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.

Appeal From The United States District Court for the Southern District of Florida,
Case No. 0:15-cv-61631-JIC (Cohn, J.)

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Biotechnology Innovation Organization certifies the following:

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

Biotechnology Innovation Organization ("BIO") (formerly Biotechnology Industry Organization)

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:

Not Applicable

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

Biotechnology Innovation Organization has no parent corporation and no publicly held company owns 10 percent or more of its stock.

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 court or agency or are expected to appear in this Court are:

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Dated: February 11, 2016 /s/ *Lisa B. Pensabene*

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INTEREST OF *AMICUS CURIAE*[1]

The Biotechnology Innovation Organization ("BIO") is the world's largest biotechnology trade organization, representing more than 1,000 member companies and research organizations—from startups to Fortune 500 companies—who research and develop biotechnological products including lifesaving medicines. Biological medicines are now used to treat previously untreatable diseases and have prolonged and improved the lives of countless patients. But, development of a biological medicine generally requires a decade or more of research, as well as a fully capitalized investment that on average exceeds $2 billion.

BIO played a leading role in the effort to establish a statutory pathway for abbreviated approval of biosimilars that would lower costs through increased competition and expand access to lifesaving medicines while protecting patient safety and promoting further biomedical innovation. The aptly named Biologics Price Competition and Innovation Act ("BPCIA" or "the Act") aims to achieve

[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), BIO states that no party or party's counsel authored this brief in whole or in part, that no party or party's counsel contributed money that was intended to fund preparing or submitting this brief, and that no person other than BIO, BIO's members, or BIO's counsel contributed money that was intended to fund preparing or submitting this brief. While Amgen is a member of BIO, it has not participated in the development or submission of this brief and in no way should be presumed to endorse the positions taken herein. The parties have consented to the filing of this brief.

those goals. Many of BIO's members are global leaders in the development and commercialization of both innovative biologics and biosimilars. Accordingly, BIO and its members have a strong interest in the proper interpretation of the critical provision of the BPCIA at issue in this case.

ARGUMENT

The BPCIA must be interpreted as it was intended—as a balance between the interests of biosimilar applicants and the innovator biologic sponsors whose products serve as the reference products for such applicants. The BPCIA's provision requiring biosimilar applicants to provide notice of commercial marketing following FDA approval is an integral part of the balance achieved by the BPCIA, and it furthers Congress' goal of ensuring that the parties can resolve any patent disputes prior to the launch of the biosimilar product.[2] The commercial-marketing notice provision cannot meaningfully serve its intended function, however, if, as Apotex argues in this case, applicants are in many circumstances free to ignore it.

[2] *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Anna G. Eshoo) ("Rep. Eshoo Statement").

I. The BPCIA Strikes A Balance Intended To Facilitate Orderly Market Entry And Spur Competition While Preserving Incentives For Innovation

The BPCIA was enacted in 2010 as part of the Patient Protection and Affordable Care Act. The BPCIA created "an abbreviated pathway for regulatory approval of follow-on biological products," *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015), which aimed at "balancing innovation and consumer interests," BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). "The objectives of the BPCI Act are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (commonly referred to as the 'Hatch-Waxman Act'), which established abbreviated pathways for the approval of drug products under the Federal Food, Drug, and Cosmetic Act (FD&C Act)."[3] As the FDA has observed, however,"[t]he implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured."[4]

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[3] FDA, Guidance for Industry, *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009* (April 2015), at 3, *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm444661.pdf.

[4] *Id.*

Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.[5] Accordingly, while Congress "borrow[ed]" from the Hatch-Waxman Act when formulating the BPCIA,[6] there are several differences between the two statutes. *See Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1276 (Fed. Cir. 2014).

For example, when a brand-name pharmaceutical manufacturer files a timely patent infringement complaint, the Hatch-Waxman Act provides an automatic 30-month stay during which the FDA cannot approve the generic unless the court finds that the patent is invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The BPCIA instead provides a 180-day period following notice of commercial marketing during which the reference product sponsor may pursue a preliminary injunction to preserve the status quo until all patent disputes are resolved. *See* 42 U.S.C. § 262(*l*)(8). But, in both cases, the statutes aim to facilitate the orderly resolution of patent disputes prior to launch; they simply employ different procedures towards that end.

