United States District Court
District of Massachusetts

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

Plaintiffs,

v.

Janssen Biotech, Inc.,

Defendant.

Case No. 1:14-cv-11613

Celltrion's Opposition To Janssen's Motion To Dismiss For Lack Of Subject Matter Jurisdiction

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INTRODUCTION

Janssen Biotech is waging a global battle against Remsima, a biological product developed by Celltrion, Inc. and sold throughout the world by Celltrion Healthcare Co. (together, "Celltrion"). Remsima competes with Janssen's expensive Remicade as a treatment option for a variety of chronic and debilitating diseases. To protect Remicade from competition, Janssen has asserted patent rights against Celltrion in Canada, denied Celltrion's requests for a license, and (through its parent) vowed to defend its Remicade patents through 2018.

The United States soon will join the 50 other countries that have approved Remsima for domestic sale. To preserve its U.S. monopoly, Janssen will claim that Remsima infringes three Remicade patents. Those patents are invalid and unenforceable. Rather than wait for Janssen to bring its baseless infringement action, Celltrion asks the Court to resolve the patent dispute now and thereby enable Celltrion to market Remsima as soon as the FDA licenses it next year.

Proposing a number of restrictive *per se* rules, Janssen contends that Celltrion's suit is premature. Janssen is wrong. Taking into account "all the circumstances," there now 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) (citations omitted). Bright-line rules, like those proposed by Janssen, have no place in the analysis. *See Organic Seed Growers & Trade Ass'n v. Monsanto Co*., 718 F.3d 1350, 1355 (Fed. Cir. 2013).

Considering *all* the circumstances, this case presents "precisely the type of situation that the Declaratory Judgment Act was intended to remedy." *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1332 (Fed. Cir. 2014). Celltrion has invested $112 million in Remsima's development. It reasonably expects Remsima will be ready for marketing in the U.S. in mid-2015,

given its proven track record and the FDA's public commitments to the timing of approval decisions. If this case is dismissed, however, Celltrion would face a huge potential delay because of the need to resolve issues concerning the validity of Janssen's patents.

Janssen also asks the Court to decline jurisdiction over this action because the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") prohibits declaratory-judgment actions filed *during* the biosimilar-approval process. The statutory prohibitions plainly do not apply to this *pre*-application action, which is independently ripe, and extending them would frustrate Congress's intent. Congress did not want manufacturers to prolong their monopolies artificially by making patent litigation drag on beyond the BPCIA's 12-year term of exclusivity. That is exactly what Janssen, whose exclusivity for Remicade has expired, is trying to do now.

REGULATORY AND FACTUAL BACKGROUND

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 therefore reduce consumer prices, Congress enacted the BPCIA and created an accelerated licensing pathway. *See* H.R. 3950–686, 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). The length of the 12-year term was the focus of intense deliberation; Congress rejected both 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).

To help bring biosimilars to market as soon as the 12-year term expires, Congress al-

lowed biosimilar manufacturers to apply for licenses up to 8 years before, leaving courts ample time to work through patent disputes that might arise. 42 U.S.C. § 262(k)(7)(B). Congress believed many patent disputes would be resolved during the 12-year term, but it was concerned that leaving any patent dispute unresolved until the end of the 12-year term would delay entry of biosimilars into the market and would effectively lengthen that term. *See 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, 46, 205 (July 14, 2009) (noting that patent litigation could take at least 3 years).

The BPCIA, accordingly, provides a mechanism to ripen otherwise unripe patent disputes during the 12-year term and "ensure 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." *Id.* at 9 (statement of Rep. Eshoo). Once a biosimilar application is filed, it infringes any patent the applicant and reference product sponsor identify in post-filing information exchanges. *See* 35 U.S.C. § 271(e)(2)(C)(i). Each side creates and exchanges a "list of patents" for which an infringement claim reasonably could be asserted. 42 U.S.C. § 262(l)(3). Then they negotiate, not over the merits of the dispute, but over which patents "shall be the subject of an" infringement action that the reference product sponsor "shall bring." *Id.* §§ 262(l)(4), (6). While the BPCIA prohibits other patent lawsuits *during* this information-exchange process, *see id.* § 262(l)(9), it does not prohibit Celltrion's suit or any other that is independently ripe and filed *before*.

