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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), *see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21, created a new regulatory pathway, 42 U.S.C. § 262(k), by which the FDA could approve a biologic product as "biosimilar to" a "reference product" that was itself previously approved under the full, traditional regulatory pathway of 42 U.S.C. § 262(a). "[B]alancing innovation and consumer interests," Pub. L. No. 111-148 § 7001(b), Congress established procedures to control and streamline patent litigation between the subsection (k) applicant (the "biosimilar applicant" or "Applicant") and the reference product sponsor (the "Sponsor" or "RPS"), *see* 42 U.S.C. § 262(*l*), triggered by the filing of an application under the new abbreviated subsection (k) pathway, *see id.* § 262(*l*)(1)(B)(i).

The petition by Apotex Inc. and Apotex Corp. (together, "Apotex") for a writ of certiorari ("Apotex's Petition") addresses part of those patent-litigation procedures, namely the requirement in subparagraph 262(*l*)(8)(A) that the Applicant provide 180 days' notice to the Sponsor before the first commercial marketing of the licensed biosimilar product.

The questions raised by Apotex's Petition are:

1. Whether there is an exemption from the requirement of 42 U.S.C. § 262(*l*)(8)(A) that the Applicant "shall provide notice" of commercial marketing to the Sponsor if

QUESTIONS PRESENTED (CONTINUED)

the Applicant discloses information to the Sponsor in accordance with 42 U.S.C. § 262(*l*)(2)(A).

2. Whether the Federal Circuit's holding that effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) may be given only after FDA licensure, is improper in view of 42 U.S.C. § 262(k)(7)(A) which prohibits the FDA from making effective an approval of a subsection (k) application until the date that is 12 years after the reference product was first licensed by the FDA.

(*See* Pet. at i-ii.)

PARTIES TO THE PROCEEDINGS

The caption identifies all parties. Petitioners are Apotex Inc. and Apotex Corp. Respondents are Amgen Inc. and Amgen Manufacturing Limited.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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JURISDICTION

Apotex seeks review of a decision affirming the grant of a preliminary injunction. (Pet. at 3.) Because the district court entered a permanent injunction from which Apotex has not appealed, however, Apotex's Petition is moot. (*See* Pet. App. at 73a.)

BRIEF IN OPPOSITION

The Petition fails to satisfy the criteria for a grant of certiorari and should be denied.

There is an elephant in the room. In the pending cases 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), Sandoz petitioned and Amgen cross-petitioned this Court to hear BPCIA issues that overlap with—and, in the case of Apotex's second Question Presented, flat-out duplicate—the issues that Apotex raises here. The Court called for the views of the Solicitor General for both *Sandoz* petitions on June 20, 2016 If the Court grants the petitions in *Sandoz* then this case will add nothing new, because the Court will decide when effective notice of commercial marketing may be given under 42 U.S.C § 262(*l*)(8)(A) and also whether applicants may choose not to provide the information required by 42 U.S.C § 262(*l*)(2)(A). If the Court denies Sandoz's petition, then it will have rejected the issues Apotex seeks to raise, because the Court will have declined to review the Federal Circuit's holding in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1357 (Fed Cir. 2015), that 42 U.S.C § 262(*l*)(8)(A) is "a standalone provision" not dependent on the information exchange processes that begin with 42 U.S.C § 262(*l*)(2)(A), *id.* at 1359-60.

Apotex's petition is also a poor vehicle for review because it is moot. Apotex appeals from the entry of a preliminary injunction, but has not appealed from the district court's final judgment, which includes a

permanent injunction. "Generally, an appeal from the grant of a preliminary injunction becomes moot when the trial court enters a permanent injunction, because the former merges into the latter." *Grupo Mexicano de Desarrollo S.A. v. All. Bond Fund, Inc.*, 527 U.S. 308, 314 (1999); *Smith v. Illinois Bell Tel. Co.*, 270 U.S. 587, 588-89 (1926).

The merits of Apotex's argument provide no basis for review either.

The Requirement of Notice: Apotex's first Question Presented addresses whether the notice-of-commercial-marketing provision in subparagraph 262(*l*)(8)(A) applies to all Applicants, or to only those (like Sandoz) that refused to provide the copy of their application for FDA licensure (variously known as a "subsection (k) application," an "abbreviated Biologics License Application," or an "aBLA") and the additional manufacturing information called for by subparagraph 262(*l*)(2)(A).

Nothing in the statute suggests that notice of commercial marketing is required for some categories of Applicants but not others; subparagraph 262(*l*)(8)(A) provides that "[t]he subsection (k) applicant shall provide" such notice:

> Notice of commercial marketing. The 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).

42 U.S.C. § 262(*l*)(8)(A). Relying on the statute's text and context, the Federal Circuit held in *Sandoz* that the notice-of-commercial-marketing provision is "mandatory," and is "a standalone notice provision" not conditioned on the other parts of subsection 262(*l*): "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Sandoz*, 794 F.3d at 1359-60. And in *Apotex*, the Federal Circuit held that *Sandoz* controls this issue: "We ruled in *Amgen v. Sandoz* that this language is, indeed, 'mandatory,' and we did not say that it was mandatory only in no-(2)(A)-notice circumstances." (Pet. App. at 15a-16a (citing *Sandoz*, 794 F.3d at 1359).)

Despite the Federal Circuit holding in *Sandoz*, Apotex argued in the district court and the Federal Circuit that notice of commercial marketing is mandatory for only those Applicants (like Sandoz) that refused to provide the subparagraph 262(*l*)(2)(A) disclosures, and not for those Applicants (like Apotex) that comply with subparagraph 262(*l*)(2)(A). Apotex relied on the phrasing of one sentence in the Federal Circuit's *Sandoz* decision: "We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory." 794 F.3d at 1360. Rather than reading this to mean that <u>even those</u> Applicants (like Sandoz) that refuse to comply with subparagraph 262(*l*)(2)(A) must still comply with subparagraph 262(*l*)(8)(A), Apotex read this sentence to imply the

converse—that subparagraph 262(*l*)(8)(A) is not mandatory where an Applicant makes the subparagraph 262(*l*)(2)(A) disclosure. In the decision below affirming the district court's grant of an injunction, the Federal Circuit "reject[ed] the asserted distinction," and held that the commercial-marketing provision is mandatory "even for an applicant in Apotex's position." (Pet. App. at 3a.)

