No. 16-1308

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

AMGEN INC. AND AMGEN MANUFACTURING LTD.,

Plaintiffs-Appellees,

v.

APOTEX INC. AND APOTEX CORP.,

Defendants-Appellants.

On appeal from the United States District Court for the Southern District of Florida, Case No. 15-61631-CIV-COHN/SELTZER, Judge James I. Cohn

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CERTIFICATE OF INTEREST

Counsel for Appellants Apotex Inc. and Apotex Corp. certify the following:

1. The full name of every party or amicus represented by me is:

   Apotex Inc. and Apotex Corp.

2. The names of the real parties in interest represented by me is:

   Apotex Inc. and Apotex Corp.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the real parties represented by me are:

   Apotex Inc. is an Ontario corporation, and is wholly owned by Apotex Pharmaceuticals Holdings Inc. (APHI), which itself is wholly owned by Apotex Holdings, Inc. (AHI). Both APHI and AHI are Ontario corporations. Apotex Corp. is a Delaware corporation and is ultimately wholly owned by AHI. Neither Apotex Inc., Apotex Corp., APHI, nor AHI are publicly traded companies.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial or agency or are expected to appear in this court are:

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, no appeal in or from the same civil action in the lower court was previously before this or any other appellate court. This case is related to *Amgen, Inc. et al. v. Apotex Inc. et al.*, Case No. 15- 62081-CIV-COHN/SELTZER, which has been consolidated with Case No. 15-61631-CIV- COHN/SELTZER, which is the subject of this appeal.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331 and 1338(a). The district court's December 9, 2015 Order granted Amgen Inc. and Amgen Manufacturing Limited's ("Amgen") motion for a preliminary injunction. Apotex timely appealed from the district court's grant of a preliminary injunction in the Order, Appx10-13, over which this Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1) and (c)(1).

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that Apotex, having chosen to participate in the disclosure requirements of the Biologics Price and Competition and Innovation Act ("BPCIA") (*viz*. 42 U.S.C. § 262(*l*)(2)(A)), must provide Amgen, the reference product sponsor ("RPS" or "sponsor"), with a notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A).

2. Whether the district court's holding that the 180-day notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) is mandatory frustrates Congress's intent to provide a sponsor such as Amgen a market exclusivity period of 12 years—not 12½ years.

3. Whether the district court erred in holding that the penalty provision of 42 U.S.C. § 262(*l*)(9)(B) is not Amgen's exclusive statutory remedy should Apotex decline to provide a notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A).

PRELIMINARY STATEMENT

This case presents a specific issue that has not been addressed by this Court: whether the notice of commercial marketing provision of the BPCIA (codified at 42 U.S.C. § 262(*l*)(8)(A))[1] is mandatory when a biosimilar applicant (here, Apotex) has chosen to participate in the disclosure requirements of 42 U.S.C. § 262(*l*)(2)(A).

Congress enacted the BPCIA to establish an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product. *See Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015) (citing Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.)). As this Court has previously recognized, "Congress established such 'a biosimilar pathway balancing innovation and consumer interests.'" *Id.* at 1351 (citing BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804). While the BPCIA allows a biosimilar applicant to rely in part on the reference product sponsor's ("RPS" or "sponsor") approved license of a reference product, this is balanced by the 12 years of market exclusivity that a sponsor receives from first licensure of its product, regardless of patent protection. *See id.* at 1351-52.

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

The BPCIA also established a two-stage protocol and timeline for the sponsor and biosimilar applicant to exchange information and resolve any patent disputes between the parties. In the *first* stage, under paragraphs (*l*)(2)-(*l*)(5) of the BPCIA, the parties may exchange information concerning the abbreviated Biologics License Application ("aBLA"), a list of patents for which a claim of patent infringement could be asserted, and statements concerning the patent(s), followed by negotiation to decide which patents should be the subject of an immediate patent infringement action. Although paragraph (*l*)(2)(A) provides that the biosimilar applicant "shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," paragraph (*l*)(9)(C) anticipates that the biosimilar applicant might elect not to provide that information and prescribes the remedy:

> 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.

If the biosimilar applicant provides the paragraph (*l*)(2)(A) information, then, under paragraph (*l*)(3), the parties exchange lists of patents that might be implicated by the proposed biosimilar product and the biosimilar applicant either

provides a detailed statement about why the listed patents are invalid or would not be infringed or else provides a statement that the biosimilar applicant will not begin commercial marketing of the proposed biosimilar before the expiration of the listed patent. After the paragraph (*l*)(3) information has been exchanged, then the parties negotiate under paragraph (*l*)(4) over which patents on the list should be the subject of a patent infringement lawsuit. If the parties cannot reach agreement, paragraph (*l*)(5) prescribes a procedure for selecting the patents for a lawsuit. Then, under paragraph (*l*)(6), the sponsor can sue the biosimilar applicant within 30 days. Paragraph (*l*)(7) provides a procedure for updating the lists of relevant patents and detailed statements of paragraph (*l*)(3) to include any patents that were issued or licensed after the paragraph (*l*)(3) lists have been exchanged. The result of this first-stage activity is a patent-infringement lawsuit and an updated list of potentially relevant patents that have not been included in the lawsuit.

In the *second* stage for resolving patent disputes, under paragraph (*l*)(8)(A), "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." If the notice is given, then the sponsor may seek an injunction under paragraph (*l*)(8)(B):

> 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).

That is, the sponsor may seek to prevent the biosimilar applicant from launching its biosimilar product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that was listed as relevant under paragraph (*l*)(3) but *not* included in the lists of patents for early litigation that were agreed upon under paragraph (*l*)(4) or selected by the procedure of paragraph (*l*)(5). This second stage of patent dispute resolution is thus designed to address patents that are *not* already the subject of a lawsuit between the parties. Paragraph (*l*)(9)(B) anticipates that the biosimilar applicant might elect not to provide the paragraph (*l*)(8)(A) notice and prescribes the remedy:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . 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).

In the present case, the parties followed paragraphs (*l*)(2)-(*l*)(5) of the BPCIA and a lawsuit was initiated under paragraph (*l*)(6). The present dispute centers on whether Apotex, having complied with paragraphs (*l*)(2)-(*l*)(5), must now provide a notice of commercial marketing under paragraph (*l*)(8)(A).

This Court's first decision interpreting the BPCIA was *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). In that case, unlike this one, biosimilar applicant Sandoz had *not* provided the information called for in paragraph (*l*)(2)(A). This Court held that the information-exchange provisions of paragraph (*l*)(2)(A) are optional, not mandatory, because paragraph (*l*)(9)(C) describes the remedy for not exchanging the paragraph (*l*)(2)(A) information. *Amgen*, 794 F.3d at 1357. This Court also held that, for companies that have elected *not* to participate in the exchange of information under paragraph (*l*)(2)(A), the notice provisions of paragraph (*l*)(8)(A) are mandatory, in part because the paragraph (*l*)(9)(B) remedy for not providing the notice cannot be applied to applicants who have not participated in the paragraph (*l*)(2)(A) information exchange. *Id.* at 1360. At issue, in the present case is whether the paragraph (*l*)(8)(A) notice provisions are also mandatory for biosimilar applicants that *do* participate in the paragraph (*l*)(2)(A) information exchange, as Apotex has done here.

