**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| **JANSSEN BIOTECH, INC. and** | ) | |
| **NEW YORK UNIVERSITY** | ) | |
| **Plaintiffs,** | ) | |
| | ) | |
| **v.** | ) | **Civil Action No. 1:15-cv-10698** |
| | ) | |
| **CELLTRION HEALTHCARE CO., LTD.,** | ) | |
| **CELLTRION, INC., and** | ) | |
| **HOSPIRA, INC.** | ) | |
| **Defendants.** | ) | |
| _____ | ) | |

**MEMORANDUM OF LAW IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND A PRELIMINARY AND PERMANENT INJUNCTION AND IN OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT**

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Plaintiffs Janssen Biotech, Inc. and New York University (collectively, "Janssen") respectfully submit this Memorandum of Law in further support of their motion for partial summary judgment and a preliminary and permanent injunction and in opposition to the cross-motion for partial summary judgment filed by Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively, "Defendants").

## INTRODUCTION

Janssen filed this motion in order to protect its statutory right to receive notice from Defendants *after* FDA decides whether to approve Defendants' biosimilar version of Janssen's Remicade and *before* Defendants begin commercial marketing. The notice is an integral part of the legislative scheme established by the BPCIA and it will permit Janssen to seek a preliminary injunction on one or more of six patents that Janssen has asserted against Defendants in this case. In its opening papers, Janssen demonstrated that Defendants' pre-approval notice was improper, that it is premature to seek preliminary relief on Janssen's patents now, and that a motion for a preliminary injunction would not be ripe unless and until FDA actually licensed Defendants' biosimilar for commercial sale.

In response, Defendants completely ignore Janssen's well-documented showing. Without discussing any of Janssen's patents, Defendants assert that "Janssen is free to seek injunctive relief for any of the six patents-in-suit *now*." Def. Br. 13 (Dkt. No. 51) (emphasis in original). But a preliminary injunction is appropriate when the harm is imminent and the dispute crystallized, and Defendants do not dispute Janssen's factual demonstration that such a motion "*now*" would be premature – and a waste of the time for the Court and the parties.

Instead, Defendants contend that the "notice of commercial marketing" required by section 262(l)(8) has no connection to the statutory right to seek a preliminary injunction

guaranteed by the same section. Defendants take the untenable position that there is "no precondition" at all to providing a notice of commercial marketing, Def. Br. 8, so that the notice can be provided at any time, even before filing an aBLA. They even concede that their purported notice – provided many months, and perhaps even years, before any FDA licensing decision, and unrelated to any actual impending commercial marketing – "serves no practical purpose." Def. Br. 13. That concession should be enough to reject Defendants' reading of the BPCIA. Congress did not intend the notice it demanded of biosimilar applicants prior to marketing to be a meaningless act. A proper notice of commercial marketing advises the innovator company when a biosimilar product will be imminently marketed so that it may bring a timely motion for a preliminary injunction. Defendants' purposeless notice fails to comply with the statute.

Defendants' proposed interpretation of the notice provision runs afoul of the text, structure, and purpose of the BPCIA. Embracing the flawed reasoning of one district court decision that is currently on expedited appeal to the Federal Circuit (and that has effectively been enjoined by the Federal Circuit pending its decision), Defendants contend that the statutory requirement that a notice of commercial marketing be provided for a "licensed" product does not mean what it says. Defendants' strained reading of the statute is contrary to its plain language. It is also directly contradicted by other provisions of the statute, which Defendants do not seriously address, but which make clear that the notice must be provided after FDA licenses the biosimilar and before commercial marketing begins.

Having failed to defend their position using the primary tools of statutory interpretation, Defendants contend – repeatedly but without basis – that Janssen's reading of the statute would wrongly extend from 12 to 12.5 years the period of market exclusivity created by the BPCIA. This argument is wrong on both the facts and the law. On the facts, it is undisputed that Janssen

never received 12 years – or even a day – of marketing exclusivity under the BPCIA. In return for allowing Defendants to piggyback on Janssen's pioneering research, all the BPCIA provides to Janssen is a modest 180-day window in which to seek a preliminary injunction. And on the law, in cases (unlike this one) where there is a 12-year period of exclusivity, FDA approval – and notice of commercial marketing and a preliminary injunction – can all occur within the 12-year period. Accordingly, any concern about a 12.5-year period of exclusivity is misplaced.

In Janssen's opening brief, we advised the Court that Defendants had represented that they would comply with a declaratory judgment order striking Defendants' notice of commercial marketing, Pl. Br. 21 (Dkt. No. 34-1), which would obviate the need for the Court to order the Defendants to comply with the law and refrain from marketing their proposed biosimilar until at least 180 days after they provide an effective notice of commercial marketing. Defendants now reverse course. Without explicitly saying that they will *not* comply with a Court order invalidating their notice of commercial launch, Defendants now argue that even if the Court agrees with Janssen's interpretation of the law, Defendants should not have to comply with the law and, indeed, that the Court lacks power to order their compliance. Def. Br. 16-19. In fact, the 180-day notice provision is enforceable by this Court and Defendants' failure to comply with it causes Janssen irreparable injury. The Court should enter the requested injunction. Because the merits question is one of law and there are no facts in dispute, the injunction should be a permanent injunction, not a preliminary injunction.

## I. Defendants' "Notice of Commercial Marketing" Is Ineffective

In 42 U.S.C. § 262(l)(8)(A), the BPCIA provides that 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)." The text,

structure and purpose of the statute make clear that the product that is subject of the notice must be "licensed." Because Defendants' proposed biosimilar product is not licensed, their purported notice was not only purposeless (as Defendants concede), but also legally ineffective.