That decision is faithful to the statute's text and context. Indeed, Apotex offers no textual basis for its argument. Instead, Apotex urges that a notice of commercial marketing is unnecessary where the Sponsor has received the Applicant's aBLA and manufacturing information. That is wrong, factually; the 180-day period after the notice of commercial marketing is valuable even where the Sponsor receives the subparagraph 262(*l*)(2)(A) disclosures. The Federal Circuit underscored that "[t]he purpose [of (8)(A)] is to ensure that, starting from when the applicant's product, uses, and processes are fixed by the license, the necessary decision-making regarding further patent litigation is not conducted under time pressure that will impair its fairness and accuracy." (Pet. App. at 18a (citing *Sandoz* 794 F.3d at 1358, 1360).) It is also wrong legally: Apotex may not disregard or be exempted from a law simply because it thinks a different rule would have been a better rule. The Federal Circuit construed the statute Congress actually passed, and did so correctly. Its decision presents no error for this Court to correct.

The Timing of Notice: Apotex's second Question Presented addresses whether effective notice of commercial marketing may be given only after FDA

licensure of the proposed biosimilar product, as the Federal Circuit panel held unanimously in *Sandoz*, or may be given prior to FDA licensure. This issue is squarely presented by Sandoz's own petition for a writ of certiorari. *See* Petition for a Writ of Certiorari at ii, *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (Feb. 16, 2016). If the Court grants that petition, its eventual disposition of the *Sandoz* case will resolve the issue in this case too, as it is a pure question of law. If the Court does not grant the petition in *Sandoz*, there will be no reason to grant it here either.

The Federal Circuit's decision in *Sandoz* regarding the timing of notice is correct. The words of the statute are clear: notice must be provided at least 180 days before the first commercial marketing of "the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Congress's use of these words was deliberate and meaningful. In every other place in which subsection 262(*l*) refers to the proposed biosimilar product, it uses the phrase "the biological product that is the subject of" the subsection (k) application. *See, e.g.*, 42 U.S.C. § 262(*l*)(3)(A), (B), (C), (*l*)(7)(B). The statute refers here, and here only, to "the biological product licensed under subsection (k)" because notice may be given only after the biological product has been licensed by the FDA. Apotex offers a host of policy arguments for why it thinks this is a bad rule, but those arguments, even if they were correct, cannot overcome the statute's text. The Federal Circuit's unanimous decision in *Sandoz* regarding the timing of notice is correct. It is consistent with the BPCIA's

statutory scheme and purpose and presents no conflict with any of this Court's decisions.

STATEMENT OF THE CASE

A. The Biologics Price Competition and Innovation Act of 2009

Apotex describes Congress as having enacted the BPCIA to "accelerate the availability of cheaper, generic versions" of innovative biological products. (Pet. at 4.) That is only half right. Congress sought to "balanc[e] innovation and consumer interests," Pub. L. No. 111-148, § 7001(b) (emphasis added), recognizing the importance of protecting innovators' patent rights.

Before the BPCIA, the FDA could approve a biologics license application only under the full pathway of 42 U.S.C. § 262(a), which requires submission of an elaborate data package from three phases of clinical trials to prove that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). An innovator of a new biological product was assured that—quite apart from whatever patent protection it might have—no one could copy its biological product and obtain FDA approval without following the 262(a) pathway. The cost of developing an innovative pharmaceutical product has been estimated to be over $2 billion. *See, e.g.*, Press Release, Tufts Center for the Study of Drug Development, Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study. Prior to the BPCIA,

investment by the innovator resulted in a clinical trial data package that was protected from use by would-be competitors.

The BPCIA changed that. Congress created a new abbreviated pathway for approval of biosimilars, known as "the (k) pathway" because it is codified in 42 U.S.C. § 262(k). It permits the FDA to approve a biologic product that is "highly similar" to a "reference product" that was itself approved under the traditional subsection 262(a) pathway. *See id.* § 262(i)(2)(A), (k)(3). Whereas innovators formerly enjoyed permanent, exclusive rights to their own clinical-trial data and FDA license, the BPCIA advanced the public's interest in price competition in part by diminishing innovators' rights. Congress permitted a "subsection (k) applicant," *see id.* § 262(*l*)(1)(A), (referred to herein as "Applicant") to avoid the time and costs of generating its own clinical data to prove safety and efficacy, and instead to "reference" the innovator's license and to demonstrate that its proposed product is "highly similar" to the innovator's "reference product." *Id.* § 262(i)(2), (k)(3). Congress did not create a grandfather provision to exempt biologic products licensed before the BPCIA went into effect.

At the same time, Congress protected public interest in innovation by establishing a "unique and elaborate process for information exchange between the biosimilar applicant and the [Sponsor] to resolve patent disputes," codified in subsection 262(*l*), "Patents." *Sandoz*, 794 F.3d at 1352.

When the Applicant and the Sponsor fully comply with the provisions of subsection 262(*l*), the BPCIA

contemplates two phases of dispute resolution, each targeted at orderly resolution of patent disputes. (*Accord* Pet. App. at 6a, 18a-19a (referring to two "stages" of dispute resolution).) The first phase, or stage, begins when the Applicant submits an aBLA under subsection (k). *See* 42 U.S.C. § 262(*l*)(1)(B)(i). "Not later than 20 days after" the FDA notifies the Applicant that its application has been accepted for review, the Applicant "shall provide to the reference product sponsor a copy of the application submitted" to the FDA "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). The BPCIA then provides for an information exchange by which the Sponsor and the Applicant (i) identify patents that could reasonably be asserted as infringed by the making, using, selling, offering for sale, or importation into the United States of the Applicant's proposed biosimilar product, (ii) exchange statements detailing their respective infringement, validity, and enforceability contentions or, in the alternative, a statement of intent that the Applicant's commercial marketing will not begin before patent expiry, and (iii) discuss patent licensure. *See* 42 U.S.C. § 262(*l*)(3)(A), (B), (C). If some or all patents remain in dispute, the parties cooperate to identify which patents will be included in an "Immediate patent infringement action" under paragraph 262(*l*)(6). *See id.* § 262(*l*)(4), (5), (6).

