IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., AND NEW YORK UNIVERSITY, Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	Civ. Action No. 15-cv-10698 Hon. Mark L. Wolf Hon. Judith G. Dein

PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND A PRELIMINARY AND PERMANENT INJUNCTION

Plaintiffs Janssen Biotech, Inc. and New York University (collectively "Plaintiffs") hereby move this Court to grant partial summary judgment to Plaintiffs and issue a declaratory judgment that the "notice of commercial marketing" provided by Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively "Defendants") on February 5, 2015 for their proposed biosimilar version of Remicade is legally ineffective. As set forth more fully in Plaintiffs' memorandum of law, Rule 56.1 Statement of Material Facts, and accompanying declarations and exhibits, Defendants' premature notice violates the statutory requirement under 42 U.S.C. § 262(l)(8)(A) that notice be provided only for a "licensed" product. Plaintiffs bring this motion for a declaratory judgment to obtain what Congress provided: a 180-day window – after FDA has decided to license the biosimilar and prior to market launch – that would permit an injunction to be sought on patents that are actually implicated by the FDA license, that have not expired, and that are infringed, all to avoid immediate and irreparable harm.

If necessary to secure compliance with the Court's declaratory judgment, Plaintiffs also seek, as set forth more fully in Plaintiffs' memorandum of law and accompanying declarations and exhibits, a preliminary and permanent injunction precluding Defendants from entering the market for at least 180 days after FDA approval of their proposed biosimilar and a proper notice of commercial marketing in order to permit an opportunity for Plaintiffs to seek preliminary injunctions to enforce their patents.

Accordingly, the Court should grant partial summary judgment to Plaintiffs and issue a declaratory judgment that Defendants' February 5, 2015 "notice of commercial marketing" is ineffective. The Court should also issue a preliminary and permanent injunction enjoining Defendants from commercially marketing their proposed biosimilar until at least 180 days after they provide an effective notice of commercial marketing.

REQUEST FOR ORAL ARGUMENT

Plaintiffs believe that oral argument may assist the court and hereby request oral argument on this motion.

Dated: April 8, 2015

Respectfully Submitted,

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that on April 8, 2015 counsel for Plaintiffs conferred with counsel for Defendants and, in good faith, attempted to resolve or narrow the issues presented in this motion. Defendants oppose the relief sought herein.

/s/ Heather B. Repicky
Heather B. Repicky

CERTIFICATE OF SERVICE

I certify that on April 8, 2015, this document, filed conventionally under seal, will be sent electronically to Defendants' counsel and that this document, with redacted versions of its declarations and exhibits, will be filed through the ECF system and sent electronically to the registered participants identified on the Notice of Electronic Filing and sent to those indicated as non-registered participants.

/s/ Heather B. Repicky
Heather B. Repicky

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., and NEW YORK UNIVERSITY	)	
Plaintiffs,	)	
	)	
v.	)	**No. 15-cv-10698**
	)	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

Memorandum of Law in Support of Plaintiffs' Motion for Partial Summary Judgment and a Preliminary and Permanent Injunction

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INTRODUCTION

Plaintiff Janssen Biotech, Inc. ("Janssen") spent billions of dollars and invested over fifteen years of research in discovering, developing, testing and bringing to market the revolutionary biological medicine, Remicade, which has drastically improved the lives of hundreds of thousands of patients suffering from auto-immune illnesses ranging from rheumatoid arthritis to Crohn's disease. Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. (together "Celltrion") and Hospira, Inc., are seeking approval from the Food and Drug Administration ("FDA") to sell a proposed biosimilar of Remicade, which they call Inflectra. (A biosimilar is a product that is similar, but not identical, to the innovator's biological product). Defendants rely on a new federal law, the Biologics Price Competition and Innovation Act ("BPCIA"), that permits them to piggyback on the innovative research done by Janssen rather than independently demonstrating the safety and efficacy of Inflectra.

The BPCIA recognizes that the innovator whose work is appropriated by the biosimilar maker may have dominating patents that prevent the marketing of the biosimilar, even with FDA approval. Thus, the BPCIA requires the biosimilar applicant to give 180 days "notice of commercial marketing" *after* the product has been "licensed" by the FDA and *before* commercial marketing in order to allow the innovator 180 days to bring a motion for a preliminary injunction under its patents to prevent the irreparable injury that would be caused by a precipitous market launch. Ignoring the law, Defendants have provided Janssen with a meaningless notice that they will begin commercial marketing as early as August 4, 2015, even though FDA has not granted Inflectra a license and no license – or commercial marketing – is imminent.

Plaintiffs Janssen and New York University ("NYU") bring this motion seeking summary judgment on their claim for a declaratory judgment that the "notice of commercial marketing"

provided by Defendants for their proposed biosimilar version of Remicade is legally ineffective. A preliminary injunction motion on Janssen's patents at this time, before Defendants' proposed product is "licensed," would be premature and wasteful of the resources of the parties and the Court. It is not known whether Inflectra is likely to be approved, let alone the timing and scope of any eventual approval. As a result, it is premature for Plaintiffs to know which of their patents to assert or when to assert them. There is no point, for example, in seeking a preliminary injunction if FDA never issues a license. And there is no point in seeking emergency relief on patents that will have expired by the time the FDA determines to issue a license, if it does, or whose claims would not be infringed based on the scope of any eventual FDA license.

Defendants' premature notice violates the statutory requirement that notice be provided only for a "licensed" product and it severs the statutory link between a proper notice and the right to seek a preliminary injunction. Plaintiffs bring this motion for a declaratory judgment to obtain what Congress provided: a 180-day window after FDA has decided to license the biosimilar and prior to market launch. This would permit an injunction to be sought on patents that are actually implicated by the FDA license, that have not expired, and that are infringed, all to avoid immediate and irreparable harm. In addition, if necessary to secure Defendants' compliance with the Court's order, Plaintiffs also seek a preliminary and permanent injunction precluding Defendants from entering the market for at least 180 days after FDA approval of their proposed biosimilar and a proper notice of commercial marketing.

BACKGROUND

A. Biologics

Janssen's Remicade and Defendants' proposed biosimilar are biological medicines. Biological medicines, also known as biologics, are complex molecules that are made in living

cells rather than chemically synthesized. Because the biologic manufacturing process uses living organisms, the process of manufacturing biologics is more complex and unpredictable than the process for manufacturing chemical drugs, and they are governed by separate regulatory schemes.

B. Remicade

Janssen's biologic drug Remicade® (infliximab) was one of the first drugs of its kind sold in the United States. Remicade® is a monoclonal antibody that binds to and neutralizes a substance in our bodies called tumor necrosis factor alpha or "TNFα." TNFα plays an important role in our immune systems but, if it is over-produced, it can lead to chronic diseases. Janssen spent over fifteen years of research to establish the indications for which Remicade is now known to be safe and effective. Although NYU and Janssen's predecessor Centocor first developed the antibody in 1990, Remicade was not approved for sale in the United States until 1998, when it was approved as the first biological treatment for Crohn's disease. Through extensive additional research, Janssen then showed that Remicade is also safe and effective for rheumatoid arthritis (1999), ankylosing spondylitis (2004), psoriatic arthritis (2005), and ulcerative colitis (2006).

