IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

PLAINTIFFS' SUPPLEMENTAL MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR
A PRELIMINARY AND PERMANENT INJUNCTION

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Plaintiffs Janssen Biotech, Inc. ("Janssen") and New York University ("NYU") submit this Supplemental Memorandum of Law in support of their pending motion for a preliminary and permanent injunction against Defendants Celltrion Healthcare Co., Ltd., and Celltrion, Inc. (together "Celltrion") and Hospira, Inc.

I. INTRODUCTION

On July 21, 2015, the Federal Circuit resolved the legal questions at issue in Plaintiffs' pending motion for partial summary judgment and a preliminary and permanent injunction – in Plaintiffs' favor. *See Amgen, Inc. v. Sandoz, Inc*., __ F.3d __, No. 2015-1499, 2015 U.S. App. LEXIS 12523 (Fed. Cir. July 21, 2015). Defendants concede that *Amgen* compels granting Plaintiffs' motion for summary judgment on the merits, but they contend that it is somehow "not mandatory" for them to follow the law as authoritatively interpreted by the Federal Circuit and so no injunction should follow. The defendants in *Amgen* were ordered to follow the law. For the reasons explained below, *Amgen* compels granting the same relief to Plaintiffs here.

Under the Biologics Price Competition and Innovation Act ("BPCIA"), the maker of a proposed biosimilar version of an innovative biological medicine[1] must provide notice to the innovator 180 days before the first commercial marketing of a "licensed" biosimilar product. *See* 42 U.S.C. § 262(l)(8)(A). Defendants' proposed biosimilar product has not yet been licensed by FDA for sale in the United States, yet Defendants purported to provide a "notice of commercial marketing" more than six months ago, on February 5, 2015. Plaintiffs' pending motion sought a declaration that this meaningless notice was ineffective and an order requiring Defendants to comply with the statute by refraining from marketing their proposed product for 180 days after their product is licensed, if it is, and they provide a proper notice. Dkt. No. 34.

[1] Biosimilars are analogous to generic copies of small-molecule drugs, but given the complexity of biological molecules, such copies can only be similar, not identical, to the innovative product.

Thus, as Defendants put it in their opposition papers, "[t]he 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." Dkt. No. 51 at 1 (emphasis in original).

In *Amgen*, the Federal Circuit provided the answer: "yes." The court held that under the BPCIA, a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product," and that as a result, the biosimilar applicant's pre-license notice of commercial marketing was ineffective. *Amgen*, 2015 U.S. App. LEXIS 12523, at *21 (emphasis added). Based on this conclusion, the *Amgen* court issued an injunction prohibiting the applicant, Sandoz, from entering the market for 180 days from the time it provided a proper, post-license notice. *Id*. at *27-29.

In light of the Federal Circuit's decision in *Amgen*, both parties agree that Defendants' February 5, 2015 "notice of commercial marketing" was ineffective as a matter of law and that the parties' cross-motions for summary judgment on that question have been resolved in Plaintiffs' favor. *See* accompanying Declaration of Gregory L. Diskant in Support of Plaintiffs' Supplemental Memorandum of Law in Support of Their Motion for a Preliminary and Permanent Injunction ("Diskant Decl."), Ex. 1. Despite this concession – and despite the fact that the Federal Circuit in *Amgen* issued the exact 180-day injunction that Janssen seeks here – Defendants refuse to comply with the statutory notice provision. According to Defendants, providing an effective notice of commercial marketing upon obtaining a license is somehow "not mandatory" on the facts of this case. *Id.*

Defendants rely on a misinterpretation of *Amgen*. Defendants seize on the facts that in *Amgen*, Sandoz failed to provide Amgen any pre-litigation information about its proposed

biosimilar product (whereas Defendants here provided some but not all of the required information) and that the Federal Circuit noted this in rejecting Sandoz's contention that the notice of commercial marketing is optional. But the fact that a notice of commercial marketing *was* mandatory in *Amgen* hardly suggests that it is *not* mandatory here. Defendants' situation does not differ from Sandoz's in any way that is material to the Federal Circuit's interpretation of the BPCIA. The Federal Circuit's holding, and its reasoning, dictate that a notice of commercial marketing is mandatory here, just as it was in *Amgen*.

II. *AMGEN* ORDERED THE BIOSIMILAR APPLICANT TO COMPLY WITH THE STATUTORY 180-DAY NOTICE PERIOD AFTER LICENSURE

Amgen is the first and only Federal Circuit case to interpret the patent dispute resolution provisions of the BPCIA, a 2010 statute that creates a framework for the regulatory approval of, and the resolution of patent disputes relating to, biosimilar versions of innovative biological medicines. *Amgen* addressed two provisions of the BPCIA. First, the court interpreted 42 U.S.C. § 262(l)(2)(A) ("paragraph (l)(2)(A)"), which calls for the biosimilar applicant, after its application is accepted for review, to provide the reference product sponsor ("RPS"), or innovator, a "copy of the application" and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." Second, and more relevant here, the Federal Circuit resolved the legal questions at issue in this motion concerning the meaning and enforceability of the BPCIA's "notice of commercial marketing" provision, 42 U.S.C. § 262(l)(8)(A) ("paragraph (l)(8)(A)"), which states that a biosimilar "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)".[2]

