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.	:	Civil Action No. 1:15-cv-10698-MLW

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND A PRELIMINARY AND PERMANENT INJUNCTION AND IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT ON COUNT 2 OF THE COMPLAINT
[LEAVE TO FILE GRANTED ON APRIL 29, 2015]

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INTRODUCTION

The issue here is whether, under 42 U.S.C. § 262(*l*)(8)(A), a biosimilar applicant must wait until *after* it receives FDA approval of its product before providing 180-days' notice of commercial marketing—a result that would convert a *notice* provision into an *exclusivity* provision, and give the brand an extra six months of exclusivity beyond the 12 years expressly mandated by Congress. The only court that has squarely addressed this issue rejected the notion that a biosimilar applicant must await FDA approval, holding that a plain reading of the statute allows the applicant to give "its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) . . . *in advance of receiving FDA approval*." *Amgen Inc. v. Sandoz Inc.*, 2015 WL 1264756, at *8 (N.D. Cal. Mar. 19, 2015) (emphasis added).

That decision was correct. Under the Biologics Price Competition and Innovation Act ("BPCIA"), Congress provided 12 years of exclusivity *expressly*, by providing that "approval" of a biosimilar "may not be made effective by [FDA] until . . . 12 years after . . . the reference product was first licensed." 42 U.S.C. § 262(k)(7)(A). In other words, the brand (called the "reference product sponsor" or "sponsor") gets a guaranteed, 12-year monopoly, even if its product is protected by no patents at all.

According to Plaintiffs ("Janssen"), Congress provided an automatic, six-month extension of this express 12-year monopoly—*this time, without expressly saying so*. That is, as the court in *Amgen* noted, "nonsensical." *Amgen*, 2015 WL 1264756, at *8.

Under the notice provision, the biosimilar applicant must provide notice "not later than 180 days" before it markets "the biological product licensed" by FDA under the statute. 42 U.S.C. § 262(*l*)(8)(A). The phrase "biological product licensed" merely refers to the fact that, by law, *marketing* must come after the "biological product" has been "licensed." Janssen would rewrite this plain reading to impose a precondition—namely, that the *notice* must come "after the

product has been 'licensed[.]'" (Pls. Br. at 1.) As the Northern District of California in *Amgen* held, and as we will explain, that is not what the statute says. *See* Section I.A., *infra*. Nor does the "weight of authority" support Janssen's reading. (*Id.* at 18.)

The BPCIA's text and structure do not support an implied monopoly extension, and the Federal Circuit, which is hearing the *Amgen* case on an expedited basis (with argument scheduled for June 3), is likely to affirm the Northern District of California's analysis. But even if the Federal Circuit were to agree with Janssen's reading, such a ruling, alone, would not authorize the automatic 180-day injunction Janssen seeks. Equity does not support any injunction here. Among other things, the notice provision is intended to allow the sponsor to seek an injunction based on certain patent rights—but no such rights are asserted here. Thus, the requested injunction to preserve a monopoly would serve no purpose related to statutory exclusivity or Janssen's patents. Put simply, Janssen seeks a windfall.

For all these reasons, and additional reasons discussed below, the Court should reject Janssen's bid for a windfall injunction, deny its motion, and grant our motion for partial summary judgment on Count 2 of the complaint.

BACKGROUND

A. Congress enacted the BPCIA to encourage resolution of patent disputes before FDA approves the biosimilar.

In the BPCIA, Congress created an expedited path for approving biosimilar licenses. In return for allowing the biosimilar applicant to rely on the safety and efficacy data of the reference product sponsor, "approval" of a biosimilar "may not be made effective by [FDA] until . . . 12 years after the date on which the reference product was first licensed." 42 U.S.C. § 262(k)(7)(A). The patent laws, however, may extend this monopoly protection. To avoid de-

laying competition, the BPCIA encourages the parties to resolve patent disputes and requests for injunctive relief *before* FDA approval. *See* Section I.B.2., *infra*.

B. The BPCIA offers a process for resolving patent disputes.

To identify and resolve biosimilar patent disputes, the BPCIA amends the Public Health Service Act and the Patent Act to provide a pathway for the sponsor and applicant to exchange lists of patents to be litigated. Here is how it works.

At the outset, the applicant may provide to the sponsor its application and information describing the applicant's manufacturing process. 42 U.S.C. § 262(*l*)(2)(A). If the applicant does *not* do so, the sponsor may bring an immediate declaratory judgment action for patent infringement. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). In that case, the BPCIA allows the sponsor to bring suit (or seek a preliminary injunction) at any time on any patent deemed relevant to the application.

If the applicant *does* provide the information, the sponsor reciprocates by preparing and providing a list of patents under which it "believes a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(*l*)(3)(A)(i). If the sponsor does not respond by providing its patent list, or omits some patents, the sponsor may not sue for infringement of "a patent that should have been included." 35 U.S.C. § 271(e)(6)(C). The effect of this provision, as explained by Congresswoman Anna Eshoo (a primary author of the BPCIA), is to "help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." (*See* Hoang Ex. 5, *Biologics and Biosimilars* at 9.)

If the sponsor provides its patent list, the applicant may respond with its own list of relevant patents (and also by providing a "detailed statement" of its factual and legal patent contentions relating to the patents listed by the sponsor). 42 U.S.C. § 262(*l*)(3)(B). By means of this

information exchange, the BPCIA encourages the parties to agree upon "which, if any, patents" will be the subject of an "action for patent infringement." *Id.* § 262(*l*)(4)(A).

A final list of patents that may give rise to an "immediate" patent infringement lawsuit ("final patent list") is determined by the number of patents agreed by both parties or selected by the applicant during the information exchange. *Id.* § 262(*l*)(6)(A), (B); 35 U.S.C. § 271(e)(2)(C). The BPCIA specifies when a suit may be brought on a patent depending on whether it is included in the final patent list. 42 U.S.C. § 262(*l*)(6)(A)-(B), (8)(B), (9)(A)-(C).

C. The final patent list may give rise to immediate patent litigation.

If the sponsor sues within 30 days of a patent appearing on the final patent list, it may seek the full complement of infringement remedies for that patent—including injunctive relief and damages for lost profits. 42 U.S.C. § 262(*l*)(6)(A), (B); 35 U.S.C. § 271(e)(4). But if the sponsor does not sue on a patent on the final patent list within this 30-day period, or if its suit "[is] dismissed . . . or [is] not prosecuted . . . in good faith," "the sole and exclusive remedy" is a "reasonable royalty." 35 U.S.C. § 271(e)(6)(A), (B).

Congress designed these procedures to resolve patent disputes on key patents early and before FDA approval, thus accelerating competition. For example, Congress recognized that the threat of a lost profits award against the applicant could deter it from launching its product. So Congress penalized a sponsor for delaying litigation by banning the sponsor from recovering lost profits. *See* Dkt. 41 (Defendants' opposition to Janssen's pending motion to stay this case as to the '471 patent, which shows that Janssen attempts to circumvent this limit on lost profit damages by suing and then immediately seeking to stay its own suit).

D. The notice of commercial marketing provision addresses patents not subject to immediate litigation.

So when can the parties litigate any patents that appeared in an initial patent list but did not appear on the final patent list ("non-listed patents")? In general, neither sponsor nor applicant may sue on any non-listed patent "prior to the date notice [of commercial marketing] is received under paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(A); *but see id.* § 262(*l*)(9)(B), (C) (exceptions to this general rule). The notice allows the sponsor to seek a preliminary injunction based on any non-listed patents, thus opening the door to a second phase of litigation for such patents.

This process is undisputed. As Janssen concedes, the notice of commercial marketing is directed solely to "the patents that were not selected for immediate litigation." (Pls.' Br. at 5.) Under paragraph (8)(A):

> 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). In the next subsection, paragraph (8)(B) grants the sponsor at least 180 days to "*seek* a preliminary injunction" solely "with respect to any [non-listed] patent[.]" *Id.* § 262(*l*)(8)(B) (emphasis added).

E. Defendants participated in the BPCIA patent exchange and provided their notice of commercial marketing.

FDA approved Janssen's Remicade (infliximab) biologic product in 1998. (Pls.' Br. at 3.) Because Janssen already enjoyed more than 16 years of monopoly pricing, it concedes that "the BPCIA provides [Janssen with] no non-patent exclusivity at all." (*Id.* at 5.)

Celltrion and/or Hospira seek to introduce in the United States an affordable biosimilar of Remicade to patients suffering from debilitating and potentially life-threatening diseases. (Defendants' Statement of Material Facts ("DSMF") ¶ 3.) Celltrion began developing this biosimilar in 2008. (*Id.* ¶ 4.) By 2012, Celltrion became the first company successfully to create and

obtain regulatory approval under internationally accepted guidelines for a biosimilar monoclonal antibody product. (*Id.* ¶ 6.) To accomplish this achievement, Celltrion conducted clinical trials involving over 1,400 patients in 20 countries, costing over $110 million. (*Id.* ¶¶ 4-5.) As these trials showed, Defendants' proposed biosimilar compares in safety and efficacy to Remicade sufficiently to secure regulatory approval in over 50 countries, including Japan, Canada, and in Europe. (*Id.* ¶ 8.)

In August 2014, Celltrion filed with the FDA its abbreviated Biologics License Application ("aBLA") for Celltrion and/or Hospira to engage in the commercial marketing and distribution of their proposed biosimilar infliximab product. (*Id.* ¶ 9.) FDA accepted the aBLA for review (which precedes approval) on October 7, 2014, [redacted]. (*Id.* ¶¶ 10-11.)

Following acceptance of Celltrion's aBLA for review, the parties engaged in the BPCIA's dispute resolution procedures to identify which, if any, patents would be the subject of an immediate patent infringement lawsuit. In October 2014, Defendants provided a copy of Celltrion's aBLA, including information that describes the processes used to manufacture their proposed biosimilar infliximab product. (*Id.* ¶ 12; *see* Defs.' Resp. to Pls.' Statement of Material Facts ¶¶ 10, 35-36.)

In December 2014, Janssen disclosed its patent list, which identified six patents that they believed could reasonably support a claim of infringement. (DSMF ¶ 13.) By letter dated February 5, 2015, Defendants offered no competing patent list, but instead agreed that all six patents identified by Janssen could be the subject of an immediate infringement lawsuit. (*Id.* ¶ 14.) This letter included Defendants' factual and legal patent contentions relating to the six patents identified by Janssen. (*Id.*) That same day, Defendants provided their notice of commercial market-

ing, which said that Defendants may launch the biosimilar product as early as 180 days from that notice. (*Id.* ¶ 15.)

On March 6, 2015, Janssen filed this suit on all six patents identified on its patent list, and further alleged certain violations of the BPCIA.[1] (*Id.* ¶¶ 17-21.) Without relying on any of its patents, Janssen now seeks partial summary judgment on Count 2 of its complaint declaring Defendants' notice of commercial marketing ineffective. Janssen also seeks entry of a preliminary and permanent injunction barring Defendants from launching their product for 180 days after FDA approval. For the following reasons, Janssen is not entitled to such relief.