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

Since 2008, Celltrion has been gearing up to introduce Remsima to compete with Janssen's Remicade and has spent more than $112 million developing it. Compl. ¶ 23. Clinical

trials have established Remsima's comparability to Remicade, in both safety and efficacy. *Id.* ¶ 30. Korea approved Remsima for sale in 2012; the European Medicines Agency approved it last fall. *Id.* ¶¶ 31, 32. Remsima now has been approved for marketing in 50 countries, with applications under review in another 27, and it is already being sold in 20 countries. Decl. of JaeHwee Park in Supp. of Celltrion's Opp. ("Park Decl.") ¶ 12. None has required a change to Remsima's antibody amino acid sequence, structure, and manufacturing process, and the same Remsima product is being sold all over the world. *Id.* ¶ 13.

Celltrion has been focused on FDA approval of Remsima ever since Congress enacted the BPCIA. Celltrion designed its manufacturing facilities and procedures to meet the FDA's rigorous standards. Park Decl. ¶ 27. Celltrion has been preparing its application for FDA approval of Remsima for more than a year. *Id.* ¶¶ 15-22. Celltrion met with the FDA in July 2013, submitted an Investigational New Drug application in October 2013, and completed clinical testing requested by the FDA in March 2014. Compl. ¶¶ 35–36. In April, the FDA provided Celltrion with detailed guidance as to the data and materials it should include in its application. Park Decl. ¶ 19. Celltrion has completed the studies requested by the FDA and is almost done preparing its application package, which it expects to file by the end of August. *Id.* ¶ 21.

The FDA has publicly committed to process biosimilar applications like Celltrion's in ten months or less. Decl. of Gordon Johnston in Supp. of Celltrion's Opp. ("Johnston Decl.") ¶¶ 23-24, 30. To date, the FDA has substantially met its target dates with respect to pre-application meetings with Celltrion regarding the forthcoming Remsima application. *Id.* ¶ 29. Celltrion believes the FDA will keep its commitment and approve Remsima in 2015. The belief is supported by these facts: (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 re-

viewed and approved by regulatory agencies covering 50 countries, including the rigorous European, Canadian, and Japanese authorities; (4) Celltrion's application is being prepared 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—all to satisfy U.S. demand for Remsima. Park Decl. ¶¶ 26–28; Compl. ¶¶ 64–65.

Celltrion's success has been met by Janssen's determined opposition. Overseas, Janssen has asserted Canadian patents against Remsima, filed complaints to block Remsima in Peru and Mexico, and opposed the use of the name Remsima in at least a dozen other countries. Compl. ¶¶ 53, 55–57. Domestically, Janssen has declined to grant Celltrion a license—consistent with Janssen's hostility toward all potential competitors to Remicade and similar products. *Id.* ¶¶ 52, 54, 58. Janssen's parent, Johnson & Johnson ("J&J"), has proclaimed that Remicade will enjoy U.S. patent protection until 2018 and warned that it may initiate patent infringement cases against competitors. *Id.* ¶ 60; Decl. of Joshua Dalton in Supp. of Celltrion's Opp. ("Dalton Decl.") ¶¶ 2-4. J&J even has asked the FDA to regulate biosimilars' *names*, including Remicade on the list of products it wants to protect, *see* Compl. ¶ 59; to the same end, Janssen recently petitioned the U.S. Patent & Trademark Office to cancel "Remsima" as a registered U.S. trademark, *see* Dalton Decl. ¶ 8.

