No. 16-332

IN THE
Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,
Petitioners,

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

REPLY BRIEF FOR PETITIONERS

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November 21, 2016

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CORPORATE DISCLOSURE STATEMENT

Petitioners Apotex Inc.'s and Apotex Corp.'s Rule 29.6 Statement was set forth at p. iii of the petition for a writ of certiorari, and there are no amendments to that Statement.

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The petition raises the critical question whether the BPCIA forecloses a biosimilar product from coming to market for an additional six months following the reference product's 12-year period of exclusivity, even when the applicant has disclosed all necessary information to enable patent rights to be adjudicated during that period. Amgen's opposition brief scarcely defends the absurdity of that rule in light of the facts of this case, as distinct from the facts of *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). In this case, Amgen no longer has any intellectual property rights at stake, given that it lost the underlying patent case. Yet, under the Federal Circuit's erroneous decision, Amgen gets to reap another six months of monopoly profits beyond the statutory 12-year period on a product that could help more people while saving the healthcare system billions of dollars in unnecessary expenditures. Amgen argues weakly that the petition is somehow moot and that the Sandoz case will fully dispose of the concerns raised by Apotex's petition. Neither assertion has merit.

ARGUMENT

I. THIS CASE IS PROPERLY PRESENTED TO THIS COURT

A. This Case Is Not Moot

After reviewing the information provided by Apotex in accordance with 42 U.S.C. § 262(*l*)(2)(A), Amgen asserted only three patents allegedly infringed by Apotex's biosimilar pegfilgrastim product. Pet. 7-8. One expired before this litigation began; a second expired while the litigation was underway. App. 11a-12a. Following a bench trial, the district court found that Apotex's biosimilar product did not infringe the remaining patent. App. 71a.

Notwithstanding that Apotex's biosimilar product does not infringe any patents held by Amgen, the district court, relying upon the Federal Circuit decision at issue in this petition, permanently enjoined Apotex "from any commercial marketing of Apotex's Filgrastim Product . . . until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before Apotex's Filgrastim Product is licensed by the FDA, and the 180-day notice period is exhausted." App. 73a-74a.

The district court's entry of a permanent injunction did not render this case moot. The court's determination that "permanent injunctive relief is appropriate" explicitly rested on the decision below affirming entry of the earlier temporary injunction, App. 73a; Amgen offers no explanation for how the slightly different litigation posture of the case now will cause (or, indeed, could cause) the Federal Circuit to alter the substantive rule the instant petition seeks to overturn. Indeed, appealing the permanent injunction would have been completely futile so long as the underlying precedent is undisturbed.

Moreover, the controversy at issue is "capable of repetition, yet evading review." *FEC v. Wisconsin Right To Life, Inc.*, 551 U.S. 449, 462 (2007). That is, in this case, "(1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." *Id.*

First, Apotex's claims "could not reasonably be resolved" before the district court entered final judgment. *Davis v. FEC*, 554 U.S. 724, 735 (2008). The Federal Circuit rendered the decision at issue on July 5, 2016. Just two months later, the district

court entered final judgment and converted the preliminary injunction into a permanent injunction. App. 71a-75a. Apotex filed its certiorari petition on September 9, 2016. It simply would not have been possible for Apotex to obtain this Court's review of the Federal Circuit's decision prior to entry of the permanent injunction.

Second, Apotex can "credibly claim[]" that it will be subject to an unlawful injunction in the future. *Davis*, 554 U.S. at 735. Indeed, Apotex is currently subject to a permanent injunction of identical effect to the preliminary injunction. Even setting that aside, Apotex is "at the forefront of companies who will introduce high quality biosimilar products into the US marketplace"[1] and can therefore expect to face preliminary injunctions in future BPCIA litigation if this Court does not correct the Federal Circuit's erroneous holdings.