ARGUMENT

The Court should deny Janssen's motion and enter judgment for Defendants on Count 2 of the complaint under Rule 56. Because "the interpretation of a statute or regulation presents a purely legal question," this Court may resolve the present dispute of statutory construction on summary judgment. *Strickland v. Commissioner, Maine Dept. of Human Servs.*, 96 F.3d 542, 545 (1st Cir. 1996). Defendants' notice of commercial marketing was effective because pre-FDA approval notice comports with the plain text of the BPCIA and the statute as a whole, and any other reading would give Janssen a competitive windfall.

I. Defendants properly provided a pre-approval notice of commercial marketing.

Paragraph (8)(A) is a notice provision that Janssen improperly seeks to convert into an exclusivity provision. The text has an undeniable plain meaning: notice must be given at least 180 days before the applicant begins commercial marketing, which Defendants did. Defendants'

[1] Although not relevant to these cross-motions, Janssen alleges that Celltrion refused to provide certain manufacturing information required by the BPCIA. That is false. Celltrion timely produced *its* pertinent manufacturing information. What Janssen seeks is proprietary *third-party* information to which Janssen has no right under the BPCIA. *See, e.g.*, 42 U.S.C. § 262(*l*)(1)(E) (referring to "confidential information disclosed" under the Act as "the property of the subsection (k) applicant"). (*See* Defs.' Resp. to Pls.' Statement of Material Facts ¶¶ 10, 35-36.)

interpretation not only is consistent with the plain meaning of the statute, but also avoids the public harm of extending the sponsor's exclusivity beyond the 12-year period Congress provided (*see* 42 U.S.C. § 262(k)(7)(A)) to 12.5 years. There is no basis to rewrite the statute.

A. A plain reading of the notice provision supports only Defendants' position.

1. Paragraph 8(A) contains no precondition for the notice.

"In determining the meaning of a statute, '[courts] look first to its language, giving the words used their ordinary meaning.'" *Levin v. United States*, 133 S. Ct. 1224, 1231 (2013). The plain language of paragraph 8(A) of the BPCIA contains no precondition for providing notice, saying only that it must be provided "not *later* than 180 days" before commercial marketing. 42 U.S.C. § 262(*l*)(8)(A).

According to Janssen, however, this Court should add a precondition that allows such notice only "*after* the product has been 'licensed' by the FDA[.]" (Pls.' Br. at 1.) Conversely, Janssen argues, notice is not allowed for a product, such as Defendants' biosimilar, that is merely the subject of a pending license application. (*Id.* at 12.) Janssen is wrong.

To date, only one court has squarely addressed whether the notice of commercial marketing can be provided before FDA approval (*see* Section I.A.3, *infra*), and that court rejected the precise argument Janssen raises here. Just last month, Judge Seeborg of the Northern District of California held that paragraph 8(A) of the BPCIA allows a biosimilar applicant to give "its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) . . . *in advance of receiving FDA approval*." *Amgen*, 2015 WL 1264756, at *8 (emphasis added).

Like Janssen here, Amgen argued that the term "licensed" in paragraph 8(A) tacks an additional 180-day period of patent exclusivity on top of the 12 years of statutory exclusivity—irrespective of patent protection. The threshold problem here is that, as an ordinary reading of the provision shows, "'licensed' refers only to [the] 'biological product' [that can be mar-

keted]—not the appropriate time for notice." *Amgen*, 2015 WL 1264756, at *8. This is "the more persuasive interpretation," because it "accounts for the fact that FDA approval must precede market entry." *Id.*; *see also Matamoros v. Starbucks Corp.*, 699 F.3d 129, 134 (1st Cir. 2012) ("[Courts] assume that the ordinary meaning of the statutory language expresses the legislature's intent."). In other words, Congress used the term "licensed" to signify that the applicant can market its product only after it has been approved by FDA for a license. Congress did *not* say that the notice must be sent before approval.

To see why this is the case, consider the text more closely. By its terms, the statute says that the "subsection (k) *applicant* [not a licensed entity] shall provide notice." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The "subsection (k) applicant," of course, ceases to be an "applicant" upon FDA approval and licensure. That is why the BPCIA typically refers to entities owning approved applications as "sponsors" or "holders"—precisely to distinguish them from applicants still seeking approval. *See, e.g.*, *id.* § 262(*l*)(1)(A), (m)(3). Congress here referred to the "subsection (k) applicant" because it did not expect the applicant to provide notice after FDA approval. This careful textual choice confirms the holding of *Amgen*—namely, that Congress anticipated notice to be provided by an "applicant" *before* FDA approval.

2. Paragraph 8(B) merely allows preliminary injunction motions for any non-listed patents once notice is provided.

Janssen's reliance on paragraph 8(B) fares no better. According to Janssen, this subsection implies that the sponsor will file a preliminary injunction motion "once the scope of the FDA license is known[.]" (Pls.' Br. at 9-10.) Again, Janssen distorts the statute.

As confirmed by the *actual* language of paragraph 8(B), when read with paragraph 9(A), the notice merely lifts the ban on declaratory judgment actions for non-listed patents to allow the sponsor to "seek a preliminary injunction" based on a non-listed patent. 42 U.S.C.

§§ 262(*l*)(8)(B), (9)(A). Specifically, after notice of commercial marketing is provided, paragraph 8(B) allows the sponsor to "seek a preliminary injunction prohibiting the . . . applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any [non-listed] patent[.]" *Id.* § 262(*l*)(8)(B).

This language says nothing about the timing of FDA's license. Rather, as Janssen ultimately concedes, paragraph 8(B) speaks to the optional second phase of litigation: "Under subsection (B), receipt of a notice . . . allows the . . . 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*." (Pls.' Br. at 14 (emphasis added).)

Janssen never argues, nor could it argue, that paragraph 8(B) expressly bars litigation of non-listed patents until after FDA approval. Instead, Janssen argues that it "would make no sense" if the notice "could be served at any time – even before filing an aBLA[.]" (*Id.* at 13.) But it makes perfect sense. Again, the notice of commercial marketing allows the applicant to control when any second phase of patent litigation will begin. If the applicant so desires, it can provide that notice before FDA approval to resolve by then any second-phase patent disputes on non-listed patents—as contemplated by Congress. *See* Section I.B.2., *infra*. Regardless, the question of whether *any* precondition exists is not currently before the Court.[2]

[2] For example, Janssen argues that because paragraph 8(B) refers to non-listed patents, this language implicitly bars notice of commercial marketing until "the parties have gone through the statutory pre-litigation procedures." (Pls.' Br. 14.) Whether such a precondition exists is of no moment here. Defendants provided their notice after agreeing to Janssen's patent list and, therefore, would have satisfied such a hypothetical precondition even if it existed (which it does not). (DSMF ¶¶ 14-15.)

The key question here is whether *FDA approval* is a precondition for notice of commercial marketing. It is not.

3. The weight of authority favors Defendants' plain reading of the statute.

Pointing to two decisions, Janssen says "the weight of authority favors [its] reading of the BPCIA." (Pls.' Br. 18.) Not so.

For its first decision, Janssen points to *Sandoz Inc. v. Amgen Inc.*, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013), an earlier decision by the Northern District's Judge Chesney, which Jansen says disagreed with the later analysis of Judge Seeborg (discussed above). (Pl's Br. 19.) What Janssen never mentions is that Judge Chesney, who commented on this issue as an aside, without briefing or argument, dismissed the case for lack of subject matter jurisdiction. *Sandoz*, 2013 WL 6000069, at *1. And without addressing Judge Chesney's dicta, the Federal Circuit agreed that there was no jurisdiction. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1275 (Fed. Cir. 2014). "[W]hen a suit is dismissed for lack of jurisdiction, rulings on the merits rendered prior to the dismissal are nullities, *void ab initio*[.]" *McGuire v. United States*, 707 F.3d 1351, 1359 (Fed. Cir. 2013). Of course, there was no "ruling" in the first place. But because there was no jurisdiction, even the dicta, which Janssen cites for its weight of authority, in fact was a "nullit[y]." *Id.*

Remarkably, in Janssen's only other cited decision, the court did not address the issue *at all* before dismissing for lack of subject-matter jurisdiction. *Hospira, Inc. v. Janssen Biotech, Inc.*, 2014 WL 6766263, at *1 (S.D.N.Y. Dec. 1, 2014). This means that, for its "weight of authority," Janssen points to two legal "nullities." Contrary to Janssen, the *actual* "weight of authority" here is the carefully reasoned, published decision by Judge Seeborg, entered with jurisdiction and, as discussed, on review at the Federal Circuit.

B. The BPCIA when viewed as a whole further supports Defendants' reading of the notice provision.

When read as a whole, the BPCIA confirms Defendants' position that Congress did not intend to delay notice of commercial marketing—and, with it, any phase-two patent litigation—until after FDA approval, much less extend the 12-year non-patent exclusivity by at least another 180 days. "Just as Congress' choice of words is presumed to be deliberate, so too are its structural choices." *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2529 (2013). Thus, a court must interpret a statute "as a symmetrical and coherent regulatory scheme," and "fit, if possible, all parts into an harmonious whole." *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000).

1. Congress granted 12 years of exclusivity, not 12.5 years.

The Court should also reject Janssen's statutory construction because it contravenes the express BPCIA language providing that the "exclusivity for [a] reference product" is "12 years after the date on which the reference product was first licensed under subsection (a)." 42 U.S.C. § 262(k)(7)(A). When Congress intended to expand this exclusivity, it did so expressly. *See, e.g.*, *id.* § 262(m)(2)(A) (extending the period of non-patent exclusivity to "12 years and 6 months" based on certain pediatric testing). Thus, as Judge Seeborg pointed out, the statutory reading advanced by Amgen there and Janssen here is "problematic" because of "the impact it would have on the overall statutory scheme." *Amgen*, 2015 WL 1264756, at *8. That is, such a reading would implicitly "tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy" under the BPCIA. *Id.*

Congress chose this 12-year non-patent exclusivity as the *quid pro quo* for permitting an expedited approval pathway for biosimilar products. Imposing an additional 180-day period of non-patent exclusivity would contravene the bargain struck by Congress. As the Supreme Court

instructs: "Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouse-holes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). And, as Judge Seeborg noted: "Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." *Amgen*, 2015 WL 1264756, at *8.

To escape the absurdity of its construction, Janssen says "a notice of commercial launch would *most often* be given 180 days before the expiration of the twelve-year period and be co-terminous with it." (Pls.' Br. at 20 (emphasis added).) But it fails to explain how FDA can license a biosimilar before expiration of this exclusivity period. *See* 42 U.S.C. § 262(k)(7)(A). Regardless, Janssen plainly seeks an additional 180 days of non-patent exclusivity well beyond the 12-year period here.

Janssen already has received more exclusivity than what Congress provided for in the BPCIA. Indeed, the circumstances of this lawsuit confirm that it seeks a pure windfall injunction to forestall competition. As explained in more depth below, Janssen is free to seek injunctive relief for any of the six patents-in-suit *now*. There will be no second phase of litigation in this case, because there are no non-listed patents remaining to be litigated. Thus, the notice of commercial marketing serves no practical purpose here. Yet, Janssen asks this Court to construe the notice of commercial marketing provision as essentially delaying competition for *all* biosimilars by six months. Such a delay would accomplish nothing—other than to provide sponsors like Janssen with windfall protection from competition.

2. Congress encouraged patent disputes to be resolved before FDA approval, not 180 days after approval.

According to Janssen, the Court should read FDA approval as a precondition for notice of commercial marketing to ensure "the imminence necessary to vindicate the right to move for a preliminary injunction under subsection (B)." (Pls.' Br. at 10.) Here again, Janssen is mistaken.