The Sponsor's obligation to identify patents does not end with the exchange of patent lists pursuant to paragraph (*l*)(3) or with the filing of an immediate patent litigation under paragraph (*l*)(6). Instead, if

a patent is newly issued to, or exclusively licensed by, the Sponsor after it has provided its subparagraph 262(*l*)(3)(A) list, the Sponsor must supplement that list within 30 days and the Applicant must then provide, within a further 30 days, a statement in accordance with subparagraph 262(*l*)(3)(B), providing for each listed patent either a statement that it will remain off the market until the patent expires or, on a claim-by-claim basis, a detailed statement of its factual and legal basis for believing that the patent is invalid, unenforceable, or not infringed. *See* 42 U.S.C. § 262(*l*)(7); *see also Sandoz*, 794 F. 3d at 1352.

The second phase, or stage, of the patent-dispute-resolution process begins with FDA approval of the Applicant's biosimilar application. Because a biosimilar application may be submitted four years after the reference product was first licensed by the FDA, 42 U.S.C. § 262(k)(7)(B), but the FDA may not license the biosimilar product until twelve years after the date the reference product was first licensed, *id.* § 262(k)(7)(A), the two phases of the BPCIA patent-dispute-resolution process may be separated by a period of several years.

FDA licensure of the biosimilar product authorizes the Applicant to commercially market the biosimilar in the United States. *See id.* § 262(a)(1)(A). It also triggers the Applicant's obligation to give the Sponsor at least 180 days' advance notice of the date of the first commercial marketing of the licensed biosimilar product. *See id.* § 262(*l*)(8)(A).

This is the provision addressed by Apotex's Petition. It is unlinked to, and stands independent of, the other provisions of subsection 262(*l*):

> Notice of commercial marketing. The 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).

42 U.S.C. § 262(*l*)(8)(A). It is, however, included within paragraph 262(*l*)(8), "Notice of commercial marketing and preliminary injunction." Subparagraph 262(*l*)(8)(B) provides that "[a]fter receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product," the Sponsor may seek a preliminary injunction with respect to any patent that was not listed for inclusion in the first-phase, paragraph 262(*l*)(6) "Immediate patent infringement action" either because the parties did not agree to list those patents pursuant to paragraphs 262(*l*)(4) or (*l*)(5) or because they were later-issued or -licensed patents under paragraph 262(*l*)(7). If the Sponsor seeks a preliminary injunction on one of these patents during this period of time, subparagraph 262(*l*)(8)(C) requires the parties to cooperate to expedite related discovery.

Both of Apotex's Questions Presented address the notice-of-commercial-marketing provision in subparagraph 262(*l*)(8)(A). Apotex's first Question is whether Applicants that provide the disclosures required by subparagraph 262(*l*)(2)(A)—that is, Applicants that provide their aBLA and information

about the processes used to manufacture their proposed biosimilar product—are exempt from the notice-of-commercial-marketing requirement. (*See* Pet. at i-ii.) The Federal Circuit held unanimously that the notice requirement applies to all Applicants, not just some. (Pet. App. at 15a, 26a.) Apotex's second Question Presented is whether effective notice of commercial marketing may be given only after FDA licensure of the proposed biosimilar product. (*See* Pet. at ii.) The Federal Circuit panel in *Sandoz* held unanimously that notice is effective only if given after FDA licensure, a ruling for which Sandoz itself has petitioned for a writ of certiorari in that case.

B. The *Sandoz* Case

Apotex's Petition arises in the shadow of the pending petitions in the *Sandoz* case, and thus some background on that case—drawn from the Federal Circuit's decision—helps frame the issues here.

Sandoz submitted to the FDA an aBLA for approval of a biologic product as biosimilar to Amgen's NEUPOGEN® (filgrastim). *Sandoz*, 794 F.3d at 1352. Sandoz refused to provide Amgen with a copy of its aBLA and with "such other information that describes the process or processes used to manufacture the biologic product that is the subject of" Sandoz's aBLA. 42 U.S.C. § 262(*l*)(2)(A); *see Sandoz*, 794 F.3d at 1353. Sandoz instead invited Amgen to sue it and to seek that information in discovery. Contemporaneously with informing Amgen that the FDA had accepted Sandoz's aBLA for review, and without knowing when or whether the FDA would approve that aBLA and license

Sandoz's proposed product, Sandoz purported to provide Amgen with 180 days' notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A). *See id.* at 1352-53.

Amgen sued Sandoz for patent infringement, and also brought California state-law tort causes of action. *Id.* at 1353. Amgen sought a preliminary injunction based on its state-law claims to enjoin Sandoz from launching its biosimilar product after FDA approval. *Id.* The district court denied Amgen's preliminary-injunction motion and entered judgment against Amgen's state-law claims. Amgen appealed. *Id.* at 1353-54.

A panel of the Federal Circuit (Judges Newman, Lourie, and Chen) held as follows:

1. Judge Lourie, joined by Judge Chen, held that where an Applicant refuses to provide the Sponsor with a copy of its aBLA and with the manufacturing information required by subparagraph 262(*l*)(2)(A), the Sponsor may not "compel compliance" with that provision, and the Sponsor's sole remedy is to sue for patent infringement and "access the required information through discovery." *Id.* at 1356. Judge Newman dissented, and would have held that provision of the subparagraph 262(*l*)(2)(A) information is "mandatory" and that a court may "require compliance with the obligations of the BPCIA" where an Applicant refuses to provide the required information. *Id.* at 1364, 1366 (Newman, J., dissenting).

2. Judge Lourie, joined by Judge Newman, held that notice of commercial marketing under

subparagraph 262(*l*)(8)(A) is "mandatory," and that a court may compel compliance where an Applicant refuses to give that notice. *See id.* at 1359 (majority opinion). The court rejected Sandoz's argument that it did not need to give notice of commercial marketing under subparagraph 262(*l*)(8)(A) because it had exited the BPCIA information-exchange process when it refused to provide the information required under subparagraph 262(*l*)(2)(A). The court held instead that "Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*)," *id.*, that "nothing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)," *id.* at 1360, and that "nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A)," *id.* Summarizing, the court stated, "We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory." *Id.* From this, Judge Chen dissented, and would have held that "when, as here, the (k) applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.* at 1367 (Chen, J., dissenting).