The BPCIA reflects a careful balance between the interests of innovator reference product sponsors and those of biosimilar applicants. Traditionally, an

[5] *Id.*

[6] *Id.*

applicant seeking FDA approval to commercially market a biological product was required to provide a complete, original package of clinical data to demonstrate that its product was both safe and effective, regardless of whether a similar product had previously been approved by the agency. *See Amgen*, 794 F.3d at 1351. The Act's abbreviated licensing pathway permits applicants to instead submit information showing that their product is "biosimilar" to a reference biological product that the FDA has previously approved, along with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." *Id.* (quoting 42 U.S.C. § 262(k)(5)); *see also* 42 U.S.C. § 262(k)(2)-(4), (i). The BPCIA thus relieves an applicant of the need to generate the complete package of pre-clinical and clinical data that would be required in the traditional pathway, saving the applicant significant time, risk, and expense.

The Act balances those benefits to biosimilar applicants with provisions aimed at preserving incentives to develop innovative new biologics. To that end, the Act provides a 12-year period of data exclusivity for pioneer biologics. *See* 42 U.S.C. § 262(k)(7)(A) (directing that approval of a subsection (k) 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)"). That period of data exclusivity does not prevent a competitor from pursuing approval of

a similar biological product through the traditional FDA pathway—it only prevents a competitor from seeking a "short cut" to FDA approval by relying on the FDA's prior findings of safety and effectiveness regarding the innovator's product. The 12-year data exclusivity period runs concurrently with any patent term for the product. The Act also establishes detailed and carefully structured procedures for identifying and resolving patent disputes involving biosimilar applications submitted under subsection (k). *See* 42 U.S.C. § 262(*l*); *see also* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6).

The BPCIA's patent-dispute-resolution mechanism includes a complex statutory framework for the exchange of information between the applicant and the reference product sponsor, followed by two potential "waves" of litigation. The information exchange, commonly referred to as the "patent dance," commences when the applicant provides the reference product sponsor with its biosimilar application (or "aBLA") along with information about how its proposed product is manufactured. 42 U.S.C. § 262(*l*)(2)(A). Based on the applicant's disclosures, the reference product sponsor provides the applicant with a list of patents on which the sponsor believes it could reasonably assert an infringement claim and identifies any patents it would be prepared to license to the applicant. *Id.* § 262(*l*)(3)(A). The applicant then provides, for each patent the sponsor has identified, either a detailed statement describing the bases for the applicant's opinion that the patent is

invalid or unenforceable or will not be infringed by its biosimilar, or a statement that the applicant will refrain from marketing its product until the patent expires. *Id.* § 262(*l*)(3)(B). The applicant also may provide its own list of patents on which it believes the sponsor could assert an infringement claim. *Id.* The sponsor then responds to the applicant's contentions regarding validity, enforceability, and infringement of the sponsor's patents, explaining the basis for its belief that the patents in question will be infringed by the biosimilar. *Id.* § 262(*l*)(3)(C).

Once the parties have exchanged their views, they work to determine which of the patents identified under paragraph (*l*)(3) will be the subject of an early-stage infringement action under paragraph (*l*)(6). *Id.* § 262(*l*)(4). If the parties agree about which patents should be included, the sponsor files an action for infringement of those patents. *Id.* § 262(*l*)(6)(A). If the parties cannot reach agreement, they exchange lists of the patents they each believe should be the subject of the litigation. *Id.* § 262(*l*)(5)(B)(i). In that circumstance, the sponsor generally may not list a greater number of patents than the applicant, though the sponsor is entitled to list at least one patent. *Id.* § 262(*l*)(5)(B)(ii). Once the lists have been exchanged, the sponsor initiates litigation on the patents included on the parties' lists. *Id.* § 262(*l*)(6)(B). The biosimilar applicant thus has significant power to limit the scope of early-stage litigation, and the sponsor may not have an

opportunity to litigate all patents it believes will be infringed by the biosimilar in the immediate infringement action under paragraph (*l*)(6).

