2016 WL 4921167 (U.S.) (Appellate Petition, Motion and Filing)
Supreme Court of the United States.

APOTEX INC. and Apotex Corp., Petitioners,
v.
AMGEN INC. and Amgen Manufacturing Limited, Respondents.

No. 16-332.
September 6, 2016.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit
September 9, 2016

Petition for a Writ of Certiorari

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***i** QUESTIONS PRESENTED

Congress enacted the Biologies Price Competition and Innovation Act ("BPCIA") to create an expedited pathway for the approval of more affordable, life-saving "biosimilar" drugs, which are an important, but very expensive, new class of medical products. The BPCIA seeks to balance the interests of innovation and cost competition for these multi-billion dollar products by creating a framework for efficiently resolving patent disputes between a maker of a biologic drug product (referred to in the statute as a "reference product sponsor") and a would-be competitor who seeks permission to market a "biosimilar" drug product, including in the provision concerning "notice of commercial marketing," 42 U.S.C. § 262(*l*)(8)(A).

The Court of Appeals for the Federal Circuit, however, upended Congress's careful balance when it held that (1) all biosimilar applicants are required to provide a "notice of commercial marketing," even when doing so cannot advance the resolution of patent disputes, and (2) no biosimilar applicant may provide such notice before receiving a Food and Drug Administration ("FDA") license for its biosimilar product. Those holdings improperly extend by 180 days the 12-year exclusivity period Congress granted to reference product sponsors. *See*42 U.S.C. § 262(*l*)(8)(A).

The questions presented are:

1. Whether the Federal Circuit erred in holding that biosimilar applicants that make all disclosures necessary under the BPCIA for the resolution of patent disputes (*viz.*42 U.S.C. § 262(*l*)(2)(A)) must also provide the reference ***ii** product sponsor with a notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A).

2. Whether the Federal Circuit improperly extended the statutory 12-year exclusivity period to 12 1/2 years by holding that a biosimilar applicant cannot give effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) for its biosimilar product until it receives an FDA license and therefore may not commercially market its biosimilar product for 180 days after receiving its license.

*III CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioners Apotex Inc. and Apotex Corp. state the following:

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

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***ix** Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*:

***1** Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

INTRODUCTION

This case presents fundamental questions affecting the cost and availability of biologic "miracle medicines" to the public. The Biologies Price Competition and Innovation Act ("BPCIA") - part of the Patient Protection and Affordable Care Act of 2010 - was intended to strike a balance between encouraging price competition within this important and rapidly growing category of expensive specialty pharmaceuticals and incentivizing the development of new drugs. To do so, the BPCIA regulates two types of biologies: branded reference products and generic biosimilars. To save lives - and billions of dollars in public and private funds - the BPCIA helps to speed biosimilar medicines to market, and it facilitates the resolution of patent disputes between biosimilar applicants and reference product sponsors.

In the decision below, the Federal Circuit extended by 180 days the amount of time a biosimilar applicant must wait before marketing its product - even when the brand-name producer has all of the information it needs from the biosimilar applicant to determine whether to challenge the applicant's product. The court ruled that no biosimilar applicant may provide such notice before receiving a Food and Drug Administration ("FDA") license for its biosimilar product, even as the court recognized that the FDA has never approved a biosimilar applicant prior to the expiration of the 12-year

period of exclusivity enjoyed by the branded reference. That extension confers a half-year market exclusivity period to the ***2** brand-name producer that can be worth billions of dollars in biologies' sales.

In this case and the pending case, *Sandoz Inc. v. Amgen Inc.,* No. 15-1039 (filed Feb. 16, 2016), in which this Court has called for the views of the Solicitor General, this Court has a unique opportunity to review the errors of the Federal Circuit's statutory construction in the two distinctive factual scenarios contemplated by the BPCIA: one is this case, in which petitioner Apotex provided all the information needed for Amgen to make a determination as to whether to challenge Apotex's product on patent infringement grounds; and the other is *Sandoz,* in which the biosimilar applicant decided *not* to provide that information to the brand-name manufacturer. Erring in both cases, the Federal Circuit has contorted the patent resolution procedures established by the BPCIA.