As the district court recognized, the facts of this case are distinguishable from those in the recent *Amgen v. Sandoz* case. Specifically, the district court stated that:

> However, the [*Amgen v.*] *Sandoz* decision was limited to situations where the subsection (k) applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline . . . ." Because the situation was not before it, the court did not address whether the notice provision of § 262(*l*)(8)(A) applies where the applicant, like Apotex, *did* share the information required by § 262(*l*)(2).

Appx5 (emphasis in original) (citations omitted).

The district court's erroneous decision to grant Amgen a preliminary injunction here amounts to a *de facto* 180-day extension of the 12-year exclusivity provided by the BPCIA. In so doing, the district court incorrectly interpreted both the applicable BPCIA provisions and this Court's opinion in the *Amgen v. Sandoz* case. Nothing in the BPCIA provides for an extension of the 12-year exclusivity from which Amgen has already benefited. Indeed, the BPCIA provides a remedy to Amgen if Apotex should elect not to provide the notice of commercial marketing under paragraph (*l*)(8)(A): a declaratory judgment action on any patents that Amgen has listed as relevant to Apotex's product but that are not already in litigation. *See* paragraph (*l*)(9)(B). Rather than apply the BPCIA statutory provision by its plain terms, the district court manufactured a new remedy, which in effect amounts to 180 additional days of exclusivity for Amgen. Amgen does

not need the statutory remedy of a declaratory judgment action on any paragraph (*l*)(3)-listed patents that are not already in litigation, however, because Amgen has *already* sued Apotex on all of the patents on its list. That Amgen does not benefit from the remedy provided in the statute is no reason for the district court to depart from the express BPCIA provisions and to craft a new remedy. The district court has no basis in law or fact to support its interpretation of the BPCIA based on this Court's decision in the *Amgen v. Sandoz* case, and thus its decision to grant a preliminary injunction was an abuse of discretion and should be reversed.

STATEMENT OF THE CASE

This is an appeal from the district court's Order granting Amgen's motion for a preliminary injunction preventing Apotex from commercially marketing a biosimilar version of Amgen's biological product NEULASTA®.

Apotex submitted its aBLA to FDA under the BPCIA's abbreviated pathway, seeking approval of a biosimilar version of Amgen's biological product NEULASTA®. Apotex followed the first-stage patent-dispute-resolution procedures set forth in the BPCIA, including providing the aBLA and manufacturing information to Amgen, satisfying the disclosure requirement of paragraph (*l*)(2)(A). Under this Court's holding in *Amgen v. Sandoz*, Apotex has not provided an effective notice of commercial marketing under paragraph (*l*)(8)(A).

Amgen sued Apotex in the United States District Court for the Southern District of Florida under paragraph (*l*)(6), asserting infringement of U.S. Patent Nos. 8,952,138 ("the '138 patent") and 5,824,784[2] ("the '784 patent"), and seeking a declaratory judgment that Apotex must comply with paragraph (*l*)(8)(A) of the BPCIA. Appx54-56. Apotex filed counterclaims seeking a declaratory judgment that the notice of commercial marketing under paragraph (*l*)(8)(A) is not mandatory, that the '138 patent is not infringed and is invalid, and for patent misuse. Appx145-146.

Amgen filed a motion seeking a preliminary injunction preventing Apotex from launching its pegfilgrastim product until 180 days after providing notice under paragraph (*l*)(8)(A).

On December 9, 2015, the district court granted Amgen's motion for a preliminary injunction. Appx1-9. Apotex timely appealed. Appx10-13.

STATEMENT OF FACTS

A. Amgen's Pegfilgrastim Product, NEULASTA®

Amgen received approval of its BLA for NEULASTA® in 2002. Appx129. Amgen's 12-year exclusivity provided under the BPCIA has expired. Appx130.

B. Apotex's Biosimilar Application

On October 16, 2014, Apotex submitted aBLA No. 761026, seeking FDA approval to market a biosimilar pegfilgrastim product, for which NEULASTA® is the

[2] U.S. Patent No. 5,824,784 expired on October 20, 2015.

reference product. Appx131. On December 15, 2014, Apotex received notification from FDA that its aBLA had been accepted for review. Appx136. On December 31, 2014, in accordance with paragraph (*l*)(2)(A), Apotex provided Amgen with Apotex's aBLA, which contains detailed information about Apotex's biosimilar pegfilgrastim product. *Id.*

In accordance with the patent-dispute-resolution provisions, on February 27, 2015, Amgen provided Apotex a list of patents for which Amgen purported a claim of patent infringement could reasonably be asserted against the Apotex biosimilar pegfilgrastim product ("Amgen's paragraph (*l*)(3)(A) list"). This list included the patents-in-suit, *i.e.*, the '784 and '138 patents. *Id.*

On April 17, 2015, pursuant to paragraph (*l*)(3)(B), Apotex provided Amgen with a detailed statement regarding each patent included in Amgen's (*l*)(3)(A) list ("Apotex's Detailed Statement"). Appx137. Apotex's Detailed Statement contained a certification pursuant to paragraph (*l*)(3)(B)(ii)(II) that Apotex does not intend to begin commercial marketing of Apotex's biosimilar pegfilgrastim product before the date on which '784 patent expires. *Id.* The '784 patent expired on October 20, 2015. Apotex's Detailed Statement also contained the legal and factual bases for Apotex's contention that the claims of the '138 patent are invalid, unenforceable, and/or will not be infringed by the commercial marketing of Apotex's biosimilar pegfilgrastim product. *Id.*

On June 16, 2015, Amgen provided Apotex with a statement, designated as being in accordance with paragraph (*l*)(3)(C), containing the legal and factual bases as to why the ’138 patent is infringed and is valid. Appx332. Between about June 22, 2015 and about July 7, 2015, Amgen and Apotex engaged in negotiations, pursuant to paragraph (*l*)(4). *Id.* On or about July 7, 2015, Amgen and Apotex reached agreement that should Amgen sue, the ’138 patent and the ’784 patent would be the subject of an action for patent infringement under paragraph (*l*)(6)(A). *Id.*

C. District Court Proceedings

1. Amgen’s Complaint

On August 2, 2015, Amgen sued Apotex in the United States District Court for the Southern District of Florida, asserting infringement of the ’138 patent and the ’784 patent, and for declaratory judgment that Apotex must comply with paragraph (*l*)(8)(A) of the BPCIA. Appx39-57. Amgen asked for preliminary and permanent injunctive relief on these patents. Appx56.

