No. 15-1039

IN THE
Supreme Court of the United States

SANDOZ INC.,
Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Respondents.

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

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF OF APOTEX INC. AND APOTEX CORP. AS *AMICI CURIAE* SUPPORTING PETITIONER

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March 21, 2016

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Under Rule 37.2 of the Rules of this Court, Apotex Inc. and Apotex Corp. move for leave to file the accompanying brief as *amici curiae* in support of the petition for a writ of certiorari. Written consent of petitioner is being submitted contemporaneously with this brief, but consent from respondent has not been received as of the time of the filing of this brief.

Amici Apotex Inc. and Apotex Corp. are subsidiaries of the global pharmaceutical company collectively known as Apotex, 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 petitioner that reversal of the Federal Circuit is necessary to correct the interpretation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") by a divided panel, which 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 applications under the BPCIA for pegfilgrastim and filgrastim, which are biosimilar versions of the products Neulasta® and Neupogen®, respectively, marketed by respondents 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 and for declaratory judgment related to the BPCIA's notice of commercial marketing provision, an aspect of which is the subject of the questions presented in the certiorari petition by Sandoz Inc. ("Sandoz"). Review of Amgen's case against Apotex, which presents somewhat different issues regarding the interplay of various BPCIA provisions, is currently pending at the Federal Circuit. *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. to be argued Apr. 4, 2016). Apotex thus has a significant interest in the proper interpretation and application of the BPCIA.

Apotex Inc. and Apotex Corp. should be granted leave to file the attached *amicus* brief.

Respectfully submitted,

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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.

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Apotex agrees with petitioner that reversal of the Federal Circuit is necessary to correct the interpretation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") by a divided panel, which 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 37.2(a), counsel for *amici* provided notice to all parties of *amici*'s intention to file this brief at least 10 days before its due date. 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.

[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 respondents 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 and for declaratory judgment related to the BPCIA's notice of commercial marketing provision, an aspect of which is the subject of the questions presented in the certiorari petition by Sandoz Inc. ("Sandoz"). Review of Amgen's case against Apotex, which presents somewhat different issues regarding the interplay of various BPCIA provisions, is currently pending at the Federal Circuit. *See Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. to be argued Apr. 4, 2016). Apotex thus has a significant interest in the proper interpretation and application of the BPCIA.

INTRODUCTION

This case arises from the erroneous construction and misapplication of the BPCIA, part of the Patient Protection and Affordable Care Act of 2010 that was intended to strike a balance between encouraging competition among an important and rapidly growing category of costly specialty pharmaceuticals while still providing incentives for the development of new drugs. The decision below amounts to a thumb on the scale, upsetting that balance with the anticompetitive effects of prolonging the collection of monopoly rents and bolstering already-troublesome barriers to entry for biosimilars, which are an important new class of medical products.

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.* In 2010, four of the ten top-selling branded drugs worldwide were biologics, which industry experts estimate will rise to seven of the top ten in 2016. *See* Steve Miller, Express Scripts, Presentation at FTC Biosimilars Workshop: *Customer Perspective on Biosimilars* 3

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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.

(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 but also encourages competition once that monopoly protection ends. The BPCIA allows a biosimilar applicant to submit an abbreviated Biologics License Application ("aBLA") and rely in part on the branded drug company's FDA-approved license of a reference product. *See id.* § 262(k). In this context, the branded company is referred to as the "reference product sponsor." *See id.* § 262(*l*)(1)(A). But the FDA cannot finally approve an aBLA for a biosimilar product until 12 years after the date on which the reference product was licensed, thus ensuring that 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).

The BPCIA also established a two-stage protocol and timeline for the reference product sponsor and the biosimilar applicant to exchange information and resolve any patent disputes between the parties. In the *first* stage, under paragraphs (*l*)(2)-(*l*)(7) of the

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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.