### A. Section 262(l)(8)(A) Requires That a Notice of Commercial Marketing Be Provided For a "Licensed" Product

As its text makes clear, and as Janssen demonstrated in its opening brief, section 262(l)(8)(A) requires that a biosimilar applicant provide notice at least 180 days before marketing the "biological product licensed" by FDA under subsection (k). Pl. Br. 11-13. It is impossible to provide such a notice unless there already exists a "biological product licensed" by FDA. That is, an FDA license is a condition precedent to the notice of commercial marketing.

Relying heavily on the district court decision in *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 U.S. Dist. LEXIS 34537 (N.D. Cal. Mar. 19, 2015) ("*Amgen II*"), which is now on appeal, Defendants argue that a "biological product licensed" by FDA refers to the product that FDA *will* (or *might*) license some day in the future. By Defendants' reading, Congress actually meant to refer in section 262(l)(8)(A) to a product that is merely the subject of an *application for a license.* And, by that reading, Congress seemingly thought there was some point in giving notice of "commercial marketing" of a product that did not have – and might never have – a license for commercial marketing.

Janssen demonstrated in its opening brief why this argument is incorrect and Defendants simply fail to respond to this demonstration. Pl. Br. 11-13. When Congress meant to refer to the *future* potential marketing of a product that was only the subject of an application, it said so. For example, in the so-called "patent dance" – the back-and-forth between applicant and innovator designed to identify those patents to be litigated immediately and those to be litigated later – Congress required disclosure of patents that will be infringed by the "commercial marketing of

the biological product *that is subject of the subsection (k) application*." 42 U.S.C. § 262(l)(3)(B)(ii)(I) & (l)(3)(C) (emphasis added); *accord id* § 262(l)(1)(D), (l)(3)(A)(i), & (l)(7)(B). Under the BPCIA, a "biological product licensed under subsection (k)" is not a synonym for a "biological product that is the subject of the subsection (k) application." Congress's careful choice of language in section 262(l) indicates that it meant what it said. A biological product must be "licensed" by FDA before a notice of commercial marketing can be given. *See 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).

The district court decision interpreting section 262(l)(8)(A) in *Amgen II* is in conflict with the earlier decision in *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 court in *Amgen I* concluded (as Janssen has argued) 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 "is not 'licensed under subsection (k).'" 2013 U.S. Dist. LEXIS 161233, at *6. Contrary to Defendants' argument, this ruling was not *dicta*; rather, it was the "[f]irst" ground on which the court dismissed a premature patent complaint. *Id.*

The disagreement between these courts may be shortly resolved by the Federal Circuit, which is hearing the appeal in *Amgen II* on an expedited basis. Oral argument is scheduled for June 3. Meanwhile, the Federal Circuit has granted an injunction barring the launch of the biosimilar pending appellate review. *See Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir.

May 5, 2015) (*per curiam*) (Ex. 1).[1] The injunction effectively stays *Amgen II*'s (incorrect) interpretation of section 262(l)(8)(A).

In their opposition, Defendants add an argument to advance their incorrect reading of section 262(l)(8)(A) that was not relied on by the *Amgen II* court. They assert that there is no license requirement because the notice must be given by a "subsection (k) applicant." Def. Br. 9. According to Defendants, a subsection (k) applicant purportedly "ceases to be" an applicant once its product is licensed and instead becomes a "sponsor" or "holder" of a license. *Id*. Both parts of this argument are incorrect. The BPCIA expressly defines a "subsection (k) applicant" as a "person that submits an application under subsection (k)." 42 U.S.C. § 262(l)(1)(A). Under this controlling definition, *see, e.g, Burgess v. United States*, 553 U.S. 124, 129-30 (2008) ("When a statute includes an explicit definition, we must follow that definition . . . .") (internal quotation marks omitted), a person that submits an application under subsection (k) is a subsection (k) applicant, whether or not the application has been approved. Indeed, the BPCIA expressly refers to a biosimilar maker with an approved subsection (k) application as an "applicant" on more than one occasion. *See, e.g.*, 42 U.S.C. § 262(k)(6)(B) (referring to litigation against the "*applicant* that submitted the application for the first *approved* interchangeable biosimilar biological product") (emphases added); *accord id*. § 262(k)(6)(C).

Equally incorrect is Defendants' assertion that the statute refers to approved subsection (k) applicants as "sponsors" or "holders." Def. Br. 9. In fact, those terms are used uniformly in the BPCIA to refer to innovators like Janssen who have filed BLAs based on original research under subsection (a), not biosimilar applicants like Defendants who have filed aBLAs under

[1] Exhibits 1-4 are attached to the Declaration of Andrew D. Cohen in Further Support of Plaintiff's Motion for Partial Summary Judgment and a Preliminary and Permanent Injunction and in Opposition to Defendants' Cross-Motion for Partial Summary Judgment, filed herewith.

subsection (k). Thus, the term "sponsor" is used to distinguish the owner of an original subsection (a) biological license from subsection (k) applicants. 42 U.S.C. § 262(k)(7)(C)(ii), (l). The term "holder" is used likewise to refer to the holder of a subsection (a) application, not a biosimilar applicant under subsection (k). *Id.* § 262(m)(3). The statutory text is clear: subsection (k) applicants must provide a 180-day notice of commercial marketing after their product becomes a "licensed" product.

