Nos. 15-1039 & 15-1195

IN THE
Supreme Court of the United States

SANDOZ INC.,
Petitioner,
v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Cross-Petitioners,
v.

SANDOZ INC.,
Cross-Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF APOTEX INC. AND APOTEX CORP. AS *AMICI CURIAE* SUPPORTING SANDOZ INC.

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INTEREST OF *AMICI CURIAE*[1]

Amici Apotex Inc. and Apotex Corp. are subsidiaries of the global pharmaceutical company collectively known as Apotex,[2] which is one of the world's foremost generic drug and specialty pharmaceutical research and technology leaders.

Apotex is actively working to develop and manufacture a broad portfolio of biologic drug products. Apotex believes that the benefits of biosimilars will be significant for patients, payors, and providers, and it is dedicated to increasing public availability of more affordable versions of these life-saving therapies and to generating substantial savings for the American health care system.

Apotex agrees with Sandoz Inc. ("Sandoz") that reversal of the Federal Circuit is necessary to correct the interpretation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). This decision, by a divided panel, has the effect of extending the monopolies for biologic products beyond the period specified by Congress, thereby delaying competition and consumer access to less-expensive medicines.

In recent years, Apotex has filed with the Food and Drug Administration ("FDA") applications under the BPCIA for pegfilgrastim and filgrastim, which are

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[1] Pursuant to Rule 37.6, counsel for *amici* certify that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel further certify that all parties have consented to the filing of this brief, and those written consents are being submitted contemporaneously with this brief.

[2] Apotex Inc. is an Ontario corporation and Apotex Corp. is a Delaware corporation. Both are wholly owned by Apotex Holdings, Inc.

biosimilar versions of the products Neulasta® and Neupogen®, respectively, marketed by Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen"). Amgen subsequently sued Apotex in the United States District Court for the Southern District of Florida for patent infringement by Apotex's proposed pegfilgrastim biosimilar product.

In that case, the district court granted a preliminary injunction prohibiting Apotex from commercially marketing its biosimilar product until 180 days after first receiving its FDA license and then providing a notice of commercial marketing under the BPCIA.

Upon review of Amgen's case against Apotex, the Federal Circuit applied the construction of the BPCIA's notice of commercial marketing that is now before the Court, and affirmed the district court's grant of a preliminary injunction. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060-61 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016). Apotex thus has a significant interest in the proper interpretation and application of the BPCIA.

INTRODUCTION

A. Statutory Background

This case arises from the Federal Circuit's erroneous construction and misapplication of the BPCIA, a part of the Patient Protection and Affordable Care Act of 2010. This comprehensive legislation was intended to strike a balance between encouraging competition among an important and rapidly growing category of costly specialty pharmaceuticals and incentivizing the development of new drugs.

The decision below amounts to a thumb on the scale for biologic manufacturers. The anticompetitive effects of prolonging the collection of monopoly rents by those manufacturers and bolstering already-troublesome barriers to entry for biosimilars, which are an important new class of medical products, will cost consumers and taxpayers hundreds of billions of dollars.

Prices for "biologics" – *i.e.*, large-molecule drugs that are produced in living organisms – are on average 22 times higher than prices for traditional chemical or small-molecule medications; biologics can cost more than $200,000 per year. *See* Comment of the Staff of the Federal Trade Comm'n to FDA at 3 (Oct. 27, 2015) (hereinafter "FTC Comment").[3] Moreover, prices are increasing by approximately 10-15% each year, with the average price of biologics having doubled from 2006 to 2012. *See id.* Nonetheless, in 2010, four of the 10 top-selling branded drugs worldwide were biologics, and industry experts

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[3] *Available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf.

estimated biologics would rise to seven of the top 10 in 2016. *See* Steve Miller, Express Scripts, Presentation at FTC Biosimilars Workshop: *Customer Perspective on Biosimilars* 3 (Feb. 4, 2014) ("Miller, *Customer Perspective on Biosimilars*").[4]

As part of an effort to promote competition and restrain these spiraling drug costs, Congress in the BPCIA established an abbreviated pathway for regulatory approval of follow-on biologics that are "highly similar" to the branded drug, which is referred to as the "reference product." 42 U.S.C. § 262(i)(2). The BPCIA recognizes the importance of encouraging innovation through a period of market exclusivity for the reference product. To that end, the FDA cannot finally approve an abbreviated Biologics License Application ("aBLA") for a biosimilar product until 12 years after the date on which the reference product was licensed, thus ensuring that the branded drug company, in this context referred to as the "reference product sponsor," enjoys 12 years of market exclusivity (and monopoly profits), regardless of whether it has any patent protection for its product. *See id.* §§ 262(k)(7)(A), 262(*l*)(1)(A). At the same time, however, the BPCIA encourages price competition once the sponsor's monopoly protection ends. The BPCIA therefore allows a biosimilar applicant to submit an aBLA and rely in part on the sponsor's FDA-approved license of a reference product. *See id.* § 262(k).

