Nos. 15-1039, 15-1195

In The Supreme Court of the United States

SANDOZ, INC.,

Petitioner,

v.

AMGEN, INC. and
AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN, INC. and
AMGEN MANUFACTURING LIMITED,

Petitioners,

v.

SANDOZ, INC.,

Respondent.

On Writs Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF AMICUS CURIAE COHERUS BIOSCIENCES, INC. IN SUPPORT OF PETITIONER SANDOZ, INC.

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INTEREST OF *AMICUS CURIAE*[*]

Coherus Biosciences, Inc. is a leading developer of high-quality biosimilar therapeutics. Biologic drugs, such as antibodies and growth factors, are far more complex than traditional small molecule drugs. Biologics have transformed the treatment of cancer and autoimmune diseases but have also driven up health care costs, because of their high price. Expediting approval of biosimilar drugs dramatically cuts these costs, even after accounting for the fact that biosimilars are themselves expensive to develop and often require their own clinical trials, unlike traditional "generic" versions of small molecule drugs. Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) to provide a pathway for biosimilar approval while ensuring that any related patent disputes can be resolved in an orderly, efficient manner.

Coherus has a strong interest in the proper interpretation of the two provisions of the BPCIA at issue here. The FDA has accepted Coherus's subsection (k) application for a biosimilar of Neulasta®, a drug that protects cancer patients from infection after their chemotherapy treatments. Coherus also has two other promising biosimilars in Phase 3 clinical trials, on which it intends to file subsection (k) applications. Coherus will be using the BPCIA's procedures regularly and wants to ensure they are interpreted consistently with Congress's objectives of expediting biosimilar availability and reducing costs to the public and to federal programs such as Medicare and Medicaid.

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[*] No counsel for a party authored any part of this brief or made a monetary contribution to fund its preparation or submission. No one but *amicus* paid for its preparation or submission. All parties consent to the filing of this brief.

SUMMARY OF THE ARGUMENT

1. The Federal Circuit erred by adding a new 180-day exclusivity for branded biologics without any statutory basis. The BPCIA sensibly requires subsection (k) applicants who engage in the Act's patent exchanges to give notice of commercial marketing "not later than 180 days before" the first commercial marketing of the biosimilar product, to ensure that the reference product sponsor has sufficient time to seek an injunction on any patents excluded from the parties' "first-wave" patent litigation. The Federal Circuit converted this to a requirement that a subsection (k) applicant can only give the notice after it obtains FDA approval, which means that the branded drug gets an additional 180 days of market exclusivity where, as here, the 12-year market exclusivity the statute expressly provides has expired. This result, if allowed to stand, will significantly diminish the cost savings that Congress intended the BPCIA to achieve. And it is not necessary to wait until approval, as the Federal Circuit thought, in order to have a "crystallized" patent dispute. Other statutory provisions show that Congress determined the dispute was sufficiently crystallized upon the FDA's acceptance of a biosimilar application, without waiting for approval.

2. The Federal Circuit correctly held that subsection (k) applicants can opt not to disclose their application to the reference product sponsor. That determination is consistent with the statute, preserves maximum flexibility for all parties while protecting patent rights, and expedites availability of biosimilar drugs that are expected to get quick FDA approval.

ARGUMENT

I. The BPCIA Does Not Require a Subsection (k) Applicant to Disclose Its Application to the Reference Product Sponsor.

A. The Statutory Text Neither Requires Disclosure Nor Provides a Private Right of Action to Compel It.

1. The Federal Circuit correctly determined that the BPCIA does not require the party submitting an application for regulatory approval under 42 U.S.C. § 262(k) (a "subsection (k) applicant") to disclose its abbreviated Biologics License Application (aBLA) to the holder of the reference product license (the "reference product sponsor"). Although the Act states that the subsection (k) applicant "shall provide" its application, 42 U.S.C. § 262(l)(2)(A), the word "shall" has different meanings depending on its context. *See, e.g., Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n.9 (1995) ("Though 'shall' generally means 'must,' legal writers sometimes use, or misuse, 'shall' to mean 'should,' 'will,' or even 'may.'"); David Mellinkoff, MELLINKOFF'S DICTIONARY OF AMERICAN LEGAL USAGE 402–403 (1992) ("shall" and "may" are "frequently treated as synonyms" and their meaning depends on context); Bryan A. Garner, GARNER'S DICTIONARY OF MODERN LEGAL USAGE 939 (2d ed. 1995) ("[C]ourts in virtually every English-speaking jurisdiction have held—by necessity—that shall means may in some contexts, and vice versa.").

