UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 15-cv-61631-JIC/BSS

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

DEFENDANTS APOTEX INC. AND APOTEX CORP.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND INCORPORATED MEMORANDUM OF LAW

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Amgen's theory behind its motion for a preliminary injunction rests on two propositions: 1) that the notice of commercial marketing provision in the Biological Price Competition and Innovation Act (42 U.S.C. § 262 *et seq*., "the BPCIA") is mandatory in all cases (not just when a biosimilar applicant "opts out" of the patent-dispute resolution process), and 2) that the notice of commercial marketing provision is "standalone" and operates independently of other provisions in the statute. Neither proposition is true, and Amgen must cherry-pick from both the *Amgen v. Sandoz* case and the BPCIA to argue otherwise.

Indeed, the full picture shows the weakness in Amgen's position. First, the BPCIA itself disposes of Amgen's theory in full. In short, 42 U.S.C. § 262 (*l*)(9)(B) provides Amgen with the sole remedy available when a biosimilar applicant (Apotex in this case) follows the patent-dispute resolution process but does not provide a notice of commercial marketing—allowing Amgen to file a declaratory judgment action asserting any patents on its patent list. Not coincidently, that is exactly where the parties find themselves today, with all patents from Amgen's patent list the subject of the present litigation.

In support of its selective reading of the BPCIA, Amgen misstates the holding in *Amgen v. Sandoz* by asserting that the 180-day notice of commercial marketing provision is mandatory in all cases. That is manifestly untrue—the precedent in *Amgen v. Sandoz* is directed to situations where the biosimilar applicant does not comply with the patent-dispute resolution process. There is simply no basis to assert that the Federal Circuit held that the notice provision is mandatory in *all* cases, particularly where, as here, Apotex has fully complied with the patent-dispute resolution process culminating in the present litigation. In fact, the Federal Circuit's majority opinion directly supports Apotex's interpretation of the statute.

In reality, Amgen seeks to elevate a notice provision, which is otherwise interconnected with other parts of the statutory patent-dispute resolution process, into a *de facto* marketing exclusivity. This is the core reason why Amgen is advancing this position instead of filing for patent-based injunctive relief. If Amgen had any confidence in its patent rights, it would seek to enjoin Apotex on that basis. Thus, Apotex respectfully urges the Court to reject Amgen's interpretation of the statute and deny Amgen's motion.

I. PRELIMINARY STATEMENT

This dispute concerns the notice of commercial marketing provision of the BPCIA, 42 U.S.C. § 262(*l*)(8)(A).[1] Amgen contends that this provision is mandatory, and that effective notice can only be given after FDA-approval of Apotex's biosimilar application ("aBLA"). Amgen's reading of this provision is flawed because paragraph (*l*)(8)(A) cannot be read in isolation. Indeed, paragraph (*l*)(9)(B) clearly contemplates a situation where, as here, a biosimilar applicant has provided its aBLA to the reference product sponsor ("RPS"), but subsequently elects not to provide the RPS with a notice of commercial marketing. In this scenario, the RPS has a clear statutory remedy under paragraph (*l*)(9)(B)—it can file a declaratory judgment action against the biosimilar applicant asserting any patent on its patent list. To be clear, the statutory remedy provided by the BPCIA is standing to seek patent-based injunctive relief. Indeed, nothing in the BPCIA prevents a RPS that files a declaratory judgment action under these circumstances from seeking patent-based injunctive relief.

Paragraph (*l*)(9)(B) applies to this case because Apotex, the biosimilar applicant, and Amgen, the RPS, fully engaged in the patent-dispute resolution outlined in paragraphs (*l*)(2) through (*l*)(4) of the BPCIA. Indeed, Amgen does not dispute that Apotex provided its aBLA to Amgen and that Amgen identified relevant patents on its paragraph (*l*)(3)(A) patent list. Nor does Amgen dispute that the parties exchanged detailed statements regarding infringement, validity, and unenforceability, and that the parties even negotiated which patents to include in the present lawsuit. Finally, Amgen cannot dispute that every unexpired patent identified on its patent list is the subject of the present lawsuit.

