Appeal No. 2016-1308

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellees,

– v. –

APOTEX INC., APOTEX CORP.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA IN NO. 0:15-cv-61631-JIC, JUDGE JAMES I. COHN

BRIEF FOR PLAINTIFFS-APPELLEES AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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February 4, 2016

AMENDED CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

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STATEMENT OF RELATED CASES

Plaintiffs-Appellees Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") agree with the Statement of Related Cases from Defendants-Appellants Apotex Inc. and Apotex Corp. (together, "Apotex"): There has been no prior appeal, to this or any other appellate court, in or from the same civil action in the lower court. There is one related case that may be directly affected by this Court's decision: *Amgen Inc. et al. v. Apotex Inc. et al.*, Case No. 15-62081-CIV-COHN/SELTZER (S.D. Fla.), a patent litigation involving Appellants' application to the Food and Drug Administration for approval to make and sell a biosimilar version of a different Amgen product, NEUPOGEN® (filgrastim). That action has been consolidated with this action.

Amgen further notes, for the Court's convenience, that the issues raised by this appeal overlap with those presented to the Court in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015) ("*Amgen v. Sandoz*").

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that the pre-marketing notice requirement of 42 U.S.C. § 262(*l*)(8)(A) is mandatory and applies to subsection (k) applicants who have complied with the disclosure provisions of paragraph (*l*)(2)(A), as Apotex did here, where:

   a. the statute provides that "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)" (emphasis added); and

   b. this Court held in *Amgen v. Sandoz* that the "'shall' provision in paragraph (*l*)(8)(A) is mandatory" and paragraph (*l*)(8)(A) is a "standalone notice provision" in that "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)."

2. Whether the district court acted within its discretion by enjoining Apotex from commercial marketing of its proposed biosimilar product until Apotex has complied with paragraph (*l*)(8)(A), where the district court found on the record before it that Apotex did not intend to comply with paragraph (*l*)(8)(A), that Amgen was substantially likely to prevail on the merits, and, based at least in part on a stipulation between the parties, that:

a. Amgen would suffer irreparable harm if Apotex were to commence commercial marketing of its product without complying with paragraph (*l*)(8)(A);

b. the balance of hardships weighs in favor of Amgen; and

c. the public interest will be served by an injunction.

PRELIMINARY STATEMENT

This is an appeal from a preliminary-injunction order requiring Apotex to provide notice of commercial marketing to Amgen under 42 U.S.C. § 262(*l*)(8)(A), as required by the plain text of that statutory provision and the plain words of this Court's decision in *Amgen v. Sandoz* construing that statute. Because the district court correctly concluded that Amgen is likely to succeed on the merits of its legal arguments that Apotex must provide such notice, and because Apotex stipulated and the district court found on the record before it that all of the other prerequisites for injunctive relief were satisfied, this Court should affirm.

The statute is the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), Pub. L. No. 111-148, 124 Stat. 119 (2010). Under the abbreviated regulatory pathway of the BPCIA codified in 42 U.S.C. § 262(k), Apotex applied to the Food and Drug Administration for approval of a "biosimilar" version of Amgen's NEULASTA® (pegfilgrastim), a medication that helps the body fight infection during chemotherapy. Appx3, 41, 110. In the vocabulary of the BPCIA, Amgen Inc. is the Reference Product Sponsor (or, "RPS") because Apotex chose to rely on Amgen's prior demonstration of the safety and efficacy of NEULASTA® and the resulting FDA license granted to Amgen under the traditional biologics regulatory standard, 42 U.S.C. § 262(a), as support for licensure of its biological product; and Apotex Inc. is the "subsection (k) applicant" (or, "Applicant")

because Apotex is seeking FDA approval under the BPCIA's abbreviated pathway for a biosimilar pegfilgrastim product designating Amgen's NEULASTA® as the reference product. *See* 42 U.S.C. § 262(*l*)(1)(A).

Triggered by the submission of a Biological License Application under the 42 U.S.C. § 262(k) abbreviated pathway ("aBLA"), subsection 262(*l*), entitled "Patents," lays out a series of steps by which the Applicant and the RPS exchange information and then the RPS files a patent infringement suit. That process was discussed at length in *Amgen v. Sandoz*. *See* 794 F.3d at 1351-52. One step of that process—the step at issue here—is the Applicant's provision of notice to the RPS after FDA approval of its aBLA and prior to the first commercial marketing of the licensed biosimilar product.

That provision, 42 U.S.C. § 262(*l*)(8)(A), states as follows:

> *Notice of Commercial Marketing.* The subsection (k) applicant [here, Apotex] shall provide notice to the reference product sponsor [here, Amgen] not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(emphasis added). Paragraph (*l*)(8)(B) authorizes the RPS to commence preliminary-injunction proceedings "After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product." And paragraph (*l*)(8)(C) provides for further, expedited discovery if the RPS seeks such a preliminary injunction. The pre-marketing notice also acts to lift

statutorily imposed limitations on declaratory-judgment actions with respect to certain drug patents. *See* 42 U.S.C. § 262(*l*)(9)(A); 28 U.S.C. § 2201(b).

Despite the plain language of the statute, Apotex argues that it need not give pre-marketing notice at all because it complied with paragraph (*l*)(2)(A) of the BPCIA and gave Amgen a copy of its aBLA. The district court correctly concluded that Apotex is wrong: the "commercial marketing notice and 180 day period in § 262(*l*)(8)(A) is mandatory" and is not optional in instances where the Applicant complied with § 262(*l*)(2). Appx4-6. As the district court noted, "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)." Appx6.

This is not an issue of first impression, as Apotex asserts. (Blue Br. at 3.) In *Amgen v. Sandoz,* this Court interpreted and expressly concluded that paragraph (*l*)(8)(A) is mandatory: "A question exists, however, concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is." *Amgen*, 794 F.3d at 1359 (emphasis added). This sentence is not limited to certain circumstances or certain Applicants; it is an unqualified assertion that paragraph (*l*)(8)(A) is mandatory.

This Court also concluded in *Amgen v. Sandoz* that paragraph (*l*)(8)(A) is not tied to other provisions of subsection 262(*l*), but instead stands alone: "Paragraph

(*l*)(8)(A) is a standalone notice provision in subsection (*l*) . . . ." *Id.* Thus, this Court concluded that the pre-marketing-notice requirement of paragraph (*l*)(8)(A) is not conditioned on whether an Applicant provides the RPS with a copy of its aBLA and manufacturing information under paragraph (*l*)(2)(A): "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Id*. at 1360.

In its Blue Brief, Apotex does not mention, cite, or engage with these passages in *Amgen v. Sandoz*. Likewise, in the district court, Apotex was completely silent on them. Rather, Apotex relies on a sentence at the end of the majority's discussion of paragraph (*l*)(8)(A) to argue that paragraph (*l*)(8)(A) is not mandatory if an Applicant provides its aBLA to the RPS: "We 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. Apotex reads this to imply the converse, that paragraph (*l*)(8)(A) is not mandatory if an Applicant provides its aBLA to the RPS, as Apotex did.

Neither that specific sentence nor the decision in *Amgen v. Sandoz* exists to benefit Apotex. And Apotex's reading of this sentence—to limit the mandatory nature of paragraph (*l*)(8)(A) to certain Applicants but not others—is too broad. The sentence comes after this Court already held as a matter of law that paragraph

(*l*)(8)(A) is mandatory and a "standalone provision" which is not conditioned on paragraph (*l*)(2)(A). *Id.* at 1359-60. The sentence does not then narrow the Court's statutory construction of paragraph (*l*)(8)(A); rather it applies the Court's holding to the facts of the *Amgen v. Sandoz* case to determine that Sandoz was subject to the mandatory pre-marketing notice required in (*l*)(8)(A) even though Sandoz did not comply with paragraph (*l*)(2)(A). *Id.*

Therefore, the district court correctly concluded that Apotex must provide notice of commercial marketing, after FDA approval of its aBLA and at least 180 days before that commercial marketing begins. Appx5-6. In *Amgen v. Sandoz*, this Court forbade Sandoz from marketing its biosimilar product until 180 days after the day of notice of first commercial marketing. "Sandoz . . . may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015," *Amgen*, 794 F.3d at 1360-61. That is the same relief that the district court ordered here. Accordingly, Amgen respectfully requests that this Court affirm the district court's grant of a preliminary injunction to Amgen.