As shown by debate during enactment of the BPCIA, the law is designed to encourage resolution of patent disputes *before* FDA approval. Indeed, according to congressional testimony by the Biotechnology Industry Organization ("BIO"), which represents brands like Janssen, the BPCIA was designed to impose "patent review procedures that will *precede approval of a biosimilar[.]*" (DSMF ¶ 23 (emphasis added).) As explained by Jeffrey Kushan of BIO, "nearly all stakeholders" support such pre-approval litigation procedures:

> *Nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues before a biosimilar is approved and placed on the market.* The reasons are simple; patent litigation commenced only after the biosimilar product is launched will lead to a longer period of uncertainty about patents and will cause greater market disruptions concerning the biosimilar product.

(*Id.* ¶ 24 (emphasis added).) BIO stressed the importance of "resolv[ing] patent disputes concurrently with the approval process," which is to say, not *after* FDA approval. (*Id.* ¶ 25.) Simply put, the law "must . . . provide[]" "[s]ufficient time for resolution of patent disputes *prior to follow-on biologic approval*[.]" (*Id.* (emphasis added).)

The president of the American Intellectual Property Law Association ("AIPLA") agreed. Of primary concern to the AIPLA was that "the patent dispute resolution mechanism should operate *prior to FDA approval* of the biosimilar product." (*Id.* ¶ 27 (emphasis added).) She advocated for "a streamlined, efficient litigation scheme that encourages resolution of patent infringement claims by the reference product holder as well as by third-party patent holders *before FDA approval* of the follow-on product." (*Id.* ¶ 26 (emphasis added).)

The statutory language reflects this intent. As discussed, the BPCIA encourages the sponsor to identify all potentially relevant patents early in the exchange and (with harsh penalties) further encourages the sponsor to bring an immediate patent suit on all patents identified on the final patent list. 35 U.S.C. § 271(e)(6)(C); 42 U.S.C. § 262(*l*)(6)(A), (B). The way this process works, such lawsuits will be filed before, potentially even years before, FDA approval. The statute also authorizes pre-approval declaratory judgment actions under certain circumstances. *Id.* § 262(*l*)(9). Janssen has not questioned whether those disputes have achieved the "imminence necessary" for litigation.

Nor has Janssen pointed to any statutory limit on preliminary injunctions pertaining to those BPCIA-encouraged lawsuits (other than the traditional four-factor test), even if a motion were filed before FDA approval. Courts have routinely entertained preliminary injunction motions even though the generic drug manufacturer was merely *seeking* FDA approval. *See, e.g.*, *Glaxo Group Ltd. v. Ranbaxy Pharms, Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001); *Apotex Inc. v. Eisai Inc.*, 2010 WL 3420470, at *4 (M.D.N.C. Aug. 27, 2010); *The Research Found. v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 644 (D. Del. 2010).

There is no reason to think that Congress encouraged pre-approval litigation for the vast majority of cases brought under the BPCIA, but not for litigation based on non-listed patents. Janssen thus is wrong to say that notice of commercial marketing must await FDA approval to "provide[] only a modest 180-day time period after approval of a biosimilar in which to adjudicate a potential motion for preliminary injunction." (Pls.' Br. at 20.) That would certainly help delay competition in this case (relief Janssen seeks without pointing to any of its patents). But it is not, and should not be, the law.

In sum, a plain reading of notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A), along with the BPCIA as a whole, confirms that such notice may be provided before FDA approval. Thus, the Court should enter summary judgment for Defendants on Count 2 of Janssen's complaint.

II. The Court should reject Janssen's request for a windfall 180-day injunction.

Even if Janssen's reading of the BPCIA were correct (it is not), the Court should reject its request for a windfall injunction delaying competition by 180 days. "A preliminary injunction is an 'extraordinary and drastic remedy' . . . that 'is never awarded as of right.'" *Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 32 (1st Cir. 2011) (citations omitted). Janssen has failed to show that any remedy based on the BPCIA's notice provision is warranted here, much less the "extraordinary and drastic remedy" of injunctive relief.

The First Circuit applies "a four-part framework for use in determining whether the grant or denial of preliminary injunctive relief is appropriate." *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 15 (1st Cir. 1996). "[T]rial court[] must consider (1) the likelihood of success on the merits; (2) the potential for irreparable harm if the injunction is denied; (3) the balance of relevant impositions, i.e., the hardship to the nonmovant if enjoined as contrasted with the hardship to the movant if no injunction issues; and (4) the effect (if any) of the court's ruling on the public interest." *Id.*; *see also Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998) (holding that "the procedural law of the regional circuit" applies to the grant of a preliminary injunction even though the Federal Circuit will hear the appeal). As shown below, none of the four factors support the requested injunction.

A. Janssen's claim for an injunction based on an alleged statutory violation lacks merit.

In Count 2 of the complaint, Janssen seeks an injunction by alleging (1) that Defendants violated paragraph 8(A) by providing notice of commercial marketing before FDA approval, and (2) this alleged statutory violation "has caused and will cause Plaintiffs injury, including irreparable harm. . . ." (Dkt. 1 at 31.) Even under Janssen's (incorrect) reading of the notice provision, it still could not succeed on the merits of that claim.

1. Count 2 fails to state a claim because Janssen has not pleaded, and cannot prove, injury caused by the alleged statutory violation.

Janssen's Count 2 ignores a crucial point: The notice of commercial marketing merely lifts the bar on litigating *non-listed patents*. There are no such patents, because Janssen already has asserted in this case all six patents identified in the pre-litigation patent exchange. (*See* Carey Decl. ¶¶ 15, 16; Pls.' Br. at 3-4.) This undisputed fact belies any claim of "injury" here. (Dkt. 1 at 31.)

And "injury," of course, is an element of a claim asserting a statutory violation. *See, e.g.*, *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 134 S. Ct. 1377, 1390 (2014) ("[W]e generally presume that a statutory cause of action is limited to plaintiffs whose injuries are proximately caused by violations of the statute."). As a matter of law, Janssen is not injured, much less proximately so, by the alleged premature notice of commercial marketing. After all, that notice merely allows sponsors to "seek a preliminary injunction" on a non-listed patent (42 U.S.C. § 262(*l*)(8)(B))—and no such patent exists here. As a result, Count 2 fails to state a claim upon which relief can be granted and, therefore, should be dismissed for this reason alone. Fed. R. Civ. P. 12(b)(6).

2. Congress did not confer a private right of action to remedy a premature notice of commercial marketing.

Even if Janssen could show an injury tied to paragraph 8(A), the BPCIA contains no "rights-creating language" entitling it to bring a private right of action to remedy that injury. *See Alexander v. Sandoval*, 532 U.S. 275, 288 (2001) (quotation omitted). Instead, Congress expressly set forth the remedy for a violation of the notice provision—namely, "[i]f a subsection (k) applicant fails to complete an action required . . . under . . . paragraph 8(A)." 42 U.S.C. § 262(*l*)(9)(B). That remedy allows the sponsor to sue immediately and seek a preliminary injunction to enforce its patent rights: "[T]he reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent" the sponsor believes is infringed by the biosimilar. *Id.*; *accord Amgen*, 2015 WL 1264756, at *6 ("subparagraph (*l*)(8)(B) is clear in providing the remedy of a preliminary injunction for failure to give the 180-day notice required in (*l*)(8)(A)").

Congress knows how to create a right of action when it wants to, and it did not do so here. For example, in the Hatch-Waxman Act, which addresses small-molecule drugs (as opposed to biologics), Congress enacted a "counterclaim" that "enables a generic competitor to obtain a judgment directing a brand to 'correct or delete' certain patent information that is blocking the FDA's approval of a generic product." *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012). A generic may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information. . . ." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

In the BPCIA, Congress just as easily could have provided that a sponsor may "assert a claim seeking an order requiring" an applicant to comply with the patent exchange or, more specifically, requiring the applicant to stay off of the market until 180 days after FDA approval. It did not do so—even though it expressly provided a remedy for statutory violations elsewhere in

the BPCIA, such as the "Effect of violation" provision that authorizes injunctive relief to remedy an unauthorized disclosure of confidential information. 42 U.S.C. § 262(*l*)(1)(H).

As emphasized by the Supreme Court, "[t]he courts should not create liability . . . where Congress has elected not to[.]" *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014). This basic tenet of statutory construction controls here. And Janssen is not left without a remedy—it can seek injunctive relief based on its "final patent list" patent protection. But it has chosen not to do that. Count 2 should be dismissed for this reason as well.

3. Inferring congressional intent to institute an automatic 180-day injunction would violate *eBay*.

Janssen cannot escape its lack of injury and lack of private right of action by arguing that the statute requires an automatic 180-day injunction irrespective of patent rights. To the contrary, the notion that the BPCIA's notice provision creates an implied right to an automatic, statutory injunction runs headlong into the Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), which rejects any kind of "general rule" for an automatic injunction under the Patent Act. 547 U.S. at 393-94 (citations marks omitted). As the Court stated: "We hold . . . that . . . whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id*. at 394. After all, "[a]s [the Supreme] Court has long recognized, a major departure from the long tradition of equity practice should not be lightly implied." *Id*. at 391 (quotation omitted).

Equity does not support any injunctive relief here. Janssen invites this Court to imply from the BPCIA a "major departure" from the "long tradition of equity practice." *Id*. The notice of commercial marketing provision says nothing about an automatic injunction. Yet, Janssen

asks this Court effectively to rewrite the notice provision as imposing such an injunction (with the underlined language added to the actual statutory language):

> **(B) Preliminary injunction**
> The court shall order an injunction prohibiting commercial marketing of the biological product licensed under subsection (k) for 180 days beginning on the date notice of commercial marketing was provided under subparagraph (A). After receiving the notice under subparagraph (A) and before such date of the first commercial marketing . . . the reference product sponsor may seek a preliminary injunction prohibiting the section (k) applicant from engaging in the manufacture or sale of such biological product until the court decide the issue of patent validity, enforcement, and infringement with respect to any [non-listed] patent[.]"

42 U.S.C. § 262(*l*)(8)(B) (underlined language not in statute).

As in *eBay*, such a dramatic change in the law imposing an automatic injunction must not be "lightly implied." 547 U.S. at 391. There is no basis in the statute, equity, or common sense to delay commercial marketing for even a day—much less 180 days—unless an injunction is justified on the merits of a patent claim. That is why the actual language of the statutory provision merely allows the "sponsor [to] *seek* a preliminary injunction" based on a non-listed patent. 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). If no preliminary injunction for such a patent is sought and justified, none is merited.

It would be particularly inappropriate to read automatic injunction language into the notice provision—i.e., "the court shall order an injunction"—because Congress used that phrase elsewhere in the BPCIA itself. When amending the Patent Act, Congress provided that, "[f]or an act of infringement . . . *[t]he court shall order a permanent injunction* prohibiting any infringement of the patent by the biological product" under certain circumstances not relevant here. 35 U.S.C. § 271(e)(4) (emphasis added). And elsewhere in the BPCIA, Congress provided that the unauthorized disclosure of confidential information "shall be deemed to cause [the applicant] to suffer irreparable harm," and thus "the court shall *consider* immediate injunctive relief. . . ." 42

U.S.C. § 262(*l*)(1)(H) (emphasis added). Thus, Congress knew how to address injunctive relief in the BPCIA when it wanted to—whether by commanding that "*the court shall order*" the injunction, or that "*the court shall consider*" an injunction. Here it did neither.