Papering over the clear statutory construct of paragraph (*l*)(9)(B), Amgen spends many pages arguing that the Federal Circuit's opinion in the *Amgen v. Sandoz* case supports its interpretation of the BPCIA. To the contrary, the Federal Circuit's opinion actually supports Apotex's interpretation, not Amgen's. Specifically, the majority held that when a biosimilar applicant chooses **not** to provide its aBLA to the RPS, as was the case with Sandoz, then the notice of commercial marketing is mandatory. *See Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1360 (Fed. Cir. 2015). **That is not what happened in this case, where Apotex provided its pegfilgrastim aBLA to Amgen**. Importantly, the same majority suggested that if a biosimilar

[1] The various paragraphs of 42 U.S.C. § 262 (*l*) that are the subject of this opposition may be referred to as "paragraph (*l*)__" throughout.

applicant provides the RPS with its aBLA and thus complies with paragraph (*l*)(2)(A) of the statute, as Apotex has done here, the RPS's remedy for the biosimilar applicant's decision not to provide a notice of commercial marketing is laid out in paragraph (*l*)(9)(B), as explained above. *See id.* at 1359.

Additionally, there is no need to look further than the purpose of the notice of commercial marketing to understand why it cannot be mandatory for a biosimilar applicant that has provided its aBLA to the RPS and engaged in the patent-dispute resolution. Importantly, the notice of commercial marketing only gives Amgen standing to seek a preliminary injunction based on patents from its patent list that have not yet been asserted. Here, Apotex and Amgen agreed that the present litigation would include **all** of the unexpired patents from Amgen's patent list. Therefore, even if Apotex were to provide Amgen a notice of commercial marketing, Amgen has no statutory recourse because no patents remain from its list that could be asserted in a declaratory judgment action. Thus, in this case a mandatory notice of commercial marketing would serve no purpose except to give Amgen an improper 180-day exclusivity on top of the 12 years of exclusivity it has already enjoyed under the BPCIA.

All of this begs the question: Why didn't Amgen file for a preliminary injunction based on the patents that are currently in this lawsuit? Amgen certainly could have done so, as such relief was requested in its Complaint. (*See* D.E. 1, Prayer for Relief at ¶¶ B, E.) When the BPCIA addresses injunctive relief, it refers to patent-based injunctive relief, not injunctive relief based on the statute. Amgen can point to no provision in the BPCIA that provides for injunctive relief based on the statute, as it requests here. Indeed, the BPCIA contains no rights-creating language that would entitle Amgen to a private right of action to enforce the statute.

In the end, this case is a result of the parties following the BPCIA to arrive where Congress intended—in a lawsuit that involves patents that were negotiated by the parties. Amgen has no basis to file a motion for a preliminary injunction based solely on its erroneous interpretation of the BPCIA. Therefore, Amgen's motion must be denied.

II. FACTUAL BACKGROUND

Apotex has incorporated all facts necessary to resolve Amgen's motion into the Argument section below. However, the following facts are undisputed and critical to understanding why Amgen's motion for a preliminary injunction must fail:

1) Apotex provided Amgen with its pegfilgrastim aBLA and manufacturing information pursuant to paragraph (*l*)(2)(A) (D.E. 42 at 6);
2) Amgen provided Apotex with a list of patents that it reasonably believed a claim of patent infringement could be asserted pursuant to paragraph (*l*)(3)(A) (*Id.*);
3) Apotex provided Amgen with a statement that it would not market prior to the expiration of two of the patents on Amgen's patent list and a detailed statement of its factual and legal basis why the only remaining patent on Amgen's patent list would not be infringed or is invalid pursuant to paragraph (*l*)(3)(B) (*Id.*);
4) Amgen provided Apotex with a detailed statement as to why the only remaining patent was infringed and is not invalid pursuant to paragraph (*l*)(3)(A) (*Id.*);
5) The parties negotiated and decided that all of the unexpired patents from Amgen's patent list would be litigated pursuant to paragraphs (*l*)(4) and (*l*)(5) (*Id.* at 6-7);
6) Amgen's Complaint, filed August 2, 2015, asserted all of the unexpired patents from its patent list, included a declaratory judgment claim for these patents, and asked for preliminary and permanent injunctive relief on these patents (*Id.* at 7); and
7) No unasserted patents remain from Amgen's patent list that are not in the present litigation. (*Id.* at 6-7).