STATEMENT OF THE CASE

Apotex has applied for FDA approval to make and sell a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product. Appx3, 41, 110. FDA has not yet approved that application. This is a patent-infringement case brought by Amgen against Apotex pursuant to paragraph (*l*)(6) of the BPCIA. Appx39-107.

While Apotex complied with the early steps of the BPCIA's patent-dispute process, *see id.* § 262(*l*)(1)-(6), after this Court decided *Amgen v. Sandoz* Apotex announced that it would not provide the pre-marketing notice required by paragraph (*l*)(8)(A). Appx180, 188-190, 191-92. Amgen sought, and the district court granted, a preliminary injunction prohibiting Apotex from commercial marketing of its biosimilar pegfilgrastim until Apotex complies with the notice provisions of that paragraph. Appx9. To do so, Apotex must give notice of commercial marketing only after FDA approval of its application, and must then wait 180 days after giving that notice before it begins commercial marketing of the licensed biosmilar product. *Id.*

This is an appeal from the grant of that preliminary injunction.

STATEMENT OF THE FACTS

A. Amgen's NEULASTA® (Pegfilgrastim) Product

Amgen Inc. discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Appx39, 108-09. Amgen Manufacturing Limited manufactures and sells biologic medicines for treating diseases in humans. Appx39, 109.

Amgen's NEULASTA® (pegfilgrastim) is a recombinantly produced protein that stimulates the production of neutrophils, a type of white blood cell. Appx46-

47, 116, 175-76. It is used to counteract neutropenia, a neutrophil deficiency that makes a person highly susceptible to life-threatening infections and is a common side effect of certain chemotherapeutic drugs. *Id.*

In 2002, Amgen obtained regulatory approval for NEULASTA® under the traditional biologics regulatory pathway, 42 U.S.C. § 262(a). Appx179-82, 201-03. To do so, Amgen demonstrated to FDA that NEULASTA® "is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). Amgen Inc. is the owner of the FDA license for NEULASTA®. *Id.*

The value of the biological license for NEULASTA® to Amgen, to would-be Applicants and to society is the direct result of significant investments by Amgen. That is not unusual. Developing innovative pharmaceutical products requires enormous amounts of time, human resources, and money. The average cost to develop a new drug (including the cost of failures) exceeds $1 billion. Appx181, 204-11, 227.

As the BPCIA recognizes, Amgen and other innovative biopharmaceutical companies seek to protect their investments through patenting their inventions. Amgen is asserting two patents in this case—U.S. Patent Nos. 8,952,138 and 5,824,784—that are directed to pegfilgrastim and to methods of making recombinant proteins like pegfilgrastim. Appx45-46, 58-76, 77-107.

B. Apotex's aBLA for Biosimilar Pegfilgrastim

Apotex Inc. develops, manufactures, and sells pharmaceuticals, including generic medicines. Appx109. Apotex Corp. markets pharmaceuticals in the United States, including generic medicines. *Id.*

Apotex filed an aBLA under the BPCIA's abbreviated pathway, 42 U.S.C. § 262(k), seeking approval of its biosimilar pegfilgrastim product, designating Amgen's NEULASTA® as the reference product. Appx47, 116-17. On December 16, 2014, Apotex notified Amgen that FDA had accepted Apotex's aBLA for review. Appx48, 117. FDA has not yet approved Apotex's aBLA.

C. The Parties' Exchanges of Information Pursuant to the BPCIA

Prior to the enactment of the BPCIA, innovators enjoyed permanent and exclusive rights to their clinical trial data and FDA license, and FDA would approve a second manufacturer's version of a licensed biologic only under the traditional, full regulatory pathway of 42 U.S.C. § 262(a), which typically involves three phases of clinical trials to prove safety and efficacy. *See Amgen*, 794 F.3d at 1351.

Congress enacted the BPCIA as part of the Affordable Care Act, because it was "the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804. In creating the abbreviated regulatory pathway,

Congress advanced the public's interest in price competition in part by decreasing innovators' rights. *See Amgen*, 794 F.3d at 1351-52. Applicants can now "reference" the innovator's license pursuant to the BPCIA, and thereby rely on the innovator's prior demonstration of safety and efficacy. *See* 42 U.S.C. § 262(k); *Amgen,* 794 F.3d at 1351. This saves the Applicant significant time, risk, and expense, and lets the Applicant enter a market with established demand for the product.

On the other side of the balance, Congress protected the public's interest in fostering innovation—the purpose of patents—by establishing a mechanism by which the RPS receives information, notice, and a period of time to assess and act on its patent rights, without imposing on the courts for emergency relief to prevent actual injury from patent infringement. *See* 42 U.S.C. § 262(*l*); *Amgen*, 794 F.3d at 1351-52.

The BPCIA established a patent-dispute-resolution regime that includes amendments to Titles 28, 35, and 42 of the United States Code. *Amgen*, 794 F.3d at 1352. The BPCIA made submission of an aBLA an artificial act of patent infringement, *see* 35 U.S.C. § 271(e)(2)(C), and allowed aBLAs to be submitted, and thus infringement suits to be filed, as early as 8 years before FDA approval of the biosimilar product, *see* 42 U.S.C. § 262(k)(7)-(8). The BPCIA also provided for infringement suits to be filed on the RPS's patents even after FDA approval,

but before commercial marketing of the biosimilar product first begins. *See* 42 U.S.C. § 262(*l*)(8)(B), (9)(A). And although the BPCIA put limits on declaratory-judgment actions, *see* 28 U.S.C. § 2201(b) and 42 U.S.C. § 262(*l*)(9), by making submission of an aBLA an artificial act of patent infringement Congress gave the RPS access to the courts without the need to plead jurisdiction under another Patent Act provision and without the attendant risk that a court might decline to exercise its discretionary power to declare the rights of the parties under the Declaratory Judgment statute. *See* 35 U.S.C. § 271(e)(2)(C); *Amgen*, 794 F.3d at 1352. The BPCIA "established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes." *Amgen*, 794 F.3d at 1352. That process is embodied in 42 U.S.C. § 262(*l*), "Patents."

The BPCIA contemplates two phases when the Applicant and the RPS fully comply with the patent provisions of the statute, each targeted at orderly resolution of patent disputes. The first phase begins with the Applicant's submission of an aBLA, as it did here with Apotex's submission. Within 20 days after FDA notifies a biosimilar Applicant that its aBLA has been accepted for review, the Applicant gives the RPS a copy of its aBLA and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," 42 U.S.C. § 262(*l*)(2)(A); *Amgen*, 794 F.3d at 1352. FDA

accepted Apotex's aBLA for its biosimilar pegfilgrastim product on December 15, 2014. Appx136. Apotex notified Amgen the next day, and thereafter provided its aBLA to Amgen. Appx48, 117. Apotex did not provide any additional manufacturing information, but Amgen has no basis to contend any such additional manufacturing information existed, and agrees for purposes of this motion that Apotex satisfied paragraph (*l*)(2)(A).

Next follows a sequential exchange of "lists of patents for which" the parties "believe a claim of patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents." *Amgen*, 794 F.3d at 1352. The RPS initiates the exchange with a patent list in accordance with 42 U.S.C. § 262(*l*)(3)(A). The Applicant "may" respond with its own list of additional patents that could be infringed, but must provide—"shall provide"—for each listed patent either a statement that it will remain off the market until the patent expires or, on a claim-by-claim basis, a detailed statement of its factual and legal basis for believing that the patent is invalid, unenforceable, or not infringed. 42 U.S.C. § 262(*l*)(3)(B). Finally, the RPS then "shall provide," for the disputed patents, a detailed statement that each patent will be infringed and a response to the Applicant's invalidity and unenforceability contentions. *Id.* § 262(*l*)(3)(C).

Apotex and Amgen engaged in the exchanges described in paragraph (*l*)(3). The exchange was complete by June 16, 2015. Appx48, 117-18.

The next step in this first phase of the BPCIA is for the parties—informed by the prior exchange—to attempt to agree, under paragraph (*l*)(4), on which of the patents listed pursuant to paragraph (*l*)(3), if any, should be included in an immediate patent-infringement action and, failing agreement, to follow a dispute-resolution procedure under paragraph (*l*)(5) to identify those patents. *See Amgen*, 794 F.3d at 1352. Either way, once the parties have arrived at the list of patents on which suit will be brought, the RPS is then directed to bring an "Immediate patent infringement action" on each of the listed patents within 30 days. 42 U.S.C. § 262(*l*)(6); *Amgen*, 794 F.3d at 1352. The Applicant must provide the complaint to FDA, which must publish it in the Federal Register. 42 U.S.C. § 262(*l*)(6).