In *Amgen*, the RPS or innovator, Amgen, moved for judgment on the pleadings and a preliminary injunction contending that Sandoz, the biosimilar applicant, had violated the BPCIA by failing to provide the pre-litigation information required by paragraph (l)(2)(A) and by filing a premature paragraph (l)(8)(A) notice of commercial marketing before its proposed biosimilar product had been licensed. Sandoz responded that the requirements of paragraphs (1)(2)(A) and (l)(8)(A) are optional, that the paragraph (l)(8)(A) notice could be provided before licensure, and that, in any event, Amgen was not entitled to an injunction enforcing the provisions. The district court agreed with Sandoz on all points. *Amgen, Inc. v. Sandoz, Inc*., No. 14-cv-4741, 2015 U.S. Dist. LEXIS 34537, at *33-35 (N.D. Cal. Mar. 19, 2015), *aff'd in part and vacated in part*, No. 2015-1499, 2015 U.S. App. LEXIS 12523 (Fed. Cir. July 21, 2015). On appeal, the Federal Circuit affirmed the district court's conclusion that it was not mandatory for the biosimilar applicant to provide the pre-litigation information specified in paragraph (l)(2)(A), *Amgen*, 2015 U.S. App. LEXIS 12523 at *12-*19, but it reversed the district court on three other issues. The *Amgen* court held: (1) that under paragraph (l)(8)(A), an effective notice of commercial marketing could only be provided *after* FDA licensure and *before* commercial marketing; (2) that a notice of commercial marketing under paragraph (l)(8)(A) is a standalone provision not dependent on the other provisions of subsection (l) and compliance with the provision by Sandoz was mandatory; and (3) that Amgen was therefore entitled to an automatic statutory injunction

[2] Janssen's pending motion is limited to the notice of commercial marketing provision of 42 U.S.C. § 262(l)(8)(A). However, Janssen also alleges in the complaint that Defendants have violated paragraph (l)(2)(A) by failing to provide required manufacturing information in addition to their application. Dkt. No. 1 at ¶¶ 104-110. As discussed below, Defendants cannot dispute that they only provided their application and did not provide any additional manufacturing information.

barring Sandoz from launching its biosimilar until the expiration of the 180-day notice period. *Id*. at *19-*28.

With respect to the timing of the notice of commercial marketing, the Federal Circuit reasoned that the statutory requirement that notice pertain to a "licensed" product, coupled with the fact that Congress used different language elsewhere in the statute to refer to a product that was not yet licensed, "compels" the conclusion that "a subsection (k) applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." *Id.* at *21 (emphasis added). Furthermore, the court held, "Congress intended the notice to follow licensure" to "ensure the existence of a fully crystallized controversy regarding the need for injunctive relief" and to provide a "defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." *Id.* at *22-*23.

Having determined that the notice of commercial marketing must come after licensure, the Federal Circuit "conclude[d]" that "paragraph (l)(8)(A) is mandatory." *Id.* at *25. "A question exists, however, concerning whether the 'shall' provision in paragraph (l)(8)(A) is mandatory. We conclude that it is." *Id.* Although the court determined that the other pre-litigation provisions of subsection (l) were optional in nature, the notice of commercial marketing is a "standalone notice provision." *Id.* at *27. "[N]othing in paragraph (l)(8)(A) conditions the notice requirement on paragraph (l)(2)(A) or other provisions of subsection (l)." *Id.* (In fact, as the court noted, Sandoz had not complied with any of those provisions. *See id*. at *8.). Meanwhile, the "purpose of paragraph (l)(8)(A) is clear: requiring notice of commercial marketing be given to allow the RPS [the innovator] a period of time to assess and act upon its patent rights." *Id.* at *27.

Finally, the Federal Circuit did not even entertain Sandoz's argument that it should nevertheless not be enjoined to follow the mandatory requirements of the BPCIA. Rather, the Federal Circuit imposed an 180-day injunction as a matter of course: "Sandoz therefore may not market [its product] before 180 days" after providing a proper, post-license notice of commercial marketing. *Id*. at *27-*28. *Amgen* compels the same result here.

III. A NOTICE OF COMMERCIAL MARKETING IS MANDATORY UNDER *AMGEN*

Defendants argue that even though (as they now concede) their notice of commercial marketing was legally ineffective, an effective notice of commercial marketing is "not mandatory" and they should not be ordered to provide one. Diskant Decl. Ex. 1. Remarkably, Defendants go so far as to assert that *Amgen compels* denial of Plaintiffs' motion for injunctive relief. They argue that because the court cited Sandoz's failure to comply with the optional provisions of paragraph (l)(2)(A) in holding that the notice of commercial marketing provision under paragraph (l)(8)(A) was mandatory, *Amgen* somehow held that paragraph (l)(8)(A) was not really mandatory, or was only sometimes mandatory. Defendants argue that *Amgen* "held that the BPCIA does not require applicants like Celltrion that have timely produced its aBLA [abbreviated biological license application] to provide any notice of commercial marketing, thus foreclosing the relief Janssen requests in its motion for injunctive relief." *Id*.