III. LEGAL STANDARD

A party moving for a preliminary injunction must show that: (1) it has a substantial likelihood of success on the merits; (2) a substantial likelihood it would be irreparably harmed if injunctive relief were denied; (3) that the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest. *See Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc); *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998). In the 11th Circuit, "[a] preliminary injunction is an extraordinary and drastic remedy not to be granted unless the movant clearly established the 'burden of persuasion'" as to all four elements. *Siegel*, 234 F.3d at 1176. As such, the 11th Circuit uses a "sequential" test which requires the movant to establish each of the four factors independently. *See id.* Preliminary injunctions will be denied due to a failure to show one element. *See Palmer v. Braun*, 287 F.3d 1325, 1329 (11th Cir. 2002). Further, the 11th Circuit requires a "substantial likelihood" of success on the merits. *Id.*

IV. ARGUMENT

Because the parties agree that Amgen's motion must be denied if Amgen cannot prove success on the merits, the parties have stipulated to the remaining factors of the test for preliminary injunctive relief.

Amgen is not entitled to injunctive relief because its interpretation of the BPCIA is wrong. Instead, both the BPCIA and the Federal Circuit's opinion in the *Amgen v. Sandoz* case support Apotex's interpretation of the statute. Because Apotex provided its pegfilgrastim aBLA to Amgen and engaged in the patent-dispute resolution, Apotex is not required to provide a notice of commercial marketing. If Apotex fails to do so, the statute provides Amgen with a remedy, which is to file a declaratory judgment action on the patents from its patent list. Indeed, Amgen has already done just that, filed for a declaratory judgment action on all of the unexpired patents from its patent list. If Amgen wants to keep Apotex's pegfilgrastim product off the market, it should instead seek to do so based on its patents, which relief is clearly available to it under the statute. Instead, Amgen is attempting to delay Apotex's launch based on a misinterpretation of the statute in order to obtain relief that the statute does not provide. In sum, Amgen's motion is premised entirely on an incorrect interpretation of the BPCIA, is improper, and must be denied.

A. Amgen's Interpretation of Paragraph (*l*)(8)(A) of the BPCIA Would Render Paragraph (*l*)(9)(B) Superfluous

1. Paragraph (*l*)(9)(B) Provides Amgen With A Remedy If Apotex Fails to Provide a Notice of Commercial Marketing under Paragraph (*l*)(8)(A)

Because Apotex provided its pegfilgrastim aBLA to Amgen and engaged in the patent-dispute resolution with Amgen, Apotex is not required to give a notice of commercial marketing to Amgen. If Apotex chooses not to provide a notice of commercial marketing, paragraph (*l*)(9)(B) provides Amgen with a remedy. Paragraph (*l*)(9)(B) states:

> **(B) Subsequent failure to act by subsection (k) applicant**
> ***If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under*** paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or ***paragraph (8)(A)***, the 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 included in the list described in paragraph (3)(A), including as provided under paragraph (7). (emphasis added).

Notably, "paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or ***paragraph (8)(A)***" are steps that follow a biosimilar applicant providing its aBLA pursuant to paragraph (*1*)(2)(A). Thus, if a biosimilar applicant provides its aBLA to the RPS but fails to complete any of these next steps, paragraph (*l*)(9)(B) applies.

Where, as here, a biosimilar applicant has provided its aBLA, paragraph (*l*)(9)(B) clearly recognizes that a biosimilar applicant may elect not to provide a notice of commercial marketing (referred to as paragraph 8(A) in paragraph (*l*)(9)(B)). There is no other reasonable interpretation of paragraph (*l*)(9)(B). Just as clear is Amgen's remedy in such a situation—file a declaratory judgment action asserting one of the patents from its list. Importantly, mandatory compliance with paragraph (*l*)(8)(A) after Apotex has provided its pegfilgrastim aBLA to Amgen would render paragraph (*l*)(9)(B) superfluous, and statutes are to be interpreted, if possible, to avoid rendering any provision superfluous. *See Amgen*, 794 F.3d. at 1356 (citing *Marx v. Gen. Revenue Corp.,* 568 U.S. __, 133 S. Ct. 1166, 1178 (2013) ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme."); *TRW Inc. v. Andrews,* 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." (internal quotation marks omitted))).

