing only that a single "representative of the owner of a patent exclusively licensed to a reference product sponsor … *may* be provided" a copy of the subsection (k) application—but not the list of potentially relevant patents). When Celltrion and Janssen under-

[13] This section of Kennedy's brief was cut and pasted from the motion to dismiss that Janssen filed against Celltrion in the District of Massachusetts; the only changes are substituting "Kennedy" for "Janssen" and a few changes to verb tenses. *See* Janssen MTD at 17–18.

take the information-exchange process, Kennedy will take no part in it. So, even if the process were a dispute-resolution process, it could not possibly resolve Celltrion's dispute with Kennedy.

Kennedy briefly contends that suits like Celltrion's must be dismissed to close a loophole by which "every prospective biosimilar applicant will be able to evade" the information-exchange process. MTD at 18. As explained above, Congress designed the process to provide certainty and to ripen unripe disputes so that a court can adjudicate them in a timely fashion without practically extending the 12-year exclusivity term. *See* pp. 3–4, *supra*. Here, Celltrion's dispute is the exception because it is *independently* ripe and because Remicade's 12-year term has *already* expired. There is no loophole, and the Court should reject Kennedy's effort to misuse a tool for promoting competition as a weapon to delay it.

III. THIS COURT SHOULD NOT STAY THIS LITIGATION.

Kennedy's final, alternative argument is that this Court should stay this case pending recently initiated proceedings before the PTO. MTD at 19–21. Kennedy's argument is misplaced. Stays of litigation challenging the validity of a patent are not routine (at least, not when the stay is requested by the patentee). This Court has already devoted substantial time and resources to analyzing the invalidity of Kennedy's patents, the PTO proceedings could last years, and in the end they may not fully resolve the issues most important to Celltrion. And a stay is particularly inappropriate where, as here, some of the PTO proceedings were initiated by Kennedy itself.

As Kennedy acknowledges, "[i]n determining the appropriateness of the stay, three factors are to be considered: (1) whether a stay will simplify the issues in question and trial of the case; (2) the stage of the proceedings; and (3) whether a stay will prejudice the nonmoving party." *Touchtunes Music Corp. v. Rowe Int'l Corp.*, 676 F. Supp. 2d 169, 177 (S.D.N.Y. 2009). All three of these factors weigh against stay in this case.

(1) A stay will not simplify the issues in question.

Kennedy is wrong to claim that this "Court stands to benefit from the reexamination record and any analysis provided by the PTO's expert." MTD at 20. This Court already has extensively analyzed the majority of claims in the '442 and '120 patents, and did so almost two years before the PTO even began its review. A stay will not necessarily simplify the issues before the Court. Moreover, certain grounds of invalidity alleged by Celltrion—lack of adequate written description, lack of enablement, and indefiniteness—cannot be presented in the reexamination of the '120 patent. And Kennedy has full control over the framing of the reissue proceedings it initiated for the '442 and '537 patents.[14] It is thus far from clear what (if any) issues could be simplified, and Kennedy provides no details on this point.

(2) This case is not in its early stages.

Kennedy pretends that this case arrives in this Court as a blank slate. *See* MTD at 9, 22. But this Court's invalidation of many of the claims of the '442 patent (affirmed by the Federal Circuit) and the invalidation of many of the claims of the '120 patent based on collateral estoppel permits the remaining issues to be dealt with efficiently, and likely on summary judgment. In fact, this Court's detailed (and affirmed) Findings of Fact and Conclusions of Law in the *AbbVie* litigation alone support the invalidation of all remaining claims of the '442 and '120 patents and all claims of the '537 patent at issue here. Little, if any, further discovery will be needed here.

(3) Celltrion faces severe prejudice if a stay is granted.