Janssen offers no basis for the Court to read into the BPCIA's notice provision language creating a claim and remedy Congress knew how to use and conspicuously avoided. Janssen is unlikely to succeed—in fact, it cannot succeed, as a matter of law—on the merits of its claim that the BPCIA authorizes a claim and injunction remedy under the circumstances here.

B. Janssen has failed to demonstrate irreparable harm.

Janssen also has failed to show irreparable harm. "In most cases . . . irreparable harm constitutes a necessary threshold showing for an award of preliminary injunctive relief." *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). "The burden of demonstrating that a denial of interim relief is likely to cause irreparable harm rests squarely upon the movant." *Id.* Janssen has fallen far short of meeting this burden as well.

1. Janssen has failed to show irreparable harm flowing from patent rights.

The BPCIA contemplates two bases to delay competition—the statutory exclusivity (generally 12 years) and patent rights. But Janssen points to neither. Given that the statutory exclusivity has long expired, "[t]o show irreparable harm, it is necessary [for Janssen] to show that [an alleged] infringement caused harm[.]" *Apple, Inc. v. Samsung Electronics Co., Ltd.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). This means it must establish a sufficient "causal nexus between [the defendant's] infringement and the alleged harm to [Janssen]." *Id.*; *see also Takeda Pharms USA, Inc. v. West-Ward Pharm. Corp.*, 2014 WL 5780611, at *7 (D. Del. Nov. 4, 2014), *aff'd*, No. 2015-1139 (Fed. Cir. Jan. 9, 2015) (district court applying *Apple* in pharmaceutical context).

No injunction should issue because Janssen has failed to argue any "causal nexus" to infringement, much less prove it. *Apple*, 678 F.3d at 1324; *see Amgen*, 2015 WL 1264756, at *10.

2. Janssen has failed to show any irreparable procedural injury flowing from the alleged premature notice.

Janssen also has failed to identify any "procedural injury," much less irreparable injury, flowing from the alleged premature notice of commercial marketing. Only in limited circumstances, not present here, do courts recognize irreparable harm from the violation of a procedural right. And none of the cases cited by Janssen helps it here. For example, in *Sierra Club v. Marsh*, the First Circuit found that a failure to comply with a permit decision-making process threatened environmental harm that the process was intended to protect. 872 F.2d 497, 500 (1st Cir. 1989). The other cases cited by Janssen address similar situations where a procedure protected a substantive right that would have been abrogated absent injunctive relief. Here, in contrast, Janssen has no substantive rights protected by the paragraph 8(A) notice procedure.

As discussed, this notice provision is designed to address a situation not present here—giving the sponsor 180 days before biosimilar launch to seek an injunction based on a patent the sponsor had been barred from enforcing. As Judge Seeborg correctly found under similar circumstances (and assuming a violation of the BPCIA's procedural rights), the sponsor there was unable to demonstrate irreparable harm absent proof of patent infringement. *Amgen*, 2015 WL 1264756, at *10. So too here.

3. Janssen's purported evidence of irreparable harm amounts to pure speculation.

The Court need not reach Janssen's purported evidence of irreparable harm given the legal flaws discussed above. Nevertheless, Janssen's speculation as to market events after the biosimilar launch also is insufficient to demonstrate irreparable harm. "Speculation or unsubstan-

tiated fears of what may happen in the future cannot provide the basis for a preliminary injunction." *In re Rare Coin Galleries of Am., Inc.*, 862 F.2d 896, 902 (1st Cir. 1988)

Janssen relies on the declaration of an economist, Dr. Henry G. Grabowski, to support the allegation that the "premature launch" of Defendants' biosimilar "would cause immediate and irreparable harm to Janssen Biotech." As discussed in the declaration of Dr. Atanu Saha, however, Dr. Grabowski's assertions amount to unsupported speculation.

First, Dr. Grabowski fails to provide any economic data analysis to support his opinion that the premature launch of Defendants' biosimilar would have a severe adverse impact on sales of Remicade and another Janssen product, Simponi Aria®. Instead, he relies on speculation by executives. (*See, e.g.*, Grabowski Decl. ¶¶ 48-51.) Dr. Grabowski ignores empirical data from international markets where an infliximab biosimilar has been introduced as early as 2013. These data show that the impact on Remicade sales varies considerably across early-launch countries. In fact, in five of the seven countries examined by Dr. Saha, Remicade sales actually increased after biosimilar infliximab was launched. (Saha Decl. ¶¶ 15-16.) Any extrapolation of a severe adverse effect upon launch in the United States without consideration of these factors would be dubious, at best.

Second, Dr. Grabowski's conjecture that the launch of Defendants' biosimilar would result in a reduction in research and development ("R&D") spending by Janssen and its parent company, Johnson & Johnson ("J&J"), is contradicted by his own data. (Grabowski Decl. ¶¶ 63-67.) A basic analysis of Dr. Grabowski's data shows that while changes in R&D spending are strongly correlated with changes in *overall* Janssen sales, changes in R&D spending are, at most, very weakly correlated with changes in *Remicade* sales. (Saha Decl. ¶¶ 17-19.) And, of course, J&J—a large multinational company, with over $74 billion in annual sales and a very diverse

revenue base—has sufficient resources to weather any losses due to competition from Defendants in this instance. (*Id.* ¶ 21.) Remicade U.S. sales are [redacted] of J&J's revenue, and any lost sales due to biosimilar competition would be a mere fraction of that percentage. (*Id.*)

Third, Janssen has no reliable evidence that competition from Defendants would "hamper" Janssen's efforts to compete with third parties. Dr. Grabowski merely speculates that, if a physician were presented with a choice between Remicade and a biosimilar, she "*may* choose" neither in favor of "courses of treatment that utilize competitors' promoted products." (Grabowski Decl. ¶ 68 (emphasis added).) Such speculation falls far short of the showing necessary for irreparable harm. *Cf. Matrix Group Ltd., Inc. v. Rawlings Sporting Goods Co., Inc.*, 378 F.3d 29, 34 (1st Cir. 2004) ("[W]e find this particular claim of irreparable injury [to good will and relationships with third parties] too speculative and unsubstantiated to warrant disturbing the district court's judgment denying an injunction."). In fact, as noted, empirical data in five of the seven countries examined by Dr. Saha actually showed *growth* in Remicade sales upon market entry of a biosimilar. (Saha Decl. ¶ 15.)

Even if Janssen's evidence showed that competition from Defendants could have an effect on Janssen's sales or market share, that would *not* be sufficient—as a matter of law—to establish irreparable harm. *See Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1347-48 (Fed. Cir. 2006) ("[W]e do not doubt that generic competition will impact Abbott's sales of Biaxin XL, but that alone does not establish that Abbott's harm will be irreparable."); *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F. 2d 679, 683 (Fed. Cir. 1990) (The Federal Circuit rejected the patentee's argument that "its 'potential lost sales' alone demonstrate 'manifest irreparable harm,' [because] acceptance of that position would require a finding of irreparable harm to every

manufacturer/patentee, regardless of circumstances."). Janssen's evidence of irreparable harm, like its legal arguments, thus falls short of satisfying its heavy burden.

C. The balance of hardships and the public interest weigh against the requested injunction.

An injunction delaying competition by 180 days would cause substantial, competitive hardship to Defendants. They have spent years and expended significant resources—totaling well over $110 million in out-of-pocket external costs in addition to significant internal manpower and corporate resources—in R&D to prepare for the commercial marketing of their proposed biosimilar. (Park Decl. ¶ 5.) Unlike drug applications under the Hatch-Waxman Act, where a mere showing of bioequivalence is required, Defendants have invested in multiple clinical studies to prove biosimilarity (*id.* ¶ 7)—meaning "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2)(B).

Defendants' biosimilar will be one of the first to market in the U.S. and thus presents a substantial opportunity for Defendants to grow their businesses and reputations as industry pioneers. (*Id.* ¶ 19.) An injunction impeding this launch for 180 days following approval would disrupt Defendants' ongoing business operations in preparing a distribution network that will allow them to sell the biosimilar product as soon as they can after obtaining FDA approval. (*Id.* ¶ 20; Pompe van Meerdervoort Decl. ¶¶ 6-7.)

Finally, patients suffer financial harm each day that they must wait for a less expensive, competing infliximab biosimilar product—particularly after FDA has approved the drug. Janssen argues that the public interest in fostering innovation outweighs this harm. (Pls.' Br. at 25.) Not so. Congress already considered that public interest when it granted the reference product sponsor a period of patent-based exclusivity (35 U.S.C. § 271(e)(2)(C)), and a period of non-

patent exclusivity (42 U.S.C. § 262(k)(7)(A)). And Janssen already has benefited from these exclusivities by charging monopoly pricing for 16 years (well more than the 12-year exclusivity). As discussed, they are *not* even asserting—and could not claim—any patent rights to extend that monopoly through injunctive relief. Instead, they seek to delay competition based on a mere procedural technicality that has no impact on this case. Such an injunction cannot possibly further any public interest—it simply would provide Janssen a monopoly windfall.

For the above reasons, even if this Court were to find that the 180-day notice of commercial marketing must await FDA approval, neither the statute, equity, nor common sense supports the extraordinary injunction remedy Janssen seeks. This Court should reject its effort to bar Defendants from launching their less-expensive biosimilar once FDA concludes it is safe and effective for consumers.

CONCLUSION

Defendants respectfully request that this Court deny Plaintiffs' motion for partial summary judgment and a preliminary and permanent injunction and, instead, grant Defendants partial summary judgment on Count 2 of Plaintiffs' complaint. To the extent the Court enters an injunction, however, Defendants request an appropriate bond under Fed. R. Civ. P. 65(c).

Dated: April 29, 2015

Respectfully submitted,

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

By their attorneys,

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 29, 2015.

/s/Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

4841-8570-9091.1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., and
NEW YORK UNIVERSITY

Plaintiff,

v.

CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., AND
HOSPIRA, INC.

Defendants.

Civil Action No. 1:15-cv-10698

[redacted]

DECLARATION OF ATANU SAHA, PH.D.

I. ACADEMIC AND PROFESSIONAL EXPERIENCE

1. I am an Executive Vice President and Head of the New York Office of Compass Lexecon. I am an expert in damage analysis, specializing in the application of economics and finance to complex business litigation.

2. I have over 20 years of experience in the area of economic and litigation consulting. I have provided expert testimony and consulting analysis in numerous prior matters, including matters involving the pharmaceutical industry, managed care providers, and third party payers. Most of these matters entailed complex data analyses and assessment of economic harm.

3. I have served as an expert in prior engagements for both plaintiffs and defendants, wherein I have undertaken economic analyses in a wide range of settings and industries. In particular, I have examined the market dynamics of branded and generic pharmaceutical products and I have co-authored a peer reviewed scholarly study on the issue of brand market share erosion following entry of generic substitutes.