2. Paragraphs (*l*)(9)(A) and (*l*)(9)(B) Provide for Declaratory Judgment Relief in Two Different Situations

Amgen makes much of paragraph (*l*)(9)(A) and erroneously argues that this paragraph of the statute does not allow Amgen to file a declaratory judgment until Apotex has provided the notice of commercial marketing. That is simply incorrect. Paragraph (*l*)(9)(A) states:

> **(A) Subsection (k) application provided**
> If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of ***any patent that is described in clauses (i) and (ii) of paragraph (8)(B).*** (emphasis added).

The bolded and italicized portion above is important because it enables an understanding of how paragraphs (*l*)(9)(A) and (*l*)(9)(B) fit together. Paragraphs (*l*)(8)(B)(i) and (ii), which are referenced above, state:

> **(B) Preliminary injunction**
>
> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) 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 patent that is—
>
> **(i) included in the list** provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); **and**
>
> **(ii) not included**, as applicable, on—
>
> **(I)** the list of patents described in paragraph (4); or
>
> **(II)** the lists of patents described in paragraph (5)(B).

42 U.S.C. § 262(*l*)(8)(B) (emphasis added).

The list provided by the RPS under paragraph (*l*)(3)(A) referred to in clause (i) above is Amgen's patent list. However, clause (i) cannot be read in isolation because of the "and" that connects it with, and requires it to be read in view of, the provisions of clause (ii). Whereas clause (i) is inclusory, clause (ii) is exclusory and places limitations on the patents upon which a RPS can seek injunctive relief. Specifically, clause (ii) excludes all patents described in paragraph (*l*)(4) or (*l*)(5)(B), which in this case, refers to the patents that Amgen and Apotex agreed to include in the current litigation. Therefore, because the parties in this case chose to include all of the patents from Amgen's list in the current litigation, there are no patents under clauses (i) and (ii) of paragraph (*l*)(8)(B) left for Amgen to assert in a declaratory judgment action.

Returning to paragraph (*l*)(9)(A), the statute is clear that Amgen cannot file a declaratory judgment action on patents referenced in clauses (i) **and** (ii) of paragraph (*l*)(8)(B) until after a notice of commercial marketing is provided by the biosimilar applicant. That makes sense since paragraph (*l*)(9)(A) allows only those patents not involved in a lawsuit to be asserted, and the RPS would need to file a declaratory judgment action before asking for injunctive relief. Logic dictates that these are the same patents that paragraph (*l*)(9)(A) is referring to when read in conjunction with paragraph (*l*)(9)(B). Indeed, paragraph (*l*)(9)(B) could not refer to a remedy for the RPS for a biosimilar applicant's failure to provide a notice of commercial marketing if

paragraph (*l*)(9)(A) would not allow the RPS to file a declaratory judgment action unless that very same notice of commercial marketing was provided.

B. *Amgen v. Sandoz* Supports Apotex's Interpretation of the Statute

Amgen argues that the majority in *Amgen v. Sandoz* held that the notice of commercial marketing under paragraph (*l*)(8)(A) is mandatory in all instances. This is simply incorrect. Instead, the majority held "[w]e therefore conclude that, **where, as here, 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." *Amgen*, 794 F.3d at 1360 (emphasis added). Thus, the majority in *Amgen* explicitly stated that its holding was limited to scenarios in which a biosimilar applicant elects not to follow the BPCIA pathway, and thus does not provide its aBLA to the RPS at the outset. Here, it is undisputed that Apotex provided its aBLA and required manufacturing information to Amgen by the statutory deadline. Therefore, the Federal Circuit's holding in *Amgen* does not control, but instead is only instructive.