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

Janssen's reading of subparagraph(A) is consistent with its placement as part of section 262(l)(8). That section is entitled "[n]otice of commercial marketing and preliminary injunction," and the title accurately captures its meaning. The obligation to give notice of commercial marketing of a "licensed" product created by section 262(l)(8)(A) is necessary to vindicate the right to move for a preliminary injunction created by section 262(l)(8)(B). Pl. Br. 10-11. Moreover, the 180-day period provided in paragraph (8)(A) in which to seek the preliminary injunction permitted by paragraph (8)(B) makes sense only if the product is first "licensed" for commercial marketing, so that the harm to be enjoined is imminent and the dispute to be resolved has crystallized.[2] In that event, 180 days is a reasonable amount of time for the innovator to seek preliminary injunctive relief. Otherwise, the notice period bears no relationship to the right that is provided. A premature notice does not present an urgent situation

[2] Defendants' contention that there is no "statutory limit" on preliminary injunction motions "other than the traditional four-factor test" misses the point. Def. Br. 15. The traditional four-factor test itself requires imminent harm for a preliminary injunction to be granted. Pl. Br. 10. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The Hatch-Waxman cases cited by Defendants, Def. Br. 15, do not change the imminence requirement. Meanwhile, the Hatch-Waxman Act provides nothing comparable to the BPCIA notice provision and opportunity to litigate preliminary injunctions. In addition, in Hatch-Waxman cases, there is no need for the dispute to be crystallized by FDA approval. Drugs subject to Hatch-Waxman are automatically approved for the same indications as the innovative product, unlike the BPCIA where the indications are unknown until approval, so that the need for a preliminary injunction on particular patents remains uncertain. Pl. Br. 11.

warranting emergency relief by the court. At the same time, a premature notice permits commercial launch immediately upon FDA license without leaving time for a preliminary injunction to be sought when the dispute is genuinely exigent and concrete. Reading section 262(l)(8) to require the notice to be provided upon FDA licensure allows subparagraphs (A) and (B) to make sense as a coherent whole.

In response, Defendants do not really dispute the reasonableness of this reading of section 262(l)(8). Instead, they argue that a "notice of commercial marketing is directed solely to 'the patents that were not selected for immediate litigation,'" Def. Br. 5, and bears no connection to a motion for a preliminary injunction where, as here, the applicant has insisted on litigating all patents immediately, Def. Br. 9-10. Here, Defendants ignored the statutory procedures for selecting patents for immediate litigation and there was never agreement between the parties about which patents to litigate at which times. Compl. ¶¶ 111-114 (Dkt. No. 1). Instead, Defendants unilaterally purported to make that decision.[3] But in any event, this argument is contrary to the language and structure of the statute.

By its terms, the requirement to provide a notice of commercial marketing does not depend on whether all patents are selected for immediate litigation or not. 42 U.S.C. § 262(l)(8)(A). Recognizing this, Defendants provided a purported notice of commercial marketing to Janssen. They did not take the position that the notice requirement was inapplicable here although Defendants (wrongfully) insisted that Janssen bring suit on all of its patents immediately. Thus, Defendants' contention that the notice of commercial marketing

[3] This statutory violation is the basis of Count I of the Complaint. Compl. ¶¶ 137-144. Since Defendants refused to comply with the mandatory provisions for selecting patents for immediate litigation and instead declared the BPCIA provisions "moot[]," *id.* ¶¶ 111-113, Carey Decl. ¶ 25 (Dkt. No. 37), none of Janssen's patents has been properly identified as either subject to immediate litigation or the second phase of litigation under the BPCIA.

requirement applies *solely* where there are non-selected patents to litigate in the second phase is belied by their own actions.

Defendants' argument appears to be that although the notice of commercial marketing is mandatory, it is a meaningless act that "serves no practical purpose" unless there are patents that have been excluded from immediate litigation. Def. Br. 13. That is indeed the implication of Defendants' reading of the statute, but that is a reason to reject Defendants' interpretation, not to accept it. If Congress had intended the notice of commercial marketing requirement to be meaningful only where there are non-selected patents remaining for second-phase litigation, it would have expressly limited the requirement to those circumstances, as it did elsewhere in the statute. *See, e.g.*, 42 U.S.C. § 262(l)(4)(B) (identifying procedures that are required "[i]f" the parties "fail to agree" on patents for immediate litigation); *id.* § 262(l)(6)(A) (identifying the requirements "[i]f" the parties "agree"). The fact that the notice requirement contains no such limitation indicates that it *does* serve a practical purpose, even if there are no second round patents to assert. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("A court must . . . interpret the statute 'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole.'") (internal citations omitted).

While it is true that the language of paragraph (8)(B) refers expressly to non-selected patents, this is because the innovator is barred from litigating those patents before the notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). Because the statute imposes no such limitation on the litigation of patents selected for immediate litigation, there is no need for express authorization to bring a preliminary injunction motion. But where, as here, litigation is not complete, the notice of commercial marketing requirement provides an unconditional 180-

day period that may be used to bring a motion for a preliminary injunction on any and all patents still in dispute.

This "practical purpose" for the notice requirement is exemplified by the facts here – which Defendants do not dispute. FDA's consideration of Defendants' application has been indefinitely delayed and FDA has given no public indication that it is likely to be approved. At this time, a motion for a preliminary injunction is premature, and will possibly be unnecessary, for *each* of Janssen's patents. Pl. Br. 15-17. One patent is on treating an indication that may not be approved; one will expire less than 180 days from today; one is in reexamination; and three are manufacturing patents for which Defendants have not provided sufficient information to determine infringement.[4] For example, it makes no sense – and would be an unwarranted burden on the Court – for Janssen to seek a preliminary injunction on its 396 patent addressed to a method of using infliximab to treat Crohn's disease, when FDA may not approve Defendants' biosimilar for the treatment of Crohn's disease. If a notice of commercial marketing is provided after an FDA decision to license Defendants' biosimilar, then Janssen will have a 180-day period in which to assess each of its patents and determine whether, upon the facts that then exist, a motion for a preliminary injunction is appropriate. That is the purpose of the notice requirement, and it is both practical and mandatory.