4. Prior to joining Compass Lexecon, I held senior positions at a number of economic consulting firms. Additionally, I was a tenure-track professor for four years at Texas A&M University, where I taught Ph.D.-level courses in econometrics and applied economics. I am the author of numerous refereed journal articles, monographs and book chapters on topics that include statistical and econometric methods. I have published peer-reviewed journal articles in the area of pharmaceutical economics, and my financial research has been cited in numerous publications, including The Wall Street Journal, The Economist, The New York Times, The Chicago Tribune, The New Yorker and USA Today. I hold a Ph.D. from the University of California, Davis, with applied economics and econometrics as my fields of specialization. I am the recipient of the Graham and Dodd Award, which recognizes excellence in financial writing.

5. My curriculum vitae, including a list of cases in which I have testified as an expert witness at trial or by deposition, is attached as Exhibit 1. The documents that I have relied on are listed in Exhibit 2.

6. My analyses, opinions, and conclusions are based solely on the work performed by me, and those under my supervision, through the date of this declaration. This declaration is subject to change or modification should additional relevant information become available which bears on the analysis, opinions, or conclusions contained herein. Compass Lexecon is being compensated for my time, as well as those who have assisted me. Our compensation is not dependent on the outcome of this matter.

II. ASSIGNMENT

7. It is my understanding that Dr. Henry G. Grabowski ("Dr. Grabowski") has been asked to assess the expected harm to Janssen Biotech Inc. ("Janssen") that would result if Hospira Inc. ("Hospira") "prematurely launches"[1] its biosimilar infliximab product.[2] I have been asked by counsel for the Defendants Hospira and the Celltrion entities to evaluate and comment on assertions made by Dr. Grabowski in his declaration filed April 8, 2015 (the "Grabowski Declaration") related to the potential premature launch of Hospira's biosimilar infliximab. Specifically, I have been asked to evaluate Dr. Grabowski's opinion that "the premature launch of the defendants' proposed biosimilar version of Remicade® would cause immediate and irreparable harm to Janssen Biotech…[in] the form of commercial, scientific, and societal opportunities that may be forgone, or that may remain unrealized, in the event of [Hospira's]

[1] It is my understanding that Dr. Grabowski is defining "premature launch" as a situation in which "defendants bring their proposed biosimilar product to market before allowing Janssen Biotech a 180-day period after FDA approval to seek a preliminary injunction..." (Grabowski Declaration ¶9). Throughout my declaration, for ease of exposition, I have adopted Dr. Grabowski's terminology of "premature launch." I offer no opinion, however, on whether such a launch would, in fact, be premature.

[2] Grabowski Declaration ¶9.

proposed biosimilar launch, even if the defendants are subsequently enjoined from selling their product."[3]

III. SUMMARY OF OPINIONS

8. Dr. Grabowski's assertion that the "premature launch of the defendants' proposed biosimilar version of Remicade® ***would cause*** [emphasis added] immediate and irreparable harm to Janssen Biotech"[4] is unfounded, based on conjectures, and ignores available empirical evidence. Specifically,

a) Dr. Grabowski's assertion that "…the impact of biosimilar entry on the reference drug is likely to be severe"[5] and lead to irreparable harm, is simply a conjecture. Not only does Dr. Grabowski fail to provide any support, based on economic data analysis, for his opinion that the premature launch of a biosimilar infliximab would have a severe adverse impact on Remicade® sales, he makes no attempt to estimate or quantify what that impact would be.

b) Dr. Grabowski's declaration also suffers from a material inconsistency. On the one hand, he opines that the lost Remicade® sales resulting from a premature launch of biosimilar infliximab is "very difficult to calculate"[6] and "impossible to quantify with any degree of certainty."[7] On the other hand, he claims with certainty (yet without support) that "[t]he defendants' premature biosimilar launch ***would cause*** [emphasis added] a rapid and substantial loss of sales and market share of Remicade®."[8] In other words, Dr. Grabowski claims

[3] Grabowski Declaration ¶12.
[4] Grabowski Declaration ¶12.
[5] Grabowski Declaration ¶42.
[6] Grabowski Declaration ¶14.
[7] Grabowski Declaration ¶19.
[8] Grabowski Declaration ¶13.

that, while he does not know with reasonable certainty the extent of biosimilar launch-induced loss of Remicade® sales, he knows with full certainty that this loss of sales would be severe, leading to irreparable harm.

c) Dr. Grabowski's claim that the launch of biosimilar infliximab in the U.S. is likely to have a market impact similar to the market impacts observed in Germany and Sweden is meaningless because this claim is based, in part, on the market share changes for small-molecule generic entry (not biosimilar infliximab entry) in those countries. It is important to note, while Dr. Grabowski asserts Germany and Sweden to be the benchmarks for assessing impact on Remicade® sales in the U.S., he chooses to ignore actual available empirical data from other countries in Europe and Asia where Remicade® and biosimilar infliximab are currently sold and where the biosimilar product has been available for over a year or more.[9] Had Dr. Grabowski examined the data from these countries, he would have found, as I show in this declaration, the impact of biosimilar launch on Remicade® sales varies considerably across countries, with several countries showing increases in Remicade® sales after biosimilar launch has occurred. Thus, one cannot conclude that the impact on Remicade® sales in the U.S. of a biosimilar launch would be negative, let alone be severe.

d) Dr. Grabowski's conjecture that the launch of biosimilar infliximab would result in a reduction in Janssen's research and development ("R&D") spending is contradicted by data contained in Exhibit 1 of his own declaration. An analysis of the data presented in Dr. Grabowski's Exhibit 1 demonstrates that while changes in R&D spending are strongly correlated with changes in overall Janssen sales,

[9] Grabowski ¶47; Hospira 2014 Annual Report at 7.

changes in R&D spending are, at best, very weakly correlated with changes in Remicade® sales. This finding contradicts Dr. Grabowski's claims of irreparable harm due to loss of R&D spending.

e) In making his irreparable harm arguments, throughout the declaration, Dr. Grabowski conjectures about the likely adverse impact on "…Johnson & Johnson, Janssen Biotech's parent company…."[10] Yet, Dr. Grabowski ignores the fact that Johnson & Johnson ("J&J") is a large multi-national company, with over $74 billion in annual sales[11], and a very diverse revenue base. Not only does Dr. Grabowski fail to quantify the impact on Remicade® sales, he fails to establish any causal link between a premature infliximab launch by Hospira and claimed irreparable harm to J&J.

f) Finally, Dr. Grabowski's declaration is internally inconsistent. In order to support his conjecture of loss of Remicade® market share, Dr. Grabowski asserts that a premature biosimilar launch would adversely impact Remicade® sales in a manner similar to the impact of a generic launch of a small-molecule drug on a branded product. However, in attempting to support his other points, Dr. Grabowski draws a clear distinction between the markets for biosimilar drugs and conventional generics.

[10] Grabowski Declaration ¶15.
[11] Johnson & Johnson 2014 10-K at 3.

IV. DR. GRABOWSKI'S OPINIONS REGARDING IRREPERABLE HARM ARE UNFOUNDED

9. Dr. Grabowski's assertion that "…in this case, the impact of biosimilar entry on the reference drug is likely to be severe"[12] and that Hospira's "proposed biosimilar infliximab product would greatly erode sales and market share of Remicade®"[13] leading to irreparable harm, are simply conjectures that are not supported by any analysis. Nowhere in his entire declaration does he provide any independent data analysis that attempts to quantify the potential impact on Remicade® sales, if any, attributed to a premature biosimilar launch. The only independent support that Dr. Grabowski seems to provide for this opinion is: (i) his own academic research regarding the impact of generic entry on branded small-molecule drugs, which, by his own admission, is unlikely to be relevant for assessing impact on Remicade® sales; and, (ii) the market impact of non-infliximab biosimilar drugs in Germany and Sweden.[14]

10. Dr. Grabowski states that, "[i]n the case of small-molecule drugs, the economic mechanisms described in Section V above lead to a rapid and drastic loss in sales, prescriptions, profits, and market share for branded drugs upon the entry of their generic equivalents."[15] While I have no reason to dispute this observation, it is unclear what bearing it has on the issues at hand. Dr. Grabowski himself acknowledges that market dynamics of generic entry are not necessarily relevant for assessing the impact of biosimilar entry. Dr. Grabowski admits that "[s]o far, there is no precedent of biosimilar entry in the U.S. Therefore, it is **unknown**

[12] Grabowski Declaration ¶42.
[13] Grabowski Declaration ¶46.
[14] [redacted]
[15] Grabowski Declaration ¶41.

[emphasis added] whether the impact of biosimilar entry on a reference biologic drug would be close to the impact observed, on average, in cases of generic entry for small-molecule drugs."[16] He also points out that the market share changes in response to a biosimilar entry may be closer to competition observed between small-molecule branded drugs.[17] However, despite these admissions, Dr. Grabowski asserts: "...in this case, the impact of biosimilar entry on the reference drug is likely to be severe."[18]

11. Dr. Grabowski's claim that Germany and Sweden are relevant benchmarks for assessing the impact of biosimilar infliximab entry in the U.S. is similarly flawed because it is based, in part, on small-molecule generic substitution in those countries.[19,20]

12. In a further effort to support his opinion that Germany and Sweden are appropriate benchmarks, Dr. Grabowski references the market impact of biosimilar entry on Eprex® and Neupogen® in Germany, France, Italy, Sweden, and the United Kingdom.[21] However, Dr. Grabowski provides no support of comparability between either of these two drugs and Remicade®, while at the same time admitting that "the impact of biosimilar entry varies **across different drugs** [emphasis added] and countries."[22] He goes on to state: "... the experience with biosimilar entry is so far non-existent in the U.S., and very limited in Western Europe ... [T]he experiences of drugs that could potentially serve as benchmarks to analyze

[16] Grabowski Declaration ¶42.
[17] Dr. Grabowski states, "competition between a reference biologic drug and its biosimilar version may be closer to competition observed between small-molecule branded drugs with comparable outcomes within the same therapeutic category than competition between a small-molecule reference drug and its interchangeable generic." *See,* Grabowski Declaration ¶42.
[18] Grabowski Declaration ¶42.
[19] Grabowski Declaration ¶45.
[20] Grabowski Declaration Footnote 71. See Grabowski, H., et al., "Biosimilar Competition: Lessons from Europe," *Nature Reviews Drug Discovery*, Vol. 13, 2014, pp. 99–100 at p. 100. "It is difficult to generalize across different health-care systems, but Germany and Sweden arguably provide the closest cases to the United States. Both countries have relatively high prices for innovative drug products, ***a history of generic utilization*** and a decentralized approach to drug utilization and reimbursement" [emphasis added].
[21] Grabowski Declaration ¶¶43-44.
[22] Grabowski Declaration ¶45.

impact of biosimilar entry on Remicade® **have not been uniform** [emphasis added] and, therefore, the choice of benchmark would have a substantial effect on the estimated lost sales."[23] Yet, Dr. Grabowski asserts with certainty that the "proposed biosimilar infliximab product would greatly erode sales and market share of Remicade®."[24]

13. In fact, Dr. Grabowski's declaration is marked by this material inconsistency. On the one hand, Dr. Grabowski opines that the sales lost by Janssen due to a premature launch of biosimilar infliximab would be "very difficult to calculate"[25] and it is "impossible to quantify with any degree of certainty."[26] On the other, Dr. Grabowski states with certainty (yet without support) that "[t]he defendants' premature biosimilar launch ***would cause*** [emphasis added] a rapid and substantial loss of sales and market share of Remicade®. Consequently, profits derived from Remicade® **would decrease** [emphasis added] significantly."[27] In other words, Dr. Grabowski claims that, while he does not know with reasonable certainty the extent of biosimilar launch-induced loss of Remicade® sales, he knows with full certainty that this loss of sales would be severe, leading to irreparable harm.