The BPCIA also established a detailed, carefully calibrated framework for the efficient resolution of

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[4] *Available at* https://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%20Workshop%3A%20Impact%20of%20Recent%20Legislative%20and%20Regulatory%20Naming%20Proposals%20on%20Competition/miller.pdf.

patent disputes between the reference product sponsor and the biosimilar applicant. *See id.* § 262(*l*). Congress designed a series of choices in two stages, through which the biosimilar applicant may elect to share critical information with the reference product sponsor in an effort to streamline patent disputes. And at each such opportunity, the statute also offers the reference product sponsor recourse in the event the biosimilar applicant chooses not to share such information.

Stage 1: Information Exchange and Initial Litigation

In the *first* stage, under paragraphs (*l*)(2)-(*l*)(7) of the BPCIA,[5] the parties may exchange information concerning the aBLA, a list of patents for which a claim of patent infringement may be asserted against the biosimilar applicant, and statements concerning the patent(s), followed by negotiation to decide which patents should be the subject of an immediate patent-infringement action. Specifically, paragraph (*l*)(2)(A) provides that the biosimilar applicant "shall provide to the reference product sponsor a copy of the application submitted . . . under subsection (k), and such information that describes the process or processes used to manufacture the biological product that is the subject of such application," not later than 20 days after the FDA accepts the application for review. When the biosimilar applicant provides those paragraph (*l*)(2)(A) disclosures, its action initiates a series of exchanges under paragraphs (*l*)(3)-(*l*)(7), with each successive exchange reliant on the performance of one of more preceding exchanges.

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

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.

But if the biosimilar applicant elects not to share its application and manufacturing information with the reference product sponsor under paragraph (*l*)(2)(A), then paragraph (*l*)(9)(C) provides the reference product sponsor with a remedy: "If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product."

Stage 2: Enforcement and Dispute Resolution

In the *second* stage for resolving patent disputes, under paragraph (*l*)(8)(A), the biosimilar 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)." When the applicant gives notice, the sponsor may seek an injunction under paragraph (*l*)(8)(B): "After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent" that was described as relevant during the information

exchange outlined in paragraph (*l*)(3) and that is not already the subject of litigation.

If the biosimilar applicant elects not to give notice of commercial marketing under paragraph (*l*)(8)(A), then paragraph (*l*)(9)(B) also provides the reference product sponsor with a remedy: "If a subsection (k) applicant fails to complete an action required of the . . . applicant under . . . paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability of any patent" submitted to be relevant during the information exchange described in paragraphs (*l*)(2)-(*l*)(5), including any newly issued patent deemed relevant.

B. Procedural Background

The decision under review became the Federal Circuit's first case interpreting the BPCIA. In this case, Sandoz elected not to provide the information specified in paragraph (*l*)(2)(A). And the Federal Circuit held that Sandoz was not required to do so, confirming that the information exchange described in paragraphs (*l*)(2)-(*l*)(5) is optional and that paragraph (*l*)(9)(C) provides an appropriate remedy to the reference product sponsor in the event that a biosimilar applicant elects not to engage in the information exchange. Pet. App. 18a.[6] The Federal Circuit also held that a biosimilar applicant such as Sandoz that chooses not to engage in the information exchange described in paragraph (*l*)(2)(A) must provide to the reference product sponsor the notice of commercial marketing described in paragraph (*l*)(8)(A). *See id.*

[6] References to "Pet. App. __a" are to the appendix to the certiorari petition filed in No. 15-1039.

at 26a ("We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the [reference product sponsor] by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory."). The court further held that such an applicant could provide that notice of commercial marketing only after the issuance of the FDA license for its biosimilar product. *Id.* at 21a-22a.

But the Federal Circuit left unanswered how its limited rulings regarding the paragraph (*l*)(8)(A) notice of commercial marketing should be applied to scenarios in which a biosimilar applicant did chose to participate in the paragraph (*l*)(2)(A) information exchange. The court of appeals answered that critical question in a companion case, *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016).

A brief summary of the facts of the *Apotex* case follows. In 2002, Amgen received a license for a brand-name biologic with the active ingredient pegfilgrastim. *Id.* at 1055. In 2014, Apotex applied for an FDA license to market a biosimilar pegfilgrastim product in accordance with the BPCIA. *Id.* After the FDA accepted Apotex's application for review, Apotex timely provided Amgen with a copy of that application and the other information specified in paragraph (*l*)(2)(A). *Id.* at 1059. Thereafter, Apotex and Amgen engaged in the exchange of patent information contemplated by paragraphs (*l*)(3)-(*l*)(5). Apotex also attempted to provide Amgen with the notice of commercial marketing described in paragraph (*l*)(8)(A). *Id.* The parties ultimately agreed to litigate all unexpired patents, of which there is currently only one remaining. *Id.*

Amgen subsequently filed its complaint in the United States District Court for the Southern District of Florida. The district court granted a preliminary injunction prohibiting Apotex from commercially marketing its biosimilar product until waiting 180 days after first receiving its FDA license and then providing a new notice of commercial marketing. *Id.* at 1060.

On appeal, the Federal Circuit discounted the significant factual distinctions between the *Apotex* case and *Sandoz* – namely, that Apotex faithfully engaged in the information exchange precipitated by the paragraph (*l*)(2)(A) disclosures and that all relevant patents had thereby already become the subject of litigation. Relying on the *Sandoz* decision now under review, the Federal Circuit decreed, *first*, that applicants are required to provide a notice of commercial marketing "whether or not a (2)(A) notice was given" and, *second*, that "[t]he (8)(A) requirement of 180 days' post-licensure notice . . . [is] enforceable by injunction." *Id.* at 1060-61.