[4] Contrary to Defendants' assertion that they have provided Janssen with all of the required manufacturing information, Def. Br. 7 n.1, Defendants provided only their aBLA and nothing else prior to this lawsuit. *See* Carey Decl. Ex. D, at 2 (letter from Defendants stating that "Celltrion provided Janssen a copy of its aBLA 125544 . . . . Janssen has not shown that it is entitled to, or even needs, documents providing further detail of the steps of Celltrion's manufacturing process."). Indeed, despite months of requests, it is only last week that Defendants' provided a complete copy of the aBLA itself and a few additional documents. Defendants' continue to refuse to provide other mandatory information. Defendants' further assertion that the information Janssen seeks is solely in the possession of third parties is belied by Defendants' non-infringement contentions, which purport to deny infringement by reference to (but without substantiation of) the very information that Defendants have refused to provide. *See id.* Ex. E, at 46, 52-53.

### C. Section 262(l)(8)(B) Confirms That There Is a "Condition Precedent" to a Notice of Commercial Marketing

Defendants' argument that "licensed" does not mean "licensed" eliminates the condition precedent to serving a notice of commercial marketing. As Defendants' previously argued in an unsuccessful attempt to institute premature patent litigation, *see* Carey Decl. ¶ 32, this implies that the notice can be served before undertaking the BPCIA dispute resolution process and even prior to filing an aBLA.[5] As Defendants now implicitly concede, the argument that there is no precondition to a notice of commercial marketing is demonstrably incorrect.

Paragraph (8)(B) explicitly permits the filing of a preliminary injunction upon the receipt of a notice of commercial marketing with respect to patents that were "not included" on the list of patents for immediate litigation. That means, at a minimum, that the notice must follow the BPCIA's "patent dance." Until the statutory information exchanges and good faith negotiation are complete, which Defendants refused to do here, there is no list of first- or second-phase patents. Paragraph (8)(B) cannot be read to authorize a motion for a preliminary injunction on a non-existent list of patents. Pl. Br. 14-15. Rather, the premise of paragraph (8)(B) is that there is a precondition for the notice of commercial launch. Reading subparagraphs (A) and (B) together, that precondition is an FDA license.

Defendants have no answer to this argument and so they dodge the question. In their purported notice of commercial marketing, provided to Janssen on February 5, 2015, they broadly asserted that "*the statute* . . . [does not] include a condition precedent to providing notice." Carey Decl. Ex. F (emphasis added). Now they shrink that broad assertion down to the

[5] Rejecting this argument, the district 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." *See Hospira Inc. v. Janssen Biotech, Inc.*, 113 U.S.P.Q. 1260, 1262 (S.D.N.Y. 2014).

narrower claim that "*paragraph 8(A)* of the BPCIA contains no precondition for providing notice." Def. Br. 8 (emphasis added).

This more tailored articulation based on paragraph (8)(A) alone does not engage on Janssen's point. The point is that subparagraphs (B) and (A) must be read together and, so read, it is plain that the statute does include a condition precedent to notice. The notice must be given *some* time after the patent dance has been completed, or paragraph (8)(B) makes no sense. Defendants essentially concede that this is true. They write "[w]hether such a precondition exists is of no moment here" because, supposedly, "the question of whether *any* precondition exists is not currently before the Court." Def. Br. 10 & n.2 (emphasis in original). But that is precisely the question raised by the parties' competing interpretations of the statute: is there a statutory precondition for notice and, if so, what is it? Defendants' dodge concedes the answer. Paragraph (8)(B) assumes that there is some precondition because notice must be given after the patent dance is complete; and paragraph (8)(A) prescribes the precondition – a product must be "licensed" before a notice of commercial marketing can be provided. Pl. Br. 15.

**D. Defendants' Arguments About Congressional Intent Are Incorrect**

Defendants' principal arguments are not based on an analysis of section 262(l)(8), but rather on misplaced allegations about the purpose of the BPCIA. First, Defendants contend that Janssen's reading of the statute would frustrate congressional intent by improperly extending from 12 to 12.5 years the period of marketing exclusivity granted to innovators. Second, they argue that Congress intended all patent litigation under the BPCIA to be completed prior to launch of the biosimilar. Both arguments are incorrect.

### 1. The Notice of Commercial Marketing Does Not Extend the Statutory Exclusivity Period

Defendants argue that, whatever the language of section 262(l)(8) provides, it is necessary to read the requirement of an FDA license out of the notice provision in order to avoid adding an extra 180 days of market exclusivity onto the twelve years the BPCIA provides: "Congress granted 12 years of exclusivity, not 12.5 years." Def. Br. 12-13. Defendants return to this argument repeatedly. Yet it is incorrect. The 180-day notice provision is not an exclusivity provision but rather a procedural requirement to ensure that innovators will have a timely opportunity to enforce their patent rights prior to the commercial launch of a biosimilar product. Defendants' contention that the notice requirement conflicts with the statute's exclusivity provision is premised on two glaring errors.