3. The court also addressed when legally effective notice of commercial marketing may be given. On this point, the panel was unanimous, holding that "under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." *Id.* at 1358 (majority opinion).

"Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief" and "provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." *Id.*

Sandoz petitioned this Court for a writ of certiorari, presenting two questions: whether notice of commercial marketing is effective only if given after FDA licensure, and whether treating the notice-of-commercial marketing provision as a standalone requirement and creating an injunctive remedy is improper. *See* Petition for a Writ of Certiorari at ii, *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (Feb. 16, 2016). Amgen opposed Sandoz's petition, and conditionally cross-petitioned for a writ to review the Federal Circuit's holding that the Applicant is not required to provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). *See* Brief in Opposition, *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (Mar. 21, 2016); Conditional Cross-Petition for a Writ of Certiorari, *Amgen v. Sandoz*, No. 15-1195 (Mar. 21, 2016). On June 20, 2016, the Court called for the views of the Solicitor General with respect to both petitions. The Solicitor General has not yet expressed his view, and both petitions remain pending.

C. Factual Background

1. Apotex's aBLA and its Initial Notice of Commercial Marketing

Amgen discovered, developed, and markets NEULASTA® (pegfilgrastim), a genetically

engineered protein that stimulates the production of neutrophils, a type of white blood cell. It is used to counteract neutropenia, a neutrophil deficiency that makes a person highly susceptible to life-threatening infections and is a common side effect of certain chemotherapeutic drugs. (*See* Pet. App. at 3a.)

In 2002, NEULASTA® was licensed by the FDA based on data generated from a full preclinical and clinical development program under the traditional regulatory pathway, 42 U.S.C. § 262(a). (*See id.*) Amgen obtained regulatory approval by demonstrating to the FDA that NEULASTA® "is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). Amgen Inc. is the owner of the FDA license for NEULASTA®. (*See* CAFC J.A. at 201-03.)

Apotex filed an aBLA under the BPCIA's abbreviated pathway, 42 U.S.C. § 262(k), seeking approval of its biosimilar pegfilgrastim product, designating Amgen's NEULASTA® as the reference product. (Pet. App. at 3a, 11a.) On December 15, 2014, the FDA had accepted Apotex's aBLA for review. (*Id.* at 11a.) The FDA has not yet approved Apotex's aBLA.

Apotex notified Amgen of the FDA's acceptance of its aBLA and on December 31, 2014 provided its aBLA to Amgen. (*See id.* at 11a.) Apotex did not provide any additional manufacturing information, but Amgen has no basis to contend any such additional manufacturing information existed, and agrees for purposes of this petition that Apotex satisfied subparagraph 262(*l*)(2)(A).

Amgen and Apotex followed the information-exchange provisions of paragraph 262(*l*)(3) and, pursuant to paragraph 262(*l*)(4), agreed on the two patents on which Amgen would bring an immediate patent infringement action under paragraph 262(*l*)(6). (*Id.* at 11a-12a.) On August 6, 2015, Amgen timely filed suit on those patents. (*Id.* at 12a.)

During the course of the BPCIA information exchange, on April 17, 2015, Apotex purported to provide notice of commercial marketing to Amgen. (*Id.* at 11a.) Amgen responded on May 8, 2015, asserting that—as Amgen contended in the *Sandoz* case then pending before the Federal Circuit—subparagraph 262(*l*)(8)(A) notice cannot be given until after FDA licensure. (*See* CAFC J.A. at 185-87.)

When the Federal Circuit agreed with that proposition, Apotex changed its tack. On August 24, 2015, Apotex's counsel wrote to Amgen's counsel to assert that, under *Sandoz*, Apotex believed that it was not required to give 180 days' notice under subparagraph 262(*l*)(8)(A) at all, because Apotex—unlike Sandoz—had provided its aBLA under subparagraph 262(*l*)(2)(A). (*See* CAFC J.A. at 191-92.)

2. The District Court's Grant of a Preliminary Injunction

In response to Apotex's newly asserted position that it had no obligation to provide notice of commercial marketing, Amgen sought a preliminary injunction restraining Apotex from commercial

marketing of its biosimilar pegfilgrastim product on any license issuing from its aBLA until it provides 180 days' notice after FDA approval of that product. (Pet. App. at 28a.)

The district court ruled for Amgen, holding that the BPCIA requires Apotex to provide Amgen with at least 180 days' notice of first commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.* at 36a-37a.) It concluded that Apotex's compliance with paragraph 262(*l*)(2) does not cause the "shall" in paragraph 262(*l*)(8)—the same "shall" that the Federal Circuit termed "mandatory" in *Sandoz*—to become optional. (*See id.* at 33a.) The district court explained that "neither the statute nor the *Sandoz* decision condition the 180 day notice provision of § 262(*l*)(8)(A) upon a subsection (k) applicant's compliance with § 262(*l*)(2)." (*Id.*) The district court noted that 180 days' notice to Amgen will likely result in a more crystallized patent litigation before the court, as the *Sandoz* court had recognized. (*See id.* at 33a-34a (citing *Amgen*, 794 F.3d at 1358).)

The district court enjoined Apotex from commercial marketing of its pegfilgrastim product "until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before its pegfilgrastim biosimilar product is licensed by the FDA, and the 180-day notice period is exhausted." (Pet. App. at 37a.)

3. The Federal Circuit Decision

Apotex appealed. The Federal Circuit (Judges Wallach, Bryson, and Taranto) unanimously affirmed the district court's grant of an injunction, rejecting Apotex's "asserted distinction" that pre-

marketing notice is required only where an Applicant refuses to provide the subparagraph 262(*l*)(2)(A) information disclosure, as Sandoz had done, and not where an Applicant provides that information, as Apotex did. (Pet. App. at 2a-3a.) The court held "that the commercial-marketing provision is mandatory and enforceable by injunction even for an applicant in Apotex's position." (*Id.* at 3a.)