ARGUMENT

I. THIS CASE IS RIPE BECAUSE THE DISPUTE BETWEEN CELLTRION AND JANSSEN 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 is rooted in Article III of the Constitution, which limits federal jurisdiction to "cases and controversies." *MedImmune*, 549 U.S. at 127. After *MedImmune*, a declaratory-judgment action is ripe for adjudication if "the facts alleged, *under all the circumstances*, show 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). Compared to the Federal Circuit's pre-*MedImmune* approach, which required reasonable apprehension of imminent suit, 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).

No bright-line rules govern. *See Danisco*, 744 F.3d at 1331 (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 the 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. Tube Master, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008). A dis-

pute may be "definite and concrete … even in situations in which there was no indication that the declaratory judgment defendant was preparing to enforce its legal rights." *Danisco*, 744 F.3d at 1329-30. In arguing that Celltrion must prove an absolute certainty, *see* MTD at 8–9, Janssen contradicts the Supreme Court's flexible standard. *See, e.g.*, *Susan B. Anthony List v. Dreihaus*, No. 13-193, slip op. at 8 (U.S. June 16, 2014) (noting that, for purposes of Article III standing, "[a]n allegation of future injury may suffice if the threatened injury is certainly impending, *or* there is a substantial risk that the harm will occur") (quotation marks omitted) (emphasis added).

In this case, all the circumstances weigh in favor of jurisdiction. They include Celltrion's substantial preparation to market Remsima; the fact that Remsima's formula is fixed and will not change in any way relevant to the three disputed patents; Janssen's aggressive efforts to defend its patents and oppose Remsima; and Janssen's repeated refusal to grant licenses to Celltrion. Notably, Janssen has not offered Celltrion a covenant not to sue—the only way to provide Celltrion with the assurances sufficient to defeat jurisdiction over this case. *See, e.g.*, *In re Columbia Univ. Patent Litig.*, 343 F. Supp. 2d 35 (D. Mass. 2004).

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 Celltrion has engaged in "significant, concrete steps to conduct [potentially] infringing activity" that create an immediate and real dispute. *Cat Tech*, 528 F.3d at 881. 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. ¶¶ 4, 23; Park Decl. ¶ 5.

- Celltrion has obtained approvals for Remsima in 50 countries and has launched (with its licensees) in 20 countries. Compl. ¶¶ 25, 31-33; Park Decl. ¶¶ 9-12.

- 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. ¶¶ 30, 35–36; Park Decl. ¶¶ 7, 17-18.

- Celltrion has worked closely with the FDA in preparing its application, which Celltrion has told the FDA it will file by the end of August. Celltrion is incorporating the FDA's suggestions in its application materials, and the FDA has indicated that no other steps are required before Celltrion files. Park Decl. ¶¶ 15-21.

- Celltrion's manufacturing facilities already satisfy the FDA's stringent standards, and Celltrion has built the manufacturing capacity to have stockpiles of Remsima ready for sale as soon as the FDA approves it. Compl. ¶¶ 63-64; Park Decl. ¶¶ 27-28.

- Celltrion has established a marketing infrastructure in the United States. Compl. ¶¶ 63-64; Park Decl. ¶ 26.

Minimizing those substantial preparations, Janssen proposes a bright-line rule that Celltrion cannot maintain suit until it submits its biosimilar application and receives FDA approval. *See* MTD at 8–9. But an actual controversy can exist before a declaratory-judgment plaintiff obtains regulatory approval. A plaintiff need only have "embarked upon a protracted and costly process of obtaining regulatory approval," as that conduct "evinces the kind of 'concrete steps' or 'meaningful preparation' needed to establish an actual controversy under 'all the circumstances.'" *Infinitech, Inc. v. Vitrophage, Inc.*, 842 F. Supp. 332, 337-38 (N.D. Ill. 1994) (citation omitted).[1] Similarly, Judge Young found jurisdiction when a plaintiff had completed