In addition, the "predicate" for the preliminary injunction "remain[s] undisturbed." *Firefighters Local Union No. 1784 v. Stotts*, 467 U.S. 561, 569 (1984). Unless the holdings of the Federal Circuit are overturned, Apotex and similarly situated biosimilar applicants will be forced to provide notice of commercial marketing and to delay by six months the commercial marketing of life-saving drugs. Because the BPCIA specifically provides reference product sponsors the unqualified right to seek a preliminary injunction upon receipt of the notice of commercial marketing, *see* 42 U.S.C. § 262(*l*)(8)(B), declaring a challenge to a preliminary injunction in BPCIA litigation moot upon entry of a permanent injunction

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[1] Press Release, Apotex, *Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Pegfilgrastim* (Dec. 17, 2014), https://www.apotex.com/global/about/press/20141217.asp.

will either thwart review of the legal bases for such injunctions or, at the least, require duplicative and unnecessary appeals of the preliminary and final injunctions.

Thus, to abandon the case now would "prove more wasteful than frugal." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 191-92 (2000). Not only do the parties to this case have a "continuing interest" in the resolution of the questions before the Court, *id.*, but those questions will continue to arise in BPCIA litigation. *See* Pet. 20 n.10 (collecting cases filed under the BPCIA). No good purpose is served by treating the permanent injunction as somehow obviating the underlying substantive error of the Federal Circuit's controlling precedent under review here.

B. The Issues Raised In This Appeal Were Properly Preserved

Contrary to Amgen's assertion (at 28) that Apotex "advances a new argument in its Petition," Apotex has made clear from the commencement of this litigation that, "because no unasserted patents remain from Amgen's patent list, the notice of commercial marketing serves no purpose." Supp. App. 2a. That is, "because Apotex followed the disclosure provisions of paragraph (*l*)(2)(A)," Amgen had "ample time" and all the information it required "to review Apotex's aBLA and manufacturing information" and to determine what patent rights were implicated. Supp. App. 5a.

As detailed below, requiring a notice of commercial marketing in such circumstances – and forbidding a biosimilar applicant from providing such notice before obtaining FDA approval of its biosimilar application – is anathema to the text and purpose of the BPCIA and a matter of significant public concern.

II. THE FEDERAL CIRCUIT MISREAD THE BPCIA

A. The Decision Below Cannot Be Justified By Reference To The Text Or Purpose Of The BPCIA

As Amgen acknowledges (at 8), Congress crafted the BPCIA to balance the interests of cost competition and innovation and, thereby, to increase Americans' access to biosimilar drugs. *See* Pet. 23-27. The Federal Circuit's decision upsets that balance by placing a thumb on the scale in favor of reference product sponsors.

To begin with, the statute clearly offers biosimilar applicants a choice between two possible paths for resolving patent disputes. *See* Pet. 5-7. The applicant may either choose to engage in the information exchange described in paragraphs (*l*)(2)-(*l*)(5), as Apotex did here – in which case a notice of commercial marketing is superfluous – or provide a notice of commercial marketing pursuant to paragraph (*l*)(8)(A). If the applicant declines to do the former, the sponsor's remedy is in paragraph (*l*)(9)(C); if it declines to do the latter, the sponsor's remedy is in (*l*)(9)(B).[2]

Apotex does not argue that biosimilar applicants may entirely escape the notice provisions of the BPCIA. Rather, Apotex argues that the BPCIA requires that only one kind of notice be given, in order to facilitate the resolution of patent disputes. Notwithstanding Amgen's parade of hypotheticals

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[2] Amgen's assertion (at 26) that "[s]ubparagraph 262(*l*)(9)(B) is not a remedy" is incorrect. Indeed, even the Federal Circuit repeatedly characterized the paragraph (*l*)(9)(B) declaratory judgment action as a "remedy." App. 21a-24a.

(at 28-29, 37-28), there is simply no argument that requiring both forms of notice serves the public interest – in this case or any other.

First, there are no later-issued or -licensed patents at issue in this case; indeed, there are *no* patents of any kind remaining at issue. Moreover, were there any such patents, *see* 42 U.S.C. § 262(*l*)(7), the reference product sponsor could, based on the information received from the biosimilar applicant, initiate a second information exchange pursuant to paragraph (*l*)(3), following which the exchange would iterate the process kicked off by the biosimilar applicant's disclosure under paragraph (*l*)(2).