Regarding the former holding, the Federal Circuit reasoned that "[t]he language of (8)(A) is categorical" because "[i]t contains no words that make the applicability of its notice rule turn on whether the applicant took the earlier step of giving the (2)(A) notice that begins the § 262(*l*) information-exchange process" and because "[t]here . . . is no other statutory language that effectively compels a treatment of (8)(A) as non-mandatory." *Id.* at 1061. The court of appeals also rejected the argument "that paragraph (9) of § 262(*l*) makes a declaratory-judgment action, discussed in (9)(B), the exclusive remedy for violations of (8)(A)." *Id.* at 1063.

Regarding the timing of the notice of commercial marketing and the injunctive relief granted to Amgen, the Federal Circuit reasoned that the BPCIA "establishes the 12-year date only as an earliest date, not a latest date, on which a biosimilar license can take effect" and that, in any case, "any . . . delay beyond 12 years should occur less and less as time goes by" because, "as time passes, more and more of the reference products will be newer, and a biosimilar-product applicant, entitled to file an application a mere four years after licensure of the reference product, . . . can seek approval long before the 12-year exclusivity period is up." *Id.* at 1061-62 (citing Pet. App. 22a).

Taken together, the Federal Circuit's decisions in *Sandoz* and *Apotex* rob biosimilar applicants such as Apotex and Sandoz of a central tenet of the BPCIA's design, *viz.*, control over the scope of the first-stage patent litigation by the applicant under paragraph (*l*)(2)(A). The court of appeals' holdings award reference product sponsors such as Amgen a new, extra-statutory remedy: an injunction against commercial marketing of an FDA-approved biosimilar product until 180 days after post-approval notice is given. This exclusivity windfall exceeds the 12-year exclusivity period granted by Congress.

SUMMARY OF ARGUMENT

Congress struck a careful balance in the BPCIA between, on the one hand, encouraging competition to lower the soaring prices for biologic medications and, on the other hand, maintaining incentives for the development of new drugs. It did so by coupling an abbreviated pathway to expedite the market availability of biosimilar products with a 12-year period of exclusivity for branded reference products.

I. The Federal Circuit erroneously held that 42 U.S.C. § 262(*l*)(8)(A) requires that a biosimilar applicant wait until after it receives FDA approval before providing effective notice of commercial marketing to the reference product sponsor. The court also erred in creating an extra-statutory injunctive remedy for reference product sponsors in the event biosimilar applicants choose not to provide such notice. Those decisions have the effect of extending the 12-year exclusivity period and delaying the onset of price-lowering competition from biosimilar products. The Federal Circuit's erroneous interpretation of this important new framework is contrary to the statute's plain text and purpose.

Paragraph (*l*)(8)(A) provides that a "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)." Although the use of the word "shall" in isolation implies a mandatory obligation, the text of the statute as a whole indicates that is the case only for those biosimilar applicants that wish to avail themselves of the enumerated expedited procedures.

The Federal Circuit recognized as much, holding that, although the BPCIA repeatedly directs that a

biosimilar applicant "shall" take certain actions, it is not always the case that they "must" do so. Pet. App. 14a-15a. The Federal Circuit explained that "'shall' in paragraph (*l*)(2)(A) does not mean 'must'" because, among other provisions, paragraph (*l*)(9)(C) "explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline" and provides a consequence for the applicant's failure to do so. *Id.* at 15a-16a.

That same logic applies with full force to the BPCIA's notice of commercial marketing provision. Paragraph (*l*)(9)(B) provides the exclusive remedy to reference product sponsors in the event that an applicant elects not to provide the notice of commercial marketing described in paragraph (*l*)(8)(A): "*If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph (8)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability" of those patents raised during the earlier information exchange between the parties. The Federal Circuit's imposition of an injunction to enforce its flawed interpretation of paragraph (*l*)(8)(A) as mandatory thus renders the paragraph (*l*)(9)(B) penalty provision superfluous.

Moreover, the court's ruling produces consequences that contravene the legislative intent of the BPCIA to facilitate the early resolution of patent disputes between the parties. For example, the BPCIA does not require a biosimilar applicant to give notice of commercial marketing if it made the disclosures set forth in paragraph (*l*)(2)(A) and fully engaged in the subsequent patent resolution framework. Under such

circumstances, a notice of commercial marketing serves no purpose. If paragraph (*l*)(8)(A) were mandatory for applicants who complied with paragraph (*l*)(2)(A) and engaged in the information exchange described in paragraphs (*l*)(3)-(*l*)(5), then reference product sponsors would have no need of the remedy specified in paragraph (*l*)(9)(B). Thus, with no further patent rights remaining for the reference product sponsor to assert, an approved biosimilar product is needlessly kept off the market for an additional 180 days.

II. The Federal Circuit's erroneous decision is inconsistent with Congress's purpose in decreasing the total health care costs of the United States government and the American people. If upheld, the Federal Circuit's statutory interpretation will delay patient access to more affordable biosimilar medicines.

New competition between branded reference products and biosimilars can help ameliorate rising health care costs and is expected to translate into major savings for consumers, including public-sector health plans and the federal government. Lower prices also mean better consumer access.