First, Janssen does not contend that Congress granted it 12.5 years of market exclusivity. Janssen never received any statutory exclusivity from Congress, and it is not seeking a "windfall" by asking for the statutory 180-day period to bring a proper motion for a preliminary injunction. *Id.* at 13. As Defendants elsewhere concede, Remicade had been on the market for twelve years by the time the BPCIA was enacted and so was never shielded from biosimilar competition by the statute for even one day. *Id*. at 5. Defendants argue that "[i]mposing an additional 180-day period of non-patent exclusivity would contravene the bargain struck by Congress." *Id*. at 12. But the "bargain" that Defendants seek to enforce is one where Defendants receive the ability to use Janssen's data to obtain marketing approval and *Janssen gets no period of exclusivity at all* – not even 180 days in which to litigate a preliminary injunction to protect it from irreparable harm. That is no bargain at all.

The second flaw in Defendants' argument is that its premise is wrong. Reading section 262(l)(8)(A) to provide a 180-day opportunity to litigate a preliminary injunction would not, in

the typical case, extend the 12-year exclusivity period. The better reading of the statute is that the two periods would typically run concurrently rather than consecutively. Pl. Br. 20. That is because, as Defendants agree, Def. Br. 1-2, the BPCIA explicitly permits FDA to approve a biosimilar license (but not to make it effective) while the twelve years of marketing exclusivity is still in effect. *See* 42 U.S.C. § 262(k)(7)(A) ("[a]pproval of a[] [biosimilar] application . . . may not be *made effective*" during the exclusivity period) (emphasis added); *accord id*. § 262(a)(1)(A) (providing that no person may sell a biologic in the United States unless a "biologics license under this subsection or subsection (k) is *in effect*") (emphasis added). If approval occurs during the exclusivity period (effective at its expiration), the biosimilar applicant may provide its notice of commercial marketing before the expiration of twelve years, and the notice provision would not delay commercial launch.

It is only where, as here, FDA does not approve the biosimilar application during the 12-year exclusivity period that the 180-day notice period provides a protected window for bringing a motion for a preliminary injunction at a time when the biosimilar applicant could have otherwise entered the market. In these circumstances, it is not the 12-year exclusivity period that delays commercial launch; such an unapproved product could not in any event have been marketed during those twelve years. Because the exclusivity period has no effect in the absence of FDA approval, providing a modest period of time for a motion for a preliminary injunction after approval in these circumstances does not confer a "windfall" upon innovators. It merely ensures that they will not be irreparably harmed by infringing market entry before their patents have been preliminarily adjudicated.

### 2. Congress Did Not Intend All Litigation to Be Completed Before FDA Approval

Defendants also contend that Congress intended all patent disputes to be resolved before FDA approval, not after. They use this argument seemingly to dispute the propriety of allowing a preliminary injunction to be filed when launch is imminent. This argument is incorrect. Defendants cite snippets of legislative history that are addressed to two early versions of the proposed legislation – versions that did *not* provide for two phases of patent litigation and did *not* require a notice of commercial launch or permit the filing of a preliminary injunction upon such a notice. *Compare* Def. Br. 3, 14, *with* Hoang Decl. Ex. 5, at 17, 65, 202-03 (Dkt. No. 53-5) (hearing focused on the two biosimilars bills pending before the House, H.R. 1548, 111th Cong. (2009) (the "Eshoo-Barton Bill"), and H.R. 1427, 111th Cong. (2009) (the "Waxman-Deal Bill")); *see also* H.R. 1548, 111th Cong. § 101 (Ex. 2); H.R. 1427, 111th Cong. § 3 (Ex. 3).[6] This legislative history has no relevance here.

As set forth in detail in Janssen's reply memorandum in support of its motion for a stay of litigation of one of its patents, the notion that the BPCIA requires pre-launch "patent certainty" is wrong. Dkt. No. 57-1, at 3-4. The BPCIA's two-phase litigation structure permits some patents to be subject to early litigation, while others will not even be asserted until immediately before commercial launch (or later). *See* 42 U.S.C. § 262(l). First-phase patents may be litigated during the approval process – but only if there is time. That may happen with respect to future applicants, but in cases like this one, where there is no 12-year period of exclusivity, there is no time for pre-approval resolution of patent litigation. Indeed, on the facts of this case, even

[6] Because the legislative history that Defendants cite is unrelated to the bill that was passed, the Biotechnology Industry Organization, whose testimony Defendants misleadingly quote, Def. Br. 14, actually supports Janssen's reading of the law that was enacted by Congress. *See* Brief of *Amicus Curiae* Biotechnology Industry Organization in Support of Reversal or Remand 3, 18-21, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. Apr. 14, 2015) (Ex. 4).

Defendants agree that Janssen could not have filed suit on any of its patents until after February 5, 2015, yet they promise a launch as early as August 4, 2015 – a grossly insufficient amount of time for a final adjudication of the six asserted patents if the BPCIA promised some kind of pre-launch "patent certainty."

Meanwhile, this argument has no place whatsoever with respect to second-stage patents. Second-stage patents, by design, cannot be litigated until the notice of commercial marketing is provided, 180 days before commercial launch. Defendants implausibly suggest that "[i]f the applicant so desires," it can file an early notice of commercial marketing "before FDA approval to resolve by then any second-phase patent disputes on non-listed patents." Def. Br. 10. This scenario makes no sense. In the legislative scheme, the applicant already has the ability to insist on early litigation of whichever patents it wishes in the first phase. *See* 42 U.S.C. § 262(l)(5)-(l)(6).