2. Apotex’s Answer and Counterclaims

On October 5, 2015, Apotex answered and counterclaimed.[3] Appx108-149. Apotex counterclaimed for declaratory judgments that the notice of commercial

[3] A corrected version of Apotex’s Answer and Counterclaims was filed on October 23, 2015 because page 33 of the pleading filed on October 5, 2015 was inadvertently omitted.

marketing under paragraph (*l*)(8)(A) is not mandatory, non-infringement and invalidity of the '138 patent, sham litigation, and patent misuse. *See id.*

3. Amgen's Motion for a Preliminary Injunction

On October 16, 2015, Amgen filed a motion requesting the district court to enter a preliminary injunction, enjoining Apotex from commercial marketing of its biosimilar pegfilgrastim product until Apotex provides Amgen proper notice, at least 180 days before first commercial marketing but not before Apotex's biosimilar pegfilgrastim product is licensed by FDA. Appx150-174. Because the parties agree that Amgen's motion must be denied if Amgen cannot prove success on the merits, the parties stipulated to the remaining factors of the test for preliminary injunctive relief. Appx196-200.

4. The District Court's Order

On December 9, 2015, the district court granted Amgen's motion for a preliminary injunction. The district court held that "[i]f the FDA approves Apotex's Biologics License Application for its pegfilgrastim product, Apotex must provide Amgen with at least 180 days notice before the date of the first commercial marketing of the biological product approved by the FDA." Appx9. The district court rejected Apotex's argument that a biosimilar applicant that met the disclosure requirements of paragraph (*l*)(2)(A) is not required to give a notice of commercial marketing. *See* Appx5-6. In so doing, the district court stated that

"[n]othing in the statute or the *Sandoz* decision leads to or supports such a result; neither the statute nor the *Sandoz* decision condition the 180 day notice provision of § 262(*l*)(8)(A) upon a subsection (k) applicant's compliance with § 262(*l*)(2)." *Id*. Citing *Amgen v. Sandoz*, the district court stated that giving notice of commercial marketing after licensure allows the sponsor to effectively determine whether, and on which patents, to seek a preliminary injunction from the court. Appx6 (citing *Amgen*, 794 F.3d at 1358).

The district court discounted Apotex's argument that a mandatory notice of commercial marketing after FDA licensure would provide Amgen with a *de facto* 180 days of exclusivity. *See* Appx6-7. The district court stated that Apotex's case is atypical, and cited the *Amgen v. Sandoz* statement "[t]hat extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." *Id.* (citing *Amgen*, 794 F.3d at 1358).

The district court rejected Apotex's argument that making the notice of commercial marketing for all biosimilar applicants mandatory, even when the applicant complied with the disclosure requirements of paragraph (*l*)(2)(A), would render the penalty provisions of paragraph (*l*)(9)(B) superfluous. *See* Appx7-8. The district court held:

> Subsection 262(*l*)(9) gives the RPS the option to file a declaratory judgment action if the subsection (k) applicant fails to comply with § 262(*l*)(8)(A), but is not an exclusive remedy. As the *Sandoz* court ruled, an injunction to compel compliance with the

> 180-day notice provision of § 262(*l*)(8)(A) is another remedy. The BCPIA [sic] simply does not give the subsection (k) applicant the power to nullify the RPS' statutory right to 180 days notice of approval prior to marketing based on whether or not the subsection (k) applicant complies with § 262(*l*)(2).

Appx7.

Apotex filed a notice of appeal on December 10, 2015. Appx10-13.

SUMMARY OF THE ARGUMENT

This case presents a specific issue that has not been addressed by this Court: whether the notice of commercial marketing provision of the BPCIA, paragraph (*l*)(8)(A), is mandatory when a biosimilar applicant (here, Apotex) has chosen to participate in the disclosure requirements of 42 U.S.C. § 262(*l*)(2)(A). This issue of first impression is of great importance not only to the parties here, but to the biopharmaceutical industry as a whole.

There is no dispute that the parties in this case followed the information-exchange provisions of paragraphs (*l*)(2)-(*l*)(5) of the BPCIA. This dispute centers on whether Apotex, having complied with paragraphs (*l*)(2)-(*l*)(5) must now provide a notice of commercial marketing provision under paragraph (*l*)(8)(A). The district court erred in holding that Apotex is required to give Amgen notice 180 days prior to commercial marketing of its biosimilar product even though Apotex satisfied the disclosure requirement of paragraph (*l*)(2)(A).

First, the plain text of the statute indicates that the notice provision of paragraph (*l*)(8)(A) is not always mandatory because paragraph (*l*)(9)(B) anticipates that the biosimilar applicant will not always give such notice and provides the exclusive remedy for the sponsor. If paragraph (*l*)(8)(A) were always mandatory, then the provisions of paragraph (*l*)(9)(B), which describe the remedy available to the RPS if the biosimilar applicant does not give the specified notice, would be superfluous. Basic canons of statutory construction urge strongly against construing a statute in a way that makes some of its provisions superfluous. *See infra* Part I.A.

Although this Court held in *Amgen v. Sandoz* that the paragraph (*l*)(8)(A) notice is mandatory for parties who elect *not* to participate in the information exchange of paragraph (*l*)(2)(A), that case neither held nor implied that the notice provisions would also be mandatory for those parties who, like Apotex here, voluntarily complied with the first-stage information exchanges contemplated by the statute. Indeed, the logic of *Amgen v. Sandoz*—concluding that information-exchange provisions of paragraph (*l*)(2)(A) are not mandatory because otherwise the remedy provision of paragraph (*l*)(9)(C) would be superfluous—strongly supports Apotex's interpretation of the notice requirement as optional for parties who comply with the statute's first-stage information-disclosure requirements. *See Amgen*, 794 F.3d at 1357. Applying the *Amgen v. Sandoz* majority's reasoning to

the facts at hand, it follows that a biosimilar applicant such as Apotex that satisfies the disclosure requirements of paragraph (*l*)(2)(A) should not be required to provide a notice of commercial marketing under paragraph (*l*)(8)(A) because the BPCIA provides a remedy for the sponsor (Amgen) to file a declaratory judgment action. Accordingly, just as the information disclosure requirement of paragraph (*l*)(2)(A) is not mandatory because the penalty provision of paragraph (*l*)(9)(C) expressly provides the sponsor a remedy if a biosimilar applicant opts not to participate in the information exchange process, the notice requirement of paragraph (*l*)(8)(A) is not mandatory because the penalty provision of paragraph (*l*)(9)(B) expressly provides the sponsor a remedy if a biosimilar applicant opts not to give notice of commercial marketing after it elects participate in the exchange. *See infra* Part I.B.