The Federal Circuit's decision will delay Americans' realization of those economic and medical benefits – thwarting Congress's years-long effort to close the biologics loophole in the Hatch-Waxman Act. The BPCIA completed a project three decades in the making: balancing cost competition and innovation for all types of pharmaceuticals. And its framework for the abbreviated approval of biosimilars is arguably even more essential to health care today than when the Hatch-Waxman Act was enacted in 1984.

To ensure that Americans are able to realize the benefits of biosimilars and of continued brand-name

biologic innovation, Congress specifically prescribed a 12-year period of exclusivity for brand-name reference products.[7] By extending that exclusivity period in all cases, the Federal Circuit's decision impedes Americans' access to life-saving biosimilar drugs and could add billions of dollars to household and government health care costs.

ARGUMENT

The Federal Circuit's decision misreads the BPCIA's text and upsets Congress's careful balance between cost-saving competition and life-saving innovation. Congress sought to promote the former through the creation of an abbreviated pathway for the approval of biosimilar products and the latter by preserving a 12-year exclusivity period for brand-name reference product sponsors. The Federal Circuit threw up a roadblock in the abbreviated pathway by mandating that biosimilars provide a notice of commercial marketing even when doing so cannot advance the orderly resolution of patent disputes. And, adding insult to injury, the court's rulings functionally extended the 12-year exclusivity period by an extra six months, diverting hundreds of billions of dollars from taxpayers and health care consumers to biologic manufacturers. Together, those errors impermissibly favor reference product sponsors. If not corrected, they will substantially increase

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[7] In fact, the Obama Administration's Office of Management and Budget ("OMB") proposed reducing the market exclusivity period afforded to reference product sponsors from 12 years to 7 years in order to achieve $3 billion in savings over 10 years to federal health programs including Medicare and Medicaid. *See* OMB, Exec. Office of President, *Fiscal Year 2014: Budget of the U.S. Government* 40 (Apr. 2013), *available at* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf.

Americans' health care costs and needlessly delay access to life-saving biosimilar medications.

I. THE FEDERAL CIRCUIT MISREAD THE BPCIA

A. The BPCIA Allows Biosimilar Applicants To Give Notice Of Commercial Marketing Before FDA Approval

The Federal Circuit is incorrect that biosimilar applicants must wait to give effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8) only after the FDA has approved a biosimilar application substantially for the reasons that Judge Chen gave in his cogent dissent. The court also erred in creating an injunctive remedy in the event a biosimilar applicant chooses not to give notice of commercial marketing. The Federal Circuit's ruling is inconsistent with the statute's text and the purpose of the notice provision. And the ruling has the pernicious and costly effect of automatically granting the reference product sponsor a 180-day windfall of extra monopoly profits after FDA approval of a biosimilar application, all to the detriment of patients who need and deserve more affordable biosimilar options. If Congress had wanted to impose a 12-and-a-half-year waiting period before biosimilar products could be brought to market, it could have done so. Instead, Congress enacted a 12-year waiting period. The Federal Circuit should have respected that carefully considered legislative choice.

1. The BPCIA's Plain Text Neither Requires a Waiting Period Nor Provides an Injunctive Remedy for Lack of Notice

Paragraph (*l*)(8)(A) calls on a biosimilar applicant to "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). The product to be marketed commercially will, of course, need to be licensed before it can be marketed, and the passage makes clear that notice is required for biosimilar applicants seeking approval under subsection (k) (as contrasted with the traditional pathway for biologics approval under subsection (a)).

On its face, however, this provision says nothing about FDA approval being required before notice is given. The notice requirement is imposed on the "subsection (k) applicant," a choice of words that strongly suggests that notice can be given before the application has been approved. If Congress had thought otherwise, it would have imposed the requirement on the "subsection (k) licensee," or otherwise have denoted the completion of the application process. The Federal Circuit nevertheless ruled that the phrase "licensed under subsection (k)" carried with it the requirement that the product be licensed not only before commercial marketing but also before effective notice of commercial marketing can be given. This reading places more interpretive weight on the word "licensed" than it can reasonably bear when the phrase is considered in the context of the statute as a whole.

Furthermore, the Federal Circuit's ruling that commercial marketing could be enjoined in this case until 180 days after FDA approval is in tension with paragraph (*l*)(9)(B) of the statute. That provision prescribes the remedy in the event that the biosimilar applicant elects not to provide notice of commercial marketing:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

42 U.S.C. § 262(*l*)(9)(B). The court correctly recognized 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 [the information-exchange provisions of] paragraph (*l*)(2)(A)." Pet. App. 25a. The court concluded, however, that the provision "does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id.* The Federal Circuit then crafted its own extra-statutory remedy – an injunction preventing commercial marketing until 180 days after notice has been given – to fill in what it regarded as a gap in the statute.

There is no gap to fill, however. As Judge Chen explained in his dissent, "the absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary." *Id.* at 51a (Chen, J., dissenting-in-part). A reference product sponsor does not need the remedy in paragraph (*l*)(9)(B) if the biosimilar applicant does not comply with paragraph (*l*)(2) because, if that happens, other provisions of the law – 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), to be precise – "already grant the right to file, immediately, an unrestricted patent infringement action." Pet. App. 51a (Chen, J., dissenting-in-part). The Federal

Circuit thus distorted the remedial scheme created by Congress to fill an imagined gap in the scheme that does not exist.