C. Plaintiffs' Patents Relating to Remicade

In the course of developing Remicade, Janssen has obtained or exclusively licensed a number of patents covering infliximab itself, its uses in treating disease, and its manufacture. In this action, Plaintiffs assert six of these patents:

- United States Patent No. 6,284,471 ("the 471 patent") which covers the infliximab monoclonal antibody in Remicade.
- United States Patent No. 7,223,396 ("the 396 patent") which covers novel uses of infliximab to treat patients with Crohn's disease.

- U.S. Patent No. 5,807,715 ("the 715 patent") which covers methods of producing functional antibodies that specifically bind antigens.

- U.S. Patent No. 7,598,083 ("the 083 patent") and U.S. Patent No. 6,900,056 ("the 056 patent") which cover cell growth media for growing biological products.

- U.S. Patent No. 6,773,600 ("the 600 patent") which covers novel methods of purifying biological products so that they are suitable for use in human medicines.

D. The BPCIA's Abbreviated Biosimilar Pathway

Until recently the U.S. did not provide any abbreviated regulatory pathway for the approval of follow-on versions of successful biologics. Before the enactment of the BPCIA in 2010, the only way to obtain approval of a biological medicine was to file an original biological license application ("BLA") supported by a full complement of pre-clinical and clinical data.

The BPCIA created an abbreviated pathway for FDA approval of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" as a product that (1) is "highly similar to the reference product"; and (2) has "no clinically meaningful differences" from the reference product in terms of "safety, purity, and potency." 42 U.S.C. §§ 262(i)(2)(A), (B). Under the BPCIA, an abbreviated biological license application ("aBLA") for a biosimilar product may rely on FDA's prior determinations of safety, purity, and potency for the reference product. *See* 42 U.S.C. § 262(k)(2)(A)(iii)(I). The BPCIA provides a mechanism for a biosimilar maker to piggyback on the work done by the innovator and to gain licensure to commercialize its product sooner and more cheaply than through an original BLA.

E. The BPCIA's Exclusivity and Patent Dispute Resolution Provisions

The BPCIA's purpose is to establish "a biosimilars pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). In return for enabling biosimilar applicants to rely on the expensive research of innovators, the

statute provides the benefit of twelve years of non-patent exclusivity to innovative biologics before a biosimilar can be marketed. 42 U.S.C. § 262(k)(7). Because exclusivity is measured from the date of first marketing, even before the BPCIA was enacted in 2010, the benefit provided by the BPCIA is reduced for biologics introduced before 2010. For Remicade and other biologics introduced in 1998 or earlier, the BPCIA provides no non-patent exclusivity at all.

The BPCIA's non-patent exclusivity provisions supplement rather than replace patent protection. To facilitate the orderly assertion of patent rights, Congress created a set of mandatory procedures for resolving patent disputes before a biosimilar product could enter the market. These procedures, set forth in 42 U.S.C. § 262(l), establish a two-phase litigation process. In the first phase, which may begin as many as eight years before the exclusivity period ends, the parties undertake an intricate and carefully orchestrated pre-litigation process, sometimes called the "patent dance," to select patents for immediate litigation. 42 U.S.C. § 262(l)(2)-(l)(6). In the second phase, which begins when the biosimilar applicant is licensed and provides a 180-day notice of commercial marketing, the innovator may assert the patents that were not selected for immediate litigation and may bring a motion for preliminary injunction to enforce its patents. 42 U.S.C. § 262(l)(8). The notice of commercial marketing provision is at the heart of this motion: "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A).

F. Defendants' Pending Application for a Remicade Biosimilar

Defendants are developing a proposed biosimilar to Remicade, to be manufactured by Celltrion in Korea and marketed in the U.S. by Hospira. Defendants submitted an aBLA for their product on August 8, 2014 and the FDA accepted that application for review on October 7,

2014. Soon thereafter, Defendants provided Plaintiffs with their aBLA, giving Plaintiffs notice of their intent to obtain an FDA license for commercial marketing. As noted above, because Remicade was approved in 1998, it receives no benefits from the twelve-year non-patent exclusivity provision of 42 U.S.C. § 262(k)(7). The only BPCIA protections for Remicade come from the statute's patent dispute resolution procedures, including the 180-day notice provision.

To date, FDA has not approved Defendants' aBLA or given any indication whether it will be approved, when it will be approved, or what the scope of any approval will be. FDA had planned to consider Defendants' product at a meeting with its Arthritis Advisory Committee on March 17, 2015. On February 25, 2015, FDA postponed the meeting indefinitely, citing "information requests pending with the sponsor of the application." (U.S. Food and Drug Administration, POSTPONED: March 17, 2015: Arthritis Advisory Committee Meeting Announcement, http://www.fda.gov/advisorycommittees/ucm433919.htm). The status of Defendants' aBLA and the timetable for a decision on approval are therefore unknown.

G. Defendants' Ineffective Notice of Commercial Marketing

Defendants have taken the untenable position that the statutory notice of commercial marketing, triggering the second phase of BPCIA litigation and the innovator's right to bring a preliminary injunction, can be provided at any time and does not have to await FDA license, or even the filing of an aBLA with FDA. In a declaratory judgment action seeking to invalidate Plaintiffs' patents, co-defendant Hospira argued that a court pleading asserting a future intent to market "should satisfy the Act's notice provision, which does not prescribe any particular form," and thus constituted Defendants'180-day "notice of commercial marketing," even though Defendants had not yet filed an aBLA. *See Hospira, Inc. v. Janssen Biotech, Inc.,* No. 14-cv-7049 (S.D.N.Y. Oct. 16, 2014) (Dkt. No. 42 at 22). The court dismissed Hospira's action. "Despite Hospira's best attempts to twist the BPCIA to serve its interests without hindering its

pursuit of litigation, this effort fails." *Hospira, Inc. v. Janssen Biotech, Inc*., 113 U.S.P.Q.2d 1260, 1262 (S.D.N.Y. 2014).

Undaunted, Defendants adhere to the view that there is no condition precedent to giving the statutory notice of commercial marketing. By letter dated February 5, 2015, Defendants asserted that they would begin commercial marketing of their proposed biosimilar product "as early as 180 days from the date of this notice," *i.e.*, by August 4, 2015. Carey Decl. ¶ 31. Defendants claimed that notice at any time was appropriate because the BPCIA does not "include a condition precedent to providing notice." *Id.* Because Defendants' product is not yet licensed, the effect of Defendants' purported "notice" is to deny Plaintiffs the statutory 180-day window *after* license and *before* launch in which to seek a preliminary injunction.

ARGUMENT

Because there are no disputed issues of fact and the question is solely one of law, Plaintiffs seek partial summary judgment granting them a declaratory judgment that Defendants' notice of commercial marketing is ineffective and that the BPCIA requires the 180-day notice to be provided after the proposed biosimilar product is licensed. Because Defendants' failure to comply with this requirement will cause Plaintiffs irreparable harm, if it is necessary to secure Defendants compliance with the Court's ruling, Plaintiffs also request a preliminary and permanent injunction to prevent Defendants from marketing their biosimilar product sooner than 180 days after proper notice is given.