In so doing, the Federal Circuit has upset the careful balance between biologic price competition and innovation negotiated by Congress. The Circuit-manufactured 180-day extension of the period of exclusivity conferred by Congress to brand-name manufacturers has anticompetitive effects, prolongs the collection of monopoly rents, and bolsters already-troublesome barriers to entry for biosimilars. The Federal Circuit's judicially-crafted alteration to the BPCIA, therefore, presents an issue of national importance.

Because the Federal Circuit has now decided the crucial statutory construction issues, this Court will not have another opportunity to correct that court's error in the context of multi-billion dollar biologies markets. That fact confirms the urgency of this Court granting certiorari now.

*3 OPINIONS BELOW

The opinion of the court of appeals (App. 1a-27a) is reported at —— F.3d ——, 2016 WL 3606770. The order of the district court (App. 28a-37a) is not reported.

JURISDICTION

The court of appeals entered its judgment on July 5, 2016. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Biologies Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 119, are set forth at App. 76a-109a.

STATEMENT OF THE CASE

A. Statutory Background

1. Biologies are large-molecule drugs that are produced in living organisms. Some biologies are "miracle medicines" with the capacity to help patients suffering from serious diseases in ways that traditional medicines now available cannot. *Examining Food and Drug Administration Follow-On Biologies: Hearing Before the Sen. Comm. on Health, Education, Labor, and Pensions,* 110th Cong. 1 (2007) (hereinafter "*Examining Food and Drug Administration Follow-On Biologies*") (opening statement of Sen. Kennedy). Consequently, a tremendous market has developed for biologies. In 2010, four of the ten top-selling branded drugs worldwide were biologies. See Steve Miller, Senior V.P. & Chief Med. Officer, Express Scripts, Presentation at FTC Biosimilars Workshop: *Customer Perspective on Biosimilars* 3 (Feb. 4, 2014) (hereinafter

"Miller, *Customer* ***4** *Perspective on Biosimilars*"). [1] Industry experts estimate that seven of the ten top-selling branded drugs this year are likely to be biologies. *Id.*

Yet biologies are also tremendously expensive. The cost of a biologic drug is on average 22 times higher than the cost of a traditional chemical or small-molecule medication. *See* Comment of the Staff of the Federal Trade Comm'n to Food & Drug Admin. 3 (Oct. 27, 2015) (hereinafter "FTC Comment"). [2] And the cost keeps rising - increasing on average 10-15% each year. *See id.* In fact, the average price of biologics doubled from 2006 to 2012. *See id.*

In 2010, Congress acted to accelerate the availability of cheaper, generic versions of these expensive, branded medicines. Toward that end, Congress guaranteed the branded companies a 12-year period of exclusivity, before which the FDA cannot grant a biosimilar drug an effective license via the pathway set forth in the BPCIA. *See*42 U.S.C. § 262(k)(7)(A). But to promote competition and prevent the high cost of biologies from further increasing the costs of health care, Congress in the BPCIA also established an abbreviated pathway for the regulatory approval of biologies that are "highly similar" to a branded reference product. *Id.* § 262(i)(2).

2. Section (k) of the BPCIA provides that, to obtain approval via the abbreviated pathway, a biosimilar applicant must submit to the FDA an abbreviated ***5** Biologies License Application ("aBLA"). *See id.* § 262(k). An aBLA relies, in part, on the branded drug company's FDA-approved license of the reference product. See *id.* The branded drug company is therefore known as the "reference product sponsor" or, simply, the "sponsor." *See id.* § 262(*l*)(1)(A). [3]

Section (*l*) of the BPCIA establishes a framework for the efficient resolution of patent disputes between the reference product sponsor and the biosimilar applicant. Twice, the statute offers the applicant the opportunity to streamline patent disputes by sharing critical information with the sponsor. And in each case, the statute offers the sponsor recourse in the event the applicant chooses not to do so.