2. Imposing a Waiting Period Is at Odds with the Purpose of the BPCIA Patent Dispute Resolution Provisions

The purpose of the paragraph (*l*)(8)(A) notice is to allow the reference product sponsor to seek relief under paragraph (*l*)(8)(B), which provides:

> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
>
> (i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
>
> (ii) not included, as applicable, on—
>
> (I) the list of patents described in paragraph (4); or
>
> (II) the lists of patents described in paragraph (5)(B).

42 U.S.C. § 262(*l*)(8)(B). That is, the reference product sponsor may seek to prevent the biosimilar applicant from launching its biosimilar product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that was listed as relevant under paragraph (*l*)(3)

but not included in the lists of patents for early litigation that were agreed upon under paragraph (*l*)(4) or selected for litigation by the procedure of paragraph (*l*)(5). Paragraph (*l*)(8)(B) thus addresses patents that are *not* already the subject of a lawsuit between the parties. The provision is necessary because without it paragraph (*l*)(9)(A) would prevent the reference product sponsor from asserting the patents on the paragraph (*l*)(3) list that were not already in litigation.

Very often, there will be no such patents. For example, in Amgen's own subsequent litigation with Apotex concerning a biosimilar version of pegfilgrastim, all of the patents identified as relevant under paragraph (*l*)(3) were already part of the lawsuit. Amgen had no additional patents to add to the case after receiving notice of commercial marketing. Under those circumstances, if notice of commercial marketing is required at all, then requiring Apotex to wait to give notice of commercial marketing until after the FDA has approved its biosimilar application under subsection (k) serves no purpose; the delay in giving notice extends by 180 days the period of time in which patients and insurers must pay monopoly prices to the seller of the branded reference product even though the seller cannot use that time to resolve additional patent disputes.

Indeed, Amgen tried and lost its patent case against Apotex. The district court concluded that Apotex's manufacturing process did not infringe Amgen's patent. *See* Findings of Fact and Conclusions of Law at 19-26, *Amgen Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER (S.D. Fla. Sept. 6, 2016) (reproduced in the appendix to Apotex's certiorari petition filed in No. 16-332 at 59a-67a);

Final Judgment at 1, *Amgen Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER (S.D. Fla. Sept. 6, 2016) (reproduced in the appendix to Apotex's certiorari petition filed in No. 16-332 at 71a). Thus, Amgen exhausted its patent rights, and the "categorical" 180-day injunction imposed by the Federal Circuit in Amgen's case against Apotex will operate only to keep a non-infringing, cost-saving, FDA-approved biosimilar product out of the hands of consumers for six months longer than Congress intended. *See Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1062 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016).

Even when there are additional relevant patents to assert, moreover, the purpose of the notice provision is more logically fulfilled *before* the FDA approval of the subsection (k) application than afterward. The BPCIA created an artificial act of infringement based on the filing of the application under subsection (k), which allows the reference product sponsor to assert its patents against the biosimilar applicant before the application has been approved. If, however, notice of commercial marketing could be given only after FDA approval, then there would be no need for the artificial act of infringement that the BPCIA creates. Instead, the patent owner could bring a conventional declaratory judgment suit and seek a preliminary injunction without the need for the early patent dispute resolution procedures that the BPCIA makes available.

B. The Federal Circuit's Ruling Is Inconsistent With Other BPCIA Provisions

Congress plainly expected that biosimilar applicants and reference product sponsors would engage in the information exchange and patent negotiations

described in paragraphs (*l*)(2)-(*l*)(5) and (*l*)(7).[8] The Court should therefore evaluate the meaning of the

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[8] *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on Judiciary*, 111th Cong. 9 (2009) (hereinafter "*Biologics and Biosimilars*") (statement of Rep. Eshoo) ("H.R. 1548 also establishes a simple, streamlined patent resolution process. This process would take place within a short window of time, roughly 6 to 8 months after the biosimilar application has been filed with the FDA. It will help 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. . . . Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patents' validity or applicability."), *available at* https://judiciary.house.gov/_files/hearings/printers/111th/111-73_51014.PDF; *id.* at 197 (statement of Teresa S. Rea, President, American Intellectual Property Law Association) ("[H.R. 1548] addresses the need for an exchange of information concerning the follow-on product to allow a preliminary infringement analysis. The notice and certification provisions in H.R. 1548 would limit the patents that may be challenged to those which the patent holder believes are infringed by the follow-on product."); *see also* Krista H. Carver *et al.*, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 802-06 (2010) (describing how the patent provisions of H.R. 1548 were incorporated into the final legislation), *available at* https://www.cov.com/-/media/files/corporate/publications/2010/01/an-unofficial-legislative-history-of-the-biologics-price-competition-and-innovation-act-of-2009.pdf; *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 116 (2007) (hereinafter "*Assessing the Impact*") (statement of Bruce Downey, Chairman of the Board, Generic Pharmaceutical Association) ("I think we need to have a provision that would permit resolution of intellectual property disputes

paragraph (*l*)(8)(A) notice provision against the other BPCIA provisions that inform Congress's intent.