Rather, the notice of commercial marketing requirement is for the benefit of the patent holder, not the applicant. Whether patents are litigated in the first stage or second stage, nothing in the BPCIA guarantees that the litigation will be completed prior to launch. Indeed, the BPCIA specifies that money damages for infringement are available in both cases. *See* 35 U.S.C. § 271(e)(4)(C). The notice provision protects the patent owner by ensuring the opportunity to seek a preliminary injunction on any patents still in dispute before launch.

## II. Janssen Is Entitled to a Permanent Injunction Requiring Defendants to Comply with the 180-Day Notice Requirement

Prior to submitting its opening brief, Janssen asked Defendants whether they would comply with a declaratory judgment in Janssen's favor, without the need for an injunction. In language that was pre-approved by Defendants, Defendants "advised us that they will comply with any court order and that may obviate any need for injunctive relief in this case." Pl. Br. 21.

Defendants have now reversed course. In their opposition, Defendants contend that "[e]ven if Janssen's reading of the BPCIA were correct" they should not be enjoined to comply with the statute. Def. Br. 16.

In other words, Defendants assert that even if the Court concludes that the BPCIA requires them to give 180 days' notice of launch *after* FDA license and *before* beginning commercial marketing, so as to give the Court time to adjudicate a motion for a preliminary injunction, they will not do so unless they are so ordered by the Court. While we regret having to burden the Court with this issue, an injunction is plainly appropriate. Moreover, because both parties agree that there are no facts in dispute and that Janssen's motion presents a question of law that can be decided on summary judgment, the injunction should be a permanent injunction after a decision on the merits, not a preliminary injunction.

**A. This Court May Enforce the 180-Day Notice Requirement**

In their cross-motion for summary judgment, Defendants ask the Court to reject Janssen's reading of the statute on the merits and conclude that Defendants' notice of commercial marketing complied with the terms of section 262(l)(8)(A). But it turns out that Defendants' views about the Court's ability to interpret the statute are a one-way street. *If* (and only if) the Court agrees with Janssen, *then* Defendants contend that the Court should not address the merits after all. This is because the BPCIA purportedly does not create a private right of action, allowing the Court to interpret the statute. Def. Br. 18-19. Defendants' attempt to have it both ways fails. The Court has the power to address the merits of the dispute and to remedy Defendants' violation of the BPCIA.

There are at least two separate sources of federal judicial power to enforce the notice of commercial marketing requirement. First, the BPCIA creates an implied private right of action.

Under the case law, this conclusion follows, *inter alia*, from the following: (1) The BPCIA's notice provision "expressly identifies the class Congress intended to benefit," namely, the reference product sponsor. *Cannon v. Univ. of Chicago*, 441 U.S. 677, 690 (1979). (2) Congress expressly provided in the BPCIA that the statutory procedures would lead to private federal-court litigation between these parties. *See* 42 U.S.C. § 262(l)(6), (l)(8)(B); 35 U.S.C. § 271(e)(2)(C). (3) There is no administrative agency or other entity besides the parties that is responsible for enforcing the BPCIA's procedures. *See, e.g.*, *Ind. Prot. & Advocacy Servs. v. Ind. Family & Soc. Servs. Admin.*, 603 F.3d 365, 375-79 (7th Cir. 2010) (implied right of action where, *inter alia*, statute "lack[ed] separate administrative enforcement mechanisms").[7]

Second, and separately, the district court may issue an injunction requiring compliance with the procedures of the BPCIA under its inherent powers to supervise BPCIA patent litigation before it and under the All Writs Act, 28 U.S.C. § 1651(a) (federal courts may "issue all writs necessary or appropriate in aid of their respective jurisdictions"). *See Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1099 (11th Cir. 2004) (All Writs Act is "codification" of courts' "inherent power and the constitutional obligation to protect their jurisdiction from conduct which impairs their ability to carry out Article III functions") (internal quotation marks omitted). As part of these powers, a court may require compliance with the notice provision in order to ensure that the preliminary injunction motion contemplated by the statute may be properly adjudicated, irreparable harm avoided, and the status quo maintained. *See FTC v. Dean Foods Co.*, 384 U.S. 597, 604 (1966) (All Writs Act creates "power to issue injunctions to

[7] Defendants cite 42 U.S.C. § 262(l)(1)(H) as an example of an express right of action created by the BPCIA. Def. Br. 19. But this paragraph does not expressly create a right of action; it simply provides that injunctive relief is an appropriate remedy for a violation of the paragraph. The paragraph thus assumes the existence of a right of action rather than creates one.

preserve the status quo"); *Klay*, 376 F.3d at 1099 (courts may issue orders to "safeguard not only ongoing proceedings, but potential future proceedings") (footnote omitted).

Defendants ignore both of these bodies of law and contend that the sole remedy for a violation of the section 262(l)(8)(A) notice of commercial marketing provision is that the innovator may bring a declaratory judgment action to enforce its rights under 42 U.S.C. § 262(l)(9)(B). Def. Br. 18. This is not an answer. Paragraph (9)(B) does address the right to sue by lifting the ban on declaratory judgment actions that would otherwise remain in place until a proper notice of commercial launch. *See* 42 U.S.C. § 262(l)(9)(A). But the right to sue *after* an applicant has launched without notice does not address at all, let alone remedy, the loss of the statutory 180-day window in which to litigate *before* commercial launch. There is, accordingly, no reason to view this provision as somehow barring the courts from granting complete relief for a breach of section 262(l)(8)(A).[8]

It is inconceivable that Congress, having provided a framework for patent litigation in the federal courts, and having required a 180-day notice period in which to bring a motion for a preliminary injunction, would have wanted the notice requirement to be unenforceable by the courts. This Court has the power to enforce the notice requirement.