First, under paragraphs (*l*)(2)-(*l*)(5) of the BPCIA, the parties may exchange information concerning the aBLA and those patents the sponsor reasonably believes may be infringed, thereby ultimately arriving at a list of patents subject to an immediate action for infringement per the terms of paragraph (*l*) (6). The exchange is to begin "not later than 20 days after the Secretary notifies the … applicant that the application has been accepted for review," by which time an applicant who elects to engage in the information exchange must "provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). In the event the applicant does not provide the sponsor with that information, ***6** paragraph (*l*)(9)(C) provides the 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 a use of the biological product."

Second, under paragraph (*l*)(8)(A), the applicant may "provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." If the applicant gives notice, then the sponsor may seek an injunction under paragraph (*l*)(8)(B): "After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent" that was described as relevant during the information exchange outlined in paragraph (*l*)(3) and that is not already the subject of litigation. In the event the applicant does not give notice, paragraph (*l*)(9)(B) provides 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 ***7** information exchange described in paragraphs (*l*)(2)-(*l*)(5), including any newly issued patent deemed relevant.

3. The Federal Circuit first had occasion to interpret the BPCIA in *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *petition for cert. filed,* No. 15-1039 (U.S. Feb. 16, 2016). There, the biosimilar applicant Sandoz elected not to provide the information specified in paragraph (*l*)(2)(A).

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. *See id.* at 1357. The Federal Circuit also held that an applicant that chooses not to engage in the information exchange must provide to the sponsor the notice of commercial marketing described in paragraph (*l*)(8)(A). *See id.* at 1360. And it held that such an applicant could provide that notice of commercial marketing only after the issuance of the FDA license for its biosimilar product. *See id.* at 1358.

B. Procedural Background

1. In 2002, Amgen received a license for a brandname biologic with the active ingredient pegfilgrastim, which provides health benefits to patients undergoing chemotherapy. App. 3a. Amgen's 12-year BPCIA-guaranteed exclusivity period for its brand-name biologic has thus expired. *Id.*

In October 2014, Apotex applied for an FDA license to market a biosimilar pegfilgrastim product in accordance with the BPCIA. App. 3a, 11a. On December 15, 2014, the FDA accepted Apotex's application ***8** for review. App. 11a. Within 20 days, Apotex provided Amgen with a copy of its application and the other information specified in paragraph (*l*)(2)(A). Thereafter, Apotex and Amgen engaged in the exchange of patent information contemplated by paragraphs (*l*)(3)-(*l*)(5). During that exchange, Amgen stated that it held three relevant patents. App. 11a-12a. Apotex initially responded that it would commercially market its biosimilar product only after two of those three patents expired, and that the third patent, which expires in 2031, was invalid and would not in any case be infringed by the marketing of Apotex's biosimilar product. App. 11a. In addition, Apotex attempted to provide Amgen with the notice of commercial marketing described in paragraph (*l*)(8)(A) by sending Amgen a letter containing the notice. App. 11a-12a. Ultimately, the parties agreed to litigate all unexpired patents, of which there is currently only one remaining. *Id.*

2. On August 2, 2015, Amgen filed its complaint in the United States District Court for the Southern District of Florida. Amgen sought a declaration that Apotex violated paragraph (*l*)(8)(A) of the BPCIA "by not providing Amgen with an effective notice of commercial marketing after the Apotex Pegfilgrastim Product is licensed by FDA and at least 180 days before Apotex begins commercial marketing of the Apotex Pegfilgrasim Product." CAFC J.A. 56.

Amgen then sought, and 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 new notice of commercial marketing. App. 13a-14a. Apotex appealed the district court's grant of a preliminary injunction. App. 15a.

***9 3.** On appeal, the Federal Circuit discounted the significant factual distinctions between this 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 in an efficient manner. 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." App. 15a.

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." App. 16a. 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)." App. 21a.

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 ***10** mere four years after licensure of the reference product … can seek approval long before the 12-year exclusivity period is up." App. 17a.