Second, an optional notice of commercial marketing under paragraph (*l*)(8)(A) is fully consistent with the policies underlying the BPCIA. Because Apotex chose to disclose its aBLA pursuant to paragraph (*1*)(2)(A), Amgen has had more than 11 months to assert its patent rights. There can be no statutory purpose served by delaying the launch of an aBLA product by 180 days so that a sponsor has additional time to evaluate information that has been in its possession since the time the aBLA was first accepted at FDA. A compulsory notice of commercial marketing under paragraph (*l*)(8)(A) would provide Amgen with a *de*

facto 180 days of additional exclusivity on top of the 12 years that Amgen has already enjoyed, even though Amgen has no additional patents to assert and so can make no legitimate use of the 180-day waiting period. To be clear, if the 180-day notice of commercial marketing is mandatory and only effective after FDA-approval of an aBLA, then there is no circumstance in which a biosimilar product will enter the market prior to 12½ years from BLA licensure. The plain language of the BPCIA does not provide for such a result, and the granting of a windfall extra six months of monopoly sales for the reference product sponsor was not Congress's intent. *See infra* Part II.

Third, the reasons given by the district court in support of its contrary interpretation of the statute are unpersuasive. The district court expressed concern that Apotex's reading of the statute would cause confusion, but there is nothing confusing about a rule that applicants who comply with the information-exchange provisions of paragraph (*l*)(2)-(*l*)(5) need not comply with the notice provision of paragraph (*l*)(8). The district court expressed hope that making the 180-day notice period mandatory would result in some patents expiring before the notice period was up, but there is no logical connection between patents expiring and the 180-day notice period. *See* Appx7. The longer any litigation goes on, the better the chances that some patents will expire and some issues will become moot. That truism, however, provides no legitimate basis for requiring all biosimilar

applicants, now and in the future, to delay the launch of their biosimilar products for six months.

To the extent that the district court believed that Amgen's right to injunctive relief depends in any way on Apotex's giving notice of commercial marketing, the court was mistaken. Amgen already has the right to seek preliminary injunctive relief on the patents-in-suit, and it has no other relevant patents to assert. Under the circumstances, imposing an additional six-month delay would delay the availability of more affordable biosimilar products for no good reason. Although the district court apparently did not intend to extend the statute's 12-year marketing exclusivity period into a 12½-year period in all cases, that is the effect of its reading of the statute—a result that cannot be squared with Congress's explicit choice of a 12-year period. Finally, the district court failed to respect the exclusive remedy provided by Congress for circumstances in which an applicant does not provide the paragraph (*l*)(8)(A) notice of commercial marketing. Instead, the district court created a new, extra-statutory injunctive remedy not contemplated by Congress, in derogation of the long-standing principle that when a statute creates a right and expressly provides a remedy for violation of that right, then the aggrieved party's relief is limited to that statutory remedy. *See infra* Part III.

For the reasons stated herein, the district court's grant of an injunction is premised on an incorrect interpretation of the BPCIA and should be overturned.

STANDARD OF REVIEW

This Court applies the law of the regional circuit when reviewing and interpreting the grant, denial, or modification of a preliminary injunction. *See Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014) (citing *Aevoe Corp. v. AE Tech Co.*, 727 F.3d 1375, 1381 (Fed. Cir. 2013)).[4] Under the Eleventh Circuit's standard, Amgen's motion must be denied if it fails to show a likelihood of success on the merits. *See Palmer v. Braun*, 287 F.3d 1325, 1329 (11th Cir. 2002). The Eleventh Circuit reviews a district court's decision to grant a preliminary injunction for abuse of discretion. *See U.S. Commodity Futures Trading Comm'n v. Hunter Wise Commodities, LLC*, 749 F.3d 967, 973 (11th Cir. 2014). Here, the district court's grant of preliminary injunction was based primarily on statutory interpretation, which is a question of law. Questions of law are reviewed *de novo*. *Id.* at 974; *see also Endo Pharm. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1374 (Fed. Cir. 2014). Should this Court find that the notice of commercial marketing is not compulsory, then the district court's grant of a preliminary injunction must be reversed.

ARGUMENT

The district court erred in granting injunctive relief based on an incorrect interpretation of the BPCIA. Both the BPCIA itself and this Court's opinion in

[4] If this Court decides that the Federal Circuit standard applies, the standard is the same.

Amgen v. Sandoz support Apotex's interpretation of the statute. Because Apotex met the disclosure requirements of paragraph (*l*)(2)(A) and engaged in the patent-dispute resolution, Apotex cannot be compelled to provide a notice of commercial marketing. Had Apotex failed to meet the paragraph (*l*)(2)(A) disclosure requirements, the statute provides Amgen with a remedy under paragraph (*l*)(9)(B), *viz.* to file a declaratory judgment action on the patents from its patent list. Indeed, Amgen has already done just that, by filing for a declaratory judgment action on all of the unexpired patents from its patent list. If Amgen wants to keep Apotex's biosimilar pegfilgrastim product off the market, it should instead seek to do so based on its patents. Such relief is clearly available to Amgen under the BPCIA. Instead, the district court's erroneous decision grants Amgen a *de facto* 180-day extension of the 12-year exclusivity provided by the BPCIA. Amgen has already enjoyed its 12-year exclusivity provided by the BPCIA, and nothing in the BPCIA provides for an extension of that exclusivity. In sum, the district court's decision is premised entirely on an incorrect interpretation of the BPCIA, is improper, and should be overturned.

I. A PLAIN READING OF THE BPCIA SUPPORTS APOTEX'S INTERPRETATION THAT NOTICE OF COMMERCIAL MARKETING IS NOT COMPULSORY WHEN A BIOSIMILAR APPLICANT COMPLIES WITH PARAGRAPH (*l*)(2)(A)

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

The "Notice of commercial marketing" provision in paragraph (*l*)(8)(A) states that "[t]he 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). Although, when read in isolation, the use of the word "shall" might appear to make the provision mandatory, the statute on its face anticipates that applicants may elect not to give the paragraph (*l*)(8)(A) notice and instead accept the remedy in paragraph (*l*)(9)(B):

> ***If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under*** . . . ***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).

42 U.S.C. § 262(*l*)(9)(B) (emphasis added). Amgen could therefore file a declaratory judgment action on any patents on its paragraph (*l*)(3)(A) list that are not already the subject of litigation. In this case, there are no such patents; Amgen has already asserted all of its relevant patents against Apotex.

Making paragraph (*l*)(8)(A) compulsory for biosimilar applicants that complied with paragraph (*l*)(2)(A) would render paragraph (*l*)(9)(B) superfluous. If compliance with paragraph (*l*)(8)(A) were mandatory, then there would be no reason for BPCIA to explicitly provide a remedy, in paragraph (*l*)(9)(B), for a decision not to provide the notice called for in paragraph (*l*)(8)(A). Indeed, under the district court's rationale, the "penalty provision" outlined in paragraph (*l*)(9)(B) is utterly unnecessary because it covers a situation that could never happen. This cannot be a correct reading of the statute since it is well established that 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))).