III. DR. GRABOWSKI IGNORES BIOSIMILAR INFLIXIMAB SALES DATA FOR NON-U.S. MARKETS

14. Dr. Grabowski's position that a premature biosimilar infliximab launch "would greatly erode sales and market share of Remicade®"[28] also ignores relevant available empirical evidence from other countries. While Dr. Grabowski acknowledges that biosimilar infliximab has already launched in certain markets outside of the U.S. as early as 2013, he ignores the

[23] Grabowski Declaration ¶61.
[24] Grabowski Declaration ¶46.
[25] Grabowski Declaration ¶14.
[26] Grabowski Declaration ¶19.
[27] Grabowski Declaration ¶13.
[28] Grabowski Declaration ¶46.

actual sales data for these markets, relying instead on forward-looking statements made by executives at Merck & Co., Inc. and in SEC filings by J&J.[29]

15. Had Dr. Grabowski examined the data from these countries, he would have found, as I demonstrate in Table 1 below, that the impact on Remicade® sales varies considerably across different countries. In fact, in five of the seven countries listed Table 1, Remicade® sales actually increased after biosimilar infliximab launch.

Table 1: Impact of Biosimilar Launch on Remicade Sales

		Average Remicade Sales		
Country	Biosimilar Launch	Prior Quarters	After Launch Quarters	% Change
South Korea	4Q 2012	$4,940,921	$6,375,979	29%
Finland	4Q 2013	$10,210,436	$10,995,133	8%
Norway	4Q 2013	$13,003,971	$11,216,979	-14%
Czech Republic*	4Q 2013	$7,565,416	$7,992,951	6%
Portugal*	4Q 2013	$6,504,108	$6,766,356	4%
Ireland	1Q 2014	$8,696,800	$10,324,957	19%
Poland*	1Q 2014	$1,851,498	$1,417,259	-23%

* Automatic substitution is not expressly prohibited.

Note: Average Remicade Sales are calculated by averaging the revenue in each country for all quarters post-launch with available data and averaging the same number of quarters prior to the launch date to account for seasonality.

Sources: IMS Health; Smart Pharma Consulting. "Global Biosimilar Drugs Market Outlooks," February 2015; Joung, J. "Korean regulations for biosimilars," *Generics and Biosimilar Initiative Journal,* 4(2) 2015.

16. Thus, one cannot conclude from available data that the impact on Remicade® sales from a biosimilar launch in the U.S. would be negative, let alone be severely so.

[29] Grabowski Declaration ¶¶47-49.

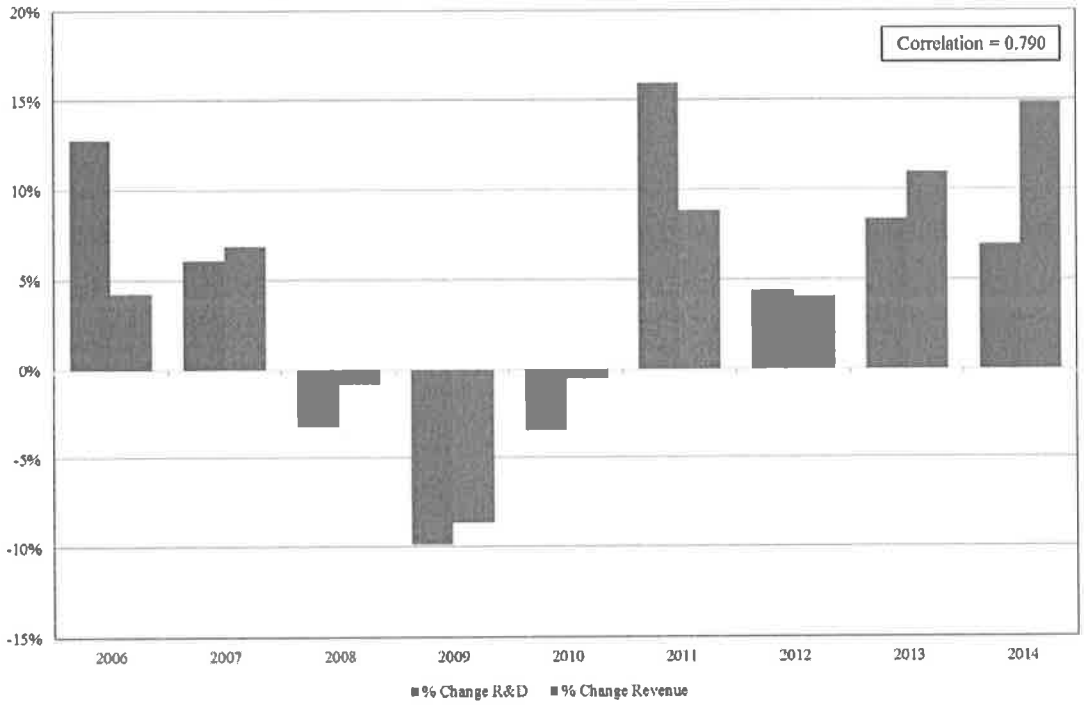
IV. DATA CONTAINED IN DR. GRABOWSKI'S OWN DECLARATION DO NOT SUPPORT HIS OPINIONS REGARDING R&D, LOSS OF SPECIALIZED LABOR, AND NOVEL TREATMENTS

17. Dr. Grabowski's assertion that "any decrease in Remicade® sales…[is] likely to also reduce … R&D expenditures"[30] is contradicted by data contained in his own declaration. These data do not support his claims of irreparable harm related to the reduction of R&D expenditures, the loss of specialized labor, and the loss of novel therapies that would have otherwise been developed.

18. Figures 1A and 1B contain an analysis of the data found in Exhibit 1 of the Dr. Grabowski's declaration, and demonstrate that changes in R&D spending are strongly correlated with changes in overall Janssen sales (with a correlation of nearly 0.8). In nine out of nine years in the period 2006-2014, changes in R&D spending are directionally (*i.e.,* up or down) the same as the changes in Janssen sales. However, this is not the case when the changes in R&D spending are compared to the changes in Remicade® sales: in three years (2008, 2009, 2010), R&D spending declined despite increases in Remicade® sales. The data show that changes in R&D spending is at best, very weakly correlated (with correlation less than 0.3) with changes in Remicade® sales.

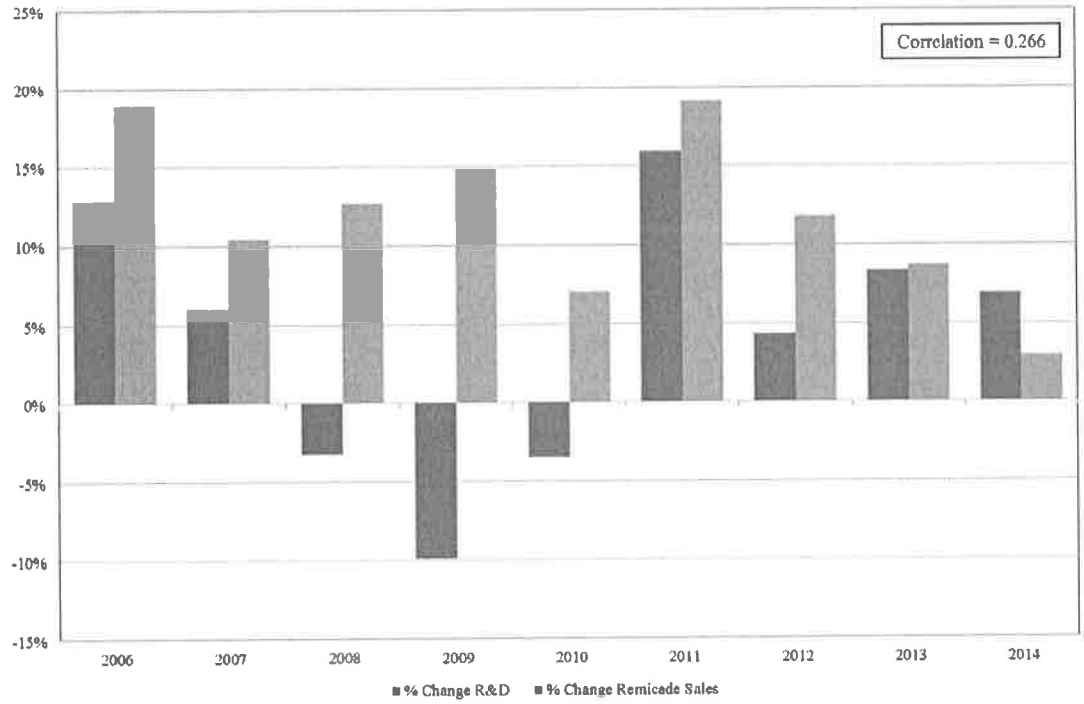
[30] Grabowski Declaration ¶32.

Figure 1A: Janssen R&D and Revenue (YoY %)



Source: Grabowski Declaration Exhibit 1.

Figure 1B: Janssen R&D and Remicade Sales (YoY %)



Source: Grabowski Declaration Exhibit 1.

19. These findings suggest that a change in Remicade® sales do not necessarily correspond to a change in Janssen R&D expenditures, contradicting Dr. Grabowski's claims of irreparable harm due to loss of R&D spending, specialized labor, and societal opportunities related to novel treatments.

V. DR. GRABOWSKI FAILS TO ESTABLISH ANY CAUSAL LINK BETWEEN A PREMATURE BIOSIMILAR LAUNCH AND CLAIMED IRREPARABLE HARM TO J&J

20. In making his irreparable harm arguments, throughout his declaration, Dr. Grabowski conjectures about the likely adverse impact on "…Johnson & Johnson, Janssen Biotech's parent company…."[31] For example, one of his sections in his declaration is titled: "The Importance of Remicade® to Janssen Biotech's and **Johnson & Johnson's Financial Health** [emphasis added]."[32] He further opines: "The decrease in R&D funding **at the Johnson & Johnson level** [emphasis added] would translate in the decrease of R&D funding available to Janssen companies. Sales from Remicade® also support the **employment of Johnson & Johnson's employees** [emphasis added] across different departments and subsidiaries, including Janssen Biotech."[33] Thus, it is clear that Dr. Grabowski claims that his irreparable harm arguments extend to J&J.

21. In making these arguments, particularly regarding the importance of Remicade® to the "financial health" of J&J, Dr. Grabowski provides no support as to how the supposed unquantifiable yet "severe" impact on Remicade® sales could reasonably lead to irreparable harm to J&J. Importantly, he ignores that the fact that J&J is a large multi-national company, with over $74 billion in annual sales and a very diverse revenue base, as shown in Table 2 below.

[31] Grabowski Declaration ¶15.
[32] Grabowski Declaration p. 12.
[33] Grabowski Declaration ¶32.