Defendants' attempt to salvage their position fails. As noted, *Amgen* directly addressed the "question . . . concerning whether . . . paragraph (l)(8)(A) is mandatory" and answered it in the affirmative. *Amgen,* 2015 U.S. App. LEXIS 12523 at *25. Although the *Amgen* court, not surprisingly, cited the facts of the case before it to explain *why* a proper paragraph (l)(8)(A) notice of commercial marketing is mandatory, it did not hold that notice is optional in any

circumstances. On the contrary, the reasoning of *Amgen* compels the conclusion that a notice of commercial marketing is mandatory in all circumstances, and certainly here.

A. Paragraph (l)(8)(A) Is a "Standalone Provision" That Does Not Depend on the Other Sections of the BPCIA

Paragraph (l)(8)(A)'s language is unequivocal: "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) (emphasis added). The basic flaw in Defendants' argument that this language is somehow optional – because Defendants supposedly complied in part with paragraph (l)(2)(A) by providing a copy of their aBLA to Janssen – is that it ignores the unequivocal holding of the *Amgen* court that "[p]aragraph (l)(8)(A) is a standalone notice provision in subsection (l). . . . Unlike the actions described in paragraphs (l)(3) through (l)(7), which all depend on, or are triggered by, the disclosure under paragraph (l)(2)(A), nothing in paragraph (l)(8)(A) conditions the notice requirement on paragraph (l)(2)(A) or other provisions of subsection (l)." *Amgen*, 2015 U.S. App. LEXIS 12523 at *27.

Two consequences flow from the fact that paragraph (l)(8)(A) is a standalone provision. First, in contrast to the rest of the statutory scheme, there is no reason in construing this standalone provision to depart from the usual rule that that presence of the word "shall" in paragraph (l)(8)(A) is mandatory. *Id.* at *25 ('the word 'shall' . . . presumptively signals a statutory requirement"); *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007) ("Use of the word 'shall' in a statute generally denotes the imperative"); *BlackLight Power, Inc. v. Rogan*, 295 F.3d 1269, 1273 (Fed. Cir. 2001) (the word "shall" imposes a duty); *Grav v. United States*, 886 F.2d 1305, 1307-08) (Fed. Cir. 1989) (the word "shall"

indicates the action is mandatory). It is simply irrelevant that the *Amgen* court construed other parts of the statute to be voluntary.

Second, because paragraph (l)(8)(A) is a standalone provision, Defendants' claim that they are excused from its mandatory language because they purportedly complied with *other* independent provisions of the BPCIA makes no sense. As the *Amgen* court held, the mandatory language of section (l)(8)(A) is *not* conditioned on any of the preceding paragraphs of subsection (l). In fact, that is precisely the point the court was making when it concluded that paragraph (l)(8)(A) is a standalone provision. There is no condition precedent elsewhere in the statute to the requirement that the applicant provide 180-day notice of commercial marketing to the innovator. As a result, it can make no difference to the applicant's duty to comply with the 180-day notice provision whether the applicant has, or has not, served its aBLA on the innovator.

Defendants' support for this untenable distinction comes from Judge Chen's dissent, which disagrees with the Court's conclusion that section (l)(8)(A) is a standalone provision and thus reads the court's holding as depending on whether the applicant did, or did not, comply with what the court found to be the optional provisions of the BPCIA. *Amgen,* 2015 U.S. App. LEXIS 12523 at *52-54 (Chen, J., dissenting). The dissent argues (like the Defendants here) that the Court's opinion requires a notice of commercial marketing, and "an automatic injunction," *only* when an aBLA has not been served. *Id*. at *58. It acknowledges that this is a "peculiar" outcome, which yields the "uncomfortable result" that "the language of (l)(8)(A) is interpreted in two different ways, based on the (k) applicant's actions." *Id.* at *58-*59. This would indeed be a peculiar reading of the statute.[3]

[3] It is hazardous, of course, to rely upon a dissent's interpretation of the Court's opinion. *See, e.g., Clark v. Dugger*, 901 F.2d 908, 914 n.4 (11th Cir. 1990) ("The concerns of a dissenting justice do not, however, control the meaning of a majority opinion, ...); *United States v.*

In fact, there is thus no principled basis for concluding that paragraph (l)(8)(A) is sometimes mandatory and sometimes optional. Judge Lourie, speaking for the *Amgen* majority, said: "A question exists, however, concerning whether the 'shall' provision in paragraph (l)(8)(A) is mandatory. ***We conclude that it is***." *Id.* at *25 (majority opinion) (emphasis added). Judge Newman, concurring in this portion of the opinion (and thus providing the two-judge majority), wrote, "I agree with the court that ***notice of issuance of the FDA license is mandatory,*** and that this notice starts the 180-day stay of commercial marketing. . . ." *Id.* at *34-*35 (Newman, J., concurring in part, dissenting in part) (emphasis added).