Here, the statutory context shows that "shall" means "may," because it identifies a consequence when the subsection (k) applicant does not disclose its application—the reference product sponsor can immediately sue for infringement of "any patent that claims

the biological product or a use of the biological product." *See* 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). The statute's express inclusion of these remedies shows that Congress contemplated that a subsection (k) applicant might chose to not disclose its aBLA. If Congress had not contemplated this possibility, there would have been no need set out express remedies for non-disclosure.

2. The statute's remedy for non-disclosure—*i.e.*, an immediate right to sue for infringement—also leaves no room for an implicit private right of action to compel disclosure. "[E]xpress provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Alexander v. Sandoval*, 532 U.S. 275, 290 (2001). This Court therefore has refused to infer private rights of action that appeal to a court's equitable powers when Congress explicitly provides a different remedy. *See, e.g., Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1385 (2015) (no private right of action to enforce provision of the Medicaid Act requiring states to act in a certain way where the statutory remedy was for the federal government to withhold funds for violations); *Alexander*, 532 U.S. at 290 (same for a provision of Title VI of the Civil Rights Act); *Stoneridge Inv. Partners v. Scientific-Atlanta*, 552 U.S. 148, 162-63 (2008) (refusing to infer private cause of action against alleged aiders and abettors of securities fraud where the statute for an action by the SEC against them). The same rationale applies here and forecloses judicial creation of a private right for anyone to compel disclosure of a subsection (k) applicant's aBLA.

Creating a private right of action would also create new ambiguities about the statutory procedure.

Assuming a reference product sponsor could file an action compelling disclosure of the biosimilar's application, and a court ordered the disclosure, what would happen next? Would the parties then be required to engage in the patent exchanges, negotiations, and first-wave litigation in § 262(l)(3)-(6), even though the reference product sponsor already has the right to sue for patent infringement? If so, what would happen to the reference product sponsor's ability to file an immediate infringement suit under § 262(l)(9)(c) once a court compelled disclosure? Would that remedy disappear, once the application had been disclosed? And, if not, how would it make sense both to have that remedy remain intact, and also to have the parties engage in the § 262(l)(3)-(6) negotiations and litigation? The statute does not address any of these questions, because it did not contemplate a private right of action. None have easy answers, and all would be avoided by declining to infer a right of action that Congress never provided.

Moreover, it is unnecessary to infer such a cause of action. As noted, the reference product sponsor can file an infringement suit immediately on any patent it is concerned the subsection (k) applicant may infringe. *See* 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii); *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000) (holding the patentee has a Rule 11 basis to sue where information about a defendant's product is not publicly available and it declines to provide it). Once the patent infringement litigation begins, the reference product sponsor can obtain the subsection (k) applicant's aBLA through document requests under Federal Rule of Civil Procedure 34. That is exactly what happened here. (Pet. App. 10a.) So there is no need to create a

new cause of action that will result in satellite litigation over disclosure when those issues will be resolved in the litigation that the statute expressly permits.

B. The Statute Protects All Parties' Rights and Preserves Flexibility by Making Disclosure Optional.

The statutory scheme of optional disclosure protects both parties' rights and allows flexibility for dealing with patent disputes, while still preserving an important role for the statutory exchanges.

1. The statute, appropriately, allows subsection (k) applicants to choose the most efficient path in the particular circumstances. For example, a subsection (k) applicant who believes it will obtain swift FDA approval, and who knows that there are no legitimate patent issues blocking approval, may conclude that withholding its application will expedite its path to market. The Act's patent exchanges take a significant amount of time—up to 230 days before a suit is filed. *See* 42 U.S.C. § 262(l)(3)-(6). Such an applicant may prefer to withhold its application, which would clear the way for immediate litigation and launch upon FDA approval, assuming, as discussed below, that the Federal Circuit's erroneous grant of an extra 180-day exclusivity is corrected. This case closely tracks that scenario—241 days elapsed between the FDA accepting Sandoz's application and approving its product. (Pet. App. 8a-9a.) If Sandoz had engaged in the statutory disclosures, it would have faced more hurdles to launching its product immediately upon approval. A patent infringement suit would have only just been filed on day 230, with little chance for a district court to analyze whether a preliminary injunction should issue by day 241. The court might be inclined (at least initially) to issue the injunction to avoid irreparable

harm to the reference product sponsor, even if the patent claims were exceedingly weak. In that situation, both the parties and the court would benefit by allowing the reference product sponsor to sue immediately, so that the district court had significant time to consider whether to issue an injunction before FDA approval.