[1] *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 investing more than $150 mil-

four of six Phase III clinical trials of its biologic drug, intended to file an application soon after the complaint (and another within a couple years), and expected FDA approval in 12 to 14 months. *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 581 F. Supp. 2d 160, 167 & n.1 (D. Mass. 2008), *vacated in part on other grounds*, 580 F.3d 1340 (Fed. Cir. 2009).[2] Celltrion's allegations are similar, so Celltrion's dispute is similarly ripe. Janssen should not be surprised: it has successfully relied on *nearly identical* allegations to demonstrate ripeness in the past.[3]

Moreover, having completed Phase III clinical testing and concluded all pre-filing discussions with the FDA about its application, Celltrion is miles ahead of the plaintiffs in the cases Janssen cites. *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); *Teletronics Pacing System, 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 when the product might *ever* be available or whether it *ever*

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lion in research and development concerning Avonex and another $24 million in stockpiling and preparing to market the drug").

[2] The facts in the text are drawn from Roche's motion, which Judge Young found "wanting" without discussion. *See* Defts.' Mem. in Support of Motion to Dismiss, *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, No. 05-12237, 2006 WL 1324515, § III.B.1 (D. Mass. Apr. 11, 2006).

[3] In a 2008 declaratory-judgment complaint seeking to invalidate a patent potentially infringed by its drug ustekinumab, Janssen's predecessor (Centocor) made allegations nearly identical to Celltrion's here. *See Centocor Ortho Biotech Inc. v. Genentech, Inc. & City of Hope*, Civil Case No. 08-03573 MRP (C.D. Cal. filed May 30, 2008). Centocor had not yet obtained FDA approval of ustekinumab, and it alleged its patent dispute was ripe because: "[a]ll Phase III clinical trials believed necessary to support an application for [FDA] approval have been completed"; the FDA had been reviewing the application for three months before Centocor filed suit; "Centocor expect[ed] to obtain regulatory approval to market and sell ustekinumab in the United States within the next year"; and Centocor had been had been "making substantial preparations to market and sell ustekinumab in the United States upon receipt of regulatory approval[to do so.]" Decl. of Jason Weil in Supp. of Janssen's Mot. to Dismiss, Ex. 10, ¶¶ 39–40.

would be used in an infringing way once it was available). Celltrion's progress also distinguishes this case from another case Janssen cites, *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 and had neither established the safety and efficacy of its product nor presented any data to the FDA. Also unlike Celltrion, Sandoz had not obtained regulatory approval of its product in dozens of other jurisdictions.

Janssen speculates that "[i]t is entirely possible that the FDA will require Celltrion to do additional testing" and "FDA review is likely to take longer than it otherwise might because the FDA knows that the industry will scrutinize" its decision. MTD at 9. These are the musings of J&J's employee, Dr. Siegel. With no personal knowledge of Celltrion's dealings with the FDA, his speculation cannot counter Celltrion's allegations based on its own experiences. 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 will include 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 previous experience 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. 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 would require enhanced scrutiny, as Dr. Siegel speculates, it would have implemented a longer review goal for the first couple of years. *Id*. ¶ 26.

2. Remsima is a substantially fixed product.

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 biologics was the model Congress used for the BPCIA. *See* Weil Declaration, Ex. 3 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. ¶¶ 18, 23. Celltrion expects to receive purchase orders for Remsima before approval and is preparing to stockpile Remsima for immediate sale after approval. Park Decl. ¶¶ 25, 28. Celltrion's expectations 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 337 n.4.

