IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

AMGEN INC. and AMGEN MANUFACTURING LIMITED	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 15-cv-61631-JIC/BSS**
	)	
APOTEX INC. AND APOTEX CORP.,	)	
Defendants.	)	
_____	)	

MOTION OF JANSSEN BIOTECH, INC. FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS AMGEN INC.'S AND AMGEN MANUFACTURING LIMITED'S MOTION FOR PRELIMINARY INJUNCTION

Janssen Biotech, Inc. ("Janssen") moves for leave to file the attached brief as *amicus curiae* (Exhibit A hereto) in support of Plaintiffs Amgen Inc.'s and Amgen Manufacturing Limited's Motion for Preliminary Injunction. Janssen notified both parties prior to seeking leave to file this brief. Amgen informed us that they do not oppose. Apotex informed us that they do not consent.

Janssen is currently litigating a similar issue in the District of Massachusetts, *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Mar. 6, 2015), and believes that the Court may benefit from an additional perspective on the seemingly arcane but highly consequential question at issue in this motion. The ultimate resolution of this question is of fundamental importance to the operation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").

The fact, extent, and manner of participation by an *amicus curiae* are within the sound discretion of the Court. *See Resort Timeshare Resales, Inc. v. Stuart*, 764 F. Supp. 1495, 1501 (S.D. Fla. 1991). Janssen's brief will be helpful to the Court because, among other things, it highlights additional circumstances within Janssen's experience that illustrate how a mandatory notice of commercial marketing furthers the statutory purpose of the BPCIA as described in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). The brief also provides an additional reason why Apotex is mistaken to assert that a statutory 180-day notice is not mandatory because the BPCIA provides a remedy for non-compliance.

Janssen therefore respectfully requests that the Court grant this motion for leave to file the attached brief.

CERTIFICATE OF GOOD FAITH CONFERENCE

Pursuant to Local Rule 7.1(a)(3), undersigned counsel for Janssen Biotech certifies to the Court that counsel for Janssen has conferred with counsel for Amgen and Apotex in a good faith effort to resolve by agreement the issues raised in this motion As noted above, Amgen informed us that they do not oppose, while Apotex informed us that they do not consent.

Dated October 30, 2015

By: */s/ John A. Camp*

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CERTIFICATE OF SERVICE

I certify that on October 30, 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/ John A. Camp

IN THE UNITED STATES DISTRICT COURT
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AMGEN INC. and AMGEN MANUFACTURING LIMITED **Plaintiffs,**	)	
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APOTEX INC. AND APOTEX CORP., **Defendants.**	)	

[PROPOSED] MEMORANDUM OF LAW
OF *AMICUS CURIAE* JANSSEN BIOTECH, INC.
IN SUPPORT OF PLAINTIFFS AMGEN INC.'S AND AMGEN MANUFACTURING LIMITED'S MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

I. Introduction and Interests of *Amicus Curiae*

Amicus curiae Janssen Biotech, Inc. ("Janssen") files this brief in support of Amgen's motion for a preliminary injunction because we are currently litigating a similar issue in the District of Massachusetts and believe that the Court may benefit from an additional perspective on the seemingly arcane but highly consequential question at issue in this motion.[1] The ultimate resolution of this question is of fundamental importance to the operation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), the statute governing the approval of biosimilars, or follow-on versions of innovative biological medicines.

Amgen's motion concerns 42 U.S.C. § 262(*l*)(8)(A) ("paragraph (*l*)(8)(A)") of the BPCIA, which requires a biosimilar applicant to provide the innovator or "reference product sponsor" ("RPS") 180 days' notice before the first commercial marketing of its biosimilar product. In *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), the only appellate decision to address the BPCIA to date, the Federal Circuit expressly rejected the position that every U.S. biosimilar applicant (including Apotex here) had taken up to that time, namely that the paragraph (*l*)(8)(A) notice could be provided *before* a proposed biosimilar product was licensed for sale in the United States. The *Amgen* court held that a biosimilar applicant may "only give effective notice of commercial marketing *after* the FDA has licensed its product." *Id.* at 1357 (emphasis added).

The biosimilar applicants' position that a notice of commercial marketing could be provided before approval would have rendered the requirement toothless, since applicants could – and, indeed, did – provide notice long before commercial launch was imminent in an attempt to

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[1] *Amicus* notified both parties prior to seeking leave to file this brief. Amgen informed counsel for Amicus that they do not oppose. Apotex informed counsel for Amicus that they do not consent.

Neither party's counsel authored any part of this brief. No party, party's counsel or other person besides Janssen contributed money to fund the preparation or submission of this brief.

preserve their rights to launch at their convenience. The *Amgen* court explained that the notice requirement, rather than being a mere formality, provided a "defined statutory window" of 180 days after approval and before commercial marketing in which the "court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product," including by considering and potentially adjudicating a motion for a preliminary injunction based on the innovator's patents. *Id.* at 1358. This "defined statutory window" is a fundamental element of the BPCIA's scheme for the adjudication of patent disputes.