REASONS FOR GRANTING THE PETITION

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 brandname 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 - it functionally extended the 12-year exclusivity period by an extra six months. Together, those errors put a thumb on the scale in favor of reference product sponsors. If not corrected, they will substantially increase Americans' health care costs and needlessly delay access to lifesaving biosimilar medications. Because no other appellate court will interpret the BPCIA, this Court's review is necessary to correct the Federal Circuit's erroneous reading of the statute on a question that affects multi-billion dollar markets for a range of life-saving drugs.

*11 I. THE FEDERAL CIRCUIT MISREAD THE BPCIA

A. The Federal Circuit's Decision Cannot Be Reconciled With The BPCIA's Text And Structure

The BPCIA does not require a biosimilar applicant to give a 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.

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 not the case.

The Federal Circuit recognized as much in *Sandoz.* There, the court held that, although the BPCIA repeatedly directs that an applicant "shall" take certain actions, it is not always the case that they "must" do so. 794 F.3d at 1355. The Federal Circuit explained that " 'shall' in paragraph (Z)(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 1355-56.

That same logic applies with full force in the present case. Paragraph (*l*) (9)(B) provides a remedy to sponsors in the event that an applicant elects not to provide the notice of commercial marketing described ***12** in paragraph (Z)(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.

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 paragraph (*l*)(9)(B) would be superfluous - sponsors would have no need of the remedy specified therein. And this Court clearly has stated that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews,* 534 U.S. 19, 31 (2001) (internal quotation marks omitted).

Notwithstanding the paragraph (*l*)(9)(B) remedy, the Federal Circuit erroneously implied the existence of an atextual injunctive remedy extending the 12-year exclusivity period by 180 days based upon a purely theoretical concern over a "race to court" resulting in "the hurried motion practice that [paragraph (*l*)(8)(A)] is designed to replace by ensuring a defined amount of time for pre-launch litigation." App. 24a-25a. *First*, even if the paragraph (*l*) (8)(A) notice is mandatory, nothing in that paragraph requires that the notice post-date FDA licensure of the biological product, and pre-licensure notice would guarantee sponsors adequate time to consider their legal options. *Second*, as this case illustrates, a "race to court" is unlikely ever to come to pass. Here, ***13** Apotex provided Amgen with a pre-licensure notice of commercial marketing that adequately informed Amgen of its intentions and thus enabled Amgen to take all steps necessary to vindicate its legal rights. *See supra* pp. 7-8. Even had it not done so, however, Apotex's disclosures pursuant to paragraph (*l*)(2)(A) gave Amgen all the information it needed to pursue an orderly defense of its patent rights, such that all relevant patents are already the subject of litigation. *See supra* pp. 7-8. Indeed, the BPCIA explicitly anticipates that the sponsor will be able to generate "a list of patents for which [it] believes a claim of patent infringement could reasonably be asserted" based upon the applicant's paragraph (*l*)(2)(A) disclosures, even if not all such patents are immediately litigated. 42 U.S.C. § 262(*l*)(3)(A).

Moreover, Amgen has now tried and lost its patent case. The district court concluded that Apotex's manufacturing process does not infringe Amgen's patent. App. 59a-67a. Thus, Amgen has exhausted its patent rights and the 180-day injunction imposed by the Federal Circuit serves no logical purpose. In this instance, the Circuit's bar will operate only to keep a non-infringing, cost-saving FDA-approved biosimilar product out of the hands of consumers for an additional six months.

The Federal Circuit's assertion that the 180-day extension of the statutory exclusivity period occasioned by its holding in this case "should occur less and less as time goes by" is also inaccurate. App. 17a. The Federal Circuit supposes that, as applicants begin to model their biosimilar products on newer reference products, they will be able to "seek approval long before the 12-year exclusivity period is up." *Id.* The court then suggests that "the ***14** FDA may … issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." *Id.* But that speculation by the Federal Circuit panel finds no basis in fact: there is currently no FDA policy for licensing applicants prior to the expiration of the exclusivity period.[4] The statutory imbalance between applicants and sponsors and between cost competition and innovation can be better and more swiftly resolved by reversing the Federal Circuit's erroneous decision.