Although it is theoretically possible that the FDA could decline to approve Remsima for all uses requested by Celltrion (the possibility is remote, given that only one country of 50 has done so),[4] this does not affect Celltrion's concrete interest in protecting itself from Janssen's assertion of rights in its Remicade patents. Janssen does not dispute that the '452, '471, and '396 patents cover Remicade or that Remsima is a biosimilar of Remicade (their amino acid sequence

[4] The one exception is Canada. Janssen contends that this outlier decision is sufficient to assume that the dispute over the '396 patent is off the table. MTD at 10. But the fact that the vast majority of countries have approved Remsima for the treatment of Crohn's disease, and Celltrion's undisputed intention to seek similar approval in the United States, Park Decl. ¶¶ 9-12, 22-25, establish a concrete dispute under *MedImmune* and makes *Matthews* inapposite.

and mechanism of action are identical, Park Decl. ¶ 3). Unless Janssen offers a covenant not to sue, it has no basis to argue that future FDA action will render any of its three patents irrelevant.

Contrary to Janssen's current position, Congress did not believe FDA approval was necessary to commence patent litigation between a reference product sponsor and a biosimilar manufacturer. The BPCIA *requires* a reference product sponsor to bring a patent infringement action against a biosimilar applicant within 30 days after the parties assemble a list of relevant patents. 42 U.S.C. § 262(k)(3)–(6). Since that mandatory lawsuit is concrete enough for judicial resolution without prior FDA approval (and without necessarily even knowing what indications will eventually be approved), so is Celltrion's complaint.

C. Janssen's Worldwide Efforts To Insulate Remicade And Oppose Remsima Demonstrate A Real And Substantial Dispute Between The Parties.

1. Celltrion anticipates suit based on Janssen's prior litigious conduct.

Contrary to Janssen's assertions, Celltrion's case for jurisdiction is based upon much more than the "mere … existence" of Janssen's patents. MTD at 11. It is based on Janssen's aggressive legal strategy to secure and protect its monopoly over TNF-α-inhibiting cA2 antibody-based drugs and the Remicade patents until 2018. "Prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy." *Prasco, LLC v. Medicis Pharmaceutical Corp*., 537 F.3d 1329, 1341 (Fed. Cir. 2008).[5] In this case, that circumstance weighs strongly in favor of finding jurisdiction.

Janssen has sued its competitors for infringement of patents covering TNF-α-inhibiting antibodies, supporting Celltrion's belief that Janssen will do the same here. In 2007 and 2009, for instance, Janssen's predecessor Centocor drafted new patent claims and sued Abbott Labora-

[5] Indeed, 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.

tories for patent infringement over a product called Humira, a TNF-inhibiting antibody drug that competes with Remicade. *See Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1346–47 (Fed. Cir. 2011).[6] Janssen's litigation in these similar cases is sufficient to demonstrate an actual controversy here. *See Alpharma, Inc. v. Purdue Pharma LP*, 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 (an actual controversy was established when the plaintiff "watched [the patentee] sue each of the other leading [market participants]," demonstrating an "aggressive litigation strategy").

Janssen also has targeted Celltrion directly, with unyielding opposition to Remsima in other jurisdictions. Janssen has obstructed Remsima on all fronts—patent, trademark, and regulatory—substantiating Celltrion's fear of suit:

- In Canada, Janssen sought a declaration that Remsima infringes a patent purporting to cover uses of Remicade. Compl. ¶ 53. Janssen is no mere "third party" in that suit. *See* MTD at 14. J&J's 2013 Form 10-K discloses that it holds the exclusive license to the patent at issue in that case. Dalton Decl. ¶ 4.

- In Mexico, Janssen has urged authorities not to approve Remsima. Compl. ¶ 56.

- Janssen has opposed Celltrion's trademark applications for "Remsima" or sought to invalidate the trademark in 12 countries, including the United States. *Id.* ¶ 55.

- J&J petitioned a Peruvian court to suspend marketing authorization for Remsima. *Id.* ¶ 57.

- J&J has asked the FDA to regulate the names of biosimilars and specifically invoked Remicade as a product it seeks to protect. *Id.* ¶ 60.