I. LEGAL STANDARDS

The Federal Circuit will have jurisdiction over any appeal of this action because the BPCIA is a statute "relating to patents." 28 U.S.C. § 1295. The Federal Circuit, however, "appl[ies] the law of the regional circuit" – here the First Circuit – "unless the issue pertains to or

is unique to patent law." *Monsanto Co. v. E.I. du Pont de Nemours & Co.*, 748 F.3d 1189, 1196 (Fed. Cir. 2014). Summary judgment and preliminary and permanent injunction standards are therefore governed by First Circuit law.

Partial summary judgment may be granted as to a particular "claim" even if it is not sought for every claim asserted in the complaint. Fed. R. Civ. P. 56(a); *Hines v. State Room, Inc.*, 665 F.3d 235, 236 (1st Cir. 2011). "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Claims presenting "pure questions of law, including issues of statutory interpretation" are amenable to resolution on summary judgment. *Chiang v. Verizon New England Inc.*, 595 F. 3d 26, 34 (1st Cir. 2010).

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success." *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 546 n.12 (1987).

"Fed. R. Civ. P. 65(a)(2) specifically authorizes a court to 'order the trial of the action on the merits to be advanced and consolidated with the hearing of the application' for preliminary injunction." *Boston Celtics Ltd. P'ship v. Shaw*, 908 F.2d 1041, 1050 (1st Cir. 1990); *see also K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 913-14 (1st Cir. 1989). Since "courts do not hold a 'trial' where no genuine issue of material fact is in dispute, this provision logically authorizes whatever 'summary judgment' proceedings are appropriate." *Boston Celtics*, 908

F.2d at 1050 (citation omitted). Where, as here, "plaintiffs present the Court with a question of law, not fact," a district court is "able to make a merits determination on the record before it" and consolidation of the preliminary and permanent injunction hearing is appropriate. *Hoai v. Superior Court*, 473 F. Supp. 2d 75, 78 n.4 (D.D.C. 2007). Plaintiffs therefore request that the Court consolidate preliminary and permanent injunction proceedings related to this motion.

II. DEFENDANTS' PURPORTED "NOTICE OF COMMERCIAL MARKETING" IS INEFFECTIVE

The language, structure, and purpose of the BPCIA all require a product to be "licensed" before a notice of commercial marketing so as to provide an opportunity for a preliminary injunction to be sought prior to launch to protect against imminent irreparable harm. If an FDA license were not a condition precedent to giving notice as Defendants contend, then the statutory linkage in 42 U.S.C. § 262(l)(8) between notice and the right to seek a preliminary injunction before commercial marketing would be severed. Such a reading of the statute is inconsistent with its text – which requires that the product be "licensed" before notice – and with the structure and purpose of the statute, which also assume that license precedes notice.

A. Section 262(l)(8) Provides for a Preliminary Injunction Motion Upon Notice That a "Licensed" Product Will Imminently Be Marketed

As is clear from its title, "[n]otice of commercial marketing and preliminary injunction," and its text, section 262(l)(8) creates a right to seek a preliminary injunction that is triggered by a notice of commercial marketing of a "licensed" product. Subsection (A) requires the biosimilar applicant to provide 180 days' notice before the commercial launch of a "biological product licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A). Subsection (B) permits the innovator to file a motion for a preliminary injunction based on patents that were not subject to immediate litigation once the notice of commercial marketing is provided. This combination makes clear that the function of the notice of commercial marketing is to permit the innovator to initiate a

second phase of patent litigation once the scope of the FDA license is known and the marketing of the proposed biosimilar product is imminent, and to do so by a motion for a preliminary injunction before the launch of the biosimilar causes irreparable injury.

The statutory requirement that a biosimilar product be "licensed" before the notice of commercial marketing follows directly from the notice's function and purpose as a trigger for a preliminary injunction motion. *See, e.g., Abramski v. United States*, 134 S. Ct. 2259, 2267 (2014) (In interpreting a statute, the court "must (as usual) interpret the relevant words . . . with reference to the statutory context, 'structure, history, and purpose.'") (quoting *Maracich v. Spears*, 133 S. Ct. 2191, 2209 (2013)). In general, a preliminary injunction will not be an option if commercial launch is not imminent. A preliminary injunction is not available "simply to prevent the possibility of some remote future injury." *Winter*, 555 U.S. at 22. To be entitled to a preliminary injunction, a plaintiff "must show that the injury complained of is of such imminence that there is a 'clear and present need for relief to prevent irreparable harm.'" *Sierra Club v. Larson*, 769 F. Supp. 420, 422 (D. Mass. 1991) (citations omitted). The license requirement of subsection (A) ensures the imminence necessary to vindicate the right to move for a preliminary injunction under subsection (B).

In contrast, Defendants' reading of the statute would sever section 262(l)(8)'s explicit linkage between the notice and the ability to bring a preliminary injunction. If, as Defendants contend, a license were not a condition precedent to a notice of commercial marketing and the notice could be provided at any time, biosimilar applicants could (and, based upon experience so far, would) effectively eliminate the right to seek a preliminary injunction upon receipt of the notice by providing a premature notice at a time when commercial launch is not imminent. Unable to seek injunctive relief based on the statutory notice, innovators would be left to guess

about the timing of first commercial marketing and would not be assured that the court would be able to consider a motion for a preliminary injunction before the biosimilar applicant launched its product. This would cause irreparable harm to the innovator even if an injunction were later granted, an injury that the statute is plainly designed to prevent.

In addition to guaranteeing imminence, by requiring notice to be given only after the FDA approves the biosimilar, the statute permits the innovator the opportunity to select which of its patents are appropriate for immediate relief. In this way, the statute ensures the existence of a fully crystallized controversy warranting the "extraordinary remedy" of a preliminary injunction. *Trebro Mfg., Inc. v. Firefly Equip., LLC,* 748 F.3d 1159, 1165 (Fed. Cir. 2014) (quoting *Winter*, 555 U.S. at 22). Until the aBLA is approved, many features of the proposed product remain unknown and subject to change, *e.g*., approved uses, dosage regimen, route of administration. Without that knowledge, there will be large numbers of patents whose relevance is unknown – because, *e.g*., they cover indications that may or may not be approved, or implicate processes that may or may not be used in the ultimate commercial product. There may even be patents, as in this case, that will expire within 180 days of the license and that would not be litigated if the biosimilar were required to wait 180 days after license to launch. Congress avoided uncertainty – and allowed the innovator to seek emergency relief based on concrete facts – by requiring the notice of commercial launch to be given only after the FDA licensed the biosimilar for commercial sale.