B. *Amgen v. Sandoz* Does Not Compel a Different Result

As this Court in *Amgen v. Sandoz* 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." *Id.* at 1360 (emphasis added). Thus, the Court in *Amgen* explicitly stated that its holding was limited to scenarios in which a biosimilar applicant did not follow the first-stage BPCIA patent dispute-resolution pathway, and thus did not provide its aBLA to the sponsor in accordance with paragraph (*l*)(2)(A). 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 under the facts of this case, but rather applies to a case in which the biosimilar applicant did not provide the aBLA to the reference product sponsor within the applicable time period.

Moreover, the Court in *Amgen* provided guidance regarding whether a biosimilar applicant could be compelled to provide the notice of commercial marketing provision of paragraph (*l*)(8)(A), 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). In this passage, the Court implicitly recognized that there could be situations where, as here, a biosimilar applicant fails to comply with the notice of commercial marketing provisions. Finally, the Court noted that if this happens, the sponsor can seek recourse under the provisions of paragraph (*l*)(9)(B). While the Court found that this provision did not apply in Sandoz's case because Sandoz did not comply with paragraph (*l*)(2)(A), the Court's opinion is fully consistent with Apotex's reading of the statute, under which the second-stage paragraph (*l*)(8)(A) notice is not mandatory for parties who have gone through the first-stage information exchange of paragraphs (*l*)(2)-(*l*)(5).

Further, this Court's holding that Sandoz could not be compelled to follow the patent-dispute resolution procedures of the BPCIA is also instructive here. Unlike Apotex, Sandoz did not provide its aBLA to Amgen. This Court held that Sandoz could not be compelled to provide its aBLA or follow the patent-dispute resolution procedures because paragraph (*l*)(9)(C) provided Amgen with its remedy:

> 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.

Paragraph (*l*)(9)(C); *see Amgen,* 794 F.3d at 1357.

Applying this Court's reasoning to the facts at hand, it follows that a biosimilar applicant such as Apotex that provides its aBLA but then fails to provide a notice of commercial marketing under paragraph (*l*)(8)(A), likewise leaves the sponsor (Amgen) with the remedy expressly set forth in the statute.

Moreover, in considering the interplay of various provisions of the BPCIA, this Court 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, that conclusion 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 sponsor pursuant to paragraph (*l*)(2)(A) would render paragraph (*l*)(9)(B) superfluous.

This Court's analysis in *Amgen* is also instructive on the word "shall" as used in the BPCIA. In *Amgen*, this Court 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 sponsor may bring an infringement action under paragraph (*l*)(9)(B). This in and of itself indicates that the "shall" in paragraph (*l*)(8)(A) does not and cannot mean "must" regardless of the other applicable circumstances.

Judge Chen's partial dissent in *Amgen v. Sandoz* also supports Apotex's interpretation. In dissenting from that portion of the opinion that made the notice provisions of paragraph (*l*)(8)(A) mandatory, Judge Chen stated 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 recognized that if a biosimilar applicant complies with the patent-dispute resolution process as Apotex did in this case, that biosimilar applicant may still ultimately not comply with the notice of commercial marketing requirement of paragraph (*l*)(8)(A). Judge Chen further recognized that the exclusive remedy in such a situation existed in paragraph (*l*)(9)(B), which "comes from the plain language of the statute . . . ." *Id.*

Accordingly, the statute's plain language, as supported by the logic underlying this Court's decision *Amgen v. Sandoz*, supports the conclusion that the notice provision of paragraph (*l*)(8)(A) is not mandatory for parties who, like Apotex here, have complied with the first-stage information-exchange provisions of paragraphs (*l*)(2) through (*l*)(5).

II. APOTEX'S INTERPRETATION OF THE STATUTE COMPORTS WITH CONGRESS'S PURPOSES IN ENACTING THE BPCIA

In the BPCIA, Congress struck a careful balance between the rights of sponsors, of biosimilar applicants, and the public's dual interests in promoting innovation and increasing competition through easier, speedier access to biosimilar products. Critically, Congress enacted a 12-year market exclusivity for reference

product sponsors—not a 12½-year market exclusivity. Apotex's interpretation of paragraph (*l*)(8)(A) honors the balance that Congress struck; Amgen's interpretation would grant all sponsors an extra six months of highly profitable market exclusivity, even when, as here, the sponsors have no additional patents to assert and so can derive no legitimate benefit from the notice. When an applicant such as Sandoz in its case with Amgen elects not to provide its aBLA to the relevant sponsor, the majority in *Amgen v. Sandoz* perhaps believed that it made sense to require notice and a six-month delay before commercial marketing in order to allow the sponsor more time to evaluate its patent positions. *See id*. at 1360. In contrast, because Apotex followed the disclosure provisions of paragraph (*l*)(2)(A), Amgen has now had more than 11 months to review Apotex's aBLA and manufacturing information. Amgen has therefore had more than ample time to identify all of the patents that it believed could be reasonably asserted against Apotex based on Apotex's aBLA and manufacturing information. Thus, where, as here, the biosimilar applicant has followed the patent-dispute resolution procedures of the BPCIA, there can be no statutory purpose served by delaying the launch of a biosimilar product by another 180 days just so the sponsor has additional time to evaluate information that has already been in its possession since the time the aBLA was first accepted at the FDA.

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.[5] As a result, the BPCIA provides that a biosimilar applicant's aBLA **cannot be approved** by FDA, and therefore the biosimilar applicant does not receive licensure, until 12 years after approval of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). What is more, FDA has stated that "Section 351(k)(7)(A) of the PHS Act states that 'approval of . . . [a biosimilar application] may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).'"[6]

Thus, even if an aBLA is filed during the 12-year market exclusivity period as suggested by the district court (and as this Court suggested in dicta in *Amgen v. Sandoz*), the FDA will not approve that aBLA until after expiration of the 12-year

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[5] *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.").

[6] *See* FDA, *Memorandum Re: Exclusivity Expiry for Neupogen (filgrastim) BLA 103353* (June 26, 2014), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000AdminCorres.pdf (emphasis added).

market exclusivity period. Consequently, if the 180-day notice of commercial marketing is mandatory and only effective after FDA-approval of an aBLA, then there is no circumstance in which a biosimilar product will enter the market prior to 12½ years from BLA licensure.