A second wave of litigation, however, may follow, affording the parties a chance to resolve any remaining patent disputes before the biosimilar's market launch. Paragraph (*l*)(8)(A)—the provision at the center of the present case—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)." *Id.* § 262(*l*)(8)(A). Once the sponsor receives that notice, the Act permits the sponsor to seek a preliminary injunction prohibiting the applicant from engaging in commercial sale or manufacture of the biosimilar until the parties can resolve any remaining disputes about patents identified in the information exchange that were not part of the early-stage litigation, as well as any newly issued or licensed patents. *Id.* § 262(*l*)(8)(B); *see id.* § 262(*l*)(7). The Act's second-wave litigation provisions not only protect the rights of sponsors, but also serve as an important practical check on the biosimilar applicant's power to restrict unreasonably the first wave of litigation described above.

A careful reading of this complex and balanced statutory scheme leads to the inescapable conclusion that Congress designed the BPCIA's patent-dispute-resolution process "to ensure that litigation surrounding relevant patents will be

resolved expeditiously *and prior to the launch of the biosimilar product*, providing certainty to the applicant, the reference product manufacturer, and the public at large."[7]

All interested parties stand to benefit from having a meaningful opportunity to resolve patent disputes prior to the biosimilar's launch. It is advantageous to no one (including, most importantly, patients) for a biosimilar to launch under a cloud of uncertainty. The reference product sponsor should not effectively lose the exclusionary rights provided by its patents because it does not have sufficient opportunity or information to enforce those rights prior to the launch of a biosimilar. Nor should a biosimilar applicant have to face the specter of an infringement suit—and significant and possibly business-crippling damages—upon launch. And because patients generally cannot be switched back and forth between biological products without the threat of safety concerns or reduced efficacy, it is imperative to minimize the uncertainty regarding the legality of a biosimilar market launch.

Indeed, although in recent biosimilar litigation the parties have disagreed about exactly how the BPCIA should be implemented, all appear to agree that resolving patent issues prior to the biosimilar's launch is a key goal. For example, in litigation relating to the reference product etanercept (Enbrel®), the biosimilar

[7] Rep. Eshoo Statement at 9 (emphasis added).

applicant filed a declaratory judgment action for non-infringement and invalidity at the beginning of phase III clinical trials, before its application was (or could have been) filed.[8] The applicant explained that, "[b]y filing its complaint in 2013, [it] sought to ensure sufficient time for the litigation so that it would be able to obtain a final district court judgment before its intended commercial marketing,"[9] and reasoned that "companies will not launch biosimilar products with billion-dollar damages claims outstanding."[10] Although the reference product sponsor argued that the case was not ripe because no application had been filed, it noted that, if and when one was, the action should proceed via the BPCIA, which included "a framework to allow patent disputes to unfold prior to market entry by a biosimilar."[11] Similarly, in a series of four actions related to reference product

[8] Complaint for Declaratory Judgment of Patent Invalidity and Non-Infringement ¶ 42, *Sandoz Inc. v. Amgen Inc.*, No. 3:13-cv-2904, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013), ECF No. 1 ("Sandoz recently initiated a Phase III clinical study" and "[t]he first patient was enrolled in June 2013.").

[9] Corrected Non-Confidential Brief of Plaintiff-Appellant Sandoz Inc. at 18, *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014) (No. 2014-1693), ECF No. 29.

[10] *Id.* at 23.