Janssen tries to write off its prior litigious conduct as "largely unrelated to Remsima and the patents-in-suit." MTD at 11; *see generally id.* at 11–15 (repeating that "unrelated litigation"

[6] Abbott is not the only competitor Janssen has targeted. In 2008, Centocor sued Genentech and City of Hope to obtain a declaration that their patents licensed to Janssen in connection with Remicade were invalid and unenforceable. Compl. ¶ 52.

and "unrelated activities" involving "different patents" do not create an actual controversy). In Janssen's view, prior litigation is irrelevant unless it concerns the exact same product, *id.* at 12, or the exact same "challenged patents," *id.* at 11. The law is not so hyper-technical. A declaratory-judgment plaintiff's apprehension of suit is reasonable when the patentee has sued others "for the same technology as is now covered by the patents in suit" and remains "engaged in a course of conduct that shows a willingness to protect that technology." *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1159–60 (Fed. Cir. 2006) (citations omitted); *see also 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 *Janssen's product and/or related patents* because that demonstrates Janssen's willingness to protect its product against competitors. Here, each of the identified U.S. lawsuits involved Remicade or patents covering Remicade.

Contrary to Janssen's contentions, *see* MTD at 13–15, "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 of 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 infringement suits in foreign forums based on corresponding foreign

patents and against the plaintiff's products at issue satisfy jurisdictional requirements).

Courts also have found ripeness based on non-patent litigation. In *Teva Pharmaceuticals*, a regulatory proceeding initiated in Canada to oppose marketing approval for a generic drug was "relevant to the reasonable apprehension analysis" because it demonstrated that the patentee "will not stand quietly by while manufacturers attempt to bring generic versions of its products to market." 301 F. Supp. 2d at 824.[7] Under *MedImmune*'s totality-of-the-circumstances test, this Court cannot ignore prior litigious conduct even if it is not strictly related to patent law.

2. Through its public statements and refusal to grant Celltrion licenses, Janssen has confirmed its intent to assert its patent rights.

A patentee's refusal to grant a license "suggests that there is an active and substantial controversy between the parties." *Arkema*, 706 F.3d at 1358. Janssen does not dispute that it repeatedly has refused to enter a licensing relationship with Celltrion. Compl. ¶¶ 54, 58. Moreover, J&J has publicly asserted that Remicade will enjoy U.S. patent protection until 2018 and such patents will protect J&J against competition from entities that try to introduce Remicade biosimilars. For example, on a conference call in November 2013, J&J's CFO acknowledged "the threat of biosimilars" to Remicade, but stated that "we don't view it as a significant threat" because "Remicade . . . has patent protection . . . in the US through 2018." Dalton Decl. ¶ 2, Ex. 1; *see also id.* ¶ 3, Ex, 2 (J&J's CFO stating in September 2013 that investors should not be concerned about U.S. biosimilar competition because "the U.S. business is patent protected through

[7] *See also Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (finding reasonable apprehension of suit based upon defendant's earlier suit for misappropriation of trade secrets regarding the same technology because "[f]iling a lawsuit for patent infringement would be just another logical step in [the defendant's] quest to protect its technology"); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987) (considering misappropriation of trade secrets related to the technology covered by the patents-in-suit); *Alpharma*, 634 F. Supp. 2d at 631 (finding "[m]ost relevant" the patentee's filing of a Citizen's Petition with the FDA regarding a drug product similar to the one developed by the plaintiff).

2018"). And in its latest 10-Q, J&J specifically identified Celltrion as one of those threats, noting that "Celltrion alleges that it will be seeking FDA approval to make and sell its own biosimilar version" of Remicade and, if it is "approved and introduced to the market, loss of exclusivity would likely result in a reduction in sales." J&J 10-Q, May 2, 2014, at 20. J&J also warned its shareholders that"[i]f any of the [three disputed] patents is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions" of Remicade." *Id.* Dalton Decl. ¶ 5, and Ex. 4; *see also id.* ¶ 4, Ex.3 (noting that "[s]ales of the [Janssen's] largest product [Remicade] . . . accounted for approximately 9.4% of the Company's total revenues for fiscal 2013. Accordingly, ***the patents related to this product are believed to be material to the Company***") (emphasis added). These "public statements and annual reports" confirm Janssen's "intent to continue an aggressive litigation strategy." *See Micron*, 518 F.3d at 901.