What is more, the majority in *Amgen* provided guidance regarding whether the notice of commercial marketing provision of paragraph (*l*)(8)(A) is mandatory, stating that:

> While it is true that **paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A)**, it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with. Indeed, the consequence specified in paragraph (*l*)(9)(B) is a declaratory judgment action brought by the RPS based on "any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)." 42 U.S.C. § 262(*l*)(9)(B). Here, however, because Sandoz did not provide the required information to Amgen under paragraph (*l*)(2)(A), Amgen was unable to compile a patent list as described in paragraph (*l*)(3)(A) or paragraph (*l*)(7).

Id. at 1359 (emphasis added). Thus, the majority in *Amgen* discussed the interplay between paragraphs (*l*)(8)(A) and (*l*)(9)(B), and stated explicitly that there may be situations where, as here, a biosimilar applicant elects not to comply with the notice of commercial marketing provisions. Further, the majority indicates that this choice is only available to a biosimilar applicant that has complied with paragraph (*l*)(2)(A). Finally, the majority states that if this happens, the RPS can seek recourse under the provisions of paragraph (*l*)(9)(B). While the majority states that this does not apply in Sandoz's case because they did not comply with

paragraph (*l*)(2)(A), this scenario is precisely what has happened here between Amgen and Apotex. Thus, the majority opinion supports Apotex's reading of the statute, not Amgen's misinterpretation.

Further, the majority's holding that Sandoz was not required to follow the patent-dispute resolution procedures of the BPCIA is instructive here. Unlike Apotex here, Sandoz did not provide its aBLA to Amgen. The majority held that Sandoz was not required to provide its aBLA or follow the patent-dispute resolution procedures because paragraph (*l*)(9)(C) provided Amgen with a remedy. What was that remedy? Amgen could file a declaratory judgment action. Paragraph (*l*)(9)(C) of the BPCIA states that:

> If a subsection (k) applicant ***fails to provide the application and information required under paragraph (2)(A), the 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*** that claims the biological product or a use of the biological product. (emphasis added).

Applying the *Amgen* majority's reasoning to the facts at hand, it follows that a biosimilar applicant such as Apotex that provided its pegfilgrastim aBLA but elects not to provide a notice of commercial marketing under paragraph (*l*)(8)(A), likewise leaves the RPS (Amgen) the same remedy under paragraph (*l*)(9)(B). What is that remedy? The statute enables Amgen to file a declaratory judgment action.

Moreover, in considering the interplay of various provisions of the BPCIA, the *Amgen* majority held that "[i]mportantly, mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Amgen*, 794 F.3d at 1356. Again this supports Apotex's interpretation of the statute, mandating compliance with the notice of commercial marketing provision under paragraph (*l*)(8)(A) after a biosimilar applicant provided its aBLA to the RPS pursuant to paragraph (*l*)(2)(A) would render paragraph (*l*)(9)(B) superfluous.

As it did in the Amgen case, Amgen makes much of the word "shall" as used in the BPCIA. The majority's answer in *Amgen* is also instructive in this case. In *Amgen*, the majority stated:

> However, the "shall" provision in paragraph (*l*)(2)(A) cannot be read in isolation. In other provisions, the BPCIA explicitly contemplates

> that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It specifically sets forth the consequence for such failure: the RPS may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Those latter provisions indicate that "shall" in paragraph (*l*)(2)(A) does not mean "must." And the BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A).

Id. at 1355-56. Applying the same logic, the "shall" provision in paragraph (*l*)(8)(A) cannot be read in isolation. Other provisions of the BPCIA explicitly contemplate that a biosimilar applicant might not provide a notice of commercial marketing. Further, the BPCIA specifically sets forth the consequence for such a failure: the RPS may bring an infringement action under paragraph (*l*)(9)(B). Paragraph (*l*)(9)(B) indicates that "shall" in paragraph (*l*)(8)(A) does not mean "must." Additionally, the BPCIA has no other provision that grants a procedural right to compel compliance with the notice of commercial marketing requirement of paragraph (*l*)(8)(A).