The effect of Amgen's interpretation of the statute is thus to extend the statutory monopoly by six months, thus granting a windfall to reference product sponsors at the expense of patients who would benefit from more affordable biosimilar products. The plain language of the BPCIA does not support that position, and this result was not Congress's intent

III. THE REASONS GIVEN BY THE DISTRICT COURT FOR ITS INTERPRETATION ARE UNPERSUASIVE AND WOULD PRODUCE CONSEQUENCES NOT INTENDED BY CONGRESS

A. The Reasons Offered by the District Court for Rejecting Apotex's Statutory Construction are Unpersuasive

No Confusion or Uncertainty: The district court expressed concern that "[t]he scenario proposed by Apotex would result in confusion and uncertainty, as well as inconsistent results, depending upon which route a subsection (k) applicant chooses to travel." Appx5. In fact, Apotex's interpretation would create neither confusion nor uncertainty. Under the majority's holding in *Amgen v. Sandoz*, those applicants who decline to participate in the paragraph (*l*)(2)-(*l*)(5) information exchanges are obliged to comply with the notice requirement of paragraph (*l*)(8). In contrast those applicants (here, Apotex) who do participate in the paragraph

(*l*)(2)-(*l*)(5) information exchanges may elect not to comply with the notice requirement (and thus run the risk of additional litigation under paragraph (*l*)(9)(B)). What the district court described as inconsistent results are nothing more than parties living with the consequences of their own choices. And Apotex's interpretation of the statute has the added benefit of creating an incentive for parties to agree to engage in the optional information exchanges of paragraphs (*l*)(2)-(*l*)(5).

Potential Patent Expiration Irrelevant: The district court indicated that mandatory compliance with the notice requirement and 180-day waiting period could "result in more crystallized patent litigation" simply because occasionally some patents will expire during the 180-day waiting period: "one of the patents Amgen has filed suit on in this Court may well expire before the 180 day period ends; under Apotex's construction of § 262(*l*)(8)(A), the Court would be forced to rule on the validity of that patent now, even though that patent claim may be moot by the end of the 180 day period." Appx7. As the case currently stands, however, the district court has several live patents before it. Depending upon how long the litigation takes, it is possible that one of them will expire before the litigation is completed. The longer the litigation goes on, the greater the chances that patents will expire and issues will become moot. But that is true regardless of whether Apotex follows the notice and waiting provisions of paragraph (*l*)(8)(A). The

district court's interest in not having to resolve potentially difficult issues of patent infringement and validity in this particular case should not be permitted to color the interpretation of a statute that will affect all biosimilar applicants in all cases and will delay the availability of countless more affordable biosimilar medicines far into the future.

Amgen's Right to Injunctive Relief Unaffected by Notice of Commercial Marketing: Although the district court's opinion is not explicit on this issue, it is possible that the district court was motivated by a concern that a failure to give notice and to wait for six months before commercially marketing a biosimilar would somehow deprive Amgen of the right to file for injunctive relief to prevent Apotex's launch. If that was the motivation, then it was based on a misunderstanding, for Amgen *already* has the right to file for injunctive relief on the patents that are the subject of the pending litigation and there is nothing about the notice of commercial marketing that affects those rights. Paragraph (*l*)(8)(B) sets forth the rights conferred upon the sponsor if a biosimilar applicant complies with paragraph (*l*)(8)(A):

> 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). In other words, after receiving notice of commercial marketing, the sponsor may seek a preliminary injunction until the court resolves the issue of validity and infringement of any patent identified by either the sponsor or the biosimilar applicant earlier in the patent-dispute resolution process but not included in the lawsuit eventually brought by the sponsor during that process. In this particular case, there are no such patents since the parties chose to include all of the patents from Amgen's and Apotex's lists in the pending litigation. Compelling Apotex to provide a notice of commercial marketing would do nothing to enlarge or diminish Amgen's right to seek injunctive relief in the pending litigation—a course of action which, notably, Amgen has thus far not pursued.

Similarly, if Amgen were to acquire or license new patents, that situation would be covered by paragraph (*l*)(7), which requires the parties to again exchange lists of patents (but now based solely on the newly acquired or licensed rights), and then determine whether or not such patents should be added to the 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. Accordingly, the district court's reasoning is unpersuasive.

B. The District Court's Reasons Would Produce Consequences Unintended by Congress

Extension of the 12-Year Exclusivity Period: Although the district court recognized that making Apotex comply with paragraph (*l*)(8)(A)'s notice requirement would result in an extra six months of marketing exclusivity for Amgen, the district court believed that this result was atypical and that, in other cases, compliance with the notice requirement would not necessarily extend the 12-year exclusivity period. Appx6-7. In support of this proposition, the district court cited, without analysis, dicta to the same effect from the *Amgen v. Sandoz* decision: "That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." *Id.* (citing *Amgen*, 794 F.3d at 1358). Both the district court's assumption and the dicta it cites, however, fail to take into account that effective notice cannot be given before FDA has approved an aBLA, and that FDA cannot approve an aBLA before the expiration of the 12-year marketing exclusivity period. *See supra* Part II. Whenever the notice requirement applies, the exclusivity period will be lengthened by six months. As discussed above, there is no justification for an extension of the monopoly period when the sponsor has received the aBLA and has already

received a detailed statement of the applicant's reasons for believing that each potentially relevant patent is invalid, unenforceable, or will not be infringed.

Disregard of Congress's Exclusive Remedy: The district court erroneously concluded that paragraph (*l*)(9)(B) was not an exclusive remedy, and that an injunction to compel compliance with the notice of commercial marketing provision under paragraph (*l*)(8)(A) was another remedy. Appx7. In support of its position, the district court quoted Judge Newman's dissent in *Amgen v. Sandoz* for the proposition that "subsection 262(*l*)(9) provides jurisdiction in the district court when a subsection (k) applicant fails to comply with subsection (*l*), but it does not ratify non-compliance . . . ." *Id.* (quoting *Amgen*, 794 F.3d at 1366 (Newman, J., dissenting)). But this Court in *Amgen v. Sandoz* rejected Judge Newman's argument on this point and held that the existence of a remedy in paragraph (*l*)(9) made non-compliance a valid option, which is why the point had to be made in dissent.

The district court's creation of an entirely new remedy that Congress did not provide in the BPCIA runs contrary to controlling U.S. Supreme Court precedent that holds that when Congress creates a new right in a statute and expressly provides the remedy for violation of that right, then the aggrieved party's relief is limited to that statutory remedy. *See, e.g.*, *Bruce's Juices v. Am. Can Co.*, 330 U.S. 743, 755 (1947) ("'[W]here a statute . . . gives a new right and declares the

remedy, . . . the remedy can be only that which the statute prescribes.'" (quoting *D.R. Wilder Mfg. Co. v. Corn Prods. Refining Co.*, 236 U.S. 165, 174-75 (1915); *Connolly v. Union Sewer Pipe Co.*, 184 U.S. 540 (1902))). The BPCIA provides one, and only one, remedy for situations where a biosimilar applicant has complied with paragraph (*l*)(2)(A) but failed to give notice under paragraph (*l*)(8)(A). It is not for the courts to craft new remedies when Congress has already exercised its power on the subject.