The court held that the language of the statute—stating that the Applicant "shall provide" notice of commercial marketing—"generally indicates that the directive is mandatory." (*Id.* at 15a.) Furthermore, "[t]he language of (8)(A) is categorical in the sense relevant here. It 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." (*Id.* at 16a.) And there is "no other statutory language that effectively compels a treatment of (8)(A) as non-mandatory, contrary to the usual meaning of its 'shall' terms." (*Id.*)

The court also rejected the notion that the Sponsor has no need for the pre-marketing notice period where the Applicant makes the subparagraph 262(*l*)(2)(A) disclosure because the Sponsor purportedly would have all the information it needed to commence litigation on all of its patents. (*Id.* at 18a-21a.) The court recognized that the statute contemplates two meaningful stages of litigation:

> § 262(*l*) affirmatively contemplates two stages of litigation (under paragraphs (6) and (8)), and it contemplates that the first stage of litigation may omit patents the reference product sponsor has good grounds to assert, whether patents already in the hands of the reference product sponsor or patents newly in its hands under paragraph (7). . . . And it provides for the reference product sponsor to "seek a preliminary injunction" after the licensure and (8)(A) notice. The 180-day period gives the reference product sponsor time to assess its infringement position for the final FDA-approved product as to yet-to-be-litigated patents. And if there is such litigation, it gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury.

(*Id.* at 18a-20a (citations omitted).)

And the court rejected Apotex's argument that the notice of commercial marketing essentially amounts to an additional six months of exclusivity for the Sponsor, just as it had rejected that argument when advanced by Sandoz: "*Amgen v. Sandoz* likewise disposes of Apotex's argument that giving (8)(A) its plain meaning would effectively extend, by six months, the 12-year exclusivity period given to a reference product sponsor by § 262(k)(7)." (*See id.* at 17a (citing *Sandoz*, 794 F.3d at 1358).)

Apotex did not seek *en banc* review.

4. Permanent Injunction

On September 6, 2016, the district court entered a final judgment permanently enjoining Apotex from commercial marketing of its pegfilgrastim product until Apotex complies with subparagraph 262(*l*)(8)(A). (Pet. App. at 73a.) Apotex has not appealed from that judgment.

5. Proceedings in This Court

Apotex filed a petition for a writ of certiorari, No. 16-332, on September 9, 2016, which was docketed on September 14, 2016. The Court extended Amgen's time to file a response to and including November 8, 2016.

REASONS FOR DENYING THE PETITION

Apotex seeks review of a decision affirming the grant of a preliminary injunction. But Apotex has not appealed from the final judgment, which includes a permanent injunction. (*See* Pet. App. at 73a.) "Generally, an appeal from the grant of a preliminary injunction becomes moot when the trial court enters a permanent injunction, because the former merges into the latter." *Grupo Mexicano*, 527 U.S. at 314; *Smith*, 270 U.S. at 588-89.

Review here is also redundant in view of the pending *Sandoz* case. And this case is poor vehicle for the Court's review in any event, because it presents no disagreement between Federal Circuit

panels across cases or a disagreement between the district court and the appellate court in this case.

There is no reason to review Apotex's first Question Presented, which addresses whether the notice-of-commercial-marketing requirement applies to Applicants that comply with the disclosure provision of subparagraph 262(*l*)(2)(A), providing the Sponsor with a copy of their aBLA and related manufacturing information. Apotex does not challenge the holding of *Sandoz* that notice of commercial marketing is mandatory. It simply wants the Court to create an extra-statutory exception for a specific subclass of Applicants, by conditioning the requirement of subparagraph 262(*l*)(8)(A) on an Applicant electing not to provide the Sponsor with the subparagraph 262(*l*)(2)(A) disclosure. Nothing in the language of the BPCIA supports Apotex's reading. As the Federal Circuit held, the notice-of-commercial-marketing requirement is categorical; it applies to all Applicants. (Pet. App. at 16a.) Other than seeking to be excused from a clear statutory command that it happens to dislike, Apotex offers no basis to conclude that the Federal Circuit erred.

And there is no reason for the Court to review Apotex's second Question Presented—addressing the timing of effective notice—because the exact same question is already presented by Sandoz's pending petition. The Court will either accept Sandoz's petition or determine that the issue does not warrant review. Either way, however, there is no reason to grant Apotex's Petition to review this same question. Apotex advances no argument that

Sandoz overlooked, and identifies no reason why the outcome here should be different than that in *Sandoz*. The issue is a pure question of law, not one of fact.

I. THE FEDERAL CIRCUIT'S HOLDING THAT THE NOTICE-OF-COMMERCIAL-MARKETING PROVISION IS MANDATORY FOR ALL APPLICANTS DOES NOT MERIT REVIEW

In *Sandoz*, the Federal Circuit held that the notice of commercial marketing in subparagraph 262(*l*)(8)(A) is "mandatory." 794 F.3d at 1360. Apotex's Petition does not challenge the notion that pre-marketing notice is mandatory for Applicants, like Sandoz, that refuse to provide their aBLA and manufacturing information.

Instead, Apotex's first Question Presented asks only 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 product sponsor with a notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A)." (Pet. at i-ii.)

In the Federal Circuit, Apotex noted a factual distinction between its conduct and Sandoz's: Apotex provided its aBLA to Amgen pursuant to subparagraph 262(*l*)(2)(A), while Sandoz had refused to do so. (Pet. App. at 2a-3a.) And Apotex sought to capitalize on the happenstance of phrasing of one sentence in the Federal Circuit's *Sandoz*

decision, in which the court concluded that "where, as [Sandoz did] here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory." 794 F.3d at 1360.

What the Federal Circuit meant by this sentence was that even where an Applicant refuses to comply with subparagraph 262(*l*)(2)(A) it must comply with subparagraph 262(*l*)(8)(A). But Apotex read this sentence instead to imply that subparagraph 262(*l*)(8)(A) is not mandatory where an Applicant makes the subparagraph 262(*l*)(2)(A) disclosure. Apotex's reading, however, does not square with the express language of subparagraph 262(*l*)(8)(A) nor the overall purpose it serves in the context of subsection 262(*l*).

As the Federal Circuit held, unanimously, all Applicants must give notice at least 180 days before the first commercial marketing of their biosimilar product. (Pet. App. at 15a, 26a.) There is absolutely no reason for this Court to grant a writ to review that Question. The Federal Circuit did not err.

The correct analysis begins, as the Federal Circuit's did, with "the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). The "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997).