Apotex and Amgen agreed that Amgen would file suit under paragraph (*l*)(6) on two patents, U.S. Patent Nos. 8,952,138 and 5,824,784. Appx48-49, 118. Amgen did so on August 8, 2015. Appx39. This is that lawsuit.

D. Further Steps Under the BPCIA and Pre-Marketing Notice

The RPS's obligation to identify patents does not end with the exchange of patent lists pursuant to paragraph (*l*)(3) or with the filing of an immediate patent litigation under paragraph (*l*)(6). Instead, if a patent is newly issued to, or exclusively licensed by, the RPS after it has provided its paragraph (*l*)(3)(A) list,

the RPS must supplement that list within 30 days. *See* 42 U.S.C. § 262(*l*)(7); *see also Amgen*, 794 F.3d at 1352. Within 30 days thereafter, the Applicant "shall provide" the RPS with a statement in accordance with paragraph (*l*)(3)(B), providing for each listed patent either a statement that it will remain off the market until the patent expires or, on a claim-by-claim basis, a detailed statement of its factual and legal basis for believing that the patent is invalid, unenforceable, or not infringed. *See* 42 U.S.C. § 262(*l*)(3)(B), (7); *see also Amgen*, 794 F.3d at 1352.

These newly issued or licensed patents, along with patents that were initially listed under paragraph (*l*)(3) but not listed for inclusion in the paragraph (*l*)(6) lawsuit, then become subject to 42 U.S.C. § 262(*l*)(8), entitled "Notice of commercial marketing and preliminary injunction." *See Amgen*, 794 F.3d at 1352. That paragraph contains the requirement of pre-marketing notice, the provision at issue on this appeal, 42 U.S.C. § 262(*l*)(8)(A).[1]

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[1] Apotex suggests that where there are newly issued or newly licensed patents identified under paragraph (*l*)(7), that provision "requires the parties to again exchange lists of patents . . . , and determine whether or not such patent should be added to the pending litigation." (Blue Br. at 34.) Paragraph (*l*)(7) only "requires" the RPS to supplement the (*l*)(3)(A) list and the Applicant to provide a statement in accordance with (*l*)(3)(B). That provision is silent regarding the parties determining whether or not such patents are added to the paragraph (*l*)(6) lawsuit. Notably, paragraph (*l*)(7) makes no reference to paragraphs (*l*)(3)(C), (*l*)(4), (*l*)(5), or (*l*)(6), but it does reference paragraph (*l*)(8), and paragraph (*l*)(9)(A) limits the parties' ability to bring declaratory-judgment actions on those newly issued or newly licensed patents before the RPS receives the Applicant's notice of commercial marketing under paragraph (*l*)(8)(A). Thus, while the issue is not before the Court on this appeal, the more natural reading of these provisions is not

The second phase of the BPCIA's orderly resolution of patent disputes starts at FDA approval of the Applicant's biosimilar product. FDA licensure of the biosimilar product authorizes the Applicant to commercially market the biosimilar in the United States. It also triggers the Applicant's obligation to give the RPS at least 180 days' advance notice of the date of the first commercial marketing of the licensed biosimilar product. *See* § 262(*l*)(8)(A); *Amgen*, 794 F.3d at 1358. As this Court observed, "Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the RPS at least 180 days prior to commercial marketing of its product licensed under subsection (k), which then allows the RPS a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents." *Amgen*, 794 F.3d at 1352. Paragraph (*l*)(8) provides:

> (8) Notice of commercial marketing and preliminary injunction
>
> (A) Notice of commercial marketing
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before

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that the parties are required to determine whether these patents are added to a pending paragraph (*l*)(6) litigation but rather as Apotex itself says earlier in its brief: "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." (Blue Br. at 5.)

> the date of the first commercial marketing of the biological product licensed under subsection (k).
>
> (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). "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." *Amgen*, 794 F.3d at 1360.

On April 17, 2015, Apotex purported to provide notice of commercial marketing to Amgen. Appx179, 183-84. Amgen responded on May 8, 2015, asserting that paragraph (*l*)(8)(A) notice cannot be given until FDA approves the Applicant's aBLA, among other things, because the statute refers to "the biological

product licensed under subsection (k),” and there is no product licensed prior to FDA approval. Appx180, 185-87.

E. Limitations on Declaratory Judgments

The BPCIA borrows from the Hatch-Waxman Act and prohibits gaming the system by placing limits on any actions for declaratory judgments with respect to patents that do not make the list, pursuant to either paragraph (*l*)(4) or (*l*)(5), for the immediate patent infringement action under paragraph (*l*)(6), plus later-issued or -licensed patents under paragraph (*l*)(7). Assuming compliance with the BPCIA patent provisions, that limitation first ends when the Applicant gives at least 180 days’ advance notice of first commercial marketing of the licensed biosimilar product. Thus, paragraph (*l*)(9) provides:

> (9) Limitation on declaratory judgment action
>
> (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).

Deferring the availability of declaratory-judgment actions until the Applicant provides the notice of commercial marketing benefits both the Applicant and the RPS, for example by ensuring that both parties earnestly engage in the first phase of the BPCIA’s patent-resolution process and providing clarity that the

respective rights of the parties are and will be preserved. If the Applicant fails to complete an action, the limitation on declaratory-judgment actions is maintained with respect to the Applicant but not with respect to the RPS:

> (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).
>
> (C) Subsection (k) application not provided—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.

42 U.S.C. § 262(*l*)(9)(B), (C).

F. The *Amgen v. Sandoz* Decision

This Court's decision in *Amgen v. Sandoz* is controlling precedent, and it also explains some of Apotex's actions.

Sandoz sought (and eventually received) FDA approval to market a biosimilar version of another of Amgen's biological products, NEUPOGEN® (filgrastim). *Amgen*, 794 F.3d at 1352-53. On July 8, 2014, Sandoz notified

Amgen that it had filed an aBLA for its filgrastim product, that it believed the application would be approved in the first half of 2015, and that Sandoz "intended to launch its biosimilar product immediately upon FDA approval." *Id.* Sandoz deemed that to be notice under paragraph (*l*)(8)(A) even though FDA had not yet approved its aBLA. *Id.* at 1353. Further, Sandoz informed Amgen that Sandoz had chosen not to proceed in accordance with paragraph (*l*)(2)(A) and would not provide Amgen with its aBLA and manufacturing information. *Id.* Amgen sued Sandoz in the Northern District of California for patent infringement and for state-law conversion and unfair competition based on underlying violations of the BPCIA, and sought a preliminary injunction to compel Sandoz to provide the disclosure called for by paragraph (*l*)(2)(A) and to compel Sandoz to provide at least 180 days' notice of first commercial marketing after, but only after, FDA approval of Sandoz's application. *Id.*

While the motion was pending in the district court, on March 6, 2015, FDA approved Sandoz's aBLA. *Id.* That day, Sandoz again provided 180 days' notice of commercial marketing, maintaining that its July 2014 notice had been effective but nevertheless giving "a 'further notice of commercial marketing' to Amgen on the date of FDA approval." *Id.*

The district court denied Amgen's motion and entered judgment against Amgen on its state-law claims, interpreting paragraph (*l*)(2)(A) as permitting non-

disclosure subject only to the consequences set forth in paragraph (*l*)(9)(C), interpreting paragraph (*l*)(8)(A) as permitting notice of commercial marketing before FDA approval and finding, based on these interpretations of the statute, that Sandoz had not violated the BPCIA. *Id.*

Amgen appealed. Under the four-factor test for injunctive relief, this Court granted Amgen's motion for an injunction pending appeal, and enjoined Sandoz from "marketing, selling, offering for sale, or importing into the United States its FDA-approved ZARXIO® biosimilar product until this Court resolves the appeal." Appx193-95; *see also Amgen*, 794 F.3d at 1362.

After receiving full briefing and hearing oral argument, the Court affirmed in part and reversed in part. Judge Lourie wrote the Panel opinion, but was joined in different parts of that opinion by Judges Newman and Chen, who each dissented in part as well.

Regarding paragraph (*l*)(2)(A), Judges Lourie and Chen held that an Applicant does not "violate" the BPCIA by not disclosing its aBLA and manufacturing information, interpreting the "shall" of paragraph (*l*)(2)(A) as not meaning "must," in view of the existence of consequences for such failure. *Amgen*, 794 F.3d at 1355. And when an Applicant, like Sandoz, has "failed the disclosure requirement," paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e) "expressly provide the only remedies as those being based on a claim of patent infringement."