This Court should honor the plain text of the statute, its own prior logic in *Amgen v. Sandoz*, and the policies underlying the BPCIA and hold that, for parties that have complied with the information-exchange obligations of paragraphs *(l)*(2)-(*l*)(5), the notice of commercial marketing under paragraph (*l*)(8) is not mandatory.

CONCLUSION

Apotex respectfully requests that the Court reverse the district court's grant of Amgen's motion for a preliminary injunction, and remand for further proceedings based on the correct interpretation of the BPCIA.

Dated: December 30, 2015 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(A)(7)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(b). This brief contains approximately 8,415 words, excluding the part of the brief exempted by Fed. R. App. P. 32(a)(7)(b)(iii) and Fed. Cir. R. 32(b).

The brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2013 in 14-point Times New Roman type.

December 30, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of December, 2015 I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

December 30, 2015

By: */s/ Kerry B. McTigue*

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ADDENDUM

TABLE OF CONTENS TO ADDENDUM

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 15-61631-CIV-COHN/SELTZER

AMGEN, INC., and AMGEN MANUFACTURING LIMITED,,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

THIS CAUSE has come before the Court upon the Motion of Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively "Amgen") for a Preliminary Injunction DE [42]. Amgen seeks a preliminary injunction enjoining the Defendants, Apotex Inc. and Apotex Corp. (collectively "Apotex") from marketing its pegfilgrastim product until 180 days after it notifies Amgen of approval by the Federal Drug Administration ("FDA"). Amgen's Motion for Preliminary Injunction is based upon the Biologics Price Competition and Innovation Act of 2009 ("BCPIA"), 42 U.S.C.A. § 262 *et seq.*, in particular § 262(*l*)(8)(A).

For purposes of this motion, the parties have stipulated that three of the four elements needed for the issuance of a preliminary injunction are met: Apotex does not contest the elements of irreparable harm, balance of hardships or the public interest being served by an injunction. *See Bryan v. Hall Chem. Co.*, 993 F.2d 831, 835 (11th Cir. 1993)(discussing the showing needed for issuance of a preliminary injunction). The

parties have presented evidence and argument on the final element: the likelihood of Amgen's success on the merits, and the Court heard oral argument on December 3, 2015. The only issue before the Court is whether the BCPIA requires a company such as Apotex to give a company such as Amgen 180 days notice of its intent to market a licensed biosimilar product (as Amgen claims) or whether (as Apotex argues) the BCPIA merely makes the 180 days notice provision optional at the discretion of the applicant.

The BCPIA is a complex statute that attempts to establish "an abbreviated pathway for regulatory approval of follow-on biological products that are 'highly simliar' to a previously approved product ('reference product')." *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015). Typically, the maker of a biological product must obtain licensing from the Food and Drug Administration ("FDA") through the submission of clinical data that prove the safety and efficacy of its product. *Id.* In an attempt to "balance innovation and price competition," the BCPIA allows the filing of abbreviated applications ("aBLA" or "subsection (k) application") for approval of biological products that are "biosimilar" or "interchangeable" with a previously approved reference product. *Id.* This process allows a biosimilar or interchangeable product to be approved using publicly available clinical data that was produced and obtained by the sponsor of the reference product ("reference product sponsor" or "RPS"). 42 U.S.C. § 262(k)(2)-(5). The innovator RPS is protected through a statutory 12-year period of exclusivity and the right to file "infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product." *Sandoz*, 795 F.3d at 1352.

As part of this abbreviated process, a subsection (k) applicant submits an aBLA to the FDA, and then provides the RPS with a copy of the aBLA and information about the product's manufacturing. 42 U.S.C. § 262(*l*)(2). The parties then exchange lists of patents they believe may be impinged by the biosimilar product and the RPS has 30 days within which to file a patent infringement action on the listed patents. *Id.* § 262(*l*)(6). If and when the biosimilar product is approved by the FDA for sale and use, § 262(*l*)(8) provides that the biosimilar applicant "shall" provide the RPS with 180 days notice of approval before marketing the biosimilar product for sale and use in the United States. *Id.* § 262(*l*)(8). This 180-day period "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 listed or licensed patents (collectively, 'non-listed patents'), *Id.* § 262(*l*)(7)-(8)." *Sandoz,* 794 F.3d at 1352. If the biosimilar applicant fails to comply with certain provisions of subsection (*l*), including § 262(*l*)(8), the RPS (but not the applicant) may seek declaratory relief. 42 U.S.C. § 262(*l*)(9)(B) and (C).

Amgen is an RPS that developed, manufactures and markets a biologic therapy known as Neulasta, which is approved by the FDA for use in treating certain cancer patients receiving chemotherapy. Apotex submitted an aBLA to the FDA, seeking approval of a biosimilar version of Neulasta. Apotex complied with the BCPIA and disclosed its aBLA and information about its manufacturing process to Amgen, pursuant to § 262(*l*)(2). Based upon the list of patents compiled by the parties, Amgen filed this action to enforce two of its patents. Apotex has informed Amgen that it will not notify

Amgen when and if it obtains FDA approval for its biosimilar product and it will not provide the 180 days commercial marketing notice as required in § 262(*l*)(8). Amgen requests injunctive relief in the form of an order requiring Apotex to provide Amgen with notice of FDA approval of Apotex's pegfilgrastim product and to refrain from marketing its licensed product for at least 180 days from the date of such notice.

As previously stated, the issue is whether the commercial marketing notice and 180 day period in § 262(*l*)(8) is mandatory. Paragraph 262(*l*)(8) provides that "[t]he 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) (emphases added). "The word 'shall' is ordinarily the language of command." *In re Tennyson*, 611 F.3d 873, 877 (11th Cir. 2010), *quoting Alabama v. Bozeman*, 533 U.S. 146, 153, 121 S.Ct. 2079, 2085, 150 L.Ed.2d 188 (2001) (quotation omitted). However, in the realm of statutory construction, "shall" may sometimes mean "may." "Use of the word "shall" generally indicates a mandatory intent unless a convincing argument to the contrary is made." *Sierra Club v. Train*, 557 F.2d 485, 489 (5th Cir. 1977). And that is where the parties lead us: Amgen argues that "shall" means shall in all cases, while Apotex argues that "shall" means shall only in some cases.