Any other approach would make compliance with paragraph (l)(8)(A) depend on whether the applicant had complied with other provisions of the statute. This would be contrary to the direct holding of the *Amgen* court that "nothing in paragraph (l)(8)(A) conditions the notice requirement on paragraph (l)(2)(A) or other provisions of subsection (l)." *Id.* at *27 (majority opinion). As discussed below, it would also be contrary to the purpose of the statute, as construed by the court. The notice provision allows the innovator a 180-day window in which to assess its patent rights after FDA approval and before launch – a purpose having no relation to the applicant's compliance, or non-compliance, with other provisions in the BPCIA . Moreover, the BPCIA does not provide an adequate remedy for non-compliance with paragraph (l)(8)(A). Bringing a declaratory judgment action after infringement has already commenced is no remedy at all for an innovator facing irreparable injury.

There is no basis to endorse the "peculiar" result advocated by Defendants. In paragraph (l)(8)(A), "shall" means shall.

Ameline, 409 F.3d 1073, 1083 n.5 (9th Cir. 2005) (en banc) ("[D]issents, of course, are not precedential.").

B. Allowing Biosimilar Applicants to Opt Out of the Paragraph (l)(8)(A) Notice Requirement Would Eviscerate the Purpose of the Paragraph as Described in *Amgen*

As discussed above, the *Amgen* court held that the notice of commercial marketing must be provided after licensure because this was the only way to effectuate what "Congress intended." *Amgen*, 2015 U.S. App. LEXIS 12523 at *22. Congress's intent, the Federal Circuit held, was to "allow[] the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court" and to "ensure[] the existence of a fully crystallized controversy regarding the need for injunctive relief" at the time of any such preliminary injunction motion. *Id.* at *21-*22. This purpose is unrelated to whether an applicant did, or did not, previously provide pre-litigation disclosures to the innovator. Rather, it requires notice to follow licensure because until then – whether pre-litigation disclosures have been provided or not – the timing of approval, the therapeutic uses of the product, the manufacturing processes and even the composition of the product itself remain subject to change:

> We believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed. When a subsection (k) applicant files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses. Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court.
>
> Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product. If a notice of commercial marketing could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin.

Id. at *22-*23.

The purpose of paragraph (l)(8)(A) as explained by *Amgen* would be eviscerated if a biosimilar applicant could simply opt not to provide a notice of commercial marketing. Without a 180-day notice, the innovator would "be left to guess the scope of the approved license and when commercial marketing would actually begin," *id*. at *22-*23, and would therefore be forced to choose between bringing a premature preliminary injunction motion before the need to do so was "fully crystallized" by licensure, or to wait until approval and risk the irreparable harm of having a biosimilar product launch before the motion could be adjudicated. As *Amgen* holds, that is precisely what the notice requirement of paragraph (l)(8)(A) prevents.

In post-*Amgen* correspondence, Defendants contend that the paragraph (l)(8)(A) is *intended* to "serve[] no purpose" on the facts of this case, because, according to them, the only purpose of a notice of commercial marketing is to enable a declaratory judgment action on patents that were not selected for immediate litigation in the first phase of the BPCIA's patent dispute resolution process. Diskant Decl. Ex. 1; *see* 42 U.S.C. § 262(l)(3)-(6) (process for selecting patents for immediate litigation). But this is the exact same argument Defendants made prior to *Amgen*, in support of their now-rejected reading of paragraph (l)(8)(A). Dkt. No. 51 at 9-10. And, again, the only support for this position in *Amgen* comes from the ***dissent,*** which agreed with Defendants, arguing that the only purpose of paragraph (l)(8)(A) was to enable the litigation of patents excluded from the first phase of BPCIA litigation. *Amgen*, 2015 U.S. App. LEXIS 12523 at *51-*52 (Chen, J., dissenting). But the *Amgen* majority squarely rejected such a narrow view of the 180-day period. Rather, the court held that paragraph (l)(8)(A) serves a far more general purpose, unrelated to which set of patents is at issue: "requiring notice of commercial marketing be given to allow the RPS a period of time to assess and act upon its patent rights." *Id.* at *27.

Defendants' continued reliance on their rejected view of paragraph (l)(8)(A)'s purpose only underscores the fact that their current position that the statute is "not mandatory" has already been rejected by *Amgen*. It is true that ***if***, as Defendants previously argued, paragraph (l)(8)(A) allowed a notice of commercial marketing to be given at any time, even before licensure, and therefore did not require a meaningful notice that would enable an effective opportunity for a preliminary injunction, it would serve no purpose other than to enable litigation on patents that were excluded from the immediate litigation phase. But in rejecting this argument and holding that licensure is a prerequisite to notice, *Amgen* made clear that the purpose of paragraph (l)(8)(A) is to require a meaningful notice. The post-approval, pre-launch "statutory window" for assessing the need for a preliminary injunction based on a "fully crystallized" product is necessary for all patents, not just those that were excluded from the first phase of litigation. Defendants' contention that the provision "serves no purpose" in this case is directly contrary to *Amgen*.