B. Subsection (A) Requires that a Notice of Commercial Marketing Relate to a "Licensed" Product

The language selected by Congress in subsection (A) of section 262(l)(8) makes its meaning clear. "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative

purpose." *Gross v. FBL Fin. Servs., Inc*., 129 S. Ct. 2343, 2350 (2009) (internal quotation marks omitted). Subsection (A) plainly states that a product must be "licensed" to be the subject of a notice of commercial marketing. 42 U.S.C. § 262(l)(8)(A).

To initiate the notice/preliminary injunction phase of BPCIA litigation, a "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the *biological product licensed* under subsection (k)." 42 U.S.C. § 262(l)(8)(A) (emphasis added). By its terms, the 180-day notice of commercial marketing applies to a product that is "licensed." It does not apply to a product, such as Defendants' proposed biosimilar, that is not licensed but rather is the subject of a pending license application. Under the statute's plain language, such a product cannot be the subject of a notice of commercial marketing under section 262(l)(8)(A).

Defendants have contended, without explanation, that the language of the statute contains no condition precedent to giving notice. Carey Decl. ¶ 31. Yet a product that is not licensed is not a "licensed" product. The use of the past form of the verb means that the product must be "licensed" before notice can be given. That is, when section 262(l)(8)(A) says notice must be given 180 days "before the date of the first commercial marketing of the biological product licensed under subsection (k)," it is saying that notice must be given *after* the product has been licensed under subsection (k) and *before* it is commercially marketed.

For Defendants' reading to be correct, the phrase "licensed product" must refer to a product that is simply subject of an application for approval. If so, the notice provision would mean: "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *that is the subject of the subsection (k) application.*" This is plainly not what Congress said.

More important, when Congress *did* want to refer to the future "commercial marketing" of a biological product that was not yet licensed, it said so precisely and it did not call the product "licensed." Rather, on multiple occasions, Congress accurately referred to the "commercial marketing of the biological product that is the *subject of the subsection (k) application*." 42 U.S.C. §§ 262(l)(3)(B)(ii)(I) & (l)(3)(C) (emphasis added). *See also id*. §§ 262(l)(1)(D); 262(l)(3)(A)(i); & 262(l)(7)(B) (referring to the "making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application").

Clearly, Congress knew how to say what it meant. If a product is not yet "licensed under subsection (k)", a notice of commercial marketing is premature. *See, e.g., Abbott v. Abbott*, 560 U.S. 1, 33 (2010) ("In interpreting statutory text, we ordinarily presume that the use of different words is purposeful and evinces an intention to convey a different meaning.").[1]

C. Subsection (B) Confirms That a License is a "Condition Precedent" to a Notice of Commercial Marketing

The existence of a license as a condition precedent to notice is a necessary part of the structure of the statutory scheme. This is demonstrated, in particular, by subsection (B) of section 262(l)(8). *See, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 133 (2000) (courts must interpret statutes "'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole'") (citations omitted). If, as Defendants argue, an FDA license were not a condition precedent to notice and a notice of commercial marketing could be served at any time – even before filing an aBLA – the statute would make no

[1] *See also, e.g., Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (alteration and internal quotation marks omitted).

sense.

Under Defendants' reading, the notice of commercial marketing would not be a notice of commercial marketing or indeed of anything at all. The BPCIA provides for two notices to the innovator. The first notice is the provision of the aBLA, which must be supplied to the reference product sponsor within twenty days of FDA's acceptance of the aBLA for review, and which, plainly notifies the innovator of the applicant's intention to begin commercial marketing if an FDA license is obtained. 42 U.S.C. § 262(l)(2)(A). This first notice triggers the first round of disclosures and permits the initial round of patent litigation, which would be pointless if the applicant did not intend to begin commercial marketing upon licensure. The second notice, in subsection (A) of section 262(l)(8), advises the innovator that commercial marketing of a licensed product is *imminent* – as few as 180 days away. If this imminence requirement were read out of the statute, as Defendants propose, the second notice would not notify the innovator of anything it did not already know.

In fact, subsection (B) of section 262(l)(8) makes it explicit that Defendants' reading is incorrect and that the notice of commercial marketing may not be given at any time. Under subsection (B), receipt of a notice of commercial marketing allows the reference product sponsor immediately to move for injunctive relief on patents that were "included" on its list of patents for which a reasonable claim of patent infringement could be brought, but "not included" among the patents selected for immediate litigation in the immediate litigation phase. 42 U.S.C. § 262(l)(8)(B). But no list will exist on which patents are "included" or "not included" unless the applicant has first provided notice via its aBLA and the parties have gone through the statutory pre-litigation procedures. If a notice of commercial marketing could be provided before the "patent dance" is completed, subsection (B) – and the right to seek a preliminary injunction –

would be meaningless. It would include no patents at all.

Subsection (B) of section 262(l)(8) thus presupposes that a notice of commercial marketing under subsection (A) cannot be provided until *after* the information exchanges required by the BPCIA have occurred, the good faith discussions between the parties have been completed, and patents have been "included" or "not included" on the list for immediate litigation. In symmetry, subsection (A) specifies that a notice of commercial marketing cannot be given at any time, but only after the biosimilar product is first "licensed" by the FDA.

D. The Circumstances of This Case Demonstrate the Importance of Requiring Licensure Before a Notice of Commercial Marketing

The circumstances of this case perfectly illustrate Congress' wisdom in providing a 180-day preliminary injunction period *after* FDA license and *before* commercial launch. Because Defendants' product has not been approved, a motion for a preliminary injunction is premature, and possibly unnecessary, for *each* of Plaintiffs' patents. One patent is on treating an indication that may not be approved; one will expire less than 180 days from today; one is in re-examination; and three are manufacturing patents for which Defendants have not provided sufficient information to determine infringement.[2]

1. The 396 Patent (Crohn's Disease)

Plaintiffs' 396 patent covers specific methods of using infliximab to treat fistulas – abnormal connections between organs – in patients with Crohn's disease. Because the 396 patent is limited to this particular method of use, Defendants' proposed biosimilar product will infringe the patent only if it is approved for use in treating fistulizing Crohn's.

[2] Although Plaintiffs have not moved for a preliminary injunction on any of their six asserted patents at this time and instead bring this motion only to seek Defendants' compliance with the 180-day notice provision, Plaintiffs reserve the right to seek a preliminary injunction on any or all of their patents if circumstances make the need for injunctive relief imminent.

Defendants have applied for such an indication, but there is considerable doubt whether FDA will grant a license for fistulizing Crohn's disease. In Canada, where Defendants' proposed product has already been approved, the health authorities did not approve an indication for Crohn's disease, concluding that Plaintiffs' Remicade data could not be extrapolated to Defendants' product. (Summary Basis for Decision, Remsima, http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_remsima_160195-eng.php). If FDA were to take the same view, the 396 patent would not be infringed. Given the doubt whether FDA will license Defendants' product for Crohn's disease, a preliminary injunction motion on the 396 patent now could be a waste of Court and party resources. A proper construction of the statute would allow for a preliminary injunction on the 396 patent if, and only if, the FDA licenses the product for Crohn's disease.