Paragraph (*l*)(8)(A) is clear:

> The 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).

42 U.S.C. § 262(*l*)(8)(A). There is no distinction between Applicants who provide the Sponsor with the subparagraph 262(*l*)(2)(A) disclosure and those who do not. Rather, the provision applies to every Applicant, every Sponsor, and every licensed biosimilar.

Congress could have linked subparagraph (*l*)(8)(A) to subparagraph (*l*)(2)(A), as Apotex seeks to do. Congress could have written, for example, that an Applicant that elects not to provide the Sponsor with the subparagraph (*l*)(2)(A) disclosure, must give notice under subparagraph (*l*)(8)(A), or that an Applicant that elects to provide the subparagraph (*l*)(2)(A) disclosure is excused from giving notice under subparagraph (*l*)(8)(A). Congress did not do these things. Instead, Congress mandated that all Applicants give 180 days' notice before the first commercial marketing of their licensed products.

Apotex argues that the notice-of-commercial-marketing requirement is not mandatory because the Applicant's failure to comply with subparagraph 262(*l*)(8)(A) is one of the listed items in subparagraph 262(*l*)(9)(B), which Apotex wrongly describes as a "remedy" that would be "superfluous" if the notice of commercial marketing were mandatory. (Pet. at 11-12.)

Subparagraph 262(*l*)(9)(B) is not a remedy. It is part of paragraph 262(*l*)(9), "Limitations on Declaratory Judgments," which specifies when the Applicant and the Sponsor may bring declaratory-judgment actions and on what patents. If the Applicant provides a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), then until the Applicant provides the notice of commercial marketing neither the Applicant nor the Sponsor may bring a declaratory-judgment action on any "Phase 2" patent, i.e. those that are disclosed in the paragraph 262(*l*)(3) exchanges but not listed for inclusion in the paragraph 262(*l*)(6) immediate patent infringement lawsuit. 42 U.S.C. § 262(*l*)(9)(A). Where the Applicant fails to complete one of the requirements of subsection 262(*l*) after providing its aBLA and manufacturing information, the prohibition on declaratory judgments is lifted for the Sponsor but continued for the Applicant. 42 U.S.C. § 262(*l*)(9)(B).

That is not a remedy; it simply restores to the Sponsor a right to bring a declaratory-judgment action that the Sponsor already had, but that was temporarily limited by subparagraph 262(*l*)(9)(A). As an initial matter, the BPCIA does not refer to declaratory-judgment actions as remedies. Instead, it explicitly uses the term "remedy" in its traditional sense:

> For an act of infringement described in [35 U.S.C. § 271(e)(2)(C)] . . .
>
> (B) injunctive relief may be granted . . . ,
>
> (C) damages or other monetary relief may be awarded . . . , and

> (D) the court shall order a permanent injunction . . . .
>
> The remedies prescribed [above] are the only remedies which may be granted by a court for an act of infringement described in [35 U.S.C. § 271(e)(2)(C)], except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4) (emphases added).

Further, subparagraph 262(*l*)(9)(B) does not provide an exclusive remedy that renders 180 days' advance notice of commercial marketing "superfluous," as Apotex contends. As the Federal Circuit concluded, "[s]uch an exclusivity conclusion regarding (8)(A) would, in fact, make little sense." (Pet App. at 24a.)

> In the ordinary case, a declaratory-judgment action would not actually enforce the categorical "standalone," "mandatory" (8)(A) notice right, which would not be the subject of a declaratory-judgment patent-merits action. [*Sandoz*,] 794 F.3d at 1359-60. A declaratory-judgment action on the patent merits in the ordinary case would not serve (8)(A)'s essential purpose or, therefore, be a meaningful remedy *for the (8)(A) violation.*
>
> In particular, relegating a reference product sponsor to a patent-merits declaratory-judgment action would introduce the very problem of rushed decision-making as to the patent merits that it is (8)(A)'s purpose to avoid.

(Pet. App. 24a (emphasis in original).) The court noted that where an Applicant violates

subparagraph 262(*l*)(8)(A)—either by not giving 180 days' notice or by "giving a notice but then jumping the gun and entering the market before the 180 days have passed"—the Applicant would force the Sponsor "to race to court for immediate relief to avoid irreparable harm from market entry." (*Id.*) The "parties and the court, in dealing with a request for a temporary restraining order or a preliminary injunction, will engage in precisely the hurried motion practice that (8)(A) is designed to replace by ensuring a defined amount of time for pre-launch litigation." (*Id.* at 24a-25a.) The Court concluded that "(9)(B) as a 'remedy' is so gross a mismatch for the (8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as the exclusive remedy for (8)(A)'s violation." (*Id.* at 25a.)

Apotex also advances a new argument in its Petition, asserting that an Applicant's aBLA and manufacturing information give the Sponsor "all the information it need[s] to pursue an orderly defense of its patent rights," and thus that the Sponsor would have no need for a 180-day notice of commercial marketing. (Pet. at 13.) This argument was never raised below, and the record has not been fully developed between the parties. That alone makes this case a poor vehicle for review.

Apotex's position is also wrong. It is wrong because it ignores the Phase 2 patents, those that are not listed for inclusion in the paragraph 262(*l*)(6) lawsuit, by agreement or otherwise, and those patents that are later-issued or -licensed patents, which explicitly become "subject to paragraph (8)." 42 U.S.C. § 262(*l*)(7). Indeed, as the

Federal Circuit explained, subsection 262(*l*) "contemplates that the first stage of litigation may omit patents the reference product sponsor has good grounds to assert," and the 180 days allows the Sponsor to assess its infringement positions of these omitted patents with respect to the "final FDA-approved product" (Pet. App. at 18a-20a), resulting in a "more crystallized patent litigation before" the district court (Pet. App. at 34a). Yet, Apotex never even mentions the Sponsor's obligation in paragraph 262(*l*)(7) to identify later-issued or -licensed patents and the Applicant's obligation to respond with a detailed statement of its non-infringement, invalidity and/or unenforceability contentions—information that would undoubtedly be useful to the Sponsor in pursuing an orderly defense of its patent rights. *See* 42 U.S.C. § 262(*l*)(7)(B).