[11] Corrected Non-Confidential Opposition Brief of Defendants-Appellees, Amgen Inc. and Hoffmann-La Roche Inc. at 54, *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014) (No. 2014-1693), ECF No. 44. This Court affirmed the district court's dismissal of the action for lack of subject matter jurisdiction, but the panel did "not address the district court's interpretation of the BPCIA." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1275 (Fed. Cir. 2014).

infliximab (Remicade®),[12] applicants filed declaratory judgment actions after completing phase III clinical testing but prior to filing a biosimilar application.[13] Arguing for declaratory judgment jurisdiction, one of the applicants said that "the BPCIA … provides a mechanism to ripen otherwise unripe patent disputes before the 12-year term expires," and, in the words of one of the BPCIA's principal authors, "'ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.'"[14] And in the filgrastim case (Neupogen®), the reference product sponsor observed that the BPCIA "system not only benefits the reference product sponsor and the biosimilar applicant, but also … benefits the public by ensuring any disputes are

[12] *See Celltrion Healthcare Co. v. Kennedy Trust for Rheumatology Research*, No. 14-2256, 2014 WL 6765996 (S.D.N.Y. Dec. 1, 2014) (dismissing Celltrion's declaratory judgment action for lack of subject matter jurisdiction); *Hospira, Inc. v. Janssen Biotech, Inc.*, 113 U.S.P.Q.2d 1260 (S.D.N.Y. 2014) (dismissing Hospira's declaratory judgment action for lack of subject matter jurisdiction); Complaint, *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-10698 (D. Mass. filed Mar. 6, 2015), ECF No. 1 (alleging infringement based on BPCIA); Celltrion's Complaint for Declaratory Judgment, *Celltrion Healthcare Co. v. Janssen Biotech, Inc.*, No. 14-11613 (D. Mass. filed Mar. 31, 2014), ECF No. 1 (voluntarily dismissed on October 24, 2014 before a ruling on Janssen's motion to dismiss).

[13] *See Celltrion Healthcare Co. v. Kennedy Trust for Rheumatology Research*, No. 14-2256, 2014 WL 6765996, at *3 (S.D.N.Y. Dec. 1, 2014).

[14] Plaintiffs' Memorandum of Law in Opposition to Defendant Kennedy Trust's Motion to Dismiss the Complaint or to Stay the Action at 3, *Celltrion Healthcare Co. v. Kennedy Trust for Rheumatology Research*, No. 14-2256, 2014 WL 6765996 (S.D.N.Y. Dec. 1, 2014), ECF No. 23 (citation omitted).

identified and court intervention is sought *before commercial marketing of the biosimilar product begins*."[15]

II. Notice Of Commercial Marketing Is Mandatory In All Cases To Ensure That Patent Disputes Can Be Resolved As Congress Intended—Before The Biosimilar Product Is Launched

Paragraph (*l*)(8)(A)'s notice of commercial marketing occupies a key position in the BPCIA framework, the various provisions of which work together to establish an efficient system for resolving patent disputes prior to the launch of the biosimilar product. The notice required by paragraph (*l*)(8)(A) plays a critical role in the BPCIA process, allowing the reference product sponsor a 180-day window in which to assess the need for preliminary injunctive relief and kicking off the second stage of litigation, in which any disputes about patents that were not asserted in the first wave can be resolved. When the applicant provides notice under paragraph (*l*)(8)(A), the reference product sponsor is authorized to seek a preliminary injunction to preserve the status quo until any second-wave litigation is completed. 42 U.S.C. § 262(*l*)(8)(B). And once notice has been given, both the applicant and the reference product sponsor are authorized to bring a declaratory judgment action on patents that were not part of the early-stage litigation. *Id.*

[15] Notice of Motion and Motion by Amgen for Partial Judgment Under Rule 12(c) or, in the Alternative, Motion for Partial Summary Judgment Under Rule 56 at 12, *Amgen Inc. v. Sandoz Inc.*, No. 14-04741, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015), ECF No. 35 (emphasis added).

§ 262(*l*)(9)(A).[16] In *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), this Court recognized the important role that paragraph (*l*)(8)(A) plays, holding that it "is a standalone notice provision," the "clear" purpose of which is "to allow the [reference product sponsor] a period of time to assess and act upon its patent rights." *Id.* at 1359-60.