2. The statute's optional disclosure procedure still fully protects the reference product sponsor's interest in enforcing any valid and infringed patents. As noted above, the patentee can immediately sue on "any patent that claims the biological product or a use of the biological product." *See* 42 U.S.C. § 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Moreover, the statute protects the reference product sponsor from any declaratory judgment action by the subsection (k) applicant who does not disclose its application or otherwise fails to participate in the patent exchanges. *See* 42 U.S.C. § 262(l)(9)(B), (C).

Judge Newman expressed concern that these provisions would still leave the reference product sponsor without a remedy for patents covering a method of manufacturing the biologic, (Pet. App. 37a-38a), but that is incorrect. As the Federal Circuit majority pointed out, 35 U.S.C. § 271(e)(2)(C)(ii), broadly provides for an infringement action against a non-disclosing subsection (k) applicant on any patent that could have been identified during the patent exchange, which included patents of manufacturing processes. (Pet. App. 16a n.3; *Hoffman-La Roche*, 213 F.3d at 1363-65.) There is thus no situation in which a subsection (k) applicant's decision not to disclose its aBLA can impose irreparable harm on a reference product sponsor whose patent is valid and infringed.

3. Although disclosure of the application is optional, this does not render this subsection of the BPCIA irrelevant. Subsection (k) applicants still have strong incentives to disclose in appropriate circumstances. Disclosing the application under § 262(l)(2)(A) triggers a series of exchanges that allow the subsection (k) applicant to determine which patents the reference product sponsor may actually assert in litigation, and to scrutinize the basis for such an assertion. *See* 42 U.S.C. § 262(l)(3). This process could significantly narrow the parties' dispute. One example is where the reference product sponsor has patents on multiple uses of a drug, yet the subsection (k) applicant is seeking approval for only one use. The information exchange should result in patents on other uses being removed from contention. Another example of disclosure of the aBLA and the subsequent information exchange simplifying the issue for litigation is where the subsection (k) applicant has plainly designed around patents claiming a particular formulation—the patents that do not claim the subsection (k) applicant's formulation should be removed from contention. In fact, a subsection (k) applicant can notify the reference product sponsor that it will not launch its biosimilar product before the expiration of a particular patent, again taking that patent entirely out of contention. Subsection (k) applicants will prefer to use the disclosure and negotiation process to eliminate these patents up front, rather than risking an immediate suit on those patents by refusing to disclose their application.

In addition, disclosing their aBLA allows the subsection (k) applicant to control the scope and timing of the initial patent litigation. Some reference product sponsors have sought to protect their blockbuster biologics with patent thickets of enormous complexity.

See, e.g., Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. Times (July 15, 2016), *available at* http://nyti.ms/2kUxW18 ("AbbVie, the company behind Humira, has amassed more than 70 newer patents, mostly in the last three years, covering formulations of the drug, manufacturing methods and use for specific diseases."). A subsection (k) applicant can use the statutory exchanges to identify a few key patents in the thicket and litigate those first, knowing that, if it wins, the rest may swiftly fall because they present common issues, while, if it loses, it will avoid significant unnecessary litigation costs on the rest of the thicket.

There is no reason to worry that interpreting the statute as written—*i.e.*, not to compel disclosure of the application or the ensuing exchanges—will unduly deter subsection (k) applicants from using the statutory exchange process when it is the most efficient path forward.

II. The Federal Circuit Erroneously Added 180 Days of Exclusivity Not Provided in the Act.

A. The BPCIA Does Not Require Any Notice of Commercial Marketing Where, as Here, there is No Information Exchange.

The Federal Circuit first erred by holding that the statute required notice of commercial marketing at all in this case. The BPCIA includes the notice of commercial marketing as a safety-valve for parties that engage in the information and patent exchange process in § 262(l)(2)-(4). That process culminates in a first wave of patent infringement litigation where the reference product sponsor believes it has valid patents that cover the biosimilar. *See* 42 U.S.C. § 262(l)(6).