Judge Chen's dissent also supports Apotex's interpretation. Judge Chen states that:

> Notably, nothing in the majority opinion suggests that this automatic injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A). In fact, the majority's opinion creates an uncomfortable result in which the language of (*l*)(8)(A) is interpreted in two different ways, based on the (k) applicant's actions. In a situation like the present case, the (k) applicant cannot refuse to provide the 180-days' notice, because under the majority's reading, (*l*)(8)(A) authorizes an automatic entitlement to a 180 day injunction. **But if a (k) applicant complies with all the requirements specified in (*l*)(2)-(*l*)(7), then the (k) applicant may still refuse to comply with the 180-day notice provision. In this scenario, there would be no automatic injunction because (*l*)(9)(B) provides the RPS with the authorization to immediately file suit on any patent it listed under (*l*)(3)**. Thus, in one scenario, (*l*)(8)(A) provides a 180-day injunction, but in the second scenario it does not. **While the result in the latter scenario comes from the plain language of the statute**, not so with the former.

Id. at 1371 (Chen, J., dissenting-in-part) (emphasis added). Thus, Judge Chen recognizes that if a biosimilar applicant complies with the patent-dispute resolution as Apotex did in this case, the biosimilar applicant may elect not to comply with the notice of commercial marketing under paragraph (*l*)(8)(A). Further Judge Chen recognizes that the remedy in such a situation exists under paragraph (*l*)(9)(B), which "comes from the plain language of the statute . . . ." *Id.*

C. The Notice of Commercial Marketing Provision Provides Amgen a Right to Seek a Preliminary Injunction on Patents From Its List That Are Not Included In this Litigation—Which is None

One need only to look to the purpose of the notice of commercial marketing provision under paragraph (*l*)(8)(A) to understand why it cannot be mandatory for a biosimilar applicant that followed the statutory pathway by providing its aBLA to the RPS and engaging in the patent-dispute resolution. Amgen acknowledges that the only patents that come under paragraph (*l*)(8) are those from Amgen's patent list that were not included in the paragraph (*l*)(6) lawsuit. (D.E. 42 at 7.) The paragraph (*l*)(6) lawsuit is the present litigation, which involves all of the unexpired patents from Amgen's patent list. Thus, it follows that because no unasserted patents remain from Amgen's patent list, the notice of commercial marketing serves no purpose. To be clear, Amgen's right to file for a preliminary injunction on patents already in the current litigation is not predicated on any action by Apotex, but instead lies solely with Amgen's own evaluation of the merits of the current litigation. Whether or not Apotex is required to provide a notice of commercial marketing does nothing to enlarge or diminish Amgen's right to seek preliminary injunctive relief in the current litigation, which Amgen notably has elected not to seek as of yet.

What is more, any assertion by Amgen that the notice of commercial marketing would enable it to seek injunctive relief based on newly issued or licensed patents is a plainly erroneous reading of the BPCIA. In the event that Amgen acquires or licenses new patents, those would fall squarely within the provision of paragraph (*l*)(7), which requires the parties to again exchange materials under paragraphs (*l*)(3)(A) and (*l*)(3)(B), and then determine whether or not such patents should be included in any pending litigation. Further, any such newly issued or licensed patent is subject to the provisions of paragraph (*l*)(8), which as discussed at length above, provides a remedy under paragraph (*l*)(9)(B) should Apotex elect not to provide a notice of commercial marketing. Again, in the event Apotex elects not to provide a notice of commercial marketing, then paragraph (*l*)(9)(B) enables Amgen to file a declaratory judgment action on any newly listed or licensed patents under paragraph (*l*)(7) that were not included in a pending litigation. Thus, the statute provides a clear mechanism for newly issued or licensed patents to be included in a pending litigation, and a newly issued or licensed patent would do nothing to make the notice of commercial marketing a mandatory provision. Regardless, here,

Amgen has not alleged that it has any newly issued or licensed patents that may be asserted against Apotex.