### B. Defendants' Failure to Provide a Proper Notice of Commercial Marketing Will Cause Irreparable Procedural Injury to Janssen's Patent Rights

In its opening brief, Janssen showed that it is entitled to an injunction under the traditional four-factor test, which takes into account, among other things, the irreparable

[8] When Congress wanted to identify a sole remedy for a violation of the BPCIA, it said so clearly. Thus, 35 U.S.C. § 271(e)(6)(B), which was enacted as part of the BPCIA, expressly identifies "the sole and exclusive remedy that may be granted by a court" for a failure to bring a timely suit. Similarly, 35 U.S.C. § 271(e)(4), which the BPCIA made applicable to biologics, identifies "the only remedies which may be granted by a court" under certain circumstances. By contrast, 42 U.S.C. § 262(l)(9)(B) contains no such language.

procedural harm that results from being deprived of statutory procedural safeguards to protect their patent rights. Pl. Br. 8, 21-25.[9] In response, Defendants argue that the violation of a statutory procedural requirement cannot cause Janssen irreparable harm or otherwise give rise to an injunction. Def. Br. 17, 19-22. According to Defendants, irreparable harm under the BPCIA can only come from the infringement of patent rights and Janssen purportedly does not seek to enforce its patent rights here. Def. Br. 2, 21-22. This argument is hard to comprehend based on Janssen's showing; it seemingly assumes that Defendants are correct on the merits. But the issue of irreparable injury arises only if Janssen is correct on the merits, and Defendants do not really engage on that premise.

Contrary to Defendants' repeated assertion that Janssen's motion "points to" no patent rights, Def. Br. 21, Janssen explained at length in its opening brief how the notice of commercial marketing requirement protects its ability to properly assert its patent rights, Pl. Br. 15-17. Janssen has asserted six patents in the complaint and is prepared to move for a preliminary injunction on them if that becomes appropriate. Currently, however, a preliminary injunction motion on Janssen's patents is premature for the reasons detailed in its opening brief – and not rebutted in any respect by Defendants. Requiring a proper notice of commercial marketing upon the approval of Defendants' product would allow Janssen to bring a preliminary injunction motion on its patents at an appropriate time, whereas allowing Defendants' improper notice to stand directly threatens Janssen's patent rights. Pl. Br. 15-17, 22-23.

It is true that the doctrine of irreparable procedural injury, as elaborated in the seminal case *Sierra Club v. Marsh*, 872 F.2d 497, 500 (1st Cir. 1989) (Breyer, J.) and its progeny, requires

[9] Because Janssen relies on the traditional four-factor test, Defendants' argument that *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) requires this test to be applied, Def. Br. at 19, is irrelevant. *But see CoxCom, Inc. v. Chaffee*, 536 F.3d 101, 112 n.14 (1st Cir. 2008) (noting that even after *eBay*, "irreparable injury is presumed to flow" from certain statutory violations).

an underlying substantive interest that is protected by the procedures in question. But notwithstanding Defendants conclusory assertion that "Janssen has no substantive rights protected by the paragraph 8(A) notice procedure," Def. Br. 22, in fact, the test is easily met. As Janssen made clear in its opening brief, and as Defendants do not address, Janssen's patent rights are the substantive rights that the notice of commercial marketing requirement protects. Pl. Br. 22-23. If Janssen's reading of paragraph (8)(A) is correct, Defendants' violation of the notice provision is a classic example of irreparable procedural injury.

Defendants wrongly rely on the *Amgen II* decision to argue that Amgen did not prove irreparable harm arising from procedural injury. Def. Br. 22. In fact, the *Amgen II* court did not consider, because it was not asserted, whether the failure to give proper notice of commercial launch constituted irreparable procedural injury. Moreover, the Federal Circuit has now granted Amgen's motion for an injunction pending appeal, a ruling that necessarily reflects a finding by the court that Amgen faces irreparable harm from a premature launch. Ex. 1. Here, too, denying Janssen the procedural right to receive a notice of impending launch from Defendants after FDA license – at a time when the harm is both imminent and concrete – would cause Janssen irreparable injury.

### C. Defendants' Market Entry Would Cause Irreparable Harm to Janssen's Business

In its opening brief and in the accompanying declaration of Dr. Henry Grabowski, one of the world's foremost experts on the economics of the biosimilar market, Janssen demonstrated the obvious point that competition from a lower-priced copy of Remicade is likely to have a negative – but not fully quantifiable – impact on Janssen's Remicade business. Pl. Br. 23-24. Defendants' contention that Janssen's evidence is "speculation" because its product has not actually entered the market yet is specious. Def. Br. 22-23. All injunctions are based on

projections about future harm that has not yet occurred. Janssen's evidence clearly shows that it is "*likely* to suffer irreparable harm" in the absence of an injunction. *Winter*, 555 U.S. at 20 (emphasis added); *see Michigan v. U.S. Army Corps of Eng'rs*, 667 F.3d 765, 788-89 (7th Cir. 2011) (error where "the district court required a level of proof too close to certainty" with respect to irreparable harm; irreparable harm need only be "likely," not necessarily "certain to occur"); *Small v. Avanti Health Sys., LLC*, 661 F.3d 1180, 1191 (9th Cir. 2011) (noting "while 'likely' is a higher threshold than 'possible,' [plaintiffs] need not prove that irreparable harm is certain or even nearly certain" to be entitled to an injunction).