Amgen's present motion challenges a new, but equally erroneous, argument by biosimilar applicants about the meaning of paragraph (*l*)(8)(A) in the wake of the *Amgen* decision. In this action, Apotex has taken the position that even after *Amgen v. Sandoz*, a biosimilar applicant may choose not to provide the 180-day notice of commercial marketing required by paragraph (*l*)(8)(A) if it previously complied with the information disclosure requirements of the BPCIA (42 U.S.C § 262(*l*)(2)(A)). In Janssen's pending action, *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Mar. 6, 2015) ("*Janssen Biotech*"), the biosimilar applicant has taken essentially the same position. The import of the biosimilar applicants' position is that applicants would have the ability, at their discretion, to eliminate the "defined statutory window" described in *Amgen v. Sandoz.*

Like Amgen, Janssen disagrees with the biosimilar applicants' view of the BPCIA as interpreted by the Federal Circuit in *Amgen v. Sandoz.* Janssen agrees with Amgen's arguments. Rather than duplicating them here, we will highlight two points. First, a mandatory notice of commercial marketing furthers the statutory purpose of the BPCIA as described in *Amgen v. Sandoz*, a point which is illustrated by the facts in the *Janssen Biotech* litigation. Second, Apotex's argument that the statutory 180-day notice is not mandatory because the BPCIA

provides a remedy for non-compliance is wrong. The fact that an RPS may file a declaratory judgment action does not provide a remedy for failure to give a notice of commercial marketing. Not only can an RPS file such an action whether or not notice of commercial marketing is given (as Amgen points out), but more fundamentally, a declaratory judgment action is meaningless once an applicant has chosen to launch its biosimilar product without prior notice. In such a case, the RPS already has the unfettered right to file a patent infringement action against the biosimilar company under existing patent law.

II. The Purpose of Paragraph (*l*)(8)(A), as Explained in *Amgen*, Compels the Conclusion that a Notice of Commercial Marketing Is Mandatory

In the *Amgen* decision, the Federal Circuit held that the notice of commercial marketing must be provided after licensure because this was the only way to effectuate what "Congress intended." *Amgen,* 794 F.3d at 1358. 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.* The BPCIA requires notice to follow licensure because until then, 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.

As Amgen points out in its motion, the purpose of paragraph (*l*)(8)(A), as explained by the *Amgen* decision, would be eviscerated if a biosimilar applicant could simply opt not to provide a notice of commercial marketing at all. 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.*, 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 the *Amgen* decision holds, that is precisely what the notice requirement of paragraph (*l*)(8)(A) prevents.

The circumstances of the *Janssen Biotech* litigation provide a concrete example of Congress's wisdom in providing for a mandatory 180-day post-licensure period during which the innovator may bring a preliminary injunction. Defendants in *Janssen Biotech* seek to market a biosimilar version of Janssen's Remicade® (infliximab) biologic. Janssen has asserted a number of patents against the Defendants. Since Janssen filed suit last spring, a scheduled advisory committee meeting on the Defendants' proposed product was canceled and it is now uncertain when, or if, the proposed biosimilar will be approved. Prior to approval, a motion for a preliminary injunction is premature, and may turn out to be unnecessary, for *every one* of the patents Janssen has asserted. Without a 180-day window for bringing a preliminary injunction

motion after approval, Janssen would be forced to bring a motion early to protect its rights. This would impose unnecessary burdens on the parties and the courts.

In the *Janssen Biotech* case the Defendants have applied for FDA approval to market their biosimilar product to treat a whole range of autoimmune diseases, including Crohn's disease. One of Janssen's patents, the 396 patent, covers specific methods of using infliximab to treat patients with Crohn's disease. It expires in June 2016. Because the 396 patent is limited to this particular method of use, litigating this patent will be necessary if, and only if, the FDA approves the product for Crohn's disease and does so before the patent expires. (An approval that does not extend to Crohn's disease is not imaginary; that is what happened in Canada.) The scope of approval will be unknown until the FDA decides to issue a license.

Another of Janssen's patents, the 715 patent, expired on September 15, 2015 – just over six months after Janssen filed suit. Janssen filed a preliminary injunction motion seeking to enforce the 180-day notice requirement of paragraph (*l*)(8)(A), rather than attempt to bring a premature motion to enforce the 715 patent. If Apotex's reading of the BPCIA were to prevail, however, a future innovator in Janssen's position would be obliged to seek a preliminary injunction when FDA approval possibly appeared imminent, even if the patent was on the eve of expiration. Instead of that wasteful motion, Janssen was able to dismiss its claim under the 715 patent when it expired.

Yet another of Janssen's patents, the 471 patent, is in reexamination at the U.S. Patent and Trademark Office ("PTO"), has been rejected, and is the subject of an appeal to the PTO's Patent Trial and Appeal Board. Until the uncertainty caused by the reexamination is clarified, Janssen will not be in a position to move for a preliminary injunction. By the time Defendants' proposed biosimilar is approved (if it is), however, the 471 patent may have emerged from reexamination.

In that case, Janssen would use the 180-day window to seek a preliminary injunction prior to any launch by Defendants.