Thus, while the applicability of subparagraph 262(*l*)(8)(A) to Applicants who provide the subparagraph 262(*l*)(2)(A) disclosures should be answered by the unambiguous text of the statute—all Applicants "shall provide" such notice—and not by arguments about whether notice is more or less "necessary" on the facts of some cases than others, Apotex is also wrong about whether notice is necessary. The 180-day notice of commercial marketing has an important role to play in every exchange between a Sponsor and an Applicant. It provides a defined period of time for the necessary decision making regarding further patent litigation after the Applicant's "product, uses, and processes are fixed by the license," without time pressure impairing fairness and accuracy. (Pet. App. at 18a.) As the Federal Circuit noted, the 180 days "gives the parties and the district court the time for

adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury." (Pet. App. at 20a.) In holding that notice is mandatory for all Applicants, the Federal Circuit ruled correctly.

II. THE FEDERAL CIRCUIT'S HOLDING IN *SANDOZ* THAT NOTICE OF COMMERCIAL MARKETING IS EFFECTIVE ONLY AFTER FDA APPROVAL WAS CORRECT, AND IS IN ANY EVENT PRESENTED BY SANDOZ'S OWN PETITION

Apotex's second Question Presented challenges the Federal Circuit's holding in *Sandoz* that notice of commercial marketing is effective only if given after FDA licensure. Apotex argues that in so holding, the Federal Circuit "improperly extended the statutory 12-year exclusivity period to 12½ years." (Pet. at ii.) And Apotex devotes six pages of its petition to demonstrating that a 12-year exclusivity period was heavily debated in Congress. (*Id.* at 14-19.)

This exact issue is raised by Sandoz's pending petition for a writ of certiorari, in which Sandoz asks this Court to determine "[w]hether notice of commercial marketing given before FDA approval can be effective" under subparagraph 262(*l*)(8)(A). Petition for a Writ of Certiorari at ii, *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (Feb. 16, 2016).

For the same reasons set forth in Amgen's opposition to Sandoz's petition, this Court should deny Apotex's Petition to review this issue. The

Federal Circuit panel in *Sandoz* unanimously agreed that notice of commercial marketing is effective only if given after FDA licensure of the Applicant's product under subsection 262(k). 794 F.3d at 1358. That decision was correct, accords with the statutory text and purpose, and does not conflict with any decision of this Court.

Faithful to this Court's statutory-interpretation cases, the Federal Circuit began with the statute's text. *See Barnhart*, 534 U.S. at 450; *Robinson*, 519 U.S. at 340. Subparagraph 262(*l*)(8)(A) requires notice at least "180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." *Sandoz*, 794 F.3d at 1357 (emphases in original) (quoting 42 U.S.C. § 262(*l*)(8)(A). A product is "licensed" only after the FDA approves the application.

As the Federal Circuit concluded in *Sandoz*, consistent with *Robinson*, this is confirmed by the context in which that language is used. *See id.* at 1357-58. Subparagraph 262(*l*)(8)(A) is the only place in subsection 262(*l*) where Congress used the phrase "the biological product licensed under subsection (k)." Otherwise, Congress invariably referred to "the biological product that is the subject of" the subsection (k) application. *See* 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B).

Where Congress uses two different terms or phrases it is assumed to intend different meanings. *See Sandoz*, 794 F.3d at 1358 (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)). Where

Congress referred to acts preceding licensure, it referred to "the biological product that is the subject of" the subsection (k) application. And outside of subsection 262(*l*), where Congress used phrase "product licensed" it did so only in provisions unambiguously referring to products that have already been approved by the FDA. Thus, subsection 262(d) refers to the post-approval recall from the market of a "product licensed." And paragraph 262(i)(4) defines the term "reference product" to refer to the "biological product licensed under subsection (a) against which" the proposed biosimilar product is evaluated.

Given Congress's use of these phrases, the Federal Circuit concluded that the use of the phrase "product licensed" in subparagraph 262(*l*)(8)(A) meant that effective notice of commercial marketing can be given only after the FDA has approved the Applicant's aBLA and there is thus a "product licensed." *Id.*

That conclusion is also supported by other provisions of the BPCIA that suggest that FDA approval and commercial marketing will occur some six months apart. Thus, paragraph 262(k)(6) affords a period of market exclusivity for the first biosimilar that demonstrates "interchangeability" with respect to the reference product. *See* 42 U.S.C. § 262(k)(2)(B), (k)(4), (k)(6). During that period, the FDA may not approve the application for any other biosimilar claiming similarity to the same reference product. Paragraph 262(k)(6) provides that the exclusivity period ends with the first to occur of five events. Notable here is the fact that one of them is one year after the first commercial marketing of the

interchangeable biosimilar, while another is eighteen months after the approval of that biosimilar, suggesting that first commercial marketing will not occur on the heels of FDA approval, but rather will follow that approval by some 180 days. *Compare* 42 U.S.C. § 262(k)(6)(A), *with* § 262(k)(6)(C)(ii).

The Federal Circuit in *Sandoz* also considered, as required by *Robinson*, the broader context of the statute as a whole. *See* 519 U.S. at 341. The court noted that when an Applicant "files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses." *Sandoz*, 794 F.3d at 1358. The possibility of changes in the product or its uses suggests that Congress would have intended the notice of commercial marketing and its 180-day period to follow FDA approval. "Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court." *Id.*

It also ensures that the district courts receive well-developed preliminary-injunction applications, and have time to rule on those applications:

> Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during

> which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product.

Id. In contrast, if the notice of commercial marketing "could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin." *Id.*

The Federal Circuit's decision in *Sandoz* is thus consistent with the text of the provision at issue and with the surrounding context and the statute as a whole. While that should end the analysis under this Court's precedents—and result in the denial of Apotex's (and Sandoz's) petitions—Amgen notes that these petitioners' laments about an extra six months of "exclusivity" are wrong.