Indeed, when a direct competitor sells essentially the same product at a lower price, courts routinely find that the injury is not only likely, but irreparable. The irreparable injury from such competition affects not only sales, market share, and prices, but also business relationships, cross-marketing opportunities, and goodwill. Pl. Br. 23-24. *See, e.g.*, *Presidio Components, Inc. v. Am. Tech. Ceramics Corp*., 702 F.3d 1351, 1363 (Fed. Cir. 2012); *Celsis in Vitro, Inc. v. CellzDirect, Inc*., 664 F.3d 922, 930 (Fed. Cir. 2012); *Robert Bosch LLC v. Pylon Mfg. Corp*., 659 F.3d 1142, 1155 (Fed. Cir. 2011).

The efforts of Defendants and their expert, Dr. Atanu Saha, to refute Janssen's evidence fail the test of common sense. Making misleading use of data from the handful of small countries in which a biosimilar version of Remicade has already been introduced, Dr. Saha suggests that, somehow, biosimilar competition would actually *help* Janssen's United States Remicade business. Def. Br. 23; Saha Decl. ¶¶ 15-16 (Dkt. No. 51-1). But unlike Dr. Saha's, Dr. Grabowski's projections were not created for purposes of this litigation. Dr. Grabowski's opinions are based primarily on Janssen's internal projections of the impact of biosimilar market

entry on the Remicade business in the United States. Grabowski Decl. ¶¶ 49-50, 52 (Dkt. No. 36); Grabowski Reply Decl. ¶¶ 7-8, 11.

Janssen's projections were created in the ordinary course of business and take into account all the relevant information, including the selected international experience cited by Dr. Saha, and are by far the most reliable analysis of the likely impact of biosimilar competition on Remicade. *Id*. As Dr. Grabowski shows, Janssen's projections are consistent with published analyses by independent financial professionals and with the public statements – outside the context of litigation – of Defendants themselves. Grabowski Reply Decl. ¶¶ 7-11, 18. In contrast, Dr. Saha's litigation-driven opinions are unique in denying that biosimilar entry will harm Janssen's Remicade business.[10]

Dr. Saha also opines that a drop in Remicade sales would not lead to a corresponding reduction in research-and-development ("R&D") efforts. This cannot be taken seriously. Defendants cannot deny – indeed Dr. Saha expressly admits – that the overall R&D budget of Janssen's parent company, J&J, is targeted at about 20% of pharmaceutical revenues. Yang Decl. ¶ 29 (Dkt No. 35); Saha Decl. ¶ 17. This necessarily means that there is a direct linear relationship between Remicade sales and Remicade's contribution to J&J's R&D spending.

[10] Not surprisingly, as Dr. Grabowski explains, Dr. Saha's analysis does not withstand scrutiny. Janssen does not sell Remicade in Europe, but both Merck (which sells Remicade) and Hospira (which sells the biosimilar of Remicade) publicly predict a decline in Remicade sales in Europe. Dr. Saha presents no reason to disbelieve the regular-course-of-business statements of these direct competitors. Rather, he manipulates limited data from seven small countries whose aggregate sales are a fraction of Janssen's Remicade sales in the United States. In no country does Dr. Saha account for the price of Remicade, whose predictable decline may grow sales, but is an important form of irreparable injury. Moreover, it is only in the countries (Czech Republic, Finland, Ireland, and Portugal) where, for whatever reason, the biosimilar does not appear to have substantially penetrated the market and made sales that the impact on Remicade was small. In the countries where the biosimilar did penetrate the market, the negative impact on Remicade is significant, with significantly declining sales (Norway, Poland) or sharply lower growth rates (South Korea). *See* Grabowski Reply Decl. ¶¶ 13-18. In light of the realities of the U.S. market, all analysts, including Defendants themselves, believe that in the U.S., a biosimilar version of Remicade will penetrate the market. *Id*. ¶¶ 10-11, 18. The limited international data therefore confirms the obvious point that Defendants' commercial launch will harm Janssen's Remicade business.

Grabowski Decl. ¶ 32. Dr. Saha does not directly challenge that fact, and he cannot. Instead, he performed a meaningless analysis purporting to show no apparent correlation between Remicade sales and *overall* J&J R&D spending. Such an analysis is meaningless because fluctuating sales of *other* pharmaceutical products mask the indisputably direct relationship between Remicade sales and R&D spending. This specious exercise does not change the fact that the relationship exists.[11] Indeed, the relationship is a matter of J&J policy.

Janssen has demonstrated the classic forms of irreparable injury that result from head-to-head competition from a generic product. Indeed, in *Amgen II*, the only other case to address irreparable harm in the context of biosimilar market entry, the Federal Circuit recently granted an injunction pending appeal, necessarily concluding that premature market entry by the biosimilar would cause irreparable harm. Ex. 1. The same conclusion is appropriate here.

### D. The Balance of Harms and Public Interest Favor a Permanent Injunction

In this case, the balance of harms and the public interest favor whichever party is correct on the merits. Assuming that is Janssen, these factors favor an injunction. The harm of the loss of Janssen's patents rights and the irreparable injury caused by premature market entry easily offsets the harm a 180-day injunction would cause Defendants. And the BPCIA itself balances the public interest between fostering innovation (which favors Janssen) and the benefits to consumers of price reduction (which favors Defendants). Therefore, applying the BPCIA as it is written strikes the right balance, and warrants a permanent injunction.

[11] *See* Kenneth A. Bolin, Structural Equations with Latent Variables 52 (1989) ("The old saying that correlation does not prove causation should be complemented by the saying that a lack of correlation does not disprove causation.").

## CONCLUSION

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

Dated: May 20, 2015

Respectfully submitted,

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