The Federal Circuit's ruling that effective notice of commercial marketing can be given only after FDA approval of the biosimilar product means that, whenever notice is required before commercial marketing can begin, the 12-year statutory exclusivity period will be extended by 180 days. The court appears not to have fully appreciated this consequence of its decision. The court stated that "requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the twelve-year exclusivity period of § 262(k)(7)(A)." Pet. App. 22a. In support of this conclusion, the court reasoned that, although the rule resulted in an extra 180 days of exclusivity in the present case (in which the biosimilar application had been filed only after the expiration of the 12-year exclusivity period), "[t]hat extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." *Id*. This statement is a *non sequitur*. It makes no difference whether the application is filed within the 12-year exclusivity period or afterwards. If the FDA cannot approve a biosimilar application before the expiration of the 12-year exclusivity period, and if effective notice of commercial marketing cannot be given before FDA

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in advance of launching the product. . . . Many of these products do not have one or two patents, but 30, 40 patents and there are disagreements about whether we infringe or if they are valid, and there needs to be a mechanism that allows those issues to be decided before there is a launch of the product that allows both innovator and generic companies to manage the risks that they confront . . . ."), *available at* https://archive.org/details/gov.gpo.fdsys.CHRG-110hhrg40500.

approval of the biosimilar application, then, in any case in which notice is required, the applicant will need to wait an extra 180 days after the 12-year exclusivity period has expired before commercial marketing can begin. The court thus erred in creating this "extra-statutory exclusivity windfall." *Id.* at 44a (Chen, J., dissenting-in-part).

Moreover, the BPCIA does not require a biosimilar applicant to give notice of commercial marketing if it made the disclosures set forth in paragraph (*l*)(2)(A) and fully engaged in the subsequent first-stage patent resolution framework. Under such circumstances, a notice of commercial marketing serves no purpose.

Amgen's case against Apotex illustrates the severe consequences of the Federal Circuit's erroneous interpretation. Unlike Sandoz here, biosimilar applicant Apotex in that case chose to comply with the information exchange provisions of paragraphs (*l*)(2)-(*l*)(5). Thus, Apotex provided reference product sponsor Amgen with all of the information needed to litigate the relevant patents, which concluded with a judgment of non-infringement. *See supra* pp. 8-9, 19-20. Thus, in that case, Amgen has no more patent rights to assert when the FDA grants authorization for Apotex to commence commercial marketing its biosimilar product, but the bar imposed by the Federal Circuit means the American people will nevertheless have to wait an additional 180-days after FDA approval for Apotex's pegfilgrastim product to enter the market.[9]

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[9] The Federal Circuit has suggested that "the FDA may . . . issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." *Apotex*, 827 F.3d at 1062. But such speculation finds no basis in fact: there is currently no FDA policy for licensing applications prior to the expiration of

II. THE FEDERAL CIRCUIT'S DECISION CANNOT BE RECONCILED WITH THE BPCIA'S LEGISLATIVE HISTORY AND PURPOSES

The Federal Circuit read the BPCIA as having the purpose of preserving the market share of reference product sponsors. In fact, the statute was intended to increase the availability of biosimilar products by balancing the interests of reference product sponsors and biosimilar applicants and, more broadly, to balance the national interests in innovation and cost competition. Requiring a notice of commercial marketing in all cases and extending the 12-year exclusivity window upends Congress's intended balance.

A. The BPCIA Is Designed To Increase Price Competition From Biosimilar Market Entry

In a recent submission to the FDA, the FTC recognized that "[b]iosimilar competition is important because biologics are among the most promising medicines for the treatment of a variety of medical conditions for which patients have no other alternative." FTC Comment at 2-3. The FTC further noted that "the relatively high prices of biologics, combined with patient cost-sharing requirements, can limit patient access to biologics. Price competition from biosimilars would likely lead to reduced prices for, and thus greater patient access to, biologics and biosimilars." *Id*. at 3 (footnote omitted).

The FTC has predicted that, with expected discounts of up to 30% of the brand biologic product

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the exclusivity period. *See* FDA, *Memorandum re: Exclusivity Expiry for Neupogen (filgrastim) BLA 103353* (June 26, 2014), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000AdminCorres.pdf.

price, consumers stand to benefit significantly from the new market competition between lower-cost but similarly effective biosimilars. *Id*. at 5. Industry estimates suggest this competition could save consumers, including the federal government, as much as $250 billion by 2024. *See* Miller, *Customer Perspective on Biosimilars* at 7.

Congress recognized the benefits of cheaper, more widely available generic drugs in the markets for traditional small-molecule chemical medicines three decades ago. With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, known more commonly as the Hatch-Waxman Act, Congress crafted a framework with what this Court has called a "procompetitive thrust" designed both to preserve incentives for brand-named innovation and to speed the introduction of low-cost generic drugs to market. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234 (2013); *see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). The resulting surge of cheaper generic products produced significant savings for consumers. According to the Government Accountability Office ("GAO"), the total savings that accrued to the U.S. health care system from substituting small-molecule generic chemical drugs for their brand-name counterparts from 1999 to 2010 amounted to more than $1 trillion. *See* Letter from John E. Dicken, Health Care Dir., GAO, to Hon. Orrin G. Hatch, Ranking Member, Senate Comm. on Finance, at 4, 10 (Jan. 31, 2012).[10]

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[10] *Available at* http://www.gao.gov/assets/590/588064.pdf.