Kennedy asserts that it is "odd" for this Court "to initiate a discretionary declaratory judgment action while all claims currently are under review" by the Patent Office in "reissue

[14] Both reissue and *ex parte* reexamination procedures are conducted between the PTO and the patent owner. An *ex parte* reexamination may be requested by a third party, but once reexamination is ordered by the PTO, third parties are excluded from the proceedings. Manual of Patent Examination Procedure § 2254 (9th ed. 2014). Only a patent owner can request a reissue of the patent; once that process has begun, a third party may file a protest challenging patentability, but it cannot otherwise participate.

and/or reexamination proceedings, the outcome of which are not known." MTD at 2, 19. But Kennedy asserts that it "believes at least some of the claims are patentable" and that it expects the PTO to confirm their patentability. *Id*. at 19. If Kennedy is correct, the reexamination proceedings will result in a substantial delay, but the parties will end up back in this Court, litigating the invalidity of all claims-at-issue. In the meantime, the pending PTO procedures would have no effect on the validity or enforceability of the patents in question until the entire PTO process, including appeal, has concluded.[15]

In fact, the PTO is likely to take significantly longer to adjudicate those proceedings than this Court. Recent statistics from the PTO's Central Reexamination Unit confirm that, for cases appealed to the Patent Trial and Appeals Board, reexamination certificates issue on average more than three years after the request for reexamination is filed. If the case is appealed to the Federal Circuit, completion times extend on average *nearly 6 years*. *See* Adler Decl., Ex. 2. Moreover, the reissue proceedings that Kennedy initiated for the '537 and '442 patents are not conducted with "special dispatch" (unlike reexaminations), and typically take longer than two years to resolve (not counting appeals). This delay would cause substantial harm to Celltrion, especially if the FDA adheres to its schedule and approves Remsima in 2015.

Thus all three factors weigh against a stay. None of Kennedy's cited authority suggests otherwise. Some of those cases dealt only with defendants' attempts to stay infringement claims. *See, e.g., Aerotel, Ltd. v. IDT Corp.*, No. 03 Civ. 6496, 2003 WL 23100263, at *1 (S.D.N.Y. Dec. 3, 2003); *Luv n' Care, Ltd. v. Regent Baby Prods. Corp.,* 10 Civ. 9492, 2014 WL 572524,

[15] *See, e.g.*, 35 U.S.C. § 282 (providing without exception that all issued "patent[s] shall be presumed valid"); *id.* § 307 (providing that a patent is not revised during a reexamination proceeding until "the Director will issue and publish a certificate" canceling or confirming a claim, or incorporating any amended or new claim); *id.* §252 ("[t]he surrender of the original patent shall take effect upon the issue of the reissued patent").

at * 1 (S.D.N.Y. Feb. 13, 2014). In the other cases, unlike this one, the party challenging validity sought the stay, thus conceding the lack of any prejudice. *See, e.g., Gould v. Control Laser Corp.*, 705 F.2d 1340, 1341 (1983) (dismissing appeal of stay granted over patentee's objection); *Lederer v. Newmatic Sound Sys., Inc.*, 10-CV-0271 (JS)(AKT), 2011 WL 31189, at *3 (E.D.N.Y. Jan. 4, 2011) (granting stay sought by defendant in infringement proceedings); *Softview Computer Prods. Corp. v. Haworth, Inc.*, 97 CIV 8815 KMW HBP, 2000 WL 1134471, at *2–4 (S.D.N.Y. Aug. 10, 2000) (granting stay sought by party seeking declaration of invalidity).

By contrast, the District of Massachusetts rejected a patentee's request for a stay on facts very similar to those here (arising from the manufacture of generic drugs). The court noted:

> [a] stay would significantly harm the plaintiffs. While any stay is in effect, the drug companies' potential damages will mount. The uncertainty over whether they owe Columbia royalties on their products might create difficulties in pricing those products. It may also cause the drug companies to delay introduction of new products or needlessly invest money in efforts to design around an invalid patent. Such efforts are likely to be extremely costly in a highly regulated industry such as the one in which the drug companies compete because changes in their product designs or manufacturing processes may require regulatory approval.

In re Columbia Univ. Patent Litig., 330 F. Supp. 2d 12, 17 (D. Mass. 2004). In contrast to this difficulty, a stay only minimally affects the patentee's ultimate right to recovery, because "the prejudice . . . suffer[ed] as a result of . . . infringement while the case is stayed can be cured by a damages award." *Lederer*, 2011 WL 31189, at *3. The prejudice Celltrion will face if a stay is granted is thus severe and qualitatively different, and weighs heavily against Kennedy's request.

CONCLUSION

Celltrion respectfully requests that the Court deny Kennedy's motion to dismiss the Complaint or to stay the action, and grant any other relief the Court deems just and proper.

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