Janssen does not deny or qualify those statements. Instead, Janssen tries to diminish their import by suggesting that its threatened suits might fail on the merits. For instance, Janssen admits the '452 patent will expire on August 12, 2014, and notes that the Patent and Trademark Office is reviewing the '471 patent. This Court's jurisdiction over this action, however, does not depend on whether Janssen would or would not prevail in its own action (to be clear: Janssen will *not* prevail because its patents are invalid and unenforceable). Rather, this Court's jurisdiction depends on the likelihood that Janssen will try to enforce its patents.

The impending expiration of the '452 patent is beside the point. There is a real and substantial controversy *now*—over that patent, as well as the '471 and '396 patents. The '396 patent will not expire until more than a year after Remsima is likely to be approved, and Janssen fails to explain why Celltrion should have to wait even a day to market Remsima upon approval if the '452 and '396 patents are invalid and unenforceable, as Celltrion alleges.

Nor does the PTO's reexamination of the '471 patent affect this Court's jurisdiction. Unless "the [PTO] Commissioner . . . issued a certificate canceling the claims, they have not been finally determined to be unpatentable. So long as there is a valid patent, a justiciable case or controversy exists with respect to the patent infringement action in the district court." *In re Bingo Card Minder Corp.*, 152 F.3d 941, 941 (Fed. Cir. 1998) (unpublished) (citing *Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1270 (Fed. Cir. 1985)) (same); *see also* 35 U.S.C. § 307(a) (requiring certificate cancelling unpatentable claims). Janssen's contention that courts "routinely" stay patent litigations pending reexamination is untrue. MTD at 16. This Court, in fact, has declined to stay a patent case even though there was an open PTO proceeding that could have simplified or changed the issues. *See In re Columbia Univ. Patent Litig.*, 330 F. Supp. 2d 12, 17 (D. Mass. 2004). When the PTO reexamines a patent, a stay may be appropriate to protect *competitors* from infringement litigation, but it is not appropriate to protect *the patentee* from challenges to its own patents—particularly because a reexamination addresses invalidity based on prior art and publications (37 C.F.R. § 1.510(a)), whereas this litigation additionally covers invalidity based on lack of enablement, written description, and indefiniteness and unenforceability based on inequitable conduct. In addition, the reexamination is likely to last years,[8] especially because Janssen is vigorously defending the patent: Janssen vigorously defended against the PTO's initial rejection of its claim and has vowed to appeal if its validity arguments do not succeed. *See* Dalton Decl. ¶ 5. Delaying this case that long would either delay the commercial launch of Remsima for years or expose Celltrion to claims for patent infringement and substantial damages – precisely the type of controversy the Declaratory Judgment Action is designed to address.

[8] Recent statistics from the PTO's Central Reexamination Unit confirm that for cases that are appealed to the Patent Trial and Appeals Board, reexamination certificates issue on average more than three years after the request is filed. If the case is appealed to the Federal Circuit, reexamination completion times extend on average nearly 6 years. *See* Dalton Decl. ¶ 6, Ex. 5.

II. THE COURT SHOULD NOT EXERCISE ITS DISCRETION TO DISMISS.

Because this Court has jurisdiction over this action, Janssen's request that the Court exercise discretion and dismiss it—a case involving patents blocking competitor entry for a multi-billion-dollar drug—is extraordinary. "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal." *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993). Especially in "[t]he field of patent litigation," which "is particularly adapted to declaratory resolution," "[t]here must be well-founded reasons for declining to entertain a declaratory judgment action." *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355, 1357 (Fed. Cir. 2004). Janssen asks the Court to exercise its discretion to dismiss Celltrion's case only because the BPCIA's information-exchange process is supposedly "the appropriate way to resolve any future patent disputes between Janssen and Celltrion." MTD at 17. Dismissing this case for that reason would be an abuse of discretion.