J&J also has more than 100 marketed drugs and over 16 pharmaceutical drugs in late stages of development. According to Dr. Grabowski, U.S. Remicade® sales in the year prior to biosimilar launch is expected to be [redacted][34] This represents approximately [redacted], and as such, any lost sales due to biosimilar competition would be a mere fraction of that percentage.[35] In sum, Dr. Grabowski not only has failed to quantify the impact, if any, of a premature biosimilar launch on Remicade® sales, but he also has failed to establish any causal link between a premature biosimilar infliximab launch and the claimed irreparable harm to J&J.

Table 2: Johnson & Johnson Key Figures ($ in millions)

Total Assets	$131,119
Total Sales	$74,331
Major Consumer Franchise Sales	$14,496
Major Pharmaceutical Therapeutic Area Sales	$32,313
Major Medical Devices Franchise Sales	$27,522
Number of Operating Companies	265
Number of Employees	126,500
Number of Drugs Marketed	100+
Number of Pharmaceutical Drugs in Late-Stage Development	16
Number of Indications	35

Note: All figures are as of 2014, except "Number of Drugs Marketed" (2013), "Number of Pharmaceutical Drugs in Late-Stage Development" (2015), and "Number of Indications" (2015).
Sources: Johnson & Johnson 2014 10-K; Johnson & Johnson 2013 Investor Fact Sheet; Johnson & Johnson, "Janssen Pharmaceutical Companies of Johnson & Johnson Selected Pharmaceuticals in Late Stage U.S. and E.U. Development or Registration as of 4/14/15" April 14th, 2015.

[34] *See,* Grabowski Declaration ¶50. [redacted]

[35] J&J's 2014 total annual sales were $74.331 billion. *See,* Johnson & Johnson 2014 10-K at 21.

V. DR. GRABOWSKI'S DECLARATION IS INTERNALLY INCONSISTENT

22. Dr. Grabowski is internally inconsistent with regards to his opinions concerning whether or not the impact of biosimilar infliximab launch resembles the impact of small-molecule generic entry.

23. In an effort to support claims of irreparable harm to Janssen in the form of lost specialized labor, Dr. Grabowski suggests that the launch of biosimilar infliximab will be similar to small-molecule generic entry. Dr. Grabowski suggests that because "Johnson & Johnson, had to lay off 900 people in 2009 after its blockbuster drug Risperdal® became subject to **generic competition** [emphasis added]", and "**[g]eneric entry** [emphasis added] was also cited as one of the reasons why Pfizer, in 2007, had laid off approximately 10,000 workers,"[36] a premature launch of biosimilar infliximab is likely to lead to a loss of specialized labor for Janssen.

24. On the other hand, in an effort to support claims of irreparable harm due to loss of Janssen's ability to compete with third-party products and subsequent loss of market share, Dr. Grabowski ultimately concedes that the launch of biosimilar infliximab will be dissimilar to small-molecule generic entry. Specifically with respect to Janssen's ability to compete with other branded pharmaceutical products, Dr. Grabowski states that "**[i]n contrast with generic competition** [emphasis added], biosimilar entrants can be expected to engage in promotional activity with respect to product quality and drug attributes."[37]

25. Furthermore, as previously noted, in an effort to support claims of irreparable economic harm to Janssen, Dr. Grabowski suggests that the impact of a premature launch of biosimilar infliximab on Remicade® is likely to be severe, similar to that of generic entry for

[36] Grabowski Declaration ¶70.
[37] Grabowski Declaration ¶68.

small-molecule drugs.[38] However, in an effort to minimize public interest considerations, Dr. Grabowski states: "the price discount from the proposed biosimilar product is expected to be **substantially less** than price discounts afforded by small-molecule generic drugs" [emphasis added].[39]

VI. CONCLUSION

25. Throughout his declaration, Dr. Grabowski asserts without economic support that a premature biosimilar infliximab launch will have a severe adverse impact on Remicade® sales and market share, leading to irreparable harm for Janssen and J&J. However, empirical data for countries in which biosimilar infliximab is currently sold suggest that the impact on Remicade® sales varies across countries, and in many countries no negative impact has been discernable. These data suggest that one cannot conclude that the impact on Remicade® sales resulting from a premature biosimilar infliximab launch in the U.S. would be negative, let alone lead to irreparable harm to J&J. Furthermore, Dr. Grabowski's conjecture that the launch of biosimilar infliximab would result in a reduction in Janssen's R&D spending is contradicted by data contained in his own declaration. Not only does Dr. Grabowski fail to quantify the impact on Remicade® sales of a premature biosimilar launch, he fails to establish any causal link between a premature launch by Hospira and claimed irreparable harm to J&J.

April 29, 2015

Atanu Saha, Ph.D.

[38] *See Supra* ¶¶10-12. *See also,* Grabowski Declaration ¶¶41-42.

[39] Grabowski Declaration ¶20. Although he makes an effort to minimize public interest considerations, Dr. Grabowski concedes that an infliximab biosimilar launch would result in some public benefits in the form of lower prices. *See for example*, Grabowski Declaration ¶77 where he states that "[t]here may also be a substantial lag before **lower prices are passed through to consumers in the form of lower copayments**" [emphasis added].

Exhibit 1: CV of Atanu Saha, Ph.D.

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Dr. Saha is an expert in damage analysis, specializing in the application of economics and finance to complex business litigation. He has over 20 years of experience in the area of economic and litigation consulting. In the area of securities litigation he has served as an expert in cases involving 10b-5 claims, valuation of investment portfolios, and commercial damages. He has provided expert testimony in antitrust matters involving collusion, commodity price manipulation, and price-fixing allegations. Dr. Saha's research in the area of securities litigation has been cited by the 11th Circuit Court of Appeals.

Prior to joining Compass Lexecon, Dr. Saha held senior positions at other consulting firms. Additionally, Dr. Saha was a tenure-track professor for four years at Texas A&M University where he taught Ph.D.-level courses in econometrics and applied economics. Dr. Saha is the author of numerous refereed journal articles, monographs and book chapters. His research has been cited in numerous publications, including *The Wall Street Journal, The Economist, The New York Times, The Chicago Tribune,* and *USA Today.* He has served as a referee for leading economic journals, including *American Economic Review, Journal of Political Economy,* and *Economic Inquiry.* He is the recipient of the prestigious *Graham and Dodd Award* for financial research. Dr. Saha holds a Ph.D. from the University of California, Davis, and an M.A. from the University of Alberta, Canada.

PRIOR CONSULTING EXPERIENCE

Antitrust and Damage Analysis

- *Arthur Garabedian v. Los Angeles SMSA et al.* — Expert report and testimony regarding pricing conditions in the cellular communications industry. The class action lawsuit involved price fixing charges against LA Cellular and AirTouch.

- *Michael A. Lobatz, M.D. v. Airtouch Cellular Company and U.S. West Cellular of California, Inc.* — Expert analysis to evaluate the joint settlement between plaintiff class and AirTouch and US West.

- *Cardizem CD Antitrust Litigation* — Expert reports and testimony regarding pricing conditions, drug substitution rates and consumer savings in the market for brand name and generic pharmaceutical drugs.

- *Lorazepam and Clorazepate Antitrust Litigation* — Expert reports and testimony regarding the economic impact of vertical supply agreements between a generic manufacturer of two pharmaceutical products and an active ingredient supplier for these products.

- *Beer Antitrust Litigation* — Expert report and testimony regarding pricing conditions in the beer industry. Econometric analysis of beer prices charged by Anheuser Busch to its distributors.

- *Industrial Ferrosilicon Antitrust Litigation* — Expert report regarding the pricing conditions in the international ferrosilicon market. The litigation involved price-fixing allegations.

- *Vitamin Antitrust Litigation* — Expert analysis regarding the pricing conditions in the market for vitamin C. The litigation involved price-fixing allegations.

- *EMC Corporation v. Mann and Karrat* — Expert report and testimony based on economic analysis to determine whether or not the memory storage products of EMC and StorageApps compete in the same product market.

- *EMC Corporation v. D.Kempel* — Expert report determining whether or not the products of EMC and SANgate Systems compete in the same product market.

- *Liebel-Flarsheim Co. v. Medrad, Inc.* — Expert report and testimony regarding "Kodak-type" issues in the fore and after markets for power injectors.

Securities Pricing and Valuation

- *County of Orange v. McGraw-Hill Companies, Inc., d/b/a Standard & Poors* — Expert witness and testimony for the defendant, Standard & Poors. Assignment included evaluation of the investment strategy implemented by Orange County in its investment pool and the estimation of damages, if any, caused by the allegedly erroneous S&P ratings of Orange County's debt.

- *Granite Partners et al. v. DLJ and ML et al.* — Expert witness and testimony to evaluate damages suffered by the Askin Funds (Granite Partners, Granite Corporation and Quartz Hedge Funds) as a result of the liquidation of assets composed of CMOs.

- *EMC Corporation v. Joanna T. Karwowksa* — Expert Report and testimony regarding the valuation of Employee Stock Options (ESOs).

- *Amado Lopez v. Lehman Brothers et al.* — Arbitration before NASD Panel; testimony regarding the valuation of bonds.

- *Olson v. Halvorsen et al.* — Expert witness and testimony regarding fair value of Viking Global, a hedge fund, and rebuttal damage analysis.

- *Amaranth Natural Gas Commodities Litigation* — Expert analyses and testimony regarding class certification and merits issues in natural gas futures price manipulation claim.

- *Platinum and Palladium Commodities Litigation* — Expert analysis of platinum and palladium prices in response to commodity and futures price manipulation claims.

- *IRS v. Presidio Advisory Services et al.* — Expert witness and testimony regarding 'economic substance' of certain investment strategies.

- *SEC v. Hedge Fund* — Expert rebuttal analysis of SEC's allegations regarding certain trading practices of a hedge fund.

- *SEC v. optionsXpress, Inc* — Expert analysis and testimony regarding options transactions and Reg SHO issues.

- *Street Retail Inc., et al. v. Vornado Realty Trust, et al.* — Expert analysis and testimony regarding valuation of real estate assets.

- *American Stock Exchange ETF Valuation* — Analysis in a non-litigation project to evaluate the frequency and extent of 'tracking errors' of the Exchange Traded Funds introduced by the American Stock Exchange.

- *MKP Master Fund v. Salomon Smith Barney (SSB)* — Analysis of damages arising from the liquidation of the portfolio which occurred as a result of the margin calls faced by the hedge fund from its prime broker, SSB.

- *Eagle Cayman Fund v. Salomon Smith Barney* — Analysis of damages arising from the liquidation of the portfolio when the hedge fund failed meet the margin calls by SSB.
- *Medicis Pharmaceutical Corporation v. Actavis Mid Atlantic LLC* — Expert analysis and testimony regarding damages to brand franchise due to early generic entry.
- *Robert Bishop, et al. v. Kowa Pharmaceuticals America, Inc.* — Expert analysis regarding valuation of a privately held pharmaceutical firm.
- *Pharmaceutical Product Development, LLC v. TVM Life Science Ventures VI, L.P., et al.* — Expert analysis regarding valuation of privately held pharmaceutical firm.
- *Valuation of Complex Financial Assets* — Expert analysis in several matters involving valuation of MBS, RMBS, and CDO portfolios held by major investment banks.