That litigation might include only a subset of the patents that the reference sponsor has identified as potentially infringed by the subsection (k) applicant, and a declaratory judgment action by either party on the remaining patents is expressly precluded until notice of commercial marketing is given. *See* 42 U.S.C. §§ 262(l)(4)-(5) and (9)(A). Congress wanted to ensure that this procedure did not prevent a reference product sponsor from asserting a patent before a subsection (k) applicant actually starting selling its product. It provided that 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). The BPCIA then further provides that, once notice is received, the reference sponsor "may seek a preliminary injunction" on any patent that was included in the parties' initial patent lists but not actually selected for the first-wave litigation. 42 U.S.C. § 262(l)(8)(B).

That makes sense when the parties have engaged in the BPCIA's information and patent exchanges. But where, as here, the subsection (k) applicant chooses not to disclose its application, the notice of commercial marketing serves no purpose. In that situation, other provisions already give the reference product sponsor the ability to seek such relief at any time. See 42 U.S.C. § 262(l)(9)(B), (C); 35 U.S.C. § 271(e)(2)(C)(ii). Therefore, as Judge Chen observed, "[g]iven the purpose of (l)(8) and its express assumption that the parties have already performed the steps in (l)(3) and (l)(4)-(l)(5), the most logical conclusion when reading (l)(8) in context is that (l)(8)'s vitality is predicated on the performance of the preceding steps in subsection (l)'s litigation management process." (Pet. App. 49a.) The Federal Circuit thus had no basis

to impose an additional 180-day exclusivity based on the timing of a notice of commercial marketing that Sandoz shouldn't have had to give in the first place.

B. Subsection (k) Applicants Can Give the Notice of Commercial Marketing Before Receiving FDA Approval.

Even assuming the statute requires a notice of commercial marketing here, the Federal Circuit erred in holding that 42 U.S.C. § 262(l)(8) prohibits the subsection (k) applicant from giving that notice until after it receives FDA licensure (approval). Section 262(l)(8) places only one restriction on the notice's timing: the "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)." The text states only that the notice must be given by a certain date; it imposes no prohibition on giving it sooner. That should be the end of the inquiry.

The Federal Circuit suggested that the statute's reference to a "biological product licensed under subsection (k)" imposes some further timing restriction. (Pet. App. 20a-26a.) But § 262(l)(8) refers to a "licensed" product because it is describing the state of the product at the time it is marketed—a product cannot be marketed unless "a biologics license" is "in effect" for it. *See* 42 U.S.C. § 262(a)(1)(A). Nothing in the statute ties the notice date to the date of licensure. In fact, this paragraph of the statute refers to the "applicant" giving notice, which suggests it is permitted to give the notice before FDA approval—that is, while the company is still merely an "applicant," and not yet a licensee.

2. The Federal Circuit's erroneous statutory interpretation also contravenes the statutory purpose. The BPCIA was meant to expedite the entry of biosimilars after the 12-year market exclusivity period, unless the biosimilar infringes a valid patent. *See, e.g.,* Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804. Yet the Federal Circuit's decision automatically adds an extra 180 days of market exclusivity in every case where the statute's exclusivity period has already expired. That is true regardless of whether the reference product sponsor could actually meet the requirements—*e.g.*, likelihood of success on the merits of a patent infringement claim—that are otherwise needed to obtain an injunction. (Pet. App. 23a-26a (ordering issuance of injunction against Sandoz without regard to whether Amgen was likely to prevail on a patent infringement claim).) Worse yet, the extra exclusivity period applies even when there are no patents at all that can reasonably be asserted, and thus no possibility of an injunction on the merits of a patent infringement claim (the express intention of the 180 day notice provision). This interpretation does not further the public interest that Congress intended to serve with the BPCIA.

The Federal Circuit's interpretation also contradicts other statutory provisions. The statute requires the notice (and ensuing 180 day window) so that the reference product sponsor "*may seek* a preliminary injunction." 42 U.S.C. § 262(l)(8)(B). But preliminary injunctions don't issue automatically—the patentee must show "a likelihood of success on the merits," among other factors. *Munaf v. Geren*, 553 U.S. 674, 690 (2008). Under the Federal Circuit's rule, however, an automatic injunction will be in effect for 180 days regardless of whether the traditional equitable criteria for issuing such an injunction are met. That is not

permissible. *See, e.g., eBay Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 394 (2006) (halting the Federal Circuit's practice of automatically granting permanent injunctions and holding that "traditional principles of equity" govern the issuance of injunctions in patent cases).