Second, to the extent Amgen is concerned (at 38) that a biosimilar applicant "might wish not to commence immediate litigation on all patents that the Sponsor identifies in its subparagraph 262(*l*)(3)(A) list," in such a case the information exchange governed by paragraphs (*l*)(2)-(*l*)(5) will nonetheless have fully educated the reference product sponsor as to all the information necessary to vindicate its rights.

Moreover, to the extent a notice of commercial marketing is mandatory, requiring that biosimilar applicants delay such notice until the FDA grants approval of the biosimilar application is contrary to the public interest and unnecessary to the resolution of patent disputes. For example, in the Hatch-Waxman context, courts are frequently asked to determine whether a proposed generic product, as described in an Abbreviated New Drug Application ("ANDA"), will infringe. *See Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278-79 (Fed. Cir. 2013). As the Federal Circuit has recognized, waiting for FDA approval of an ANDA to crystallize

a patent controversy "unnecessarily defers resolution of the infringement issue that the Hatch-Waxman framework was intended to address earlier, generally before ANDA approval." *Id.* at 1279. The same logic applies in the BPCIA context, which, like Hatch-Waxman, was designed to abbreviate the FDA approval process for less expensive generic medicines and facilitate the resolution of patent disputes even before FDA approval. *See* Pet. 14-19.

Injunctive relief delaying the commercial marketing of a biosimilar product cannot be justified by reference to the BPCIA's text. As Apotex indicated in its petition (at 12), the injunction at issue in this case is an "atextual . . . remedy," with no basis in the BPCIA. Amgen is incorrect (at 32-33) that "provisions of the BPCIA . . . suggest that FDA approval and commercial marketing will occur some six months apart." Specifically, paragraph 262(k)(6), upon which Amgen relies, does not indicate that the notice of commercial marketing can be given only subsequent to FDA approval. Indeed, a full review of that paragraph indicates that the exclusivity period for the first biosimilar product may expire at various times, including 18 months after "a final court decision on all patents in suit," whenever such decision is rendered, even if that decision predates FDA approval of the biosimilar application, as in this case.

B. The Federal Circuit's Decision Was Not Required By Its Holding In *Sandoz*

Contrary to Amgen's assertion (at 4-6), the Federal Circuit's decision was not compelled by its holding in *Sandoz*. Instead, the court of appeals erroneously extended that holding to the second of two distinctive factual scenarios contemplated by the BPCIA (that is, to the situation in which a biosimilar applicant

chooses to engage in the information exchange precipitated by paragraph (*l*)(2)(A) – as Apotex did here, but Sandoz did not). *See* Pet. 21-23. Amgen incorrectly contends (at 2) that the questions presented here "overlap" with the questions presented to this Court in the pending petitions of *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (filed Feb. 16, 2016), and *Amgen Inc. v. Sandoz Inc.*, No. 15-1195 (filed Mar. 21, 2016).

As the district court recognized, *Sandoz* "left some ambiguity" as to biosimilar applicants' responsibility for providing a notice of commercial marketing after engaging in the information exchange described in paragraphs (*l*)(2)-(*l*)(5). App. 32a. Not only did the biosimilar applicant in *Sandoz* not engage in that exchange, the *Sandoz* panel held that exchange to be *optional*, even though paragraph (*l*)(2)(A) indicates that biosimilar applicants "shall" provide the information to be exchanged, because paragraph (*l*)(9)(C) provides a remedy for noncompliance. *See* Pet 11. Notwithstanding that holding, the Federal Circuit erroneously declared a similar use of the word "shall" in paragraph (*l*)(8)(A) (with a similar statutory remedy in paragraph (*l*)(9)(B)) to be "categorical." *See* App. 15a-16a. That holding is at odds with both the structure and the purpose of the BPCIA. As Apotex explained in its petition (at 11-14), "[a]lthough 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," just as it is not the case with regard to the language in paragraph (*l*)(2)(A).