B. The Federal Circuit's Decision Cannot Be Reconciled With The Legislative History And Policy Underlying The BPCIA

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 balance the interests of sponsors and 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.

First, 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 ***15** 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 here, an applicant has made available to the sponsor the information outlined in paragraph (*l*)(2)(A), the 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 this case, 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 had in fact already 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.

Second, the 12-year window was a carefully negotiated compromise - a "middle ground between innovator and generic interests." Krista H. Carver, *et al., An Unofficial Legislative History of the Biologies Price Competition and Innovation Act of 2009,* 65 Food & Drug L.J. 617, 817 (2010) (hereinafter "*An Unofficial Legislative History*"). [5] Defining an ***16** 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 hundreds of billions of dollars in costs to consumers, employers, and publicly funded programs like Medicare and Medicaid.

Weighing the competing interests of sponsors and applicants and of innovation and cost competition, legislators 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 Biologies Legislation* (June 27, 2007), [6] (statement of Sen. Hatch). Why? Quite simply, "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 ***17** "produce measurable savings." *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce*, 110th Cong. 2 (2007) (hereinafter "*Assessing the Impact*"). 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, a United States manufacturer, 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." *Examining Food and Drug Administration Follow-On Biologies* at 11. 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 biologies even by 10 to 25 percent, the savings are astronomical." [7] *Id.* at 6.

***18** 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.[8] And like patent ***19** 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."[9] *Biologies and Biosimilars* at 9 (statement of Rep. Eshoo) (emphasis added); *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). The Federal Circuit's assertion to the contrary undermines Congress's explicit effort to make cost-saving biosimilars available at the earliest possible date consistent with continuing innovation. *See* App. 16a-17a.

II. THIS COURT SHOULD ACT NOW TO CORRECT THE FEDERAL CIRCUIT'S MISREADING OF THE BPCIA

The BPCIA is a new law, and the Federal Circuit's decisions in *Sandoz* and in this case are the first to ***20** interpret it. But the novelty of the important questions raised in this petition ought not cause this Court to defer its review of them.[10]

There will never be a circuit split concerning the meaning of the BPCIA. The Federal Circuit "has exclusive jurisdiction over appeals from all United States District Courts in patent litigation." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993). Nor can this Court expect that the notice issue will further percolate in the Federal Circuit, which has now definitively indicated that *all* applicants will be required to provide a post-approval notice and to delay the commercial introduction of their biosimilar product by 180 days. Indeed, the Federal Circuit repeatedly has declined to revisit its holding that the paragraph (*l*)(8)(A) notice of commercial marketing is mandatory. *First*, the court declined to review its holding in *Sandoz* en banc. See Order, *Sandoz,* No. 15-1499 (Fed. Cir. Oct. 16, 2015) (per curiam). Then, in this case, the Federal Circuit declined the opportunity to distinguish its holding in *Sandoz.* It did so notwithstanding that Apotex complied with the information exchange and patent negotiation provisions of the law, and that all relevant patents identified in that process had already become the subject of litigation. If neither one of those circumstances induced the Federal Circuit to distinguish its decision in *Sandoz,* there is ***21** simply no set of circumstances in which it can be expected to do so.

This Court routinely has granted certiorari petitions in similar cases of national importance coming from the Federal Circuit. For example, this Court has taken cases construing 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. *See, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 132 S. Ct. 1670, 1675 (2012) (whether counterclaim provision under 21 U.S.C. § 355(j)(5)(C)(ii)(I) authorized challenge to accuracy of use code); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990) (whether exemption from infringement under 35 U.S.C. § 271(e)(1) applied to medical devices). Allowing the Federal Circuit's decision to stand would introduce new areas of significant uncertainty into the law. For example, if the "commercial marketing" of a biosimilar product is enjoined until 180 days after the FDA licenses that product, as the Federal Circuit has ruled, then courts can expect significant litigation regarding the scope of that injunction as pharmaceutical companies attempt to negotiate the real-world consequences of delayed launch.