For the same reason, the need for a pre-launch notice period is not limited to situations where the applicant fails to provide the pre-litigation disclosures required by paragraph (l)(2)(A). Even where the applicant provides this information, it remains the case that "the product, its therapeutic uses, and its manufacturing processes are [not] fixed" until approval, and that the need for a preliminary injunction cannot be adequately assessed until that time. *Amgen,* 2015 U.S. App. LEXIS 12523 at *22. Here, as discussed in Plaintiffs' pending motion, questions about the scope and timing of Defendants' eventual approval make it premature for Plaintiffs to bring a motion for a preliminary injunction motion on *any* of the six of the patents they have asserted. Dkt. No. 34 at 15-17. As the Federal Circuit held in *Amgen,* the purpose of the 180-day notice period is to avoid the dilemmas presented by this situation. If notice is required only

where an applicant has failed to provide pre-litigation disclosures to the innovator, the general and important purpose of the notice provision is destroyed.

C. The BPCIA Provides No Adequate Remedy for Failure to Give Notice of Commercial Marketing

Defendants contend that the paragraph (l)(8)(A) notice of commercial marketing must be optional because the declaratory judgment action permitted in paragraph (l)(9)(B) "provides Janssen's sole remedy" for failure to give notice. Diskant Decl. Ex. 1. This argument, too, is contrary to *Amgen.* *Amgen* rejected Sandoz's argument that the declaratory judgment action provided for in paragraph (l)(9)(B) is the sole remedy for its failure to provide an effective notice of commercial marketing. *Amgen*, 2015 U.S. App. LEXIS 12523 at *25-*27.

It is true that *Amgen* held, with respect to paragraph (l)(2)(A), a different provision of the BPCIA, that the specified statutory consequences for the biosimilar applicant's failure to abide by this seemingly mandatory provision were the innovator's sole remedies, and that the pre-litigation information disclosures called for by paragraph (l)(2)(A) could not be enforced by an injunction. *Amgen*, 2015 U.S. App. LEXIS 12523 at *12-*19. But in reaching this conclusion, the *Amgen* court was at pains to show that the statutory consequences were *adequate* to remedy the applicant's disregard of the statutory procedures. In contrast, as *Amgen* held, the statutory consequences for failing to provide a notice of commercial marketing are *not* adequate, and so do *not* constitute the innovator's sole remedies.

In its analysis of paragraph (l)(2)(A), *Amgen* did not hold that the mere presence of a statutory consequence for non-compliance makes compliance with the statute optional. That would be nonsensical. As Justice Holmes famously observed, compliance with the law is *always* optional. Anyone may choose to obey the law, or to breach it and suffer the consequences. Oliver W. Holmes, *The Path of the Law*, 10 Harv. L. Rev. 457, 459-62 (1897). Rather, in the

court's view, the particular statutory remedies – a paragraph (l)(9)(C) declaratory judgment claim and a 35 U.S.C. § 271(e)(2)(C)(ii) patent infringement action – would restore the innovator to effectively the same position as if the applicant had not violated paragraph (l)(2)(A). As a result, the *Amgen* court concluded that Congress intended for the particular pre-litigation procedures set forth in paragraphs (l)(2)(A) *et seq*. to be voluntary.

In reaching this conclusion, the court reasoned that over the eight-year period allowed for the BPCIA procedures to unfold, there would be no practical difference in the remedies available to the innovator, whether the applicant did or did not comply with the pre-litigation procedures of the BPCIA. If the procedures were followed, there would be disclosure of information, which would permit litigation to follow. If the procedures were not followed, the failure to provide the information was itself "an artificial 'act of infringement,'" which would also permit litigation. *Amgen*, 2015 U.S. App. LEXIS 12523 at *16. Thereupon, "[o]nce the [innovator] brings an infringement suit . . . , it can access the required information through discovery." *Id*. at *17.

That is, in the court's view, although an innovator may be unable to enforce the paragraph (l)(2)(A) pre-litigation disclosures through an injunction, the innovator can obtain disclosure of the same information by filing suit. So long as the proposed biosimilar product is not being commercially launched in the meantime, which will be typical given the eight years allowed for such litigation, discovery will ultimately leave the innovator in the same place it would have been had the applicant complied with paragraph (l)(2)(A).

As *Amgen* held, the same is not true of the notice of commercial marketing, which exists to create a short pre-launch "statutory window" for bringing a preliminary injunction motion and which cannot be remedied if the biosimilar applicant is permitted to launch without notice. *Id.* at *22. The only purported remedy for such a failure to comply with the notice provision is the

right to bring a declaratory judgement action under paragraph (l)(9)(B) on any patent identified during the pre-litigation procedures. Focusing on the facts of the case before it, the *Amgen* court concluded that such an action was not an adequate remedy because Sandoz had not complied with the patent dance at all, and thus there was no list of patents to enforce through a declaratory judgment action. While that reasoning was sufficient to dispose of the case before it, the fact is that the right to bring a declaratory judgment action is *never* an adequate remedy for a failure to provide a notice of commercial marketing.