Id. at 1357; *see generally id.* at 1353-57. From this, Judge Newman dissented, and would have held that providing the aBLA and manufacturing information is mandatory and that paragraph (*l*)(9)(C) does not excuse or ratify non-compliance with paragraph (*l*)(2)(A). *Id.* at 1364 (Newman, J., concurring in part, dissenting in part).

Turning to 180 days' notice under paragraph (*l*)(8)(A)—the provision at issue here—the Panel unanimously held that to be effective, notice may be given only after FDA approval:

> We therefore conclude that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The district court thus erred in holding that a notice of commercial marketing under paragraph (*l*)(8)(A) may effectively be given before the biological product is licensed, and we therefore reverse its conclusion relating to its interpretation of § 262(*l*)(8)(A) and the date when Sandoz may market its product.

Id. at 1358 (majority opinion).

The Panel then considered the impact of that decision on the facts of the case before it. Judges Lourie and Newman held that the requirement of notice under paragraph (*l*)(8)(A) is mandatory: "A question exists, however, concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is." *Id.* at 1359. They extended the injunction pending appeal until only

September 2, 2015, exactly 180 days after Sandoz gave post-FDA-approval notice of commercial marketing. *Id.* at 1360.

Judge Chen dissented in this part, and would have held that because Sandoz did not provide its disclosure under paragraph (*l*)(2)(A), none of the subsequent provisions, including paragraph (*l*)(8)(A), applied to the dispute between Amgen and Sandoz: when "the (k) applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.* at 1367 (Chen, J., dissenting in part).

Each of Amgen and Sandoz petitioned for en banc review, and the Court denied those petitions. Appx305-07.

G. Apotex's Newfound Position Regarding Notice Under Paragraph (*l*)(8)(A)

The decision in *Amgen v. Sandoz* rendered Apotex's April 17, 2015 notice of commercial marketing ineffective, because it was given before FDA approval of Apotex's application. An Applicant "may only give effective notice of commercial marketing after the FDA has licensed its product." *Amgen*, 794 F.3d at 1358 (emphasis added).

On August 24, 2015, Apotex's counsel wrote to Amgen's counsel to assert that, under *Amgen v. Sandoz*, Apotex believed that it was not required to give 180 days' notice under paragraph (*l*)(8)(A) at all, because Apotex—unlike Sandoz—had provided its aBLA under paragraph (*l*)(2)(A). Appx192. Apotex asserted that "because Apotex followed the pathway and provided Amgen with its application

and manufacturing information, providing a notice of commercial marketing is not mandatory." *Id.*

H. The Motion for a Preliminary Injunction

Amgen sought a preliminary injunction restraining Apotex from commercial marketing of its biosimilar pegfilgrastim product on any license issuing from its pending aBLA until it provides 180 days' notice after FDA approval of that product. Appx173. The parties agreed that whether Amgen is likely to succeed in showing that the BPCIA requires Apotex to give that notice is a question of law. Appx181, 196-200. And the parties stipulated, to the fullest extent possible, to the other elements of the test for preliminary injunctive relief, including irreparable harm, the balance of hardships, and the public interest. *Id.*

I. The District Court's Decision

The district court found for Amgen, holding that the BPCIA requires Apotex to provide Amgen with at least 180 days' notice of first commercial marketing under paragraph (*l*)(8)(A). Appx5-6. It concluded that Apotex's compliance with paragraph (*l*)(2) does not cause the "shall" in paragraph (*l*)(8)—the same "shall" that this Court termed "mandatory"—to be optional, because "neither the statute nor the [*Amgen v.*] *Sandoz* decision condition the 180 day notice provision of § 262(*l*)(8)(A) upon a subsection (k) applicant's compliance with § 262(*l*)(2)." Appx5-6. The district court noted that 180 days' notice to Amgen will likely result

in a more crystallized patent litigation before the court, a point that the *Amgen* majority also recognized. Appx7; *see Amgen*, 794 F.3d at 1358. Finally, the district court rejected Apotex's argument that treating paragraph (*l*)(8)(A) as mandatory would render paragraph (*l*)(9)(B) superfluous. Appx7. While paragraph (*l*)(9)(B) makes clear that where an Applicant fails to provide a legally effective notice as required by paragraph (*l*)(8)(A) the RPS's ability to file a declaratory-judgment action will be preserved, the district court found that paragraph (*l*)(9) is not the RPS's exclusive remedy: "[a]s the *Sandoz* court ruled, an injunction to compel compliance with the 180-day notice provision of § 262(*l*)(8)(A) is another remedy." *Id.*

The district court summarized its findings in the language of the traditional injunction factors:

> On the record before 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* [*Amgen v.*] *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).

Appx8. The district court enjoined Apotex from commercial marketing of its pegfilgrastim product "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." Appx9. Because the district court held that this injunction would cause Apotex to comply with a statute and thus "Apotex will lose nothing to which it is otherwise entitled by the entry of this injunction," the district court held that Amgen need not post a bond. *Id.*

Apotex timely appealed. Appx10-13.

SUMMARY OF THE ARGUMENT

The question on this appeal is whether the requirement in 42 U.S.C. § 262(*l*)(8)(A)—that an Applicant give 180 days' notice before beginning commercial marketing of an approved biosimilar—applies to Apotex, where the parties accept that Apotex complied with the disclosure requirements of 42 U.S.C. § 262(*l*)(2)(A). Apotex asserts that its provision of its aBLA pursuant to paragraph (*l*)(2)(A) exempted it from compliance with the pre-marketing notice requirement of paragraph (*l*)(8)(A), on the theory that providing notice under paragraph (*l*)(8)(A) is required only for Applicants (like Sandoz in *Amgen v. Sandoz*) that completely fail to provide the paragraph (*l*)(2)(A) disclosure.

Amgen respectfully submits that Apotex's argument is foreclosed by the language of the statute and by this Court's decision in *Amgen v. Sandoz*. Paragraph (*l*)(8)(A) does not exempt some Applicants and apply to others, but instead addresses all Applicants without exception: "[t]he subsection (k) applicant shall provide notice to the reference product sponsor . . . ." 42 U.S.C. § 262(*l*)(8)(A). In *Amgen v. Sandoz*, the majority expressly asked whether this provision is mandatory, and concluded that it is: "A question exists . . . concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is." 794 F.3d at 1359. The majority rejected any linkage to compliance or non-compliance with the disclosure requirements of paragraph (*l*)(2)(A), declaring

paragraph (*l*)(8)(A) to be a "standalone" notice provision and holding that "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Id.* at 1359-60.

Apotex never cites these parts of the decision. It has no answer to them. It had no answer to them in the district court, either. *See* Appx385-86, 432-34.

Based on the language of paragraph (*l*)(8)(A) and the statute's legislative purpose, and finding further support in the majority's decision in *Amgen v. Sandoz*, the district court held that the notice requirement is mandatory even for an Applicant that provides the information called for by paragraph (*l*)(2)(A). Appx4-6.

Apotex argues that *Amgen v. Sandoz* is limited to the particular facts of that case, in which Sandoz had refused to provide its aBLA and manufacturing information under paragraph (*l*)(2)(A). Apotex thus focuses on this sentence from the majority's opinion: "We 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. Apotex reads this to imply the converse, that an Applicant that does provide its aBLA and manufacturing information is excused from the notice requirement of paragraph (*l*)(8)(A). Apotex misses the point of this sentence. This sentence comes after the majority interpreted paragraph

(*l*)(8)(A) to be mandatory and a "standalone" provision that is not conditioned on paragraph (*l*)(2)(A). In this sentence, the majority considered the impact of its statutory construction of paragraph (*l*)(8)(A) to hold that the specific Applicant at issue in that appeal (Sandoz) was not exempted from paragraph (*l*)(8)(A) simply by refusing to participate in the patent-exchange provisions of subsection 262(*l*).