BPCIA,[5] the parties may exchange information concerning the aBLA, a list of patents for which a claim of patent infringement may be asserted, and statements concerning the patent(s), followed by negotiation to decide which patents should be the subject of an immediate patent-infringement action. The result of this first-stage activity is a patent-infringement lawsuit and an updated list of potentially relevant patents that have not been included in the lawsuit.

In the *second* stage for resolving patent disputes, under paragraph (*l*)(8)(A), the 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)."

In the decision under review, the Federal Circuit held that a biosimilar applicant such as Sandoz or Apotex "may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). That result awards 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.

Review of this decision by a fractured Federal Circuit panel is urgently needed to restore the statutory balance between the incentives for innovation and incentives for competition. The panel majority's error is one of national importance because it delays

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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.

patient access to more affordable biosimilar therapies and substantially increases the total health care expenditures of the United States government and the American people.

REASONS FOR GRANTING THE PETITION

In the BPCIA, Congress struck a careful balance between, on the one hand, encouraging competition to lower the soaring prices for biologic medications and, on the other hand, creating incentives for the development of new drugs. It did so through the creation of not only an abbreviated pathway to expedite the market availability of biosimilar products but also a 12-year period of exclusivity for branded reference products. In the decision under review, the Federal Circuit upset this careful balance by holding that 42 U.S.C. § 262(*l*)(8)(A) requires that a biosimilar applicant wait until after it receives FDA approval before it can provide effective notice of commercial marketing to the reference product sponsor. This decision has 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. Because no other appellate court will review this question of vital importance to the burgeoning multi-billion-dollar biosimilar industry, immediate review by this Court is warranted.

I. THE FEDERAL CIRCUIT'S EXTENSION OF THE 12-YEAR EXCLUSIVITY PERIOD HARMS THE PUBLIC AND PRESENTS AN ISSUE OF NATIONAL IMPORTANCE

The Centers for Medicare and Medicaid Services ("CMS") estimate that total health care spending in the United States accounts for at least 17.5% of the

nation's Gross Domestic Product and that, with annual spending of almost $300 billion, prescription drugs comprise about 10% of all medical costs in the United States. CMS, *National Health Expenditures 2014 Highlights* 1, 2 (Dec. 2015) ("CMS Highlights");[6] CMS, *The Nation's Health Dollar ($3.0 Trillion), Calendar Year 2014, Where It Went* (Dec. 2015).[7]

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 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* 7.

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

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

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).[8]

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

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

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).[9] 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 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 &

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

Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 471 (Sept./Oct. 2013).[10] 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. The Federal Circuit's decision thus creates an issue of national importance that warrants review by this Court.

II. THE FEDERAL CIRCUIT'S DECISION IS ERRONEOUS AND SHOULD BE REVERSED

The Federal Circuit's ruling that effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8) can be given only after the FDA has approved a biosimilar application is incorrect substantially for the reasons that Judge Chen gave in his cogent dissent. The panel majority's ruling finds no support in the text of the statute or 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 choice.

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

A. The Federal Circuit's Ruling Runs Contrary To The Statute's Text And Purpose

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 presumably would have imposed the requirement on the "subsection (k) licensee," or some similar term denoting the completion of the application process. The panel in 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.

The purpose of the paragraph (*l*)(8)(A) notice is to allow the reference product sponsor to seek a preliminary injunction 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 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 making Apotex 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.

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, 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.

Furthermore, the Federal Circuit panel majority'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 panel majority 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 panel majority 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 panel majority 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) in the event that 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. The panel majority thus distorted the remedial scheme created by Congress to fill an imagined gap in the scheme that does not exist.

B. The Federal Circuit Appears Not To Have Fully Appreciated The Consequences Of Its Ruling

The panel majority'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.[11] The panel majority appears not to have fully appreciated this consequence of its decision. The majority 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 majority 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

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[11] Whether notice of commercial marketing is required in all cases and, in particular, whether it is required when an applicant (unlike Sandoz here) has complied with the information-exchange provisions of paragraphs (*l*)(2) through (*l*)(5) is an open question that is beyond the scope of the current petition.