III. THIS CASE PRESENTS QUESTIONS OF SIGNIFICANT NATIONAL IMPORTANCE

This case raises issues beyond and different from those raised in *Sandoz*. Moreover, to the extent both petitions present the question whether the notice of commercial marketing must wait until after licensure, they simply underscore the enormous stakes at issue.

The BPCIA's legislative history reflects Congress's expectation that a shorter exclusivity period would introduce cost savings by increasing competition, as compared to a market in which the introduction of biosimilar products was delayed. Pet. 14-19. Those cost savings are clear on the face of this case.

Because Amgen's 12-year exclusivity period has expired, *see* Pet. 7, the Federal Circuit's imposition of the delayed notice of commercial marketing represents a windfall to Amgen at the expense of healthcare consumers. No biosimilar product currently competes with the reference product at issue in this litigation, Neulasta® (pegfilgrastim). In this case alone, the amount of cost savings at issue are substantial: a six-month delay in the entry of a biosimilar pegfilgrastim product would cost Americans an estimated $600 million. Pet. 24-26.

Further, the Federal Circuit's suggestion that the FDA could avoid the awful consequences of delaying competition by "issu[ing] a license before the 11.5-year mark and deem[ing] the license to take effect on the 12-year date," App. 17a, is speculative at best: no mechanism currently exists by which the FDA could issue a license in that manner.[3] Indeed, the

[3] The Federal Circuit thought that a notice of commercial marketing could be given only for a product that has already

FDA has never approved a biologics license before the conclusion of a reference product's exclusivity period – its final approvals have been effective upon issuance.

Neither the Federal Food, Drug, and Cosmetic Act nor the Public Health Service Act, as modified by the BPCIA, explicitly grants the FDA authority to issue an approval that is effective at a later date; both statutes are silent on this issue. Thus, absent new legislation, the issuance of a license with a delayed effective date would require the FDA either to engage in a rulemaking procedure or to proceed absent regulation of any kind. Neither option is likely to correct the harm caused by the Federal Circuit's erroneous interpretation of the BPCIA. *First*, rulemaking is a lengthy process not guaranteed to succeed in a timely fashion or at all. Under the best circumstances, post-dated licenses authorized by a rulemaking would be unlikely to issue for some time. Indeed, the FDA only last month released a final rule implementing amendments made to the Hatch-Waxman Act more than a decade ago. *See* 81 Fed. Reg. 69,580 (Oct. 6, 2016). *Second*, any rule allowing a license to issue prior to the expiration of the exclusivity period – and any license so issued – would likely be subject to a legal challenge from the relevant reference product sponsor.[4]

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been "licensed." *Sandoz*, 794 F.3d at 1358 (citing 42 U.S.C. § 262(*l*)(8)(A)). But the FDA cannot "ma[k]e effective" the "[a]pproval of an application" for licensure of a biosimilar "until . . . 12 years after the date on which the reference product was first licensed." 42 U.S.C. § 262(k)(7)(A).

[4] Notably, if the FDA does promulgate a tentative-approval process, any litigation challenging that process would be appealed not to the Federal Circuit, but to a regional circuit. *See*, *e.g.*, *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106,

Indeed, Amgen tellingly suggests (at 35) that a biosimilar applicant could only cut short the waiting period by recourse to the "traditional regulatory approval pathway" – that is, the arduous and expensive pathway the BPCIA was intended to circumvent.

Further, the FDA has given no sign that it is willing to issue post-dated licenses in any case. None of the agency's numerous guidance documents has proposed a process for tentative approval or for issuance of an approval with a delayed effective date. The absence of such guidance stands in stark contrast to agency regulations implementing the Hatch-Waxman Act, which provide for approvals with delayed effective dates. *See* 21 C.F.R. §§ 314.105-314.108. Moreover, given differences between the Hatch-Waxman Act and the BPCIA, it is unclear that the FDA would conclude it has the power to issue post-dated licenses. *Compare* 21 U.S.C. § 355(c)(3), (j)(5)(B) (articulating the dates upon which approval of an application "shall be made effective," depending on whether the applicant certifies that there is no relevant patent, that any relevant patents have expired, or that any relevant patents are invalid or will not be infringed), *with* 42 U.S.C. § 262(k)(7) (providing only that approval of a biosimilar application "may not be made effective by the Secretary until [after the 12-year exclusivity period expires]"). Nor is it certain that a tentative-approval mechanism would result in "biological product licensed" under the BPCIA as the Federal Circuit interprets