Judge Chen's dissent agreed with Sandoz, and would have held that once an Applicant "fails to comply with (*l*)(2)," "the provisions in (*l*)(3)-(*l*)(8) cease to matter" and the Applicant is excused from the obligation to give notice under paragraph (*l*)(8)(A). *Id.*at 1367 (Chen, J., dissenting in part). But this is not the binding precedent of the Court. The majority (here, Judges Lourie and Newman) held that paragraph (*l*)(8)(A) notice is mandatory even for an Applicant like Sandoz that "completely fails" to provide its aBLA and manufacturing information. *Id.* at 1360 (majority opinion). The sentence on which Apotex seizes underscores the conclusion that notice is mandatory for Applicants like Apotex that do provide their paragraph (*l*)(2)(A) disclosure, which is what the majority held when it declared paragraph (*l*)(8)(A) to be a mandatory, standalone provision not conditioned on paragraph (*l*)(2)(A) or anything else. *Id.* at 1359-60.

Apotex also tries to find support in paragraph (*l*)(9)(B), one of the provisions in subsection (*l*)(9), which itself is entitled "Limitations on declaratory judgment actions--." There is no support there. Subsection (*l*)(9) establishes bars to gun-

jumping akin to those in the Hatch-Waxman Act. It provides that until the Applicant gives post-FDA-approval, pre-marketing notice under paragraph (*l*)(8)(A), neither the RPS nor the Applicant may bring a declaratory judgment on patents that were not listed for the paragraph (*l*)(6) lawsuit. *See* 42 U.S.C. § 262(*l*)(9)(A). That patent-specific limitation is lifted for the RPS, but not the Applicant, if the Applicant fails to comply with its obligations under the steps of section 262(*l*). *See id.* § 262(*l*)(9)(B), (C). Apotex says the provisions of paragraph (*l*)(9)(B) are the exclusive remedy for a violation of the notice provision of paragraph (*l*)(8)(A), and thus that a court may not compel compliance with the requirement of providing paragraph (*l*)(8)(A) notice. That is triply wrong. Paragraph (*l*)(9)(B) is not a remedial provision; it provides no remedy, it just lifts a bar to filing declaratory-judgment actions. And paragraph (*l*)(9)(B) is not an exclusive provision; it says the RPS "may" bring a declaratory-judgment action, and does not preclude any other actions. The authors of the statute knew how to articulate an exclusive remedy—35 U.S.C. § 271(e)(4) does exactly that, *see Amgen*, 794 F.3d at 1356—and yet conspicuously chose not to include such language in connection with paragraph (*l*)(9)(B). Lastly, paragraph (*l*)(9)(B) does not preclude a court from issuing an injunction to require compliance with paragraph (*l*)(8)(A); the majority applied that very injunction against Sandoz in *Amgen v. Sandoz*. *Id.* at 1362.

Finally, Apotex argues that requiring it to comply with paragraph (*l*)(8)(A) would unfairly extend Amgen's statutory period of exclusivity from 12 to 12.5 years. (Blue Br. at 29.) The majority in *Amgen v. Sandoz* confronted and squarely rejected this argument, as the district court below noted. *Amgen*, 794 F.3d at 1358; Appx6-7. The 180-day notice period is not a period of exclusivity; nothing prevents another biosimilar from being on the market during that period. It is instead "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," ensuring "the existence of a fully crystallized controversy regarding the need for injunctive relief." *Amgen*, 794 F.3d at 1358.

* * * *

The district court here treated the *Amgen v. Sandoz* decision as leaving open the question on this appeal, namely whether paragraph (*l*)(8)(A) applies to an Applicant (like Apotex, but unlike Sandoz) that complies with the disclosure requirements of paragraph (*l*)(2)(A). The district court then relied on the words of the statute, its purpose, and the logic of the *Amgen v. Sandoz* decision to hold that the notice requirement of paragraph (*l*)(8)(A) applies to Apotex. Amgen respectfully submits that this is not actually a question of first impression, and that the majority's decision in *Amgen v. Sandoz* already answered whether notice under paragraph (*l*)(8)(A) is mandatory for Applicants in Apotex's position. *Id.* at 1358-

59. Notice is mandatory. But whether the question was answered by the *Amgen v. Sandoz* majority or remains open, its answer is clear. Apotex is required to give 180 days' notice after FDA approval and before commencing commercial marketing of its approved biosimilar.

In requiring Apotex to do so, the district court did exactly what the majority did in *Amgen v. Sandoz*. It ensured that an Applicant that gets FDA approval provides notice at least 180 days before the first commercial marketing of its approved product. That is exactly what the statute provides. It is all that Amgen seeks. And there was no error in the district court's grant of an injunction. Accordingly, Amgen respectfully submits that this Court should affirm the district court's entry of a preliminary injunction.

ARGUMENT

This Court applies regional circuit law—here, Eleventh Circuit law—when reviewing a district court's grant of a preliminary injunction. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1367 (Fed. Cir. 2008) (affirming the grant of a preliminary injunction on an abuse of discretion standard). The Eleventh Circuit "review[s] a district court's order granting or denying a preliminary injunction for abuse of discretion." *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998) (citations omitted) (same). Under the Eleventh Circuit's abuse of discretion standard, "a reviewing court 'must affirm unless [it] at least determine[s] that the district court has made a "clear error of judgment," or has applied an incorrect legal standard.'" *Nitro Leisure Products, L.L.C. v. Acushnet Co.*, 341 F.3d 1356, 1359 (Fed. Cir. 2003) (quoting *CBS Broadcasting, Inc. v. EchoStar Commc'ns Corp.*, 265 F.3d 1193, 1200 (11th Cir. 2001) (citations omitted)).

I. The BPCIA Requires Apotex To Provide at Least 180 Days' Notice of Commercial Marketing After FDA Approval

The BPCIA requires Apotex to provide Amgen with at least 180 days' notice of the first commercial marketing of its biosimilar pegfilgrastim product after FDA approves Apotex's aBLA. The statute itself makes that clear, as does this Court's decision in *Amgen v. Sandoz*.

A. The Statute Provides That Apotex Must Give 180 Days' Notice

"[A]ll statutory construction cases . . . begin with the language of the statute." *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1353 (Fed. Cir. 2012). "The 'first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.'" *Id.* at 1354 (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997)); *see also Intellectual Ventures II LLC v. JPMorgan Chase & Co.*, 781 F.3d 1372, 1375-77 (Fed. Cir. 2015).

> Paragraph (*l*)(8)(A) is clear:
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

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

The verb "shall" presumptively signals a statutory requirement. *See, e.g.*, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998); Antonin Scalia & Bryan A. Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 114 (2012) ("[W]hen the word *shall* can reasonably read as mandatory, it ought to be so read.").

Apotex concedes that notice under paragraph (*l*)(8)(A) is mandatory where an Applicant fails to provide a copy of its aBLA and manufacturing information under paragraph (*l*)(2)(A). It is equally true, however, that notice is mandatory where an Applicant does comply with paragraph (*l*)(2)(A), because the statute does not distinguish between Applicants who comply and Applicants who fail to comply. Indeed, the statute applies on its face to every Applicant, every RPS, and every licensed biosimilar. Congress could have linked paragraph (*l*)(8)(A) to paragraph (*l*)(2)(A), as Apotex seeks to do. Congress could have written, for example, that an Applicant that fails to provide the information required by paragraph (*l*)(2)(A) must give notice under paragraph (*l*)(8)(A), or that an Applicant that provides the information required by paragraph (*l*)(2)(A) is excused from giving notice under paragraph (*l*)(8)(A). Congress did not do these things. It simply mandated that the Applicant give 180 days' notice before the first commercial marketing of its licensed product. Based on the express language of the provision, its purpose, and the statute as a whole, that is exactly how the district court interpreted the provision.

B. *Amgen v. Sandoz* Requires Apotex to Give 180 Days' Notice

The decision in *Amgen v. Sandoz* (which was authored by Judge Lourie and joined, in relevant part, by Judge Newman) confirms that notice under paragraph (*l*)(8)(A) is mandatory. Apotex contends otherwise, asserting that it is an issue of

"first impression" whether the notice requirement of paragraph (*l*)(8)(A) applies to an Applicant (like Apotex) that provides its paragraph (*l*)(2)(A) disclosure. (Blue Br. at 15; *accord id.* at 1.) Apotex argues that *Amgen v. Sandoz* addressed only the situation in which an Applicant (like Sandoz) refuses to provide its paragraph (*l*)(2)(A) disclosure, holding that, for those Applicants, paragraph (*l*)(8)(A) notice is required. (Blue Br. at 16.)

1. Paragraph (*l*)(8)(A) Notice Is a Mandatory Standalone Provision That Is Not Conditioned on Paragraph (*l*)(2)(A)

Amgen respectfully submits that this is not an issue of first impression. The majority opinion in *Amgen v. Sandoz* provides the Court's interpretation of paragraph (*l*)(8)(A) in stark, unqualified terms that are irreconcilable with Apotex's argument.