But the abbreviated approval pathway under the Hatch-Waxman Act applied only to *bioequivalent* drugs (*i.e.*, chemical, small-molecule drugs) regulated under the Federal Food, Drug, and Cosmetic Act. In contrast, *biosimilar* drugs (*i.e.*, biologic, large-molecule drugs) regulated under the Public Health Service Act still required full, individual FDA testing and approval. That asymmetry rendered biologics broadly immune to the downward pricing pressures that affected traditional drugs. *See* Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 Health Matrix 139, 144-46 (2015).[11] Thus, the BPCIA was intended to update the American drug-approval system in keeping with global trends toward increased use of biosimilars.

Although the BPCIA is distinct from the Hatch-Waxman Act and there are significant differences between the two statutes, both share the same basic theoretical framework and use similar procedures to attain similar goals. Notably, both statutes aim to improve access to high-cost medications for populations in need while preserving the incentives to innovate new treatments and facilitating the timely identification and resolution of patent disputes. But the Federal Circuit's decision, which essentially affords reference product sponsors an automatic 180-day injunction barring sales of biosimilar drugs whenever notice of commercial marketing is required, frustrates the purpose of the statute and endangers the calculated tradeoff between price-lowering competition and incentive for innovation. Biosimilars already face significant barriers to market entry that are much more difficult to overcome than those

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[11] *Available at* http://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1021&context=healthmatrix.

typically confronting small-molecule generic chemical drugs. These barriers include difficulties associated with manufacturing, marketing, storage, distribution, delivery devices, immunogenicity (*i.e.*, adverse reactions in a patient due to live organisms), and special requirements for pharmacovigilance (*i.e.*, post-sale monitoring). *See* Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 471 (Sept./Oct. 2013).[12] An unnecessarily lengthy, unintended, and unwarranted extension of the exclusivity period will impede access to biosimilars and add hundreds of billions of dollars in costs to consumers, employers, and publicly funded programs like Medicare and Medicaid.

B. Congress Determined That A 12-Year Exclusivity Period Struck The Right Balance Between The Competing Interests

The 12-year window was a carefully negotiated compromise – a "middle ground between innovator and generic interests." Carver, *An Unofficial Legislative History*, 65 Food & Drug L.J. at 817. Defining an exclusivity period that would best promote both innovation and cost-saving generic competition was a key sticking point across years of legislative negotiations. *See id.* at 724-25 (noting that exclusivity proved early on to be a "troublesome" point of disagreement). In fact, even during final negotiations over the bill, proposals under consideration included exclusivity periods as long as 14 years and as short as five to seven. *See id.* An unnecessarily lengthy, unintended, and unwarranted extension of the exclusivity period will impede access to biosimilars and add

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[12] *Available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf.

hundreds of billions of dollars in costs to consumers, employers, and publicly funded programs like Medicare and Medicaid.

Members of Congress weighed the competing interests of sponsors and applicants and of innovation and cost competition. They emphasized the need to strike a "balance" that would "allow generic companies to do what they do best – bring low-cost versions to the market." Senate Comm. on Health, Education, Labor & Pensions, Press Release, *Lawmakers Praise Committee Passage of Biologics Legislation* (June 27, 2007) (statement of Sen. Hatch).[13] Their aim was "to lower prices and extend the availability of . . . treatments to more who need them." *Id.* (statement of Sen. Clinton). The congressional record is full of testimony from lawmakers of both parties and from others who repeatedly emphasized the importance of achieving cost savings to improve patient access.

For example, in a hearing before a Subcommittee of the House Committee on Energy and Commerce, Rep. Frank Pallone, Jr. called on Congress to "produce measurable savings." *Assessing the Impact* at 2. Representative Nathan Deal concurred, offering that Congress had before it "an opportunity to provide patients access to a lower cost alternative for their needed medications." *Id.* at 5. Likewise, the Vice President of Human Services at Caterpillar, Inc., told the Senate Committee on Health, Education, Labor, and Pensions that biologic drugs accounted for an outsized and increasingly unaffordable slice of the company's health care expenses, describing the rising costs as "simply not sustainable." *Follow-On Biologics:*

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[13] *Available at* http://www.help.senate.gov/ranking/newsroom/press/lawmakers-praise-committee-passage-of-biologics-legislation.

Hearing Before the S. Comm. on Health, Education, Labor, and Pensions, 110th Cong. 11 (2007).[14] In the same hearing, Sen. Charles Schumer acknowledged the national scope of the problem and put the potential for cost savings in perspective: "Treating [a] patient with a biologic drug can cost $100,000 a year, total cost to the nation, $32 billion. If introducing competition in this market lowers the price of biologics even by only 10 to 25 percent, the savings are astronomical." *Id.* at 6.[15]

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[14] *Available at* https://www.gpo.gov/fdsys/pkg/CHRG-110shrg34053/pdf/CHRG-110shrg34053.pdf.