The statute's 180-day period is meant to give the reference product sponsor adequate time to seek an injunction, not itself serve as an injunction. Indeed, if Congress had intended for a further, automatic 180-day delay, it would have provided for that expressly, just as it provided for an automatic 30-month stay in Hatch-Waxman litigation for small molecule generics on top of the 5-year statutory exclusivity period for new drug applications. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii), 355(j)(5)(E)(ii), 355(j)(5)(F)(ii). The absence of such statutory language here shows that Congress did not want the extra 180-day stay the Federal Circuit imposed. It also shows that, as with the patent exchanges discussed earlier, Congress certainly did not create a private right of action that allows such an injunction. *See, e.g.*, *Alexander*, 532 U.S. at 290; *Armstrong*, 135 S. Ct. at 1385; *Stoneridge*, 552 U.S. at 162-63.

C. The Federal Circuit Miscalculated the Consequences of its Extra Exclusivity.

1. The Federal Circuit downplayed the scope of the problem it had created, stating that the "extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." (Pet. App. 22a.) That assumption is incorrect, even leaving aside that Congress intended the BPCIA to benefit patients today, not just in the distant future. Today, many biosimilar applications

are pending for blockbuster biologics where the statutory market exclusivity has already expired, as the examples in the following table indicate:

Reference Drug	12-Year Exclusivity Expiration	2016 Annual Sales
Humira®	12/31/2014	$16 billion
Rituxan®	11/26/2009	$7.3 billion
Enbrel®	11/2/2010	$5.96 billion
Herceptin®	9/25/2010	$6.78 billion
Remicade®	8/24/2010	$1.62 billion
Epogen®	6/1/2001	$1.28 billion
Neulasta®	1/31/2014	$1.11 billion
Procrit®	6/1/2001	$1.06 billion
Neupogen®	2/20/2003	$765 million

See, e.g., http://bit.ly/2kBXUIh (Humira®); http://bit.ly/2kYz2LL (Enbrel®, Neulasta®, Epogen®, and Neupogen®); http://bit.ly/2ltfgZA (Procrit®, Remicade®); http://bit.ly/2keOAGV (Herceptin®, Rituxan®). Applications on biosimilars of many more such drugs will likely be filed, now that the Act provides a pathway to approval.

The Federal Circuit's extra 180-day market exclusivity will impose significant costs on consumers, insurers, and the federal government. Biologics cost, on average, over 20 times what a small molecule drug costs, with some therapies running to $200,000 a year. *See, e.g.,* LEIGH PURVIS, AARP PUBLIC POLICY INSTITUTE, A SENSE OF DÉJÀ VU: THE DEBATE SURROUNDING STATE BIOSIMILAR SUBSTITUTION LAWS 1 (2014),

available at http://bit.ly/2lyAG3i. A quintessential example is Humira®, whose annual cost per patient is $51,000 and whose 2016 annual sales were $16 billion, yet whose 12-year exclusivity ended over 2 years ago. *See* Judith A. Johnson, Cong. Research Serv., RL34045, FDA Regulation of Follow-On Biologics 1 (2010). Allowing 180 days of undeserved exclusivity for such a drug would waste billions of dollars. The cumulative impact of additional exclusivity is staggering when considered for all biologics, and it will only get worse as prices increase over time: "U.S. spending on biologics totaled $92 billion in 2013 (roughly 28 percent of all U.S. drug spending. This represented a nearly 10 percent increase over 2012 biologics spending." *See* ALEX BRILL, MATRIX ADVISORS, CONSIDERATIONS OF THE FDA'S IMPACT ON COMPETITION IN THE DRUG INDUSTRY 6 (Nov. 2014), *available at* http://bit.ly/2kvxjKq. The Federal Trade Commission reports that these increased costs will hurt everyone, not just patients on the biologics, because they "will cause the cost of health insurance to rise for all insureds, not just those using biologic products." *See* Comment of the Staff of the Federal Trade Commission, 80 Fed. Reg. 52296 (Aug. 28, 2015), *available at* http://bit.ly/1P0OJe4.