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111-12 (D.D.C.) (ruling on FDA's regulation permitting approval with delayed effective date that is merely "tentative" and not "final"), *aff'd*, 389 F.3d 1272 (D.C. Cir. 2004). Thus, the Federal Circuit's implicit blessing of tentative approval under the BPCIA does not shield the agency from legal challenge.

that phrase. For example, as to drug applications submitted under Hatch-Waxman, the FDA has been quite clear that "[a]n approval with a delayed effective date is tentative and does not become final until the effective date." 21 C.F.R. § 314.105(a). The tentative approval becomes "final and, therefore, effective only when the agency sends an approval letter to the applicant." 59 Fed. Reg. 50,338, 50,352 (Oct. 3, 1994).

This Court, therefore, ought not look to the FDA to correct the errors introduced into the BPCIA by the Federal Circuit.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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SUPPLEMENTAL APPENDIX

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 15-cv-61631-JIC/BSS

AMGEN INC. and
AMGEN MANUFACTURING LIMITED,
Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,
Defendants.

[Filed Nov. 6, 2015]

DEFENDANTS APOTEX INC. AND APOTEX CORP.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND INCORPORATED MEMORANDUM OF LAW

* * *

[Part IV.C, pp. 11-12]

C. The Notice of Commercial Marketing Provision Provides Amgen a Right to Seek a Preliminary Injunction on Patents From Its List That Are Not Included In this Litigation—Which is None

One need only to look to the purpose of the notice of commercial marketing provision under paragraph (*l*)(8)(A) to understand why it cannot be mandatory for a biosimilar applicant that followed the statutory pathway by providing its aBLA to the RPS and engaging in the patent-dispute resolution. Amgen acknowledges that the only patents that come under paragraph (*l*)(8) are those from Amgen's patent list that were not included in the paragraph (*l*)(6)

lawsuit. (D.E. 42 at 7.) The paragraph (*l*)(6) lawsuit is the present litigation, which involves all of the unexpired patents from Amgen's patent list. Thus, it follows that because no unasserted patents remain from Amgen's patent list, the notice of commercial marketing serves no purpose. To be clear, Amgen's right to file for a preliminary injunction on patents already in the current litigation is not predicated on any action by Apotex, but instead lies solely with Amgen's own evaluation of the merits of the current litigation. Whether or not Apotex is required to provide a notice of commercial marketing does nothing to enlarge or diminish Amgen's right to seek preliminary injunctive relief in the current litigation, which Amgen notably has elected not to seek as of yet.

What is more, any assertion by Amgen that the notice of commercial marketing would enable it to seek injunctive relief based on newly issued or licensed patents is a plainly erroneous reading of the BPCIA. In the event that Amgen acquires or licenses new patents, those would fall squarely within the provision of paragraph (*l*)(7), which requires the parties to again exchange materials under paragraphs (*l*)(3)(A) and (*l*)(3)(B), and then determine whether or not such patents should be included in any pending litigation. Further, any such newly issued or licensed patent is subject to the provisions of paragraph (*l*)(8), which as discussed at length above, provides a remedy under paragraph (*l*)(9)(B) should Apotex elect not to provide a notice of commercial marketing. Again, in the event Apotex elects not to provide a notice of commercial marketing, then paragraph (*l*)(9)(B) enables Amgen to file a declaratory judgment action on any newly listed or licensed patents under paragraph (*l*)(7) that were not included in a pending litigation. Thus, the statute

provides a clear mechanism for newly issued or licensed patents to be included in a pending litigation, and a newly issued or licensed patent would do nothing to make the notice of commercial marketing a mandatory provision. Regardless, here, Amgen has not alleged that it has any newly issued or licensed patents that may be asserted against Apotex.