2. The 715 Patent (Functional Antibodies)

The 715 patent is one of the early patents on methods of producing functional antibodies. It will expire on September 15, 2015 – less than 180 days from today. Because of the indefinite adjournment of the advisory committee meeting on Defendants' product, it is highly unlikely, although still possible, that Defendants' product will be approved and ready to be marketed by September 15, 2015. Given the unlikelihood that Defendants will enter the market before the expiration of the 715 patent, it would be wasteful and premature for Plaintiffs to move for a preliminary injunction on this patent. Yet Defendants' premature notice purports to permit Defendants to begin sales before the patent expires, by August 4, 2015. A proper construction of the statute would enable Plaintiffs to drop their claims under the 715 patent.

3. The 471 Patent (Infliximab Antibody)

The 471 patent covers the infliximab antibody. Defendants do not dispute that their proposed infliximab product infringes the 471 patent; they challenge only its validity. Carey

Decl. ¶ 19. The 471 patent is in reexamination at the PTO (apparently provoked by one or more of the Defendants) and its claims now stand rejected. But, as explained in Plaintiffs' motion to stay all proceedings relating to the 471 patent (Dkt. No. 8), the reexamination is not over and Plaintiffs have successfully amended the patent specification in the PTO. Although Plaintiffs believe the issued 471patent is valid, they will not be in a position to move for a preliminary injunction on the patent until the uncertainty caused by the ongoing reexamination is clarified. Carey Decl. ¶ 44. Such a motion is premature now, but by the time Defendants' product may be approved, the 471 patent may have emerged from reexamination. In that case Plaintiffs would be able to seek a preliminary injunction prior to any launch by Defendants. A proper construction of the notice provision – linking notice and the opportunity to seek a preliminary injunction – would allow for that.

4. The Manufacturing Patents

Finally, Plaintiffs have asserted three manufacturing patents, the 083 patent, the 056 patent and the 600 patent. Contrary to the BPCIA, Defendants refused during the "patent dance" to provide Plaintiffs with information describing "the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A). Instead, Defendants insisted that they would provide such information only if they were sued on these patents. Plaintiffs have now instituted suit, but do not yet have enough information to prove that Defendants infringe the manufacturing patents. In light of this uncertainty, a motion for a preliminary injunction on Plaintiffs' manufacturing patents is premature. Carey Decl. ¶ 49. A proper construction of the notice provision would allow Defendants to obtain the required information and still have 180 days after approval and before commercial launch to seek a preliminary injunction on these patents, if one were warranted.

E. The Weight of Authority Favors Plaintiffs' Reading of the BPCIA

Because the Federal Circuit has yet to issue an interpretation of the BPCIA's notice of commercial marketing provision, this Court should be guided by the text, structure, and purpose of the statute. In addition, although the district courts to consider the issue are divided, the weight of the persuasive authority favors Plaintiffs' position that a notice of commercial marketing must pertain to a licensed product and cannot, as Defendants contend, be provided at any time without "condition precedent."

To date, three district courts have considered Defendants' argument that an FDA license is not a condition precedent to a notice of commercial marketing. Two have rejected the argument and one has accepted it. In the first case, *Sandoz Inc. v. Amgen Inc*., No. C-13-2904 MMC, 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013), *aff'd on other grounds*, 773 F.3d 1274 (Fed. Cir. 2014) ("*Amgen I*"), the district court relied on the plain language of the BPCIA to conclude that a biosimilar applicant "cannot, as a matter of law, have provided a 'notice of commercial marketing'" prior to obtaining a biological license because until that time the biosimilar product "is not 'licensed under subsection (k).'" No. C-13-2904 MMC, 2013 U.S. Dist. LEXIS 161233, at *6.

In the second case, a preliminary skirmish between the parties here, the district court rejected Hospira's contention that the BPCIA did not bar its declaratory judgment action because, *inter alia*, Celltrion had purportedly already served a 180-day notice of commercial marketing, even before filing its aBLA. *See Hospira,* No. 14-cv-7049 (S.D.N.Y.) (Dkt. No. 42 at 22); *Hospira*, 113 U.S.P.Q.2d at 1262. Rejecting Hospira's arguments in whole, without focusing in particular on the notice of commercial marketing, the court observed that the "BPCIA purposefully ties the dispute resolution process to events throughout the biosimilar

approval process" and that Hospira's action was an attempt to "skirt the dispute resolution procedures Congress purposefully enacted." *Id.*

The one case ruling to the contrary, a later dispute between Amgen and Sandoz concerning a different product, *Amgen v. Sandoz*, 14-cv-04741 (Dkt. No. 105) (N.D. Cal. March 19, 2015) ("*Amgen II*") is both inapposite and unpersuasive. As part of a wide-ranging opinion rejecting the mandatory nature of *all* of the BPCIA's dispute resolution procedures,[3] the court in *Amgen II* found there was no precondition to a notice of commercial marketing. In so doing, the court did not fully grapple with the text of the BPCIA, let alone its structure and purpose.

The *Amgen II* court reasoned that a "licensed" product did not mean one already licensed because, allegedly, it would be "nonsensical" to refer to the *future* commercial marketing of an as yet unapproved product without using the *past* form adjective "licensed." *Id*. at 13. But that is not nonsensical. On the contrary, as noted above, Congress did exactly that elsewhere in the statute, repeatedly referring to the future "commercial marketing of the biological product that is the *subject of the subsection (k) application,*" 42 U.S.C. §§ 262(l)(3)(B)(ii)(I) & (l)(3)(C) (emphasis added), rather than a product that is "licensed," when that was intended. It is *Amgen II* that is contrary to the statutory language, a point the court essentially admitted by faulting the *Amgen I* decision for "looking only to the language of the statute itself." *Amgen II*, at 12-13.

Amgen II also relied on a mistaken understanding that requiring notice after licensure "would tack an unconditional extra six months of market exclusivity onto the twelve years

[3] Despite the intricate and carefully prescribed nature of the "patent dance" that precedes the first phase of BPCIA litigation, with each step stating what each party "shall" do, followed by what the other party "shall" do, the court found all of this simply optional. "Congress intended merely to encourage use of the statute's dispute resolution process" and did not require it. *Amgen II*, 14-cv-04741 (Dkt. No. 105) (N.D. Cal. Mar. 19, 2015) at 10. Plaintiffs believe this opinion is incorrect and that it will not survive review in the Federal Circuit. That aspect of *Amgen II*, however, is not germane to this motion.

reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A)." *Id.* In fact, under a proper construction, a notice of commercial launch would most often be given 180 days before the expiration of the twelve-year period and be coterminous with it. But here, as noted above, Remicade did not receive any effective non-patent statutory exclusivity from the BPCIA because it commenced commercial marketing twelve years before the BPCIA was enacted. For Remicade, the BPCIA provides only a modest 180-day time period after approval of a biosimilar in which to adjudicate a potential motion for preliminary injunction. For products like Remicade, there is no twelve years, let alone twelve and a half years, of non-patent exclusivity, as the *Amgen II* court wrongly concluded. There is only 180 days.[4]

The parties in *Amgen II* have jointly requested the district court to enter a final judgment on the issues it decided under Fed. R. Civ. P. 54(b), and have advised the court that they have agreed to an expedited schedule to seek Federal Circuit review of the decision. The case will be fully briefed by April 28, 2015, with the goal of an oral argument by June.