First, and foremost, the injury of launch without notice cannot possibly be cured by a post-launch declaratory judgment action. As the *Amgen* court recognized, the 180 day period *after* FDA approval and *before* launch is the only time under the statute when an innovator may seek an injunction on a fully crystallized controversy – a particular product approved for a particular use at a particular time. *Id.* For example, as set forth in Janssen's opening brief, it is presently unknown whether FDA will approve Defendants' biosimilar for Crohn's disease, if at all. If it does, Janssen will seek a preliminary injunction under its '396 Crohn's patent. Dkt. No. 34 at 16. If it does not, there is no basis for seeking emergency relief now. An unbroken string of Federal Circuit cases recognizes the serious risk of *irreparable* harm from the launch of lower-priced versions of branded products. *See, e.g., Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir 2011) ("money damages alone cannot fully compensate" plaintiff for "irreparable harm due to lost market share, lost business opportunities, and price erosion"); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (upholding district court's finding of irreparable harm where there was a "likelihood of price erosion and loss of market position without corresponding market expansion from the introduction of [competitor's] product"). Construing paragraph (l)(8)(A) to deny innovators the

right to seek a preliminary injunction in a short window prior to launch would cause them a serious substantive injury – one that is not remedied, even in the slightest degree, by the right to seek a declaratory judgment.

Second, and equally importantly, the right to seek a declaratory judgment is meaningless in these circumstances. By Defendants' reading of the statute, the right to bring a declaratory judgment accrues only if Defendants launch their product without proper notice (*i.e.*, "fail[] to complete an action required of the subsection (k) applicant." 42 U.S.C § 262(l)(9)(B)). The right to bring a post-launch declaratory judgment action after such a failure is an entirely superfluous right. Once an infringing biosimilar product is being offered for sale in the United States, the innovator can bring a claim for actual infringement under 35 U.S.C. §§ 271(a), (b), (c) or (g). The right to bring a declaratory judgment at that point provides no remedy whatsoever – not merely an inadequate remedy – for the applicant's failure to provide a 180-day pre-launch notice.

On the facts before it, the *Amgen* court found that the paragraph (l)(9)(B) declaratory judgment action did not provide an adequate remedy for the failure to give notice of commercial launch. *Amgen*, 2015 U.S. App. LEXIS 12523 at *26. That was correct, but that is also the case here and will always be the case. The BPCIA provides a 180-day period after FDA approval and before commercial launch "to allow the RPS a period of time to assess and act upon its patent rights." *Id.* at *27. The statute provides that such a notice "shall" be given and nothing about the statute suggests anything other than that it means what it says.

IV. EVEN IF A NOTICE WERE ONLY MANDATORY IN CERTAIN CIRCUMSTANCES, THOSE CIRCUMSTANCES ARE PRESENT HERE

Even if *Amgen* could be read to hold that paragraph (l)(8)(A) is mandatory only where the biosimilar applicant, like Sandoz, does not comply with paragraph (l)(2)(A), it would still

mean that the notice is mandatory in this case. Like Sandoz, Defendants also did not comply with the pre-litigation information disclosure requirements of paragraph (l)(2)(A). As a result, *Amgen* would be directly controlling even under Defendants' mistaken reading of the decision.

As the text of the BPCIA makes clear, paragraph (l)(2)(A) requires a biosimilar applicant to disclose not only its aBLA, but also "*such other information* that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A) (emphasis added). Here, while Defendants provided Plaintiffs a copy of their aBLA, they openly refused to provide any "other information" about their manufacturing processes. *See* Plaintiffs' 56.1 Statement of Undisputed Facts ¶ 10 (Dkt. No. 34-2); Carey Decl. ¶ 11 and Exs. A & B (Dkt. No. 37). Defendants' failure to provide the required manufacturing information put Janssen in precisely the same position with respect to its manufacturing patents as Sandoz's violations of paragraph (l)(2)(A) put Amgen. Without manufacturing information, Janssen could not fully assess infringement of their manufacturing patents prior to bringing this lawsuit. *See* Plaintiffs' 56.1 Statement of Undisputed Facts ¶ 36 (Dkt. No. 34-2); Carey Decl. ¶ 49 (Dkt. No. 37). In order to protect its rights, Janssen filed patent infringement claims on certain manufacturing patents pursuant to 35 U.S.C. § 271(e)(2)(C)(ii), which makes the failure to provide required information an act of infringement. Dkt. No. 1 at ¶¶ 170-184 . As the Federal Circuit noted, this is just what Amgen did when Sandoz failed to provide its aBLA. *Amgen*, 2015 U.S. App. LEXIS 12523 at *8-*9; *see also* Complaint for Patent Infringement, Conversion, and Unfair Competition at ¶¶ 98-106, *Amgen, Inc. v. Sandoz, Inc*., No. 14-cv-4741, 2015 U.S. Dist. LEXIS 34537 (N.D. Cal. Mar. 19, 2015).

Moreover, as the facts have unfolded, Defendants' failure to comply with paragraph (l)(2)(A) makes it particularly important for them to have a 180-day window after FDA licensure

in which to assess their rights. As set forth in Janssen's separate motion to file a new complaint, *see* Dkt. No. 69, discovery undertaken after litigation has commenced has confirmed Janssen's suspicion of infringement with respect to at least one of Janssen's manufacturing patents. Indeed, the infringement is far more widespread than Janssen could have guessed without discovery. Even so, the discovery has proceeded very slowly – not over eight years but just a few months – and Janssen is far from the position it would have been in had Defendants complied with their disclosure obligation under paragraph (l)(2)(A) in the first instance. Because of Defendants' violation of their disclosure obligations, Janssen needs the 180-day window provided by the statute in order to assess its rights and decide whether to seek a preliminary injunction barring the launch of Defendants' biosimilar.