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 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 panel majority erred in creating this "extra-statutory exclusivity windfall." *Id.* at 44a (Chen, J., dissenting-in-part).

III. IMMEDIATE REVIEW BY THIS COURT IS NEEDED TO ESTABLISH THE COMPETITIVE FRAMEWORK GOVERNING THE BIOSIMILARS INDUSTRY

The BPCIA is a new law, and the Federal Circuit's decision in this case is the first time the court of appeals has interpreted the provisions at issue. This Court may therefore find itself tempted to allow the issue to percolate in the lower courts before granting certiorari. In this case, however, further percolation offers no prospect of crystallizing the issue for this Court's review. There will never be a circuit split on the meaning of the statute because cases under the BPCIA will always end up in the Federal Circuit. Sandoz sought en banc review of the panel majority's decision in this case, but the Federal Circuit declined to hear the case en banc. Pet. App. 85a-86a. As a practical matter, therefore, the panel majority's decision in this case will determine significant aspects of the regulatory framework for the biosimilars indus-

try, with no prospect for further argument over the provisions at issue here. The adverse effects of the decision on competition and biosimilar drug prices are too important for the Court to defer its review.

This Court previously has granted review of analogous Federal Circuit decisions under the Hatch-Waxman Act, where the questions presented as a matter of first impression were intrinsically important to balancing the structure and function of the statutory framework to encourage both innovation and competition. *See*, *e.g.*, *Caraco*, 132 S. Ct. at 1675 (whether counterclaim provision under 21 U.S.C. § 355(j)(5)(C)(ii)(I) authorized challenge to accuracy of use code); *Eli Lilly*, 496 U.S. at 665 (whether exemption from infringement under 35 U.S.C. § 271(e)(1) applied to medical devices). This case deserves similar treatment.

That the 180-day waiting period for Sandoz has already run provides no basis for denying the petition because the question presented raises an issue that biosimilar applicants, including *amici*, will face repeatedly. Petitioner is correct that the 180-day period is not long enough "for the issue to be 'fully litigated prior to cessation or expiration' in a future case." Pet. 37 (quoting *FEC v. Wisconsin Right to Life, Inc.*, 551 U.S. 449, 462 (2007)). That, too, justifies this Court's immediate review.

To the extent the Court is nevertheless reluctant to grant the petition, *amici* respectfully suggest that the Court should call for the views of the Solicitor General because the federal government has an enormous interest in this case. As noted above, the BPCIA holds out the prospect of massive savings for purchases of biologic drugs. The federal government, which paid for roughly 36% of all national health

expenditures in 2014, has a significant stake in these savings. *See* CMS Highlights at 2. In fact, recognizing the critical need to lower drug costs to taxpayers and consumers and aiming to achieve an additional $3 billion in savings over ten years to federal health programs including Medicare and Medicaid, the President's Office of Management and Budget ("OMB") recently proposed *reducing* the market exclusivity period afforded to reference product sponsors to seven years, rather than the 12 years under current law, and prohibiting additional periods of exclusivity for brand biologics due to minor changes in product formulations. *See* OMB, Exec. Office of President, *Fiscal Year 2014: Budget of the U.S. Government* 40 (Apr. 2013).[12] The panel majority's decision here did just the opposite: it extended the exclusivity period by six months whenever notice of commercial marketing must be given before sales of a biosimilar product can begin. This exclusivity windfall unnecessarily denies patients access to less-expensive competing biosimilar products and ultimately will cost the health care system hundreds of billions of dollars in monopoly rents paid to reference product sponsors.

Review of the panel majority's flawed decision on this critically important issue is vital to efficient operation of the multi-billion-dollar biosimilars industry that is widely regarded by Congress, the President, patients, payers, and drug companies as essential for reducing health care costs and strengthening health programs such as Medicare and Medicaid.

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[12] *Available at* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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