A. Neither The Language Nor The Purpose Of Paragraph (*l*)(8)(A)'s Notice Requirement Is Limited To Cases In Which The Applicant Declines To Engage In The BPCIA's Information Exchanges

In *Amgen*, this Court read paragraph (*l*)(8)(A) consistent with its plain language, concluding that the "'shall' provision in paragraph (*l*)(8)(A) is mandatory." *Id.* at 1359. In the present case, Apotex argues that that common-sense holding applies only where, as in *Amgen*, the applicant has opted out of the BPCIA's information-exchange process.[17] But, neither the text of the statute, its purposes, nor this Court's decision in *Amgen* supports such a distinction.

To begin, paragraph (*l*)(8)(A) on its face does not differentiate between applicants who have complied with paragraph (*l*)(2)(A) and those who have not. It

[16] Paragraph (*l*)(9)(A) applies to applicants, like Apotex, that have provided information under paragraph (*l*)(2)(A) and otherwise engaged in the statutory exchange process. If the applicant has *not* complied with paragraph (*l*)(2)(A), the reference product sponsor—but not the applicant—would have been authorized to file a declaratory judgment action on "any patent that claims the biological product or use of the biological product" pursuant to paragraph (*l*)(9)(C).

[17] *See* Opening Brief for Defendants-Appellants Apotex Inc. and Apotex Corp. at 24, *Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. Dec. 30, 2015), ECF No. 38 ("Appellants' Br.").

simply directs that applicants "*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). Paragraph (*l*)(8)(A)'s 180-day notice requirement is not in any way conditioned on compliance with—or failure to comply with—any prior provision of subsection (*l*). *See Amgen*, 794 F.3d at 1359. There is thus no statutory basis for the distinction Apotex advocates.

Requiring applicants to provide 180-days' notice of commercial marketing, moreover, serves the same important functions regardless of whether the biosimilar applicant has participated in the BPCIA's patent dance. As this Court explained in *Amgen*, paragraph (*l*)(8) "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." 794 F.3d at 1358. Effective notice is necessary to provide clarity about "the scope of the approved license and when commercial marketing w[ill] actually begin," *id.*,[18] and to "ensure[] the existence of a fully crystallized controversy regarding the need for injunctive relief," *id.* That reasoning applies

[18] *See also id.* ("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.").

with equal force where an applicant has participated in the BPCIA's information-exchange process under paragraphs (*l*)(2) through (*l*)(5).

Apotex's proposed interpretation of paragraph (*l*)(8)(A) would permit applicants who comply with paragraphs (*l*)(2) through (*l*)(5) to bring their biosimilars to market immediately upon approval by the FDA where, as here, that approval comes after the sponsor's period of data exclusivity has expired. And if biosimilar products are launched without notice, reference product sponsors will have little choice but to rush to court to secure a temporary restraining order to protect their patent rights. In short, if applicants are excused from paragraph (*l*)(8)(A)'s notice requirement simply because they engaged in the BPCIA's patent exchanges, the result will be exactly the opposite of the "orderly process"[19] for the pre-launch resolution of patent disputes that the BPCIA was designed to provide.

B. The Commercial-Marketing-Notice Provision Applies Regardless Of Whether There Are Late-Stage Patents To Litigate

It makes no difference that, as Apotex notes, in the present case Amgen "has already sued Apotex on all of the patents on its [paragraph (*l*)(3)(A)] list."[20] The

[19] *Amgen, Inc. v. Apotex Inc.*, No. 15-cv-61631, slip op. at 6 (S.D. Fla. Dec. 9, 2015), ECF No. 71.

[20] Appellants' Br. at 8 (emphasis removed); *see id.* at 6 ("This second stage of patent dispute is thus designed to address patents that are *not* already the subject of a lawsuit between the parties."); *id.* at 19 ("Amgen already has the right to seek preliminary injunctive relief on the patents-in-suit, and it has no other relevant patents to assert."); *id.* at 29 ("[H]ere, the sponsors have no additional patents to assert and so can derive no legitimate benefit from the notice."); *id.* at 34 ("In this

BPCIA does not create an exception to paragraph (*l*)(8)(A)'s notice requirement for situations where all patents identified under paragraph (*l*)(3) are already in litigation. While receipt of the 180-day notice required by paragraph (*l*)(8)(A) triggers the reference product sponsor's right to seek a preliminary injunction on any listed patents that have not been litigated, and permits both parties to bring a declaratory judgment action to establish their respective rights as to those patents, nothing in the statute makes paragraph (*l*)(8)(A)'s notice requirement contingent on the existence of additional patents that could be the subject of late-stage litigation. Paragraph (*l*)(8)(A)'s 180-day notice requirement is distinct from the right to seek a preliminary injunction under paragraph (*l*)(8)(B) that follows from it.