* * *

No. 16-1308

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC. AND AMGEN MANUFACTURING LTD.,
Plaintiffs-Appellees,

v.

APOTEX INC. AND APOTEX CORP.,
Defendants-Appellants.

On appeal from the United States District Court for the Southern District of Florida, Case No. 15-cv-61631-CIV-COHN/SELTZER, Judge James I. Cohn

[Filed Dec. 30, 2015]

OPENING BRIEF FOR DEFENDANTS-APPELLANTS APOTEX INC. AND APOTEX CORP.

* * *

[Part II, pp. 28-31]

II. APOTEX'S INTERPRETATION OF THE STATUTE COMPORTS WITH CONGRESS'S PURPOSES IN ENACTING THE BPCIA

In the BPCIA, Congress struck a careful balance between the rights of sponsors, of biosimilar applicants, and the public's dual interests in promoting innovation and increasing competition through easier, speedier access to biosimilar products. Critically, Congress enacted a 12-year market exclusivity for reference product sponsors—not a 12½-year market exclusivity. Apotex's interpretation of paragraph (*l*)(8)(A) honors the balance that Congress struck; Amgen's interpretation would grant all sponsors an extra six months of highly profitable market exclusivity, even when, as here, the sponsors have no additional patents to assert and so can derive no legitimate benefit from the notice. When an applicant such as Sandoz in its case with Amgen elects not to provide its aBLA to the relevant sponsor, the majority in *Amgen v. Sandoz* perhaps believed that it made sense to require notice and a six-month delay before commercial marketing in order to allow the sponsor more time to evaluate its patent positions. *See id.* at 1360. In contrast, because Apotex followed the disclosure provisions of paragraph (*l*)(2)(A), Amgen has now had more than 11 months to review Apotex's aBLA and manufacturing information. Amgen has therefore had more than ample time to identify all of the patents that it believed could be reasonably asserted against Apotex based on Apotex's aBLA and manufacturing information. Thus, where, as here, the biosimilar applicant has followed the patent-dispute resolution procedures of the BPCIA, there can be no statutory purpose served by delaying the launch of a biosimilar product by another 180 days just so the sponsor has additional

time to evaluate information that has already been in its possession since the time the aBLA was first accepted at the FDA.

The 12-year exclusivity period provided by the BPCIA was a result of lengthy negotiation and determined to be commensurate in duration and scope to the patent protection typically afforded to innovative drugs.[5] As a result, the BPCIA provides that a biosimilar applicant's aBLA **cannot be approved** by FDA, and therefore the biosimilar applicant does not receive licensure, until 12 years after approval of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). What is more, FDA has stated that "Section 351(k)(7)(A) of the PHS Act states that 'approval of . . . [a biosimilar application] may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).'"[6]

Thus, even if an aBLA is filed during the 12-year market exclusivity period as suggested by the district court (and as this Court suggested in dicta in *Amgen*

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[5] *See Biologic Drugs and Innovation: Hearing Before the H. Subcomm. on Courts and Competition Policy of the Comm. on H. Judiciary*, (2009) (statement of Rep. Anna G. Eshoo), 2009 WL 2038853 ("To preserve 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.").

[6] *See* FDA, *Memorandum Re: Exclusivity Expiry for Neupogen (filgrastim) BLA 103353* (June 26, 2014), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000Admin Corres.pdf (emphasis added).

v. Sandoz), the FDA will not approve that aBLA until after expiration of the 12-year market exclusivity period. Consequently, if the 180-day notice of commercial marketing is mandatory and only effective after FDA-approval of an aBLA, then there is no circumstance in which a biosimilar product will enter the market prior to 12½ years from BLA licensure.

The effect of Amgen's interpretation of the statute is thus to extend the statutory monopoly by six months, thus granting a windfall to reference product sponsors at the expense of patients who would benefit from more affordable biosimilar products. The plain language of the BPCIA does not support that position, and this result was not Congress's intent.

* * *