Because Janssen is in the same position as Amgen with respect to its manufacturing patents, there is no possible way to distinguish the decision, even on the incoherent ground that Defendants propose. Based on Defendants' failure to comply with the paragraph (l)(2)(A) disclosure requirements, Janssen has brought claims for patent infringement pursuant to 35 U.S.C. § 271(e)(2)(C)(ii). The declaratory judgment right created by paragraph (l)(9)(B) is therefore utterly superfluous. Furthermore, although Janssen, like Amgen, asserted certain manufacturing patents to protect their rights, Janssen was also "unable to compile" a proper pre-litigation list of potentially infringed manufacturing patents pursuant to (l)(3)(A) of the BPCIA, because it lacked the information with which to do so. *Amgen*, 2015 U.S. App. LEXIS 12523 at *26. As in *Amgen*, any purported remedy in paragraph (l)(9)(B) "does not apply in this case." *Id.*

V. UNDER *AMGEN*, JANSSEN IS ENTITLED TO AN INJUNCTION ENFORCING THE STATUTORY 180 DAY NOTICE PERIOD

In addition to compelling the conclusion that Defendants are required to provide a notice of commercial marketing after their proposed biosimilar product is licensed, *Amgen* also holds that this requirement must be enforced by an injunction.

In the pending motion, Janssen presented two bases for injunctive relief: (1) an injunction is warranted to force Defendants to obey the statutory 180-day notice period in order to protect Janssen from the procedural injury of a violation of paragraph (l)(8)(A); and (2) an injunction is warranted under the traditional *eBay* factors to avoid the immense irreparable harm that an infringing launch of Defendants' proposed biosimilar product would case to Janssen's business. Dkt. No. 34 at 21-23. The *Amgen* court found the first reason, procedural injury, to be sufficient and ordered a mandatory 180-day injunction without reference to the *eBay* factors. *See Amgen*, 2015 U.S. App. LEXIS 12523 at *24-28.

Procedural injury warrants injunctive relief where a statute creates a procedural right to protect an important substantive interest (here, the irreparable harm of infringing launch) so that "irreparable injury is presumed to flow" from deprivation of that right. *CoxCom, Inc. v. Chaffee*, 536 F.3d 101, 112 n.14 (1st Cir. 2008). In such cases, an "automatic statutory injunction" is appropriate to enforce the procedural right. *Miller ex rel. S.M. v. Bd. of Educ.*, 565 F.3d 1232, 1252 n.13 (10th Cir. 2009) (statutory provision requiring maintenance of status quo during pendency of proceedings imposes "an automatic statutory injunction" on parties) (quoting *Norman K. ex rel. Casey K. v. St. Anne Cmty. High Sch. Dist. No. 302*, 400 F.3d 508, 510-11 (7th Cir. 2005)).

Amgen holds that the 180-day notice period of paragraph (l)(8)(A) should be enforced by such an automatic statutory injunction. As noted, the Federal Circuit held that an order enforcing

the notice period followed directly from the fact that it was mandatory, concluding without further discussion that "Sandoz therefore may not market Zarxio before 180 days" after it provided a proper notice. *Amgen, Inc. v. Sandoz, Inc.* 2015 U.S. App. LEXIS 12523, at *27-*28. Notably, Sandoz had vigorously argued, both before the district court and on appeal, that Amgen was not entitled to an injunction under the *eBay* factors, even if paragraph (l)(8)(A) was mandatory[4], and it prevailed on that issue in the district court. *Amgen, Inc. v. Sandoz, Inc.*, No. 14-cv-4741, 2015 U.S. Dist. LEXIS 34537, at *30-33 (N.D. Cal. Mar. 19, 2015), *aff'd in part and vacated in part*, No. 2015-1499, 2015 U.S. App. LEXIS 12523 (Fed. Cir. July 21, 2015). In concluding without any discussion of the *eBay* factors that, because the notice was mandatory, Sandoz "therefore" should be to ordered to comply with the 180-day notice period, the Federal Circuit necessarily held that paragraph (l)(8)(A) is enforceable by a statutory injunction to avoid procedural injury. This was the result even though Amgen had not sought a preliminary injunction to enforce any of its patents and apparently had no intention of doing so.

Based on the reasoning of *Amgen*, this Court does not need to address the expert and factual evidence Plaintiffs have submitted establishing their irreparable harm. *Amgen*, 2015 U.S. App. LEXIS 12523 at *24-28. It should simply issue an order requiring Defendants to comply with the requirements of paragraph (l)(8)(A). Of course, if the Court chooses to consider the evidence with respect to irreparable harm, it is more than sufficient to warrant an injunction under *eBay.*

[4] *See* Sandoz, Inc.'s Opposition to Amgen's Motion for a Preliminary Injunction at 8-24, *Amgen, Inc. v. Sandoz, Inc.*, No. 14-cv-4741, 2015 U.S. Dist. LEXIS 34537 (N.D. Cal. Mar. 19, 2015); Brief for Defendant-Appellee Sandoz, Inc. at 60-63, *Amgen, Inc. v. Sandoz, Inc.* 2015 U.S. App. LEXIS 12523 (Fed. Cir. July 21, 2015).