Moreover, paragraph (*l*)(8)(A) affords the reference product sponsor time to seek a preliminary injunction not only on paragraph (*l*)(3) patents not included in the early-stage lawsuit, but also on patents first issued or licensed *after* the sponsor provided its initial list of relevant patents under paragraph (*l*)(3)(A). *See* 42 U.S.C. § 262(*l*)(7); *Amgen*, 794 F.3d at 1352 (paragraph (*l*)(8)(A) "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

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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.").

immediate infringement action, *as well as any newly issued or licensed patents*" (emphasis added)). The notice provision of paragraph (*l*)(8)(A) also aids the orderly resolution of patent disputes in ongoing early-stage litigation by providing the reference product sponsor a 6-month window of time in which to seek a preliminary injunction in that litigation, thereby avoiding the need for emergency proceedings in response to an unannounced biosimilar launch (and their attendant disruptive effects in the marketplace). In fact, in its brief, even Apotex recognizes the possible need for preliminary injunctive relief on early-stage patents.[21]

C. Paragraph (*l*)(9)(B) Does Not Make Notice Of Commercial Marketing Optional

Apotex protests that the "plain text of the statute indicates that the notice provision of (*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."[22] But, paragraph (*l*)(9)(B) does not provide the reference product sponsor any "remedy" at all, let alone an exclusive one. Under the BPCIA, a reference product sponsor will always at some point have the opportunity to file a declaratory judgment action; the only question is when. Where, as here, the applicant has acted in accordance with the

[21] Appellants' Br. at 19 ("Amgen already has the right to seek preliminary injunctive relief on the patents-in-suit, and it has no other relevant patents to assert.").

[22] *Id.* at 16.

requirements of paragraphs (*l*)(2) through (*l*)(7), both the applicant and the sponsor are prohibited from filing a declaratory judgment action on listed patents not involved in the early-stage litigation until notice of commercial marketing is given, at which point paragraph (*l*)(9)(A) lifts that prohibition for both parties. Paragraph (*l*)(9)(B) simply provides that, if the applicant fails to give notice under paragraph (*l*)(8)(A), the reference product sponsor may proceed with a declaratory judgment action in district court—as it would have been able to do if the applicant *had* complied with paragraph (*l*)(8)(A). But, absent the advance notice contemplated by the statute, the biosimilar product could actually be on the commercial market—infringing the sponsor's patents—while the sponsor scrambles to file its suit.

Contrary to Apotex's suggestion, paragraph (*l*)(9)(B) is not rendered "utterly unnecessary" if paragraph (*l*)(8)(A) is read according to its plain terms to mandate that *all* applicants provide 180-days' notice of commercial marketing after FDA approval.[23] An applicant can, of course, fail to satisfy even a mandatory statutory requirement. And if not for paragraph (*l*)(9)(B), failure to provide notice would insulate the applicant from any potential declaratory judgment suit, because there would be no provision lifting paragraph (*l*)(9)(A)'s ban on filing such suits prior to notice of commercial marketing.

[23] Appellants' Br. at 23.

Nor does *Amgen*'s holding that disclosure of the information identified in paragraph (*l*)(2)(A) is not mandatory compel the same conclusion about paragraph (*l*)(8)(A)'s notice requirement.[24] As the Court noted in *Amgen*, 35 U.S.C. § 271(e)(4) provides "the *only remedies* which may be granted by a court for an act of infringement described in paragraph (2)," and "under § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required information under paragraph (*l*)(2)(A) is such an act of infringement." 794 F.3d at 1356 (emphasis added). There is no parallel provision purporting to provide an exclusive remedy for an applicant's failure to comply with paragraph (*l*)(8)(A).