2. The Federal Circuit's other basis for preventing subsection (k) applicants from providing notice of commercial marketing until FDA approval—*i.e.*, that this will "ensure[] the existence of a fully crystallized dispute regarding the need for injunctive relief"—is equally erroneous. The reference product sponsor and the subsection (k) applicant will already have a concrete dispute upon the FDA's acceptance of the aBLA. The statute provides that the acceptance of such an application creates a concrete dispute that can, in all

cases, serve as the basis for a claim of patent infringement. *See* 42 U.S.C. §§ 262(l)(6), 262(l)(9)(C); 35 U.S.C. § 271(e)(2)(C). A patentee can ask for a preliminary injunction in such litigation, just as could any plaintiff. Given that Congress thought that there was a sufficiently concrete controversy to provide for "first-wave" litigation upon the FDA's acceptance of the subsection (k) applicant's application, there is no reason to think that, in writing § 262(l)(8), it changed its mind and thought that the controversy on any other patents would not be sufficiently crystallized until after FDA approval.

It is true that biosimilars are complex products, that the application might be amended in response to the FDA's input, and that such amendments might impact the infringement analysis. But none of that is a reason to think that § 262(l)(8)'s required notice of commercial marketing is meant to delay litigation completely until after there is an approved product. Quite the contrary: the statute is designed to resolve some or all of the parties' patent disputes *before* the biosimilar application is approved, so that, if it turns out the proposed product will not infringe any valid patents, it can be launched—and the public can enjoy the befits that come with it—immediately upon expiration of the 12 year exclusivity. Section 262(l)(8) simply provides a safety valve that permits a reference sponsor who has engaged in the statutory patent identifications to immediately sue on any patent that the parties initially include on their lists of potential implicated patents under § 262(l)(3), yet do not include in the first-wave of litigation. After such a suit begins, the reference sponsor can propound discovery requests under Federal Rules of Civil Procedure 33 and 34 to monitor amendments to the biosimilar application, and, should such an amendment impact the

infringement analysis, it can add or remove patents from the case as appropriate, something that is routinely done in cases involving generic drugs under the Hatch-Waxman Act.

3. The Federal Circuit's added exclusivity imposed particularly unfortunate consequences this case. Sandoz's initial notice of commercial marketing (provided in July 8, 2014 at the same time the FDA accepted its application) was given 241 days before the FDA approved its product on March 6, 2015. That is a couple months more than the 180-day minimum notice that the statute would have required for Sandoz to launch on its approval date. Sandoz's initial July 8, 2014 notice also reasonably stated that it believed the application would be approved in "Q1/2 of 2015," which turned out to be true. (C.A. J.A.1472.) Had the Federal Circuit simply treated the initial notice as effective, then § 262(l)(8) would have worked precisely as it should have. Amgen would have had ample time to seek a preliminary injunction for patent infringement before launch (which it chose not to do), while Sandoz would have been able to launch its product immediately upon approval (since we know Amgen did not, in fact, seek a patent-based preliminary injunction), thus expediting cost-savings to patients, insurers, and the government, and preserving judicial resources. Instead, the public had to wait half a year after approval of Sandoz's biosimilar product to see the cost savings that the BPCIA was designed to deliver immediately.

It is not as if Sandoz provided its notice of commercial marketing in bad faith, knowing that approval was still years away. Indeed, subsection (k) applicants who engage in the information exchanges un-

der § 262(l)(2)-(4) have little incentive to give the notice before they actually believe launch is imminent. The benefit to the subsection (k) applicant of engaging in that information exchange is that it can control the pace and scope of litigation. But once the subsection (k) applicant gives notice under § 262(l)(8), it exposes itself to suit and preliminary injunction proceedings on *any* listed patent. So subsection (k) applicants won't give notice unless approval really is imminent. And the notice will not matter for subsection (k) applicants who do not engage in the § 262(l)(2)-(l)(4) information exchanges: they are immediately subject to suit on any patent anyway, regardless of whether or when they give notice. *See* 42 U.S.C. § 262(l)(9)(C). Either way, the reference product sponsor has ample time to assess the biosimilar prior to launch and seek enforcement of valid and infringed patents. As it stands now, the Federal Circuit's interpretation denies patients access to lower cost medicines and unnecessarily costs payors—including the U.S. government—billions of dollars. This Court should thus enforce the statute that Congress actually wrote and eliminate the Federal Circuit's extra 180-day exclusivity period.

CONCLUSION

For the reasons above, *amicus* encourages the Court to reverse the Federal Circuit's conclusion that 42 U.S.C. § 262(l)(8) requires that notice of commercial marketing be given only after FDA approval, creating a windfall extra 180 days of brand market exclusivity, and encourages the Court to affirm the Federal Circuit's holding that the subsection (k) applicant can opt not to disclose its aBLA under § 262(l)(2).

Respectfully submitted,

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