Mandatory: After holding in Part II.a., unanimously, that notice is effective only if given after FDA approval, *Amgen*, 794 F.3d at 1358, the *Amgen v. Sandoz* Court turned to the impact of that holding on the facts before it. While Sandoz had given pre-marketing notice long before FDA approval, it also gave a "'further' notice of commercial marketing" the day FDA approved its aBLA, and it was that second notice that was "operative and effective." *Id.* at 1359. That did not end the inquiry, however, because Sandoz also argued that it need not have given notice at all, and that it should be permitted to commence marketing immediately. *Id.*

The majority, therefore framed the next question of statutory interpretation as whether the "shall" in paragraph (*l*)(8)(A) is mandatory, and answered it in the affirmative: "A question exists, however, concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is." *Id.* The majority carved out no exceptions for some Applicants or some factual circumstances. Notice is mandatory.

Standalone: The *Amgen v. Sandoz* majority addressed the interpretative question of whether the notice requirement of paragraph (*l*)(8)(A) stands on its own, or is tied to any other statutory provision. It held: "Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*) . . . ." *Id*. The operative word in that sentence is "standalone"; everyone agrees that paragraph (*l*)(8)(A) is a notice provision. In declaring it to be a "standalone" notice provision, the majority cited a discussion from the oral argument in that case about whether, where an Applicant does not provide disclosure under paragraph (*l*)(2)(A) and thus paragraphs (*l*)(3) through (*l*)(6) and (*l*)(7) "fall away," the obligation to give notice under paragraph (*l*)(8) would also "fall away" or whether paragraph (*l*)(8) is instead "a freestanding notice provision." *See id.* at 1359-60; Oral Argument at 38:27-39:52, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. The majority

held that paragraph (*l*)(8) stands alone from, and does not rise or fall based on compliance with, those prior provisions.

Not Conditioned: The *Amgen v. Sandoz* majority specifically addressed the statutory linkage that Apotex wants to create, and rejected it. Apotex argues that whether paragraph (*l*)(8)(A) notice is mandatory turns on compliance or non-compliance with paragraph (*l*)(2)(A). But the majority held: "Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Amgen*, 794 F.3d at 1360.

The majority then addressed how this provision, as the Court interpreted it, would apply to an Applicant, like Sandoz, that failed to comply with paragraph (*l*)(2)(A), finding that those non-compliant Applicants were not excused from pre-marketing notice: "Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A)." *Id.* The majority then closed this passage in its opinion by reaffirming that its interpretation of the statute—and the mandatory nature of paragraph (*l*)(8)(A) notice irrespective of whether the Applicant provides the paragraph (*l*)(2)(A) disclosure—were consistent with the purpose of the notice: "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.*

Apotex has no answer to these parts of the majority's opinion. Indeed, it never distinguishes them, quotes them, or even cites them. Apotex pretends they do not exist. Instead, Apotex focuses on two other sentences in the majority's opinion, neither of which makes paragraph (*l*)(8)(A) notice optional, to which Amgen turns next.[2]

2. The Holding of *Amgen v. Sandoz* Applies to Applicants Like Sandoz, But Does Not Exclude Applicants Like Apotex

Apotex relies on a concluding sentence in the majority's discussion of paragraph (*l*)(8)(A): "We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing

[2] Apotex's failure to address these provisions is echoed by two of its three amici. Neither Mylan's nor the Biosimilars Council's amicus briefs mentions or explains these passages from *Amgen v. Sandoz*. Worse, Hospira and Celltrion's brief addresses these passages only by changing the text of the majority's opinion. Thus, Hospira and Celltrion quote the majority's statement that "Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A)," but they omit the "Moreover" that begins that sentence and they omit the majority's preceding sentence, which says "Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (l)(2)(A) or other provisions of subsection (l)." (Hospira and Celltrion Br. at 12.) Then, at page 15, Hospira and Celltrion rewrite the "mandatory" sentence of the majority's opinion, adding bracketed words: "A question exists . . . concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory [in light of paragraph (*l*)(9)(B)]. We conclude that it is."

information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory." *Id.* at 1360. Apotex says this sentence limits the majority's opinion to only Applicants like Sandoz that refuse to provide their aBLA.

Apotex has it backwards. This sentence does not limit the majority opinion; It confirms its breadth. The sentence applies the broader holding of the Court which precedes the sentence—that paragraph (*l*)(8)(A) is a mandatory standalone provision that is not conditioned on paragraph (l)(2)(A)—to the facts of the *Amgen v. Sandoz* appeal. Sandoz had argued that its noncompliance with paragraph (*l*)(2)(A) excused it from complying with subsequent provisions, including paragraph (*l*)(8)(A). Judge Chen, in dissent, agreed with Sandoz, treating the provisions of paragraphs (*l*)(2) through (*l*)(8) as an "integrated litigation management process," with all of the steps in paragraphs (*l*)(3) through (*l*)(8) "contingent on the (k) applicant's performance of the first 'shall' step in (*l*)(2)." *Id.* at 1367 (Chen, J., dissenting in part). To Judge Chen, once an Applicant "fails to comply with (*l*)(2)," "the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.*

But Judge Lourie, joined by Judge Newman, disagreed, and held that even an Applicant like Sandoz that "completely fails to provide its aBLA and manufacturing information" under paragraph (*l*)(2)(A) must comply with the notice requirement of paragraph (*l*)(8)(A). *Id.* at 1360 (majority opinion). The converse

is not true, however. The majority did not hold that an Applicant like Apotex that provides its aBLA is excused from providing pre-marketing notice.

On the contrary, the majority held that "Paragraph (*l*)(8)(A) is a standalone notice provision," and that "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Id.* at 1359-60. And the precise wording of this paragraph from the majority's opinion confirms the error of Apotex's argument. The majority wrote as follows:

> Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*). Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A). 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 1360. The first sentence and the last sentence speak broadly, without limitation to certain kinds of Applicants or specific situations. And the middle sentence, which begins with "Moreover," makes clear that those broad statements apply equally to Applicants like Sandoz that refuse to provide their aBLA. On Apotex's argument, that middle sentence would supplant the first and second sentences, leaving the obligation under paragraph (*l*)(8)(A) conditioned on an Applicant's compliance with paragraph (*l*)(2)(A)—precisely the opposite of what

the majority wrote. Apotex's reading of the majority opinion is irreconcilable with its text.

It is also irreconcilable with the majority opinion's authorship. This part of the Court's opinion is the majority opinion because Judge Lourie was joined in it by Judge Newman. And Judge Newman's own opinion states,

> To facilitate identification of and resolution of any patent issues, the BPCIA requires the subsection (k) applicant to notify the Sponsor at two critical stages of FDA review of the subsection (k) application. I agree with the court that the notice of issuance of the FDA license is mandatory, and that this notice starts the 180-day stay of commercial marketing, in accordance with 42 U.S.C. § 262(*l*)(8)(A).

Id. at 1362 (Newman, J., concurring in part, dissenting in part). If Apotex were correct, and the Court's discussion of the mandatory nature of paragraph (*l*)(8)(A) applied to only Applicants like Sandoz that refuse to provide their aBLA, then Judge Newman's statement of concurrence could not be reconciled with the majority holding. It is the binding opinion of the Court precisely because both Judge Newman and Judge Lourie held that paragraph (*l*)(8)(A) is mandatory for <u>all</u> Applicants.

To be clear, Judge Chen viewed the majority as having addressed this issue, and as having held that paragraph (*l*)(8)(A) is mandatory for Applicants like Sandoz but not for Applicants like Apotex. *See id.* at 1371 (Chen, J., dissenting in part). But the majority did not adopt or even respond to the dissent's

characterization of its opinion; and neither Apotex nor the district court agrees with Judge Chen's characterization. Rather, Apotex and the district court consider *Amgen v. Sandoz* to be "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,'" and that it "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)." Appx4-5 (emphasis in original); *see* Blue Br. at 15 ("This case presents a specific issue that has not been addressed by this Court").

Amgen respectfully submits that in this narrow regard—treating the issue as one of first impression—the district court erred. This is not an issue of first impression; the panel majority addressed this issue in its interpretation of paragraph (*l*)(8)(A) and resolved it against the position Apotex now advances. But the district court then went on to analyze the issue correctly, rejecting Apotex's arguments and finding that "[n]othing in the statute or the *Sandoz* decision leads to or supports" limiting paragraph (*l*)(8)(A) to only those Applicants who fail to provide information under paragraph (*l*)(2)(A). Appx5-6. "[N]either 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)." Appx6.