III. THE COURT SHOULD GRANT THIS CASE AND THE *SANDOZ* PETITION CURRENTLY PENDING BEFORE THIS COURT BECAUSE BOTH CASES PRESENT DISTINCTIVE AND RECURRING FACT PATTERNS UNDER THE BPCIA

The Federal Circuit's decisions in *Sandoz* and in this case should be considered together. To take the full measure of the BPCIA, the Court should consider the Federal Circuit's imposition of the paragraph ***22** (*l*)(8)(A) notice requirement and 180 day injunction in two distinctive contexts addressed in the statute: when the applicant fully engages in the information exchange precipitated by paragraph (*l*)(2)(A) (as in this case) and when the applicant does not (as in *Sandoz*). The Court has called for the views of the Solicitor General in the *Sandoz* case, and should consider this petition in conjunction with that one.

Even if the Court declines to grant the petition for certiorari in *Sandoz,* however, it should grant the petition in this case. Congress plainly expected that applicants and sponsors would engage in the information exchange and patent negotiations described in paragraphs (*l*)(2)-(*l*)(5) and (*l*)(7). [11] The Court ***23** should therefore evaluate the meaning of the paragraph (*l*) (8)(A) notice provision against the background actions Congress intended. That is the case here, where Apotex conscientiously engaged in the statutory information exchange, from which Amgen received all the information required to enable it to litigate its relevant patents.

IV. THIS CASE PRESENTS QUESTIONS OF SIGNIFICANT NATIONAL IMPORTANCE

The Federal Circuit's erroneous decision will substantially increase the total health care costs of the United States government and the American people, and it will delay patient access to more affordable biosimilar medicines.

Health care spending accounts for a huge part of the American economy - at least 17.5% of America's Gross Domestic Product, according to the Centers for Medicare and Medicaid Services ("CMS"). *See* CMS, *National Health Expenditures 2014 Highlights* 1, 2 (Dec. 2015). [12] And prescription drug costs in turn account for a large portion of health care spending - approximately $300 billion of $3 trillion, or 10%, again according to CMS. *See* CMS, *The Nation's* ***24** *Health Dollar ($3.0 Trillion), Calendar Year 2014, Where It Went* (Dec. 2015). [13]

New competition between branded reference products and biosimilars can help ameliorate those rising healthcare costs: the FTC estimates that biosimilars will cost up to 30% less than brand biologic drugs. *See* FTC Comment at 5. That discount is expected to translate into major savings for consumers, including public-sector health plans and the federal government. For example, the Ohio Public Employees Retirement System anticipates that the introduction of new biosimilars will save its health plan $129 million over 10 years. *See* Joyce Frieden, *Biosimilars Hold Promise, Questions*, MedPage Today (June 21, 2016). [14] And industry estimates suggest that competition between brand biologic products and biosimilars could save Americans overall, including the federal government, as much as $250 billion by 2024. *See* Miller, *Customer Perspective on Biosimilars* at 7. Lower prices also mean better consumer access to "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. In contrast, delaying the entry of a biosimilar pegfilgrastim product by six months would cost the government and health payers up to about $600 million in lost savings and impair consumer access. *See* Amgen ***25** Inc., Annual Report 42 (Form 10-K) (Feb. 16, 2016); [15] FTC Comment at 5.

The Federal Circuit's decision will delay Americans' realization of those economic and medical benefits - thwarting Congress's years-long effort to close the biologies loophole in the Hatch-Waxman Act. *See FTC v. Actavis, Inc.,* 133 S. Ct. 2223, 2234 (2013).