* * * *

For the above reasons, the 180-day notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A) cannot be provided until the proposed biosimilar product is "licensed" and Defendants' purported notice is ineffective. Because there is no dispute of material fact, Plaintiffs are entitled to summary judgment on their claim for a declaration to that effect.

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[4] In a footnote, the *Amgen II* court stated even if Sandoz had violated the notice of commercial marketing provision, it would only be subject to "the consequences prescribed in 42 U.S.C. § 262(l)(9)(B) – an action for declaratory judgment regarding patent infringement, viability, or enforceability." *Amgen II* at 14 n.8. In fact, the innovator can bring such a declaratory judgment whether notice is provided or not. *See* 42 U.S.C. § 262(l)(9)(A) and (B). Furthermore, allowing the innovator to bring a declaratory judgment action *after* the biosimilar has launched without notice is no remedy for the failure to provide prior notice of commercial marketing. Under any reading, the statute promises the innovator the right to avoid irreparable injury by bringing a preliminary injunction in the 180-day period "before" launch.

Ordinarily, parties comply with a court's declaration of the law, and we would expect Defendants to do so here. *See* Samuel L. Bray, *The Myth of the Mild Declaratory Judgment*, 63 Duke L.J. 1091 (2014). We have asked Defendants if they will agree to abide by the Court's ruling on Plaintiffs' motion. Defendants have advised us that they will comply with any court order and that may obviate any need for injunctive relief in this case. To the extent a dispute about compliance exists after Defendants file their opposition, however, the Court should issue a preliminary and permanent injunction ordering Defendants to comply with the Court's declaratory judgment.

III. IF DEFENDANTS ARE NOT PREVENTED FROM ACTING ON THEIR INEFFECTIVE NOTICE, JANSSEN WILL BE IRREPARABLY HARMED

Defendants' refusal to comply with the BPCIA's notice of commercial marketing provision deprives Janssen of the precise procedural protection the statute promises to innovators and increases the risk that Defendants will enter the market without further notice in derogation of Plaintiffs' patent rights. This would cause irreparable harm to Janssen's business.

A. Defendants' Failure to Provide a Proper Notice of Commercial Marketing Will Cause Janssen Irreparable Procedural Injury

The BPCIA's notice of commercial marketing provision provides a crucial procedural safeguard to ensure that innovators have a full and adequate opportunity to enforce their patent rights before a biosimilar product enters the market. 42 U.S.C. § 262(l)(8). As discussed above, this safeguard protects the innovator's right to seek preliminary injunctive relief in an effort to avoid irreparable harm to its business. *Id*. Although Congress did not prejudge whether any particular motion for a preliminary injunction would be successful, it expressly provided a 180-day window for bringing the motion *after* the product is "licensed" and *before* any commercial marketing. 42 U.S.C. § 262(l)(8)(A). It would defeat the purpose of this provision – and be directly contrary to its terms – if the biosimilar applicant could begin marketing during the 180-

day period. The statute itself thus contemplates that the reference product sponsor will be irreparably harmed by the absence of a 180-day period from licensure to bring a preliminary injunction. *See, e.g., CoxCom, Inc. v. Chaffee*, 536 F.3d 101, 112 n.14 (1st Cir. 2008) (noting that "irreparable injury is presumed to flow" from certain statutory violations).[5]

Indeed, it is well-established that the violation of statutory procedural safeguards can lead to irreparable harm. As the Supreme Court has recognized, "'procedural rights' are special" in that they may be asserted without establishing that the underlying harm they are meant to protect against will actually occur. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 572 n.7 (1992). Where, as here, statutory procedures are disregarded, the "'harm that the [statute] intends to prevent has been suffered.'" *Sierra Club v. Marsh*, 872 F.2d 497, 500 (1st Cir. 1989) (Breyer, J.) (quoting *Commonwealth of Mass. v. Watt*, 716 F.2d 946, 952 (1st Cir. 1983)). As the First Circuit has explained, this harm is frequently irreparable because procedural violations create an "added risk" that an underlying irreparable harm will come to pass. *Id.* at 500.[6] If the failure to comply with required procedures leads to occurrence of the underlying harm, the "legally-protected procedural interest would effectively be lost" and could not be recovered through monetary damages. *Quechan Tribe v. U.S. Dep't of Interior*, 755 F. Supp. 2d 1104, 1120 (S.D. Cal. 2010).

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[5] *See also City of New York v. Golden Feather Smoke Shop,* 597 F.3d 115, 120 (2d Cir. 2010) ("In certain circumstances, . . . we . . . employ a presumption of irreparable harm based on a statutory violation."); *Klay v. United Healthgroup, Inc*., 376 F.3d 1092, 1098 (11th Cir. 2004) ("Because Congress has the power to determine the scope of statutory rights, the proper remedies for statutory violations, and the circumstances under which those remedies should be available, the standards for granting statutorily-authorized injunctions are necessarily controlled by the statute itself.").

[6] *Accord, e.g., Sierra Club v. U.S. Army Corps of Eng'rs*, 645 F.3d 978, 995 (8th Cir. 2011); *Sierra Club v. Bosworth*, 510 F.3d 1016 (9th Cir. 2007).

Here, Defendants' failure to observe the notice of commercial marketing provisions of the BPCIA deprives Plaintiffs of statutory procedural safeguards designed to protect their patent rights, and creates an "added risk" that Defendants will be able to market their proposed biosimilar product in derogation of Plaintiffs' patent rights, irreparably harming Plaintiffs. *Sierra Club v. Marsh*, 872 F.2d at 500. This causes irreparable procedural injury.

B. Defendants' Commercial Marketing of Their Proposed Biosimilar Product Would Cause Irreparable Harm to Janssen

As explained in the accompanying declarations of Michael Yang and Henry Grabowski, Defendants' premature launch of a biosimilar version of Remicade in the United States without proper notice to Plaintiffs and the opportunity to bring a preliminary injunction would severely and irreparably injure Janssen in at least four ways.

First, Janssen's U.S. Remicade sales would decline, and Janssen would be forced to decrease prices to compete with Defendants' new biosimilar product. *See* Declaration of Michael Yang ("Yang Decl.") ¶¶ 14-27; Declaration of Henry Grabowski ("Grabowski Decl.") ¶¶ 46-56. This erosion of sales and prices for Remicade would be permanent and impossible to completely quantify. *See, e.g., Robert Bosch LLC v. Pylon Mfg. Corp*., 659 F.3d 1142, 1155 (Fed. Cir. 2011) ("money damages alone cannot fully compensate" plaintiff for "irreparable harm due to lost market share, lost business opportunities, and price erosion");[7] Grabowski Decl. ¶¶ 57-62.