3. Paragraph (*l*)(9)(B) Is Not a Remedy, Much Less an Exclusive Remedy, for Failing to Provide Notice

Apotex also focuses on the middle of a sentence in the majority opinion, 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) . . ." *Amgen*, 794 F.3d at 1359. Apotex reads this out of context to suggest that Amgen's only remedy for Apotex's repudiation of its notice obligation is to file a declaratory-judgment action under paragraph (*l*)(9)(B) and seek a patent-based preliminary injunction. Apotex places far more weight on that sentence fragment than it can bear.

Some context is helpful: In interpreting subsection 262(*l*)(2), the *Amgen v. Sandoz* majority (in that regard, Judges Lourie and Chen) found that paragraph (*l*)(9)(C) specifies part of the consequences of an Applicant's failure to comply with its paragraph (*l*)(2)(A) disclosure obligations. *Id.* at 1355-56. Specifically, where an Applicant "fails to provide the application and information required under paragraph (2)(A)," the RPS may bring an action for patent infringement under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) and "access the required information through discovery." *Id.* at 1356. Treating the "shall" in paragraph (*l*)(2)(A) as mandating compliance in all circumstances, the Court held, would render these provisions of the Patent Act and subsection (*l*) superfluous. *Id.* Importantly, the court also noted that failing to provide paragraph (*l*)(2)(A)

disclosures was "precisely" an act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii), for which another section of the Patent Act, 35 U.S.C. § 271(e)(4) limits available remedies. *Id.* Accordingly, the Court concluded that the "only" consequences for a paragraph (*l*)(2)(A) violation are those available under 35 U.S.C. § 271(e)(4). *Id.* at 1357.

There is no parallel here. No provision in the Patent Act ties patent infringement to a failure to provide paragraph (*l*)(8)(A) notice. Whereas the remedies in 35 U.S.C. § 271(e)(4) are explicitly "the only remedies which may be granted by a court for an act of infringement described in paragraph [271(e)](2)," paragraph (*l*)(9)(B) does not even use the word "remedy," much less delineate exclusive remedies. Unlike 35 U.S.C. § 271(e)(4), paragraph (*l*)(9)(B) is not a remedial provision. It details how the limitations on actions for declaratory judgment with respect to certain patents are to be applied by the courts. 28 U.S.C. § 2201(b). That is why subsection (*l*)(9) is entitled "Limitations on Declaratory Judgment." As the district court here noted, "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. . . . The BPCIA 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.

Thus, the *Amgen v. Sandoz* majority concluded that the declaratory-judgment provisions of paragraph (*l*)(9)(B) did not render notice under paragraph (*l*)(8)(A) optional. *Amgen*, 794 F.3d at 1359. It found that paragraph (*l*)(9)(B) cannot be the exclusive remedy for a violation of paragraph (*l*)(8)(A) because paragraph (*l*)(9)(B) "does not apply in" all circumstances. *Id.* And it was immediately after discussing and rejecting paragraph (*l*)(9)(B) as a consequence for failure to give paragraph (*l*)(8)(A) notice that the majority stated "Paragraph (*l*)(8)(A) is a standalone notice provision" and that "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Id.* at 1359-60.

Apotex argues that "if paragraph (*l*)(8)(A) were always mandatory, then the provisions of paragraph (*l*)(9)(B) . . . would be superfluous." (Blue Br. at 16, 23.) That is inconsistent with the majority's decision in *Amgen v. Sandoz*. It is also wrong on its merits. Paragraph (*l*)(9)(B) has an important role to play even though paragraph (*l*)(8)(A) notice is mandatory. Paragraph (*l*)(9)(B) prevents the Applicant from pursuing a declaratory-judgment action against the RPS where the Applicant does not comply with paragraph (*l*)(8)(A). In this regard, Apotex's argument overlooks that notice under paragraph (*l*)(8)(A) serves two purposes: it not only creates the 180-day "defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar

product," *Amgen*, 794 F.3d at 1358, so that the "[a]fter receiving the notice . . . and before such date of the first commercial marketing of such biological product, the [RPS] may seek a preliminary injunction," 42 U.S.C. § 262(*l*)(8)(B), it also terminates the limits on declaratory-judgment actions by the RPS and the Applicant imposed by paragraph (*l*)(9)(A). Consider a scenario in which the Applicant gives 180 days' notice under paragraph (*l*)(8)(A), and the Applicant and the RPS then each file declaratory-judgment actions (perhaps in different courts, or on different patents, or both) as permitted by paragraph (*l*)(9)(A). But then imagine the Applicant, on day 10 or 40 or 179 of the 180-day period, revokes its notice and announces its intention to begin commercial marketing immediately. The RPS could obtain an injunction to compel compliance with the 180-day notice, to preserve the status quo so that it may seek a preliminary injunction based on its patents. In addition, the Applicant's failure to comply with paragraph (*l*)(8)(A) would trigger the Applicant-specific limitation on declaratory-judgment actions in paragraph (*l*)(9)(B), extinguishing the Applicant's ability to prosecute its now-wrongly-initiated declaratory-judgment action. Given the creativity that Applicants have thus far demonstrated in pressure-testing the provisions of Section 262(*l*), this is just one example of why paragraph (*l*)(9)(B) is important—and certainly not superfluous—even though paragraph (*l*)(8)(A) notice is mandatory. But what matters here is what the district court held below and what the majority

held in *Amgen v. Sandoz*: the RPS is not required to bring a declaratory-judgment action, and may, pursuant to the court's equitable powers, obtain an injunction requiring the Applicant to comply with paragraph (*l*)(8)(A).

II. Requiring Notice Accords With the Statutory Purpose

The plain text of the BPCIA is all this Court need consider to reject Apotex's arguments. But there is more. Requiring that Applicants like Apotex that comply with paragraph (*l*)(2)-(4) also give 180 days' notice accords with the statutory purpose of the BPCIA and the role of the notice provision.

As this Court unanimously held in *Amgen v. Sandoz*, requiring notice of commercial marketing after FDA approval "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." *Amgen*, 794 F.3d at 1358. Notice of commercial marketing "allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court." *Id.* The Court rejected the idea that notice could be given before FDA approval, because pre-approval notice would leave the RPS "to guess the scope of the approved license and when commercial marketing would actually begin." *Id.* On the other hand, requiring notice to be given after FDA approval "crystallize[s]" the controversy for the court and avoids needless litigation:

> We believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses,

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

Id. As the district court here noted, "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)." Appx6.

The goals of pre-marketing notice, and the importance of a defined window in which to seek injunctive relief, are not lessened because an Applicant complies with paragraphs (*l*)(2)-(*l*)(4). Those provisions of the BPCIA do not protect the RPS or the court from the crush of a hectic preliminary injunction motion and a temporary restraining order in the days following FDA approval. Nor do they accommodate the potential change in patent rights and liabilities (*e.g.*, issuance or acquisition of new patents, expiry of existing patents, or complete adjudication of

certain patent rights) that may occur between providing the (*l*)(3)(A) list and first commercial marketing of the licensed biosimilar product. Rather, that protection comes from the 180-day window called for by paragraph (*l*)(8)(A). That is why the *Amgen v. Sandoz* majority held that notice of commercial marketing is mandatory. "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." *Amgen*, 794 F.3d at 1360.

Apotex's position is directly at odds with these statutory purposes. If Apotex were correct and an Applicant could, at its whim, nullify the notice period by choosing not to provide notice under paragraph (*l*)(8)(A), then the "RPS would be left to guess . . . when commercial marketing would actually begin." *Id.* at 1358. The RPS would have to monitor public sources even to find out when FDA approves the Applicant's aBLA, would have to sprint to court to seek a temporary restraining order just to secure time to seek a preliminary injunction, and would present the court far less than a "fully crystallized controversy" and deprive the court of the "defined statutory window" in which to "fairly assess the parties' rights prior to the launch of the biosimilar product." *Id.* Instead of an ordered, timed process, the result would be chaos, and the careful balance represented by paragraph (*l*)(8)(A) would topple in the Applicant's favor.