That Act sought to ensure Americans would receive the economic and medical benefits of generic drugs by facilitating their entrance into the markets for traditional small-molecule chemical medicines. *See Caraco Pharm.,* 132 S. Ct. at 1676; *Eli Lilly & Co.,* 496 U.S. at 676. And it was successful. Following the law's enactment, a surge of cheaper generic products produced significant savings for consumers. According to the Government Accountability Office ("GAO"), the United States health care system saved more than $1 trillion from 1999 to 2010 by substituting small-molecule generic chemical

drugs for their brand-name counterparts. See Letter from John E. Dicken, Health Care Dir., GAO, to Hon. Orrin G. Hatch, Ranking Member, S. Comm. on Fin. 4, 10 (Jan. 31, 2012).

But, "[w]hen the Hatch-Waxman law was enacted, Congress did not include biologies because at the time, such drugs were not providing the major innovations and advances … the biological sciences have brought over the past 20 years." *Examining Food and Drug Administration Follow-On Biologies* at 2 (statement of Sen. Kennedy). As a result, biologies remained stubbornly resistant to the cost ***26** competition making traditional drugs more affordable. *See* Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 Health Matrix 139, 144-46 (2015). [16]

The BPCIA thus completed a project three decades in the making: to balance cost competition and innovation for all types of pharmaceuticals. And its framework for the abbreviated approval of biosimilars is arguably even more essential to healthcare today than when the Hatch-Waxman Act was enacted in 1984. Biosimilars face significant barriers to market entry that are higher than those typically confronting small-molecule generic chemical drugs, including 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). [17]

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. [18] By extending that exclusivity ***27** period, 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.

CONCLUSION

The petition for a writ of certiorari should be granted.

Footnotes

1 *Available at* https://www.ftc.gov/system/files/documents/public_events/Follow-On%20Biologics%C20Workshop#A%20Impact %20*o*f%20Recent%C20Legislative%C20and%C20Regulatory%C20Naming%C20Proposals%C20on%20Competition/miller.pdf.

2 *Available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-adminabiosimilar.pdf.

3 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.

4 *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.

5 *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.

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

7 *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."); *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 biologies will save about $3.6 billion over 10 years"); *id.* at 9 (statement of Rep. Blackburn) ("When 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, biologies 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 biologies account for approximately $30 billion in sales. However, the cost of developing and manufacturing these biologies 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.").

8 *See Biologies and Biosimilars: Balancing Incentives for Innovation: Hearing Before the H. Comm. on the Judiciary*, 111th Cong. 8 (2009) (hereinafter "*Biologies and Biosimilars*") (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 biologies typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologies.").

9 The patent resolution provisions of H.R. 1548, 111th Cong. (2009), were substantially incorporated into the BPCIA's final text. *See An Unofficial Legislative History* at 802-06 (describing how patent provisions of H.R. 1548 were incorporated into final legislation).

10 In addition to this case and *Sandoz,* several other suits have already been filed under the BPCIA. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.,* No. 1:15-cv-10698 (D. Mass. filed Mar. 6, 2015); *Amgen Inc. v. Hospira, Inc.,* No. 1:15-cv-839 (D. Del. filed Sept. 18, 2015); *Immunex Corp. v. Sandoz Inc.,* No. 2:16-cv-1118 (D.N.J, filed Feb. 26, 2016); *Amgen Inc. v. Sandoz Inc.,* No. 2:16-cv-1276 (D.N.J, filed Mar. 4, 2016).

11 *See Biologies and Biosimilars* at 9 (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."); *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 An Unofficial Legislative History* at 802-06 (describing how the patent provisions of H.R. 1548 were incorporated into the final legislation); *Assessing the Impact* at 116 (statement of Bruce Downey) ("I think we need to have a provision that would permit resolution of intellectual property disputes 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.").

12 *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

13 *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/PieChartSourcesExpenditures2014.pdf.

14 *Available at* http://www.medpagetoday.com/publichealthpolicy/healthpolicy/58691.

15 *Available at* https://www.sec.gov/Archives/edgar/data/318154/000031815416000031/amgn-12312015xl0k.htm. Amgen's domestic sales of its pegfilgrastim product were approximately $4 billion in 2015.

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

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

18 In fact, the President's Office of Management and Budget ("OMB") recently 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.

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