D. An Optional Notice of Commercial Marketing Would Not Frustrate the Purpose of the BPCIA

Amgen argues that this Court's failure to mandate the provisions of paragraph (*l*)(8)(A) would leave Amgen to guess at the scope of Apotex's aBLA, and that only upon FDA-approval of Apotex's aBLA will the present controversy be sufficiently crystallized to enable Amgen to seek preliminary injunctive relief without burdening this Court. (*See* D.E. 42 at 14-15.) However, these arguments are plainly at odds with the statutory provisions that Amgen would seek to rely upon in order to obtain injunctive relief.

Indeed, Amgen's argument is based on the faulty premise that Apotex providing a notice of commercial marketing suddenly provides Amgen with the right to file for injunctive relief. That is not correct. Amgen already has the right to file for injunctive relief on the patents in the present litigation and there is nothing about the notice of commercial marketing that affects those rights.

What is more, because Apotex elected to follow the disclosure provisions of paragraph (*l*)(2)(A), Amgen has now had more than 10 months to review Apotex's aBLA and manufacturing information, and then identified all patents that Amgen believed could be reasonably asserted based on Apotex's aBLA and manufacturing information. All of those patents were included in this litigation. Thus, if the notice provisions are mandatory, there would be no patents under clauses (i) and (ii) of paragraph (*l*)(8)(B) left for Amgen to seek injunctive relief, as explained in detail above. Further, at no point has Amgen alleged that Apotex's disclosure of its aBLA or manufacturing information was in any way deficient. Thus, there can be no doubt that where, as here, the biosimilar applicant has followed the patent-dispute resolution process of the BPCIA, there can be no statutory purpose served by delaying the launch of an aBLA product by 180 days so that a RPS has additional time to evaluate information that has been in its possession since the time the aBLA was first accepted at the FDA.

E. A Mandatory Notice of Commercial Marketing Would Provide Amgen a *de facto* 180-Day Extension of the 12-Year Statutory Exclusivity

The BPCIA provides a 12-year exclusivity period to a RPS, the result of which is that an aBLA cannot be approved by the FDA until 12 years after approval of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). The 12-year exclusivity period provided by the BPCIA was a result of

lengthy negotiation and determined to be commensurate in duration and scope to the patent protection typically afforded to innovative drugs.[2]

Thus, a mandatory notice of commercial marketing under paragraph (*l*)(8)(A) would serve no purpose but to provide Amgen with an improper 180-day exclusivity on top of the 12 years of exclusivity it has already enjoyed. When the notice of commercial marketing serves no purpose but to provide an improper exclusivity, it cannot be mandatory.

F. Amgen Is Asking for a Remedy that the BPCIA Does not Provide

Amgen is asking the Court to provide a remedy that does not exist under the BPCIA and so cannot be granted. When a statute creates a right and expressly provides a remedy for violation of that right, as the BPCIA did in paragraph (*l*)(9)(B), then the aggrieved party's relief is limited to that statutory remedy. *See D.R. Wilder Mfg. Co. v. Corn Prods. Refining Co*., 236 U.S. 165, 174-75 (1915) ("where a statute . . . gives a new right and declares the remedy, . . . the remedy can be only that which the statute prescribes." (quoting another source)).

As explained multiple times above, Amgen filed this lawsuit asserting all of the unexpired patents from its patent list. In its Complaint, Amgen asked for both preliminary and permanent injunctive relief based on these patents. (D.E. 1, Prayer for Relief at ¶¶ B, E.) Apotex gave Amgen notice that it intends to launch its product upon FDA approval, but agreed to not launch until after a specified date.

In enacting the BPCIA, Congress could not have intended for a RPS to have any right to seek injunctive relief to enforce provisions of the statute, as Amgen has done here, especially when the parties have followed the statutory framework and are currently in a litigation that involves patents agreed upon by the parties. Indeed, the BPCIA contains no rights-creating language that would entitle a RPS, such as Amgen, standing to enforce the statute. Instead, Congress clearly intended any relief sought by a RPS under 42 U.S.C. § 262(*l*) to be patent-based, as subsection (*l*) is titled "Patents." Thus, paragraph (*l*)(8)(A) is purely a procedural