Apotex argues that notice under paragraph (*l*)(8)(A) is not required here because the purpose of that provision is to allow the RPS to seek a preliminary injunction on the paragraph (*l*)(8)(B) patents and, Apotex says, Amgen has no such patents. (*See* Blue Br. at 9, 18-19, 22, 34.) Likewise, Apotex argues that Amgen has had Apotex's aBLA for more than 11 months, more than enough time "to assert its patent rights." (*Id.* at 17.) This misunderstands one of the purposes of the notice, and the interplay between paragraphs (*l*)(8)(A) and (*l*)(8)(B). Paragraph (*l*)(8)(A) affords the RPS the time to seek a preliminary injunction on patents that were not listed for inclusion in the paragraph (*l*)(6) lawsuit and also on patents that first issue or that the RPS first licenses after the RPS provides its initial patent list under paragraph (*l*)(3)(A), *see* 42 U.S.C. § 262(*l*)(7). The notice period of paragraph (*l*)(8)(A) also affords a window of time in which the RPS can, if it wishes, seek a preliminary injunction on patents that became part of the paragraph (*l*)(6) litigation, thereby avoiding the need for emergency proceedings triggered by the unannounced commercial launch of a biosimilar product. Each of these scenarios is quite likely in a biosimilar lawsuit. Whether a preliminary injunction on a given patent is appropriate may depend on the precise formulation of the product, its approved therapeutic uses, and its method of manufacture, all of which may change during FDA review, *see Amgen*, 794 F.3d at 1358, as well as the status of the paragraph (*l*)(6) proceedings at the time the commercial notice is given.

And given that the companies that are reference product sponsors under the BPCIA are often innovators, with expanding patent portfolios, the issuance of additional patents is a very real possibility. As this Court held: Notice of commercial marketing "allows the RPS a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents." *Amgen*, 794 F.3d at 1352 (emphasis added).

Apotex has no basis to conclude that Amgen will not obtain new, relevant patents before Apotex's 180-day notice period ends. In this regard, it is worth noting that when Amgen moved for a preliminary injunction it did not know (nor has it been able to learn through discovery since then) when or if FDA will approve Apotex's application. Apotex filed its aBLA on or about October 16, 2014. Appx131. More than a year has passed, far longer than FDA's goal of reviewing 70% of 2014 biosimilar filings within 10 months.[3] The status of Apotex's application is a secret; it could have received a complete response from FDA noting major or minor deficiencies that could delay approval by many months, or it could have received no response at all. Apotex is a privately held

[3] *See* U.S. FDA, *Biosimilar User Fee Act of 2012 (BsUFA): Requirements and Implementation*, at 11, *available at* http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM321015.pdf.

company, and does not have the disclosure obligations of a public company. Thus, under the facts of this case, Amgen has no way to know now when the 180-day notice period will start or end, or to assess today what patents it will have by then obtained, what patents may by then have expired, or how other facts may develop that would inform the propriety of seeking preliminary injunctive relief on such patent(s).

Indeed, patent expiry is also a real possibility in this case. Depending on when FDA approves Apotex's aBLA, one of the two patents-in-suit may have expired by then. "[U]nder Apotex's construction of § 262(*l*)(8)(A)," the district court noted, 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." Appx7.

Apotex responds by asserting that "there is no logical connection between patents expiring and the 180-day notice period," and that the "longer any litigation goes on, the better the chances that some patents will expire and some issues will become moot." (Blue Br. at 18.) There is a logical connection: the 180-day period is designed to allow the RPS a discrete period in which to seek preliminary injunctive relief, including on patents that issue after the paragraph (*l*)(3) list has been provided. Where—as here—the Applicant does not get FDA approval on the

usual time scale, the 180-day period ensures that the RPS does not need to burden the court precipitously with an injunction application on a patent that will end up expiring before FDA approval anyway. At the time of FDA approval, the RPS can assess what patents require a preliminary-injunction application, and the Court can use the 180-day period to decide that application in an orderly fashion.

And in any event, Apotex cannot avoid the requirement of a statute by the specifics of this particular case. Sandoz, too, touted the peculiarities of its own position as a reason not to give 180 days' notice, but the panel majority rejected this: "A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case." *Amgen*, 794 F.3d at 1358. The 180-day notice period would apply to Apotex even if it were right that Amgen had no additional patents on which to seek a preliminary injunction. It is, as this Court held in *Amgen v. Sandoz,* a standalone provision. *Id.* at 1359.

III. Requiring Notice Does Not Improperly Extend Exclusivity

Apotex also argues that requiring an Applicant to give 180 days' notice "amounts to a *de facto* 180-day extension of the 12-year exclusivity provided by the BPCIA." (Blue Br. at 8; *accord id.* at 18.) As the district court recognized, this just rehashes an argument this Court rejected in *Amgen v. Sandoz*: "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."

Appx6. The majority recognized that Amgen would get in that case (and would get here) 180 days of "market exclusion." But it held that this consequence of the BPCIA is simply how the law works:

> It is true that in this case, as we decide *infra*, Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. Amgen had more than an "extra" 180 days, but that is apparently the way the law, business, and the science evolved.

Amgen, 794 F.3d at 1358. And as Judge Lourie made clear at oral argument, the statute has to be construed not with respect to specific Applicants, but in terms of what it really means: "You're probably an atypical case because you're right at the beginning. Other innovators are probably going to be within the 12 years, and of course we have to interpret the statute not just for these parties, but in terms of what it really means." Oral Argument at 49:05-25, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

Moreover, the majority decision referred to "market exclusion," as opposed to "exclusivity," with good reason. The 180-day notice period applies to only the specific biosimilar for which notice is provided. There is nothing, for example, that prohibits one biosimilar version of a product from being on the market while a second biosimilar waits the 180-day notice period to launch. But the problem with

Apotex's "exclusivity" argument is not only that it is wrong, but that it was rejected by this Court in *Amgen v. Sandoz*. *Amgen*, 794 F.3d at 1358.

IV. The Court Can Require Apotex To Comply With the Law

Finally, Apotex argues that this Court cannot compel Apotex to comply with paragraph (*l*)(8)(A) because paragraph (*l*)(9)(B) is the express and exclusive remedy for a violation of that provision. (Blue Br. at 22-23.) As set forth above, paragraph (*l*)(9)(B) is not a remedial provision, nor is it exclusive. Even apart from that, however, the notion that a federal court cannot exercise its equitable power to require an Applicant to comply with paragraph (*l*)(8)(A) is squarely foreclosed by *Amgen v. Sandoz*, in which the majority did precisely that. In *Amgen v. Sandoz*, the Court issued an injunction pending appeal, and the majority then continued that injunction until September 2, 2015, precisely 180 days after the notice that Sandoz provided to Amgen on the day of FDA approval. *Id.* at 1360-62. It did so "[i]n light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA," *id.* at 1362, including paragraphs (*l*)(8)(A) and (*l*)(9)(B).

The district court entered the same relief against Apotex that this Court entered against Sandoz. Its doing so was not error, and this Court should affirm.

V. The District Court Found, and Apotex Stipulated to, the Other Factors Favoring Grant of a Preliminary Injunction

Apotex stipulated in the district court to all of the preliminary-injunction factors other than likelihood of success on the merits, as permitted by case law, *see WIT Wälchli Innovation Techs. v. Westrick*, 12-CIV-20072, 2012 U.S. Dist. LEXIS 7933, at *10 (S.D. Fla. Jan. 24, 2012) (Cohn, J.). On the record before it, the district court found that Amgen "would suffer irreparable harm if Apotex were to commence marketing its product without complying with § 262(*l*)(8)(A)," that "the balance of hardships weighs in favor of Amgen," and that "the public interest will be served by an injunction." Appx8. Apotex does not now challenge those findings, nor has Apotex challenged the district court's holding that no bond is necessary for that injunction. Appx8-9.

CONCLUSION

For the reasons set forth above, Amgen respectfully submits that this Court should affirm the district court's entry of a preliminary injunction.

Dated: February 4, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). The brief contains 12,926 words, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b). The word count includes the words counted by the Microsoft Word 2010 function. This brief also 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). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font of Times New Roman.

Dated: February 4, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on this 4th of February, 2016, I caused the foregoing BRIEF OF PLAINTIFFS-APPELLEES AMGEN INC. AND AMGEN MANUFACTURING LIMITED to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the foregoing BRIEF OF PLAINTIFFS-APPELLEES AMGEN INC. AND AMGEN MANUFACTURING LIMITED to be electronically served on Defendants-Appellants Apotex Inc. and Apotex Corp.'s counsel of record, as follows:

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