Second, Janssen and its parent company, Johnson and Johnson ("J&J"), would have to reduce research and development expenditures across the company. Remicade is J&J's most

[7] *See also Presidio Components, Inc. v. Am. Tech. Ceramics Corp*., 702 F.3d 1351, 1363 (Fed. Cir. 2012) (holding that the district court erred in not finding irreparable harm where defendant's sales caused plaintiff to lose sales); *Celsis in Vitro, Inc. v. CellzDirect, Inc*., 664 F.3d 922, 930 (Fed. Cir. 2012) (upholding award of injunction where irreparable harm included "price erosion, damage to ongoing customer relationships, loss of customer goodwill").

successful product, and its revenue directly supports J&J's research and development spending and the attendant opportunities for unpredictable medical breakthroughs. Yang Decl. ¶¶ 28-33; Grabowski Decl. ¶¶ 28-32, 63-67, 69-71. *See, e.g. Sanofi-Synthelabo v. Apotex, Inc*., 470 F.3d 1368, 1381 (Fed. Cir. 2006) (irreparable harm included, inter alia, potential layoffs and discontinuance of research efforts); *Bio-Technology Gen. Corp. v. Genentech, Inc*., 80 F.3d 1553, 1566 (Fed. Cir. 1996) (irreparable harm where plaintiff "would be required to reduce its research and development activities").

Third, competition from Defendants' biosimilar product would hamper Janssen's efforts to compete with third-party competitors in the market. Janssen would be required to devote significant marketing resources to addressing biosimilar competition, diverting from its efforts to distinguish Remicade from its competitors, and health care providers may choose competitive products to avoid the uncertainty arising from the introduction of a biosimilar product. Yang Decl. ¶¶ 20, 34-37; Grabowski Decl. ¶ 68. *See Celsis*, 664 F.3d at 930 ("There is no effective way to measure the loss of sales or potential growth – to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer.") (internal quotation marks omitted).

Finally, Janssen's Simponi Aria®, an anti-TNF drug product that treats rheumatoid arthritis, would likely lose market share and decrease prices along with Remicade to compete with the biosimilar. Simponi Aria and Remicade are sold and marketed together, and Janssen prices them at par to avoid discouraging customers from choosing one over the other based on price. Yang Decl. ¶¶ 38-40. Any decrease in Remicade prices thus would lead to a similar reduction in Simponi Aria pricing. *Id.* This additional price erosion would be similarly irreversible, and would be difficult to quantify and to recover as damages.

IV. THE BALANCE OF HARMS AND PUBLIC INTEREST FAVOR AN INJUNCTION

The final two injunction factors – the balance of the harms and the public interest – also favor granting an injunction. With respect to the balance of harms, Plaintiffs seek only the statutorily required 180 days after license and before market launch to adequately adjudicate a potential motion for a preliminary injunction. Compliance with the law would delay the commercial launch of Defendants' proposed biosimilar product for a very modest period of time. In the absence of an injunction, however, Plaintiffs would lose their ability to prevent the marketplace disruption and irreparable harm that would occur if a preliminary injunction can only be brought after Defendants have launched their product. The harms the parties face are therefore asymmetrical and their balance favors Plaintiffs.

With respect to the public interest, the BPCIA itself strikes precisely the balance between the public interest in fostering innovation (which favors Plaintiffs) and the benefits to consumers of price reduction (which favor Defendants). *See* BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). The public interest therefore favors enforcing the BPCIA as written. *See In re Sac & Fox Tribe of the Miss. in Iowa/Meskwaki Casino Litig.*, 340 F.3d 749, 760-761 (8th Cir. 2003) (courts should give "great weight to the fact that Congress already declared the public's interest and created a regulatory and enforcement framework that balanced the [interests of the parties]"); *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1952) (Frankfurter, J., concurring) ("When Congress itself has struck the balance, has defined the weight to be given the competing [public] interests, a court of equity is not justified in ignoring that pronouncement under the guise of exercising equitable discretion.").

CONCLUSION

For the above reasons, the Court should grant partial summary judgment to Plaintiffs on their declaratory judgment claim and, if necessary, a preliminary and permanent injunction enjoining Defendants from commercially marketing their proposed biosimilar until at least 180 days after they provide an effective notice of commercial marketing in order to allow Plaintiffs the opportunity to seek preliminary injunctions to enforce their patents.

Dated: April 8, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on April 8, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

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IN THE UNITED STATES DISTRICT COURT
OF MASSACHUSETTS

JANSSEN BIOTECH, INC., AND NEW YORK UNIVERSITY, Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	Civ. Action No. 15-cv-10698 Hon. Mark L. Wolf Hon. Judith G. Dein

PLAINTIFFS' RULE 56.1 STATEMENT OF MATERIAL FACTS NOT IN DISPUTE IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, Janssen Biotech, Inc., and New York University (collectively, "Plaintiffs") respectfully submit this Statement of Material Facts Not In Dispute in Support of Plaintiffs' Motion for Partial Summary Judgment.

Remicade® and the Proposed Biosimilar of Remicade®

1. Remicade® is a biologic drug whose active ingredient is infliximab, a monoclonal antibody that binds to and neutralizes a substance in our bodies called TNFα which, if over-produced, can lead to chronic disease. Carey Decl. ¶ 4.

2. The infliximab antibody was first developed by scientists from New York University ("NYU") and Centocor, Inc., the predecessor of Janssen Biotech, Inc. ("Janssen"), in the early 1990s. *Id.*

3. Remicade was first approved for the U.S. market in 1998, nearly a decade after it was first discovered in the lab. The first indication, or use, for which Remicade® was approved was the treatment of Crohn's disease, an inflammatory bowel disease that causes inflammation of the lining of the digestive tract. Remicade® was the first biological therapy approved for Crohn's disease in the United States. *Id.* ¶ 5.

4. Subsequently, extensive additional pre-clinical and clinical development efforts led to FDA approval of Remicade® for additional indications, including rheumatoid arthritis (1999), ankylosing spondylitis, a chronic inflammatory disease of the axial skeleton (2004), psoriatic arthritis (2005), and ulcerative colitis, an inflammatory bowel disease (2006). *Id.* ¶ 6.

5. In the course of developing Remicade®, Janssen has obtained or exclusively licensed a number of patents related to infliximab, its uses in treating disease, and the processes for manufacturing infliximab. Plaintiffs assert six of these patents in this action. *Id.* ¶¶ 15-16.

6. Celltrion Healthcare Co., Inc. and Celltrion, Inc. (together "Celltrion") have undertaken the development of a proposed biosimilar to Janssen's Remicade® infliximab product. Hospira Inc. will market the proposed biosimilar product in the United States (Celltrion and Hospira together "Defendants"). *Id.* ¶ 8.

Proceedings Under the BPCIA

7. Pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"), Defendants submitted an abbreviated Biologic License Application ("aBLA") on or around August 8, 2014 seeking permission to market a proposed biosimilar version of Janssen's revolutionary biological medicine Remicade® (infliximab). *Id.*

8. Defendants' aBLA was accepted for review by the Food and Drug Administration ("FDA") in October 2014, but FDA has not yet approved the application or given any indication whether it will be approved, when it will be approved, or what the scope of any approval will be. *Id.* ¶ 9.