Janssen also holds three patents related to the manufacture of infliximab. The facts surrounding the three manufacturing patents illustrate why it is particularly important – after the *Amgen* decision – for an RPS in Janssen's position to have a 180-day window after FDA licensure in which to assess its rights. Defendants in *Janssen Biotech* refused to comply with the disclosure provisions of 42 U.S.C § 262(*l*)(2)(A) and said that they would provide manufacturing information only if they were sued on those patents. The *Amgen* court has held that compliance with these provisions is voluntary, thus assuring that this fact pattern will repeat in the future. Because refusing to provide information is a technical act of infringement under the BPCIA, Janssen thereafter filed suit. Defendants have provided limited information confirming infringement with respect to at least one of the manufacturing patents. It has also shown that the Defendants are not infringing another patent, which Janssen has dismissed. Whether Defendants infringe a third manufacturing patent is still uncertain. All of this has occurred without burdening the court with unnecessary motions for emergency relief.

Even with this progress, however, Janssen has obtained limited information and is not yet in a position to seek a motion for a preliminary injunction on the patent that it believes is infringed. The BPCIA permitted Janssen to file suit, but it also promises Janssen a 180-day window after the FDA approves the biosimilar in which to seek a preliminary injunction. Because infringement issues on manufacturing patents are complex and require discovery of the Defendant's processes before a case can be pursued, that 180-day window is essential if RPS's are to have a fair opportunity to discover the facts necessary to stop a market launch that can cause them irreparable harm.

For Janssen to move now for a preliminary injunction on any of its patents would be a burden on the court system and a waste of resources for all involved. Yet if the BPCIA's 180-day notice provision were held to be optional, Janssen and other RPS's in its position would be forced to file premature motions for a preliminary injunction to protect their patent rights. Under the interpretation put forth by Apotex and the *Janssen Biotech* Defendants, a biosimilar applicant could launch its product on the very same day that it receives FDA approval, leaving the RPS no "period of time to assess and act upon its patent rights." *Amgen*, 794 F.3d at 1360. The RPS would thus find itself between a rock and a hard place, having to choose between a burdensome and unnecessary pre-launch motion for a preliminary injunction or accepting the irreparable harm of a biosimilar launch.

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

Both Apotex and the Defendants in *Janssen Biotech* contend that the paragraph (*l*)(8)(A) notice of commercial marketing must be optional because 42 U.S.C § 262(*l*)(9)(B) provides the RPS with its sole remedy for failure to give notice: filing a declaratory judgment action against an applicant who launches without notice. Sandoz made that argument in the *Amgen* case, and lost. *Id.* at 1359-60. Focusing on the facts of the case before it, the *Amgen* court concluded that a declaratory judgment action was not a remedy because Sandoz had not complied with any of the BPCIA's dispute resolution procedures, and thus there was no list of patents to enforce through a declaratory judgment action. *Id.* 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* a remedy for a failure to provide a notice of commercial marketing.

As Amgen accurately points out in its motion, the declaratory judgment right is not a remedy for failure to prove a notice of commercial marketing because the RPS may file a

declaratory judgment action *whether or not* the notice is given. But more fundamentally, 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.* at 1358. For example, as noted above, if FDA determines to approve the *Janssen Biotech* Defendants' biosimilar for Crohn's disease, Janssen will seek a preliminary injunction under its 396 Crohn's patent.

It is no remedy to tell Janssen that it can seek a preliminary injunction on the 396 patent via a declaratory judgment action *after* FDA has approved the biosimilar for Crohn's disease and the Defendants have launched their product. As an unbroken string of Federal Circuit decisions recognizes, a product launch of a lower-priced version of a branded product causes irreparable injury to the branded competitor. *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 by the right to seek a declaratory judgment.

Second, and equally importantly, the right to seek a declaratory judgment is meaningless in these circumstances. Under the reading urged by the *Janssen Biotech* Defendants and,

potentially, Apotex, the right to bring a declaratory judgment accrues only if a competitor launches its product without proper notice (*i.e.*, "fails to complete an action required of the subsection (k) applicant," 42 U.S.C § 262(*l*)(9)(B)). Of course, failure to give notice can only occur *after* the biosimilar launches its product. 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, and seek a preliminary injunction, 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 for the applicant's failure to provide a 180-day pre-launch notice.

On the facts before it, the *Amgen* court found that the 42 U.S.C § 262(*l*)(9)(B)) declaratory judgment action did not provide a remedy for the failure to give notice of commercial launch. *Amgen*, 794 F.3d at 1359. That was correct, but that is also the case here and will always be the case. 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. Conclusion

For all the reasons set forth above and in Amgen's Motion for Preliminary Injunction, the Court should grant Amgen's Motion for a Preliminary Injunction.

CERTIFICATE OF GOOD FAITH CONFERENCE

Pursuant to Local Rule 7.1(a)(3), undersigned counsel for Janssen Biotech certifies to the Court that counsel for Janssen has conferred with counsel for Amgen and Apotex in a good faith effort to resolve by agreement the issues raised in this motion. As noted above, Amgen informed us that they do not oppose, while Apotex informed us that they do not consent.

Dated October 30, 2015

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