Dated: August 24, 2015

Respectfully submitted,

/s/ Heather B. Repicky

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CERTIFICATE OF SERVICE

I certify that on August 24, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ Heather B. Repicky
Heather B. Repicky

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF GREGORY L. DISKANT IN SUPPORT OF PLAINTIFFS' SUPPLEMENTAL MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION

I, Gregory L. Diskant, declare and state as follows:

1. I am a partner at the law firm Patterson Belknap Webb & Tyler LLP, counsel for Janssen Biotech, Inc. and New York University, and as such I am familiar with the facts stated herein.

2. Attached hereto as Exhibit 1 is a true and correct copy of an email exchange between myself and Charles B. Klein, dated July 22 and 27, 2015.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 24, 2015

Respectfully submitted,

/s/ Gregory L. Diskant

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CERTIFICATE OF SERVICE

I certify that on August 24, 2015, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ Heather B. Repicky
Heather B. Repicky

EXHIBIT 1

From: Klein, Chuck [mailto:CKlein@winston.com]
Sent: Monday, July 27, 2015 10:42 AM
To: Diskant, Gregory L. (x2710)
Subject: RE: Notice of commercial launch

Dear Greg,

Thank you for your email. We agree that the parties should withdraw their cross-motions for summary judgment on whether Celltrion and Hospira's notice of commercial marketing provided on February 5, 2015, was effective. It was not effective under the majority's decision in *Amgen Inc. v. Sandoz Inc.*, 2015 WL 4430108 at *9 (Fed. Cir. Jul 21, 2015). Of course, we reserve the right to seek appropriate relief if that ruling were changed by the *en banc* Court or the Supreme Court.

Nevertheless, you have misread the Federal Circuit's ruling as requiring Hospira/Celltrion to delay their launch until 180 days after FDA approval. The court held that the BPCIA does not require applicants like Celltrion that have timely produced its aBLA to provide any notice of commercial marketing, thus foreclosing the relief Janssen requests in its motion for injunctive relief. *Id.* at *9-*10.

The Federal Circuit concluded that, where "a subsection (k) applicant *completely fails to provide its aBLA and the required manufacturing information* to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory." *Id.* at *10 (emphasis added). Effective notice was thus mandatory in that case only because Sandoz could not rely on "any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A)." *Id.* (finding that the remedy in paragraph (*l*)(9)(B) does not apply because Sandoz did not timely provide its aBLA).

This case presents the opposite situation. Janssen has not alleged, and cannot allege, that Celltrion "completely fail[ed] to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline[.]" *Id.* Celltrion timely provided its aBLA, which includes manufacturing information, to Janssen under the BPCIA. *See* Compl. ¶ 104 ("Pursuant to section 262(l)(2)(A) of the BPCIA, Defendants began to provide Janssen with a copy of their aBLA (No. 125544) twenty days after the application was accepted for review by FDA."). Here, unlike in *Amgen*, the notice of commercial marketing is not mandatory, because the statute expressly provides a remedy when notice is not provided. Neither Celltrion nor Hospira will voluntarily agree to invoke a non-mandatory provision that would require them to delay launching their product until 180 days after licensure. Paragraph (*l*)(9)(B) provides Janssen's sole remedy. *See Amgen*, 2015 WL 4430108, at *10.

The Court's decision further confirms that paragraph (*l*)(8)(B) addresses a situation not present here and, therefore, such a launch delay would be pointless. The process underlying the notice "allows the RPS a period of time to seek a preliminary injunction *based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents (collectively, 'non-listed patents')*." *See id.* at *2 (emphasis added). Where, as here, there are no "non-listed patents," the 180-day notice provision serves no purpose.

In sum, *Amgen* bars Janssen's request for a 180-day injunction and, therefore, its motion for such relief should be withdrawn along with the cross-motions for summary judgment. If Janssen intends to seek a preliminary

injunction based on any of its asserted patents, we should discuss an appropriate schedule to avoid inconveniencing the Court with emergency motions practice.

Regards,
Chuck

From: Diskant, Gregory L. (x2710) [mailto:gldiskant@pbwt.com]
Sent: Wednesday, July 22, 2015 3:47 PM
To: Klein, Chuck
Subject: Notice of commercial launch

Dear Chuck,

Now that the meaning of section 262(l)(8)(A) has been authoritatively interpreted by the Federal Circuit, it is clear that the purported notice of commercial launch provided by Celltrion is ineffective and that an effective notice cannot be provided until after FDA approval of Celltrion's biosimilar version of Remicade. Accordingly, please confirm that Celltrion will not launch its product until 180 days after providing an effective notice of launch after an FDA approval. If Celltrion agrees to comply with this requirement, there is no need for either our motion for summary judgment on the meaning of paragraph (l)(8)(A) or our motion for an injunction on the same subject. Assuming that is so, we would like to advise the court promptly that our motion is withdrawn. Please advise me by July 29 of Celltrion's position. Thanks much.

Greg

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