First, Janssen's proposal proceeds from a false premise. The BPCIA's information-exchange process is not an alternative to litigation or a "dispute resolution" process Celltrion is trying to end-run. *Id.* at 17, 19; *see id.* at 1 (mischaracterizing the process as "a detailed and specific mechanism … to resolve patent disputes"). It is a dispute *preparation* process designed to facilitate and culminate in litigation. *See* 42 U.S.C. § 262(l)(4)(A), (6). Dismissing this case because Celltrion and Janssen have 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.

Second, forcing Celltrion and Janssen to engage in the information-exchange process before adjudicating their patent dispute would serve no purpose. Celltrion already has identified the three disputed patents, and if Janssen thinks there are more, it can file counterclaims alleging

infringement of them. The only consequence of dismissal would be to extend Janssen's exclusivity for Remicade by the time it would take to complete the information-exchange process. That would turn the process on its head. Congress designed it 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. 2–3, *supra*. Here, Celltrion's dispute is *already* ripe, and Janssen's 12-year term has *already* expired. The Court should reject Janssen's effort to misuse a tool for promoting competition as a weapon to delay it.

Third, Janssen's argument rests on an invalid policy premise. In drafting the BPCIA, 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, Janssen asks the Court to bar declaratory-judgment actions between biologics manufacturers filed *before* the information-exchange process even begins. This Court cannot use its discretion under the Declaratory Judgment Act in a way that rejects Congress's deliberate policy choice.

Janssen contends that pre-application lawsuits 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 19. There is no loophole. The process is designed to facilitate adjudication of patent disputes that are not independently ripe during the 12-year exclusivity term. Celltrion's case is exceptional because it is independently ripe and Remicade's 12-year term has already expired, meaning Remsima can be licensed and marketed in short order.

III. THE BPCIA DOES NOT BAR THIS CASE.

Janssen briefly endorses one court's holding (currently on appeal) that biosimilar manufacturers cannot sue reference product sponsors "unless and until they have engaged in a series

of statutorily-mandated exchanges of information" pursuant to the BPCIA. *Sandoz*, 2013 WL 6000069, at *2 (cited in MTD at 16 & 17 n.6). This Court should not follow that flawed holding.

By their terms, the BPCIA's prohibitions on declaratory-judgment actions apply only to actions between a "subsection (k) applicant" and a "reference product sponsor" concerning suits over patents identified in the information-exchange process. 42 U.S.C. § 262(l)(9)(A), (B). Because Celltrion has not applied to have Remsima approved as a biosimilar of Remicade, Celltrion is not a "subsection (k) applicant." And because the information-exchange process has not taken place, none of the patents at issue have been identified in that process.

The BPCIA's prohibitions on declaratory-judgment actions are not jurisdictional, either, so they do not bar or divest the Court's subject-matter jurisdiction now or after Celltrion files its application. *See* MTD at 1, 19-20. Their operative text is not the usual language of jurisdictional rules; the words "may not bring" address the propriety of parties bringing actions, not the authority of courts adjudicating them. *See, e.g.*, *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). Unlike most jurisdictional rules, the prohibitions are not absolute, and "[i]t 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). And since the Declaratory Judgment Act does not create or expand federal jurisdiction, *see Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937) (overruled on other grounds), limitations on the availability of declaratory relief have no effect on federal jurisdiction, either.

CONCLUSION

Janssen's motion to dismiss and request for jurisdictional discovery should be denied.

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Respectfully submitted,

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By their attorneys

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed through the Court's ECF notification system to be sent electronically to the registered participants as identified on the Notice of Electronic Filing on July 7, 2014.

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