[15] *See also Safe and Affordable Biotech Drugs: The Need for a Generic Pathway: Hearing Before the H. Comm. on Oversight and Gov't Reform*, 110th Cong. 2-3 (2007) (statement of Rep. Waxman) ("A new path for FDA to approve generic biologicals will save patients billions in the future and will improve access to treatments and cures . . . . For the sake of patients, their families, public and private health insurance, and taxpayers, we must find a way to introduce competition to this market. When a patent expires, we owe it to consumers to find a way through competition to lower prices and still deliver a safe and effective product."), *available at* https://www.gpo.gov/fdsys/pkg/CHRG-110hhrg40874/pdf/CHRG-110hhrg40874.pdf; *Assessing the Impact* at 7 (statement of Rep. Ferguson) (noting importance of both patient safety and cost savings and, in particular, pointing to expectation that "follow-on biologics will save about $3.6 billion over 10 years"); *id.* at 9 (statement of Rep. Blackburn) ("[w]hen the healthcare costs are skyrocketing, and we hear this every time we come in for a committee hearing, we know that people are looking for new options for lowering drug costs"); *id.* at 10 (statement of Rep. Capps) ("Quite frankly, with no competition on the markets, biologics remain out of economic reach for most of the people who need them. I hope to hear today from witnesses on how we can balance innovation with patients' needs for cheaper, more accessible drugs."); *id.* at 11 (statement of Rep. Solis) ("The manufacture of biologic medicines has the potential to save millions of lives, and biologics account for approximately $30 billion in sales. However, the cost of devel-

Ultimately, Congress provided for a 12-year exclusivity period that was intended to be commensurate in duration and scope to the patent protection typically afforded to innovative drugs.[16] And, like patent protections, the 12-year exclusivity period is not open-ended. Indeed, the congressional sponsor of key patent resolution provisions underscored the point: "In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved *before, and I emphasi[ze] the word before*, the expiration of the data-exclusivity period, H.R. 1548 also establishes a simple, streamlined patent resolution process." *Biologics and Biosimilars*

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oping and manufacturing these biologics are extremely high; and the average cost of a 1-day supply of biologic medicines is $45. As a result, the cost for patients, insurers, private companies, and Government payers are quickly growing. And I am very concerned about the high cost of these medicines, especially the cost of those treatments for many who lack healthcare insurance or who are underinsured."); *id.* at 12 (statement of Rep. Wilson) ("I commend the chairman and members of his committee for their determination to tackle this issue to see whether there is something we can do so that we create a pathway for generics that might be at less cost for a new class and a new kind of therapy in the area of medicine.").

[16] *See Biologics and Biosimilars* at 8 (statement of Rep. Eshoo) ("[T]o preserve the existing incentives for investment and innovation, the Pathway for Biosimilars Act provides a data-exclusivity period equivalent to patent protections for small molecules. The Congressional Budget Office has determined that 11.5 years is the average length of time that drugs are marketed under patent. In other words, innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics.").

at 9 (statement of Rep. Eshoo) (emphasis added);[17] *see also Assessing the Impact* at 116 (statement of Bruce Downey, Chairman of the Board, Generic Pharmaceutical Association) ("[T]here needs to be a mechanism that allows [patent] issues to be decided before there is a launch of the product that allows both innovator and generic companies to manage the risks that they confront and . . . *also allows for the earliest lawful entry of the product and doesn't allow the litigation post-exclusivity period, post-patent to delay the launch of a product*.") (emphasis added). Any assertion to the contrary undermines Congress's explicit effort to make cost-saving biosimilars available at the earliest possible date consistent with continuing innovation.

C. Notice Of Commercial Marketing Is Not Necessary In All Cases

Requiring a notice of commercial marketing in all cases cannot be justified by reference to Congress's intent to promote the introduction of biosimilar products, including by facilitating the resolution of patent disputes arising between sponsors and biosimilar applicants.

The Federal Circuit's decision erroneously requires *all* biosimilar applicants to wait an additional 180 days before undertaking to commercially market an aBLA product, notwithstanding their voluntary participation in the statutory information exchange and patent negotiation procedures. But where, as in Apotex's case, an applicant has made available to

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[17] The patent resolution provisions of H.R. 1548, 111th Cong. (2009), were substantially incorporated into the BPCIA's final text. *See* Carver, *An Unofficial Legislative History*, 65 Food & Drug L.J. at 802-06 (describing how the patent provisions of H.R. 1548 were incorporated into the final legislation).

the sponsor the information outlined in paragraph (*l*)(2)(A), the reference product sponsor has all the information needed to enforce its intellectual property rights, including "a copy of the application" and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." As such, mandating the notice of commercial marketing will in most, if not all, cases in which an applicant has provided the paragraph (*l*)(2)(A) disclosures, convey a windfall upon sponsors without providing any countervailing public benefit. In Amgen's case against Apotex, for example, not only did Apotex already provide Amgen with all the information Amgen needed to determine whether to litigate its intellectual property rights, but Amgen in fact already had undertaken to litigate all relevant patents, which Apotex's product was found not to infringe. The 180-day injunction therefore serves no purpose other than to preserve Amgen's exclusive market for an additional six months.

CONCLUSION

The judgment of the court of appeals should be reversed with respect to the questions presented in the petition by Sandoz and affirmed with respect to the question presented in the cross-petition by Amgen.

Respectfully submitted,

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