Exclusivity is a term of art in the regulatory field that has a well-understood meaning referring to limits on the FDA's exercise of its authority to approve an application or license a product, as opposed to an applicant's ability to enter the market. FDA exclusivity should not, therefore, be understood to confer market exclusivity because the latter term would wrongly suggest that FDA exclusivity necessarily confers an absence of competition (or competitors) in the marketplace. The FDA has explained: "The term *exclusivity* as applied to a particular product generally refers to a statutory limitation on FDA's ability to accept for review or to license or approve certain competing products for a specified period of time. Exclusivity provisions can be found in the Federal Food, Drug, and Cosmetic Act (FD&C Act) at, among others,

505(c)(3)(E), 505(j)(5)(F), 505A(b) and (c), 527(a), and in the PHS Act at 351(k)(7)." U.S. Food & Drug Admin., *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* (draft Aug. 2014) at 1 n.2, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf (emphasis in original). In other words, (k)(7) exclusivity means a period of time during which the FDA may not approve applications submitted under the abbreviated (k) pathway that seek to reference the license of a given biological product.

Specifically, under the BPCIA, the approval of a biosimilar application may not be made effective by the FDA under the abbreviated pathway of subsection (k) until "the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." 42 U.S.C. § 262(k)(7)(A).

This 12-year period of FDA exclusivity, however, cannot be equated with market exclusivity. During this exclusivity period under paragraph 262(k)(7), another company is always free to seek and obtain FDA approval of the same biologic product under the traditional regulatory approval pathway of subsection 262(a) using its own clinical efficacy and safety data. Indeed, another pharmaceutical company, Teva, did just that, obtaining approval on August 29, 2012 of a filgrastim product, GRANIX®, under subsection 262(a), a product that directly competes with the Amgen product at issue in *Sandoz*, NEUPOGEN® (filgrastim). *See* U.S. Food & Drug Admin., *Purple Book: Lists of Licensed*

Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Oct. 23, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.

The 180-day-notice requirement under subparagraph 262(*l*)(8)(A) confers neither FDA exclusivity nor market exclusivity. This notice provision is specific to each individual Applicant and that Applicant's ability to enter the market, not the FDA's ability to approve products under the subsection (k) pathway. Nor does it afford any "market exclusivity." Take, for example, the product at issue in *Sandoz*: filgrastim. During the 180 days after the FDA approved Sandoz's ZARXIO® product, there was already a competing filgrastim product in the market: Teva's GRANIX® product. *See id.* Apotex, too, has filed an aBLA seeking FDA approval of a filgrastim biosimilar. (*See* Pet. App. at 38a-39a.) If Apotex ever gets approval of that product, it will have to provide to Amgen notice in accordance with subparagraph 262(*l*)(8)(A) and wait 180 days before commercial marketing. But Amgen will enjoy no market exclusivity during those 180 days: ZARXIO® and GRANIX® will both be in the market, competing with Amgen's NEUPOGEN®.

What subparagraph 262(*l*)(8)(A) affords, then, is not exclusivity (either FDA exclusivity or market exclusivity), but notice and a time during which the Sponsor can seek, and the courts can efficiently address, a preliminary-injunction application.

Apotex's amici Mylan and the Biosimilars Council now argue that the Federal Circuit erred in asserting that post-licensure notice ensures a "fully crystallized controversy," because the mere existence of the first-phase, immediate patent infringement lawsuit of paragraph 262(*l*)(6) implies that the controversy crystallizes before FDA licensure. (Mylan Br. at 10.) The Biosimilars Council argues:

> If Congress intended patent litigation to occur only after there was a "fully crystallized controversy" post-licensure, it would not have permitted—indeed, encouraged—infringement lawsuits to be filed shortly after an applicant submits an abbreviated biosimilar application ("aBLA") and certainly long before approval.

(Biosimilars Council Br. at 10.) That misunderstands the flexibility afforded to the Sponsor and, more so, to the Applicant by paragraphs 262(*l*)(3) through (5). The Sponsor might well identify, in its paragraph 262(*l*)(3) list, patents covering the biosimilar molecule itself but also method-of-use patents covering a specific therapeutic indication for which the reference product has been licensed. The molecule patent would likely be a good candidate for the parties to agree to list for inclusion in the first-phase lawsuit, as any FDA approval will necessarily involve the molecule itself. The Applicant might not seek, however, or the FDA might not grant, approval for the specific therapeutic indication covered by the method-of-use patent. If the Applicant does not know whether it will seek, or obtain, licensure for

that therapeutic indication, it might seek to delay litigation of that patent until the second, post-licensure phase. That way, the parties and the Court would avoid the expense of litigating a patent that would turn out to be irrelevant.

As another example, the Sponsor might include in its subparagraph 262(*l*)(3)(A) list a patent with an expiration date near the expected time of FDA approval. If the Applicant believes that a protracted period of FDA review might result in licensure after expiration of the patent, it might seek to delay litigation of that patent until the second phase, perhaps obviating the need for that litigation.

Yet another reason an Applicant might wish to delay litigation is to avail itself of the procedures for Inter Partes Review, or "IPR," created by the America Invents Act in 2011. This Court recently addressed those procedures in *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). An Applicant that wished to avail itself of the IPR procedures before the U.S. Patent and Trademark Office might well decide to defer litigation until the conclusion of those procedures.

There are thus many scenarios in which an Applicant might wish not to commence immediate litigation on all patents that the Sponsor identifies on its subparagraph 262(*l*)(3)(A) list.

The Federal Circuit was precise in referring to a "fully crystallized controversy." *See Sandoz*, 794 F.3d at 1358. Apotex's amici describe too binary a world. To the extent that the Applicant or Sponsor believes that a patent warrants litigation in the first

phase, even without knowing the precise scope of the product, its manufacturing processes, and its therapeutic uses that the FDA will someday approve, then paragraphs 262(*l*)(4) and (5) give the Sponsor, and even more so the Applicant, the ability to list that patent for inclusion in the first-phase, paragraph 262(*l*)(6) lawsuit. If the need for patent litigation is not clear at the outset, subparagraph 262(*l*)(8)(A) allows a 180-day period after licensure in which litigation can be commenced and, if need be, a preliminary injunction sought on that patent once the controversy fully crystallizes.

In holding that the notice called for by that subparagraph is effective only if given after FDA approval, the Federal Circuit in *Sandoz* faithfully applied this Court's statutory-interpretation precedents, faithfully applied the text of the BPCIA, and did so consistently with the statutory context. There is no reason for this Court to grant a writ of certiorari to review that decision.

CONCLUSION

For the foregoing reasons, Apotex's Petition should be denied.

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