The Federal Circuit addressed the meaning of "shall" as used in § 262(*l*)(8)(A) in the *Sandoz* case, 794 F.3d 1347, but left some ambiguity which this Court must now address. In *Sandoz,* the subsection (k) applicant submitted the abbreviated application allowed by the BCPIA, but did not provide the RPS with its aBLA or manufacturing process as contemplated by § 262(*l*)(2). Even though § 262(*l*)(2) contained the word

"shall," the Federal Circuit, in a two-person majority, ruled that "shall" in the context of § 262(*l*)(2) is not mandatory. *Sandoz,* 794 F.3d at 1355-57. The court then stated that the word "shall" in the context of § 262(*l*)(8)(A) *does* mean "mandatory." 794 F.3d at 1359. "Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*), and Sandoz concedes as much. . . . . The purpose of paragraph (*l*)(8)(A) is clear: 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 1359-60. However, the *Sandoz* decision was limited to situations where the subsection (k) applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline . . . ." *Id.* at 1360. Because the situation was not before it, the court did not address whether the notice provision of § 262(*l*)(8)(A) applies where the applicant , like Apotex, *did* share the information required by § 262(*l*)(2).

Apotex would have this Court limit the *Sandoz* decision, and the mandatory nature of § 262(*l*)(8)(A), to instances where the applicant did not comply with § 262(*l*)(2) and make the notice provision of § 262(*l*)(8)(A) optional in instances where the applicant did comply with § 262(*l*)(2). This scenario was addressed by Judge Chen in his dissent to the *Sandoz* decision: "While the result in the latter scenario comes from the plain language of the statute, not so with the former. Nothing in the statute supports this peculiar outcome." *Sandoz*, 794 F.3d at 1371 (Chen, J., dissenting). This Court agrees. The scenario proposed by Apotex would result in confusion and uncertainty, as well as inconsistent results, depending on which route a subsection (k) applicant chooses to travel. Nothing in the statute or the *Sandoz* decision leads to or supports

such a result; neither the statute nor the *Sandoz* decision condition the 180 day notice provision of § 262(*l*)(8)(A) upon a subsection (k) applicant's compliance with § 262(*l*)(2).

The BCPIA is intended to provide an orderly process for evaluating patent claims in the context of biosimilar products. Indeed the *Sandoz* court (in the unanimous portion of the decision) recognized that "[g]iving 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." *Id.* at 1358. That defined statutory window exists for all biosimilar products that obtain FDA licenses, regardless of whether the subsection (k) applicant complies with § 262(*l*)(2).

The *Sandoz* court also discounted Apotex's argument that the notice provision of § 262(*l*)(8)(A) unfairly gives the RPS an additional 180 days of exclusivity. Noting that Sandoz filed its aBLA 23 years after the RPS's product was initially approved, the *Sandoz* court agreed that the RPS received an "extra" 180 days, but stated "that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity

period for other products. A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case." *Id.*

Indeed, the "extra" 180 days afforded to Amgen by the injunction it seeks will likely result in a more crystallized patent litigation before this Court. As Amgen concedes, depending on when the FDA grants Apotex's product a license, one of the patents Amgen has filed suit on in this Court may well expire before the 180 day period ends; under Apotex's construction of § 262(*l*)(8)(A), the Court would be forced to rule on the validity of that patent now, even though that patent claim may be moot by the end of the 180 day period. This fact helps illustrate the value and the purpose of applying the 180 day notice provision to all biosimilar applicants.

Finally, the Court disagrees with Apotex's argument that making § 262(*l*)(8)(A) mandatory for all subsection (k) applicants would render the penalty provisions of § 262(*l*)(9) superfluous. Subsection 262(*l*)(9) gives the RPS the option to file a declaratory judgment action if the subsection (k) applicant fails to comply with § 262(*l*)(8)(A) , but it is not an exclusive remedy. As the *Sandoz* court ruled, an injunction to compel compliance with the 180-day notice provision of § 262(*l*)(8)(A) is another remedy. The BCPIA simply does not give the subsection (k) applicant the power to nullify the RPS' statutory right to 180 days notice of approval prior to marketing based on whether or not the subsection (k) applicant complies with § 262(*l*)(2). As Judge Newman stated in her dissent in *Sandoz,* "[s]ubsection 262(*l*)(9) provides jurisdiction in the district court when a subsection (k) applicant fails to comply with subsection (*l*), but it does not ratify non-compliance; While 'a party may waive any provision, either of a

contract or of a statute, intended for his benefit' . . . . the party cannot waive or disregard a provision that benefits those in an adverse position." *Sandoz*, 794 F.3d at 1366 (Newman, J., dissenting), quoting *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995).

On the record before the Court, Amgen has established (1) that Apotex does not intend to comply with § 262(*l*)(8)(A) of the BCPIA; (2) that it would suffer irreparable harm if Apotex were to commence marketing its product without complying with § 262(*l*)(8)(A) ; (3) that the balance of hardships weighs in favor of Amgen; (4) that the public interest will be served by an injunction; and (5) that Amgen has a substantial likelihood of prevailing on the merits. The Court finds that the requested injunctive relief is appropriate. *See, Sandoz*, 794 F.3d at 1360 (enjoining Sandoz from marketing its biosimilar product before 180 days from the date it gave notice of FDA approval).

Rule 65(e), Federal Rules of Civil Procedure, requires the Court to establish an amount of a bond to secure the costs and damages the enjoined party may sustain if the injunction is wrongfully issued. Nevertheless, "it is well-established that 'the amount of security required by the rule is a matter within the discretion of the trial court . . . [,and] the court may elect to require no security at all.'" *City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. Unit B 1981); *BellSouth Telecomms., Inc. v. MCImetro Access Transmission Servs.*, 425 F.3d 964, 971 (11th Cir. 2005).

The Court finds that no bond is necessary. There are no factual disputes before the Court. It is undisputed that Apotex is not currently approved by the FDA to market

its biosimilar product and is not conducting such marketing. The requested preliminary injunction will require Apotex to notify Amgen when and if it receives FDA approval and will prohibit Apotex from marketing the approved product for 180 days after the notice is provided. This injunction maintains the status quo and leaves the parties in the position mandated by § 262(*l*)(8)(A). Apotex presented evidence of its projected income during the first 180 days of marketing its biosimilar product and requests a bond in that amount, but as the Court has found, Apotex is prohibited by statute from marketing its product for 180 days after it obtains FDA licensure. Apotex will lose nothing to which it is otherwise entitled by the entry of this injunction. Therefore, for the reasons discussed herein, it is hereby

ORDERED AND ADJUDGED that Amgen's Motion for Preliminary Injunction DE [42] be and the same is **GRANTED**. If the FDA approves Apotex's Biologics License Application for its pegfilgrastim product, Apotex must provide Amgen with at least 180 days notice before the date of the first commercial marketing of the biological product approved by the FDA. 42 U.S.C. § 262(*l*)(8)(A). Apotex and those acting in concert with it are enjoined from any commercial marketing of its biosimilar pegfilgrastim product, including selling that product or offering it for sale for use in the United States, until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before its pegfilgrastim biosimilar product is licensed by the FDA, and the 180-day notice period is exhausted. No bond is required to be posted by Amgen.

DONE AND ORDERED in Chambers, Fort Lauderdale, Florida, this 9th day of December, 2015.

JAMES I. COHN
United States District Judge