9. Shortly after their aBLA was accepted for review by FDA, Defendants provided a copy of their aBLA to Plaintiffs pursuant to the BPCIA's confidentiality restrictions. *Id.* ¶ 10.

10. Although Defendants provided their aBLA, they did not provide any "other information that describes the process or processes used to manufacture the biological product that is the subject of such application" as they were required to do under the statute. 42 U.S.C. § 262(l)(2)(A). Carey Decl. ¶ 11; *see also id.* Exs. A & B.

11. Based on the information that Defendants provided in their aBLA and Defendants' refusal to provide the required manufacturing information, on December 26, 2014, Plaintiffs provided Defendants a list of six patents for which a claim of infringement could reasonably be asserted. Carey Decl. ¶ 15.

12. On February 5, 2015, Defendants provided a statement of defenses pursuant to 42 U.S.C. § 262(l)(3)(B). *Id.* ¶ 16.

13. In connection with their statement of defenses, Defendants asserted that they did not seek to limit the patents to be litigated, and that as a result, the remaining BPCIA's pre-litigation procedures, 42 U.S.C. § 262(1)(3)-(l)(5), were moot. *Id*. ¶ 25.

14. Defendants further asserted that Janssen was required to file a lawsuit on all six listed patents within thirty days of Defendants' statement, i.e., by March 7, 2015, rather than within thirty days after the completion of the statutory pre-litigation procedures, as the BPCIA requires. *Id*. ¶ 26.

15. On March 6, 2015, Plaintiffs filed this action. Dkt. No. 1.

Defendants' Premature "Notice of Commercial Marketing"

16. On February 5, 2015, the same day they provided their statement of defenses to Plaintiffs, Defendants sent Plaintiffs a letter that they called a "notice of commercial marketing," purportedly pursuant to 42 U.S.C. § 262(l)(8)(A). Carey Decl. ¶ 30; *see also id*. Ex. F.

17. In their letter, Defendants asserted that they would begin commercial marketing of their proposed biosimilar product "as early as 180 days from the date of this notice," i.e., August 4, 2015. Defendants also asserted that the BPCIA "prescribes no form or content for the required notice, nor does it include a condition precedent to providing notice." Carey Decl. ¶ 31.

18. At the time of their purported "notice of commercial marketing," Defendants' proposed biosimilar product was not licensed. *Id*. ¶¶ 34-35.

19. Defendants previously asserted that a different document, provided before Defendants filed their aBLA, constituted a notice of commercial marketing under the BPCIA. In briefing in an unsuccessful declaratory judgment action, Hospira asserted that an earlier

declaratory judgment complaint by Celltrion alleging that it intended to sell its proposed biosimilar infliximab product in the United States "should satisfy the Act's notice provision, which does not prescribe any particular form." *See Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7059 (S.D.N.Y. Oct. 16, 2014) (Dkt. No. 42 at 22). Carey Decl. Ex. G.

20. Thus, Defendants contend that a notice of commercial marketing may be provided at any time, including before the submission of an aBLA. Carey Decl. ¶ 33.

The Prematurity of a Motion for a Preliminary Injunction on Plaintiffs' Patents

21. As far as Plaintiffs are aware, serious questions remain about whether Defendants' proposed biosimilar product will be licensed, when it will be licensed, and what the scope of any license might be. Because of these uncertainties, it is premature to bring a motion for a preliminary injunction on all the patents Plaintiffs has asserted in this action. Carey Decl. ¶ 35.

The 396 Patent

22. Plaintiffs' patent number U.S. 7,223,396 ("the 396 patent") covers specific methods of using infliximab to treat fistulas – abnormal connections between organs – in patients with Crohn's disease. Because the 396 patent is limited to these particular methods of use, Defendants' proposed biosimilar product will infringe the patent only if it is approved for use in treating fistulizing Crohn's disease. *Id.* ¶ 37.

23. Defendants have applied for such an indication but there is considerable doubt whether FDA will grant a license for fistulizing Crohn's disease. In Canada, where Defendants' proposed product has already been approved, the health authorities did not approve an indication for Crohn's disease (fistulizing or otherwise), concluding that Plaintiffs' Remicade data could not be extrapolated to Defendants' product. *Id.* ¶ 38 & Exhibit H.

24. If FDA were to take the same view as Health Canada, the 396 patent would not be infringed by Defendants' marketing of their proposed biosimilar product. Carey Decl. ¶ 40.

25. Given the doubt whether FDA will license Defendants' product for Crohn's disease, a preliminary injunction motion on the 396 patent now would be a waste of time and resources. *Id.* ¶ 39.

The 715 Patent (Functional Antibodies)

26. U.S. Patent No. 5,807,715 ("the 715 patent"), exclusively licensed by Janssen from Stanford University and Columbia University, covers methods of producing functional antibodies. It will expire on September 15, 2015 – less than 180 days from now. Carey Decl. ¶ 41.

27. Because of the indefinite adjournment of the advisory committee meeting on Defendants' product, it is highly unlikely that Defendants' product will be approved and ready to be marketed by September 15, 2015. *Id.*

28. Given the unlikelihood that Defendants will enter the market before the expiration of the 715 patent, it would be wasteful and premature for Plaintiffs to move for a preliminary injunction on this patent. *Id*. ¶ 42.

The 471 Patent (Infliximab Antibody)

29. Plaintiffs' patent number U.S. 6,284,471 ("the 471 patent"), covering the infliximab antibody, is in reexamination at the Patent and Trademark Office (apparently initiated by one or more of the Defendants) and its claims now stand rejected. The reexamination is ongoing. Carey Decl. ¶ 43.

30. In the reexamination, Plaintiffs have successfully amended the patent specification, but this amendment will not become effective until the reexamination proceeding is complete. *Id.*

31. Until a reexamination certificate issues that sets out the 471 patent's newly amended form, Janssen will not be in a position to move for a preliminary injunction on the patent. *Id*. ¶ 44.

32. By the time Defendants' product is actually approved, however, if it is, the 471 patent may have emerged from reexamination. If that occurs, Plaintiffs would then be able to seek a preliminary injunction on the 471 patent. *Id*. ¶ 45.

The Manufacturing Patents

33. Janssen has asserted three manufacturing patents: U.S. 7,598,083 ("the 083 patent"), U.S. 6,900,056 ("the 056 patent"), and U.S. 6,773,600 ("the 600 patent"). Carey Decl. ¶ 46.

34. Janssen asserted these patents under 35 U.S.C. § 271(e)(2)(C)(ii) to preserve its rights after Defendants refused to provide the manufacturing information required by the BPCIA. Instead, Defendants insisted that they would provide such information only if they were sued on these patents. *Id*. ¶ 47.

35. Plaintiffs have now instituted suit, and have renewed their requests for manufacturing information. To date, however, Janssen has still not received the manufacturing information that should have been provided in October 2104. *Id*. ¶ 48.

36. Without complete manufacturing information, Janssen does not know for certain whether Defendants infringe the manufacturing patents. In light of this uncertainty, a motion for a preliminary injunction on Plaintiffs' manufacturing patents is premature. *Id*. ¶ 49.

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Respectfully submitted,

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