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[2] *See Biologic Drugs and Innovation: Hearing Before the H. Subcomm. on Courts and Competition Policy of the Comm. on H. Judiciary*, (2009) (statement of Rep. Anna G. Eshoo), 2009 WL 2038853 ("To preserve existing incentives for investment and innovation the Pathway for Biosimilars Act provides a data exclusivity period equivalent to patent protections for small molecules. The Congressional Budget Office has determined that 11.5 years is the average length of time that drugs are marketed under patent. In other words, innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics.").

means to facilitate the resolution of patent rights. It is not surprising that the BPCIA does not contain a provision authorizing an injunction to block entry of a biosimilar product on anything other than substantive patent rights. *See* 42 U.S.C. § 262(*l*)(8)(B), (*l*)(9)(B)-(C); 35 U.S.C. § 271(e)(2)(C), (e)(4); *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-56 (Fed. Cir. 2003).

So why is Amgen not filing for patent-based injunctive relief? Only Amgen can answer that question for sure, but there is nothing preventing Amgen from doing so. Presumably Amgen has evaluated the merits of its patent case and realized that it cannot meet its heavy burden for injunctive relief that is required in this Court. Nevertheless, for the reasons stated above, Amgen is asking this Court to provide a remedy not provided by the BPCIA, and its motion should therefore be denied.

G. Amgen's Failure to Prove Success on the Merits Negates The Other Preliminary Injunction Factors

As stated earlier, because the parties agree that Amgen's motion must be denied if Amgen cannot prove success on the merits, the parties have stipulated to the remaining factors of the test for preliminary injunctive relief. Apotex does not view the stipulation as a concession; rather, Apotex views this as an agreement between the parties to focus solely on the success on the merits factor. Indeed, preliminary injunctions will be denied due to a failure to show even a single element. *Palmer*, 287 F.3d at 1329. For the reasons stated herein, Amgen cannot meet its burden on success on the merits, and its preliminary injunction motion must fail.

H. If a Preliminary Injunction is Ordered, It Should be Conditioned on the Posting of a Substantial Bond

If the Court were to issue an injunction, Amgen should post a substantial bond to ensure that Apotex is fully compensated in the event it is later determined that the injunction was improper. *See* Fed. R. Civ. P. 65(c). Without a bond, Apotex will be deprived of relief for any injury it suffers while wrongly enjoined. *See Russell v. Farley,* 105 U.S. 433, 437 (1881); *see also W.R. Grace & Co. v. Local Union 759, Int'l Union of United Rubber, Cork, Linoleum & Plastic Workers of Am.,* 461 U.S. 757, 770 n.14 (1983) ("A party injured by the issuance of an injunction later determined to be erroneous has no action for damages in the absence of a bond.").

Amgen's reliance on case law that a bond is generally not required where a party seeking the injunction has a high probability of succeeding on the merits of the claim is inapplicable

here. As Amgen acknowledges, the BPCIA is in its infancy and there is only one case to date that interprets just a part of the statute, and as noted even in that single case, Apotex's interpretation, "comes from the plain language of the statute . . . ." *Amgen*, 794 F.3d at 1371 (Chen, J., dissenting-in-part). Thus, any probability of succeeding on the merits could not reach the "high" standard in such a situation as this.

Moreover, Apotex stands to suffer significant damages from the issuance of an injunction.[3] To ensure that the bond is sufficient to protect Apotex, Apotex proposes the bond be set at the value listed in paragraph 16 of Mr. Lydeamore's Declaration.

V. CONCLUSION

For the reasons stated above, Apotex respectfully requests that the Court deny Amgen's motion.

Respectfully submitted,

Dated: November 6, 2015

By: */s/ Simeon D. Brier*

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[3] The facts supporting this statement are set forth in the Declaration of Steven Lydeamore. Apotex has submitted an Unopposed Motion to File the Declaration of Steven Lydeamore in Support of its Opposition to Plaintiffs Amgen Inc.'s and Amgen Manufacturing Limited's Motion for Preliminary Injunction and Incorporated Memorandum of Law Under Seal, as it contains sensitive business information.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 6th day of November, 2015, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached service list in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to electronically receive Notices of Electronic Filing.

/s/ Simeon D. Brier
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