D. Requiring Notice Under Paragraph (*l*)(8)(A) Does Not Improperly Extend The Statutory 12-Year Exclusivity Period

Apotex further argues that mandating notice of commercial marketing under paragraph (*l*)(8)(A) is contrary to Congressional intent—despite the statute's plain language dictating that result—because it will effectively transform the statutory 12-year exclusivity period into a 12.5-year exclusivity period.[25] But, this Court has already considered and rejected that argument in *Amgen*, explaining that "requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the twelve-year exclusivity period of § 262(k)(7)(A)." 794 F.3d at 1358. The

[24] *See* Appellants' Br. at 25-27.

[25] *See* Appellants' Br. at 28-29 ("Critically, Congress enacted a 12-year market exclusivity for reference product sponsors—not a 12½-year market exclusivity.").

Court reached that conclusion despite the fact that in *Amgen*, as in the present case, the sponsor's 12-year exclusivity period had long since expired. *Id.* The Court looked beyond the particular circumstances of the case before it and recognized that an "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.*; *see id.* ("A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case.").

Apotex disputes this Court's reasoning, arguing 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," meaning that *every* reference product sponsor will receive an "extra" 180 days of exclusivity if paragraph (*l*)(8)(A)'s notice requirement is enforced as written.[26] But that result does not necessarily follow from the statute. For example, the BPCIA does not say that the FDA cannot *approve* a biosimilar application during the 12-year exclusivity period. It instead instructs that "[a]pproval of an application … may not be *made effective*" until the exclusivity period expires. 42 U.S.C. § 262(k)(7)(A) (emphasis added). The statutory language thus leaves room for circumstances in which FDA approval *could* occur prior to the expiration of the 12-year period. Indeed, given that a biosimilar

[26] Appellants' Br. at 30 (citing 42 U.S.C. § 262(k)(7)(A)).

application can be filed at the 4-year mark, 42 U.S.C. § 262(k)(7)(B), at which point 8 years of data exclusivity remain, Congress appears to have envisioned scenarios involving FDA approval with remaining exclusivity. In such situations, the notice requirement of paragraph (*l*)(8)(A) would not necessarily provide any effective "extension of exclusivity."

The fact that other possible exclusivity scenarios exist does not change the wording of the statute or make its consistent, uniform application unfair. It is the biosimilar applicant that chooses when to file its application with the FDA, and the applicant's choice comes with timing consequences. For reference products with no remaining data exclusivity that were developed with no expectation of a biosimilar pathway, notice of commercial marketing provides a modest 6-month respite to allow the parties to resolve patent disputes before commercial launch of the approved biosimilar product, which accords with Congress' intent for an orderly process of patent dispute resolution. And the statute provides ample flexibility to accommodate future situations on their own highly specific and as-yet-unforeseeable facts.

It is unsurprising that many applicants would rather not have to comply with paragraph (*l*)(8)(A)'s notice provisions and endure the 180-day waiting period that follows commercial-marketing notice. But paragraph (*l*)(8)(A)'s notice requirement is part of the careful balance of interests struck by the BPCIA, which

also provides applicants procedural advantages of their own.[27] If applicants—or, for that matter, reference product sponsors—are free to dispense with whatever provisions they find inconvenient or otherwise undesirable, that balance will be destroyed.

CONCLUSION

The BPCIA promotes the public interest by balancing benefits to biosimilar applicants with protections for reference product sponsors. The decision below respects that balance, as well as the BPCIA's text and purpose. This Court should affirm that decision.

[27] *E.g.*, 42 U.S.C. § 262(*l*)(5)(A) ("The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor."); *id.* § 262(*l*)(5)(B)(ii)(I) ("[T]he number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).").

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7)(B)(i) because this brief contains 5,133 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This 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 2010 in Times New Roman 14-point font.

Dated: February 11, 2016 /s/ *Lisa B. Pensabene*

CERTIFICATE OF SERVICE

I hereby certify that on February 11, 2016, 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 CM/ECF system. Participants in this case are registered CM/ECF users and will be served by the CM/ECF system.

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