Securities Pricing and Securities Class Action Matters

- *Charles Fargo, et al. v. Joseph McCartney, et al.* — Expert witness and testimony for counsel for the defendant, Osicom Technologies, in a Rule 10b-5 litigation.
- *Towers Securities Litigation* — Expert analysis and testimony; event study analysis of Tower's share prices in a Rule 10b-5 class action litigation; rebuttal damage analysis.
- *Greenfield Online Securities Litigation* — Expert analysis regarding damage exposure in a Rule 10b-5 matter.
- *Jabil Circuits Option Backdating Inquiry* — Expert analysis on behalf of the Special Committee investigating whether the stock options granted to the executives of the firm were backdated.
- *Robert Bains, et al. v. Moores, et al.* — Expert rebuttal analysis of damages arising from the fall of Peregrine's share prices and event study analysis of Peregrine's stock price movement.
- *WorldCom Securities Litigation* — Analysis on behalf of defendant Citi Bank; event-study analysis of the impact, if any, of securities analysts' reports on the share prices of WorldCom in a Rule 10b-5 litigation.
- *Freddie Mac Securities Litigation* — Analysis on behalf of defendant Freddie Mac; event-study analysis and estimation of potential damages exposure in a Rule 10b-5 litigation.
- *Ahold Securities Litigation* — Analysis on behalf of defendant Ahold; event-study analysis and estimation of potential damages exposure in a Rule 10b-5 litigation.
- *Global Crossing Securities Litigation* — Analysis on behalf of defendant Citi Bank; event-study analysis of the impact, if any, of securities analysts' reports on the share prices of Global Crossing in a Rule 10b-5 litigation.

- *DeMarco v. Lehman Brothers* — Analysis on behalf of defendant Lehman Brothers; event-study analysis of the impact, if any, of securities analysts' reports on the share prices of RealNetworks in a Rule 10b-5 litigation. Class certification was denied by Judge Rakoff of SDNY.

- *The International Projects Development v. Oxbo Carbon & Minerals, et al.* — Expert rebuttal report and damages analysis in an ICC Arbitration matter.

- *Pokomtel S.A. v. SiCap AG* — Expert analysis and testimony in an ICC Arbitration matter.

- *SEC v. Thomas Fisher, et al.* — Expert analysis of damages resulting from alleged inflation of Nicor stock prices.

ERISA Litigation

- *Freddie Mac ERISA Litigation* — Expert analysis on behalf of defendant Freddie Mac. Comparative performance analysis of the retirement portfolio of Freddie Mac's employees. Rebuttal analysis of class action claims.

- *NUI ERISA Litigation* — Expert analysis on behalf of NUI. Rebuttal analysis of class action plaintiffs' damage claim.

- *The Southern Company ERISA Litigation* — Expert analysis on behalf of The Southern Company. Rebuttal damage analysis based on individual employee's investment decisions.

- *Bank of America ERISA Litigation* — Analysis on behalf of Bank of America. Rebuttal analysis of class action claims.

- *Citi ERISA Litigation* — Analysis of behalf of Citi. Expert rebuttal report and testimony regarding class action claims.

Mutual Fund Litigation

- Expert analysis on behalf of investment banks and financial institutions in several mutual fund 'market timing' and 'A versus B' shares matters. The analyses involved quantification of damages, if any, suffered by investors, using sophisticated econometric models and statistical tools.

Lost Earnings Damage Analysis

- *Boersma v. SoCalGas, et al.* — Expert Report for defendant Southern California Gas Company regarding lost wages, lost future earnings and other economic damages.

- *Parker v. Ford Motor Company, et al.* — Expert witness testimony for defendant Ford Motor Company regarding lost wages, lost future earnings and other economic damages.

- *Sanchez v. Certified Grocers, et al.* — Expert analysis for defendant Certified Grocers regarding lost wages, lost future earnings and other economic damages.

Product Failure and Product Liability

Dr. Saha has been retained as an expert witness and has consulted in several cases involving product liability and product failure. His expertise encompasses modeling and estimating a defendant's future liability stream as a defective product fails over time.

- *Byron Dahl, et al. v. Polaris Pipe Co., et al.* and *Scripps Nob Hill v. Presley Companies* — Retained by counsel for the defendant to evaluate claims of property damage arising from the alleged failure of ABS pipes.

- *Scripps Nob Hill v. Presley Companies* — Expert analysis regarding the timing and incidence of product failure.

Contract Dispute

Dr. Saha has consulted in many cases involving contract disputes and failure to perform.

- Expert testimony at an arbitration on behalf of an interdealer broker regarding breach of contract and damage analyses.

- *Sinochem (USA), Inc. v. Ideal Rattan, Inc.* — Expert testimony regarding breach of contract damages.

- *Mihaylo v. Bank of America* — Economic analysis in connection with a loan dispute involving Bank of America.

- *Compton Commercial Development Renaissance Plaza Company v. East Coast Foods, Inc.* — Damages assessment regarding breach of lease contract.

Healthcare

Dr. Saha has performed research and analysis on a range of issues related to healthcare.

- *Managed Care Consulting Firms Evaluation* — Examination of pricing techniques, analysis of performance and valuation of consulting firms operating in the managed care area.

- *Medical Products and Devices* — Calculation of the value intellectual property embodied in a variety of healthcare products, including stents and trocars, and biotech products.

REFEREED PUBLICATIONS

"A Tale of Two Anomalies: Higher Returns of Low-Risk Stocks and Return Seasonality," with C. Fiore, *The Financial Review* 50(2), 2015, 257-273.

"An Intraday Event Study Methodology for Determining Loss Causation," with A. Rinaudo, *The Journal of Financial Perspectives* 2(2), July 2014, 161-172.

"Calculating Damages in ERISA Litigation," with A. Ferrell, *The Journal of Financial Perspectives* 1(2) (2013), 93-103.

"Valuation of Cash Flows with Time-Varying Cessation Risk," with B. Malkiel, *Journal of Business Valuation and Economic Loss Analysis*, 7(1) (2012).

"Detecting Price Artificiality and Manipulation in Futures Markets: An Application to Amaranth," with H. Petersen, *Journal of Derivatives and Hedge Funds*, 18 (2012), 254-271.

"Forward-Casting 10b-5 Damages: A Comparison to Other Methods," with A. Ferrell, *Journal of Corporation Law*, 37(2) (Winter 2012), 365-387.

"DCF Valuation with Cash Flow Cessation Risk," with B. Malkiel, *Journal of Applied Finance,* 1 (2012), 175-185.

"Securities Litigation and the Housing Market," with A. Ferrell, *Journal of Corporation Law*, Fall 2009, 92-122.

"The Clustering of Extreme Movements: Stock Prices and the Weather," with B. Malkiel and A. Grecu, *The Journal of Investment Management* (2009), 20-35.

"The Loss Causation Requirement for Rule 10b-5 Causes-of-Action: The Implication of *Dura Pharmaceuticals v. Broudo*," with A. Ferrell, *The Business Lawyer*, November 2007.

"Why Do Hedge Funds Stop Reporting Their Performance?" with A. Grecu and B. Malkiel, *Journal of Portfolio Management*, Fall 2007, 119-126.

"To Bundle or Not To Bundle: Firms' Choices Under Pure Bundling," with G. Hubbard and J. Lee, *International Journal of the Economics of Business,* February 2007, 59-83.

"Complementary Goods: Prices and Consumer Welfare Under Duopoly and Monopoly," with A. Girnius and O. Andriychenko, *International Journal of the Economics of Business,* November 2006, 373-386.

"Generic Competition in the U.S. Pharmaceutical Industry," with H. Grabowski, H. Birnbaum, P. Greenberg, and O. Bizan, *International Journal of the Economics of Business,* April 2006, 15-38.

"Hedge Funds: Risk and Return," with B. Malkiel, *Financial Analysts Journal,* December 2005, 80-88. **Recipient of the Graham and Dodd "*Best Perspectives Paper*" Award, 2005.**

"Predicting The Price Effect of Mergers with Polynomial Logit Demand," with P. Simon, *International Journal of the Economics of Business,* Antitrust Special Issue, 7, (2000), 149-157.

"The Economics of Crime and Punishment: An Analysis of Optimal Penalty," with G. Poole, *Economics Letters,* 68 (2000), 191-196.

"A New Approach to Estimating Damages in Mass Torts," with L. Hilton, *International Journal of the Economics of Business,* 7 (2000), 27-46.

"He Came, He Saw, [and] He Waited: An Empirical Analysis of Inertia in Technology Adoption," with D. Dong, *Applied Economics,* 30 (1998), 893-905.

"Refutable Implications of the Firm Model Under Risk," with R. Shumway, *Applied Economics,* 30 (1998), 441–448.

"Risk Preference Estimation in the Nonlinear Mean Standard Deviation Approach," *Economic Inquiry,* 35 (1997), 770–782.

"Estimating Nested Count Data Models," with D. Dong, *Oxford Bulletin of Economics and Statistics,* 59 (1997), 423–430.

"Expo-Power: A Flexible Hazard Function for Duration Data Models," with L. Hilton, *Economics Letters,* 54, July 1997, 227–233.

"Stochastic Production Function Estimation: Small Sample Properties of ML versus FGLS," with A. Havenner and H. Talpaz, *Applied Economics,* 29 (1997), 459–469.

"Calculating Marginal Effects in Models for Zero Expenditures in Household Budgets Using a Heckman-type Correction," with O. Capps and P. Byrne, *Applied Economics,* 4 (1997), 181–185.

"Calculating Marginal Effects in Dichotomous-Continuous Models," with O. Capps and P. Byrne, *Applied Economics Letters,* 4 (1997), 181–185.

"The Economics and Econometrics of Damage Control," with C. R. Shumway and A. Havenner, *American Journal of Agricultural Economics,* 79 (1997), 773–785.

"Analysis of Food Away from Home Expenditure Patterns for US Households, 1982–1989," with P. Byrne and O. Capps, *American Journal of Agricultural Economics,* 78 (1996), 614–627.

"The Role of Information in Technology Adoption: The Case for rbST in the California Dairy Industry," with C. Klotz and L. J. Butler, *Review of Agricultural Economics,* 17 (1995), 287–298.

"Production and Savings Under Uncertainty," with R. Innes and R. Pope, *International Review of Economics and Finance,* 2 (1994), 365–375.

"A Two-Season Agricultural Household Model of Storage and Savings Under Uncertainty," *Journal of Development Economics,* 45 (1994), 245–269.

"Adoption of Emerging Technologies Under Uncertainty," with A. Love and R. Schwart, Jr., *American Journal of Agricultural Economics,* 76 (1994), 836–846.

"A Household Model of On-farm Storage Under Price Risk," with J. Stroud, *American Journal of Agricultural Economics,* 76 (1994), 522–534.

"Joint Estimation of Risk Preference and Production Technology Using the Expo-Power Utility Function," with R. Shumway and H. Talpaz, *American Journal of Agricultural Economics,* 76 (1994), 173–184.

"Compensated Optimal Response Under Uncertainty in Agricultural Household Models," *Agricultural Economics,* 11 (1994), 111–123.

"Expo-Power Utility: A Flexible Form for Absolute and Relative Risk Aversion," *American Journal of Agricultural Economics,* 75 (1993), 905–913.

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"Hedge Funds Today: Caveat Emptor," with B. Malkiel, Wall Street Journal, July 26, 2005.

"A Game Theoretic Model of Crime and Punishment," with G. Poole. Paper presented at the 73rd Annual Western Economic Association International Conference in Lake Tahoe, CA (July 1998).

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Exhibit 2: Materials Relied Upon

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