Nos. 15-1039, 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC., PETITIONER,
v.
AMGEN INC., ET AL., RESPONDENTS

AMGEN INC., ET AL., CROSS-PETITIONERS,
v.
SANDOZ, INC., CROSS-RESPONDENT

ON WRITS OF CERTIORARI TO THE U.S. COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* FOR JANSSEN BIOTECH INC. SUPPORTING AMGEN INC.

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INTEREST OF *AMICUS CURIAE*

As a company that is actively engaged in discovering, developing and marketing innovative biological medicines, Janssen Biotech, Inc. ("Janssen")[1] has a strong interest in an interpretation of the Biologics Price Competition and Innovation Act ("BPCIA") that protects the balance the statute strikes between the respective interests of innovators and biosimilar applicants.

Janssen has a particularly strong interest in this case because Janssen is one of a relatively small number of biotechnology companies that have experience litigating under the BPCIA, which was enacted in 2010 but did not lead to litigation until late 2014. The suit before this Court was the first action filed under the BPCIA. *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15–cv–10698 (D. Mass.) ("*Janssen v. Celltrion*"), involving a proposed biosimilar version of Janssen's biological medicine Remicade®, was the second. In *Janssen v. Celltrion*, as here (and as in certain subsequent BPCIA actions), the biosimilar applicants did not fulfill their statutory obligation to disclose relevant information concerning their manufacturing processes, and they provided a premature notice of commercial marketing, before their biosimilar

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[1] No counsel for a party authored this brief in whole or in part and no person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief, and those written consents are being submitted along with this brief.

product was licensed, that was recognized as ineffective after the Federal Circuit's decisions in this case and in *Amgen Inc. v. Apotex Inc.*, 827 F. 3d 1052 (Fed. Cir. 2016).

Janssen's interests as a major developer and manufacturer of new innovative biological medicines and its experience litigating patent infringement claims under the BPCIA may assist the Court in assessing the practical implications of the questions presented.

Janssen also submits this brief to highlight an important aspect of the Federal Circuit's decision below that contradicts arguments made by Sandoz, Inc., the Petitioner in No. 15-1039, and its *amici*. Sandoz argues that the "Federal Circuit turned [the] mere notice provision [of 42 U.S.C. § 262(*l*)(8)(A)] into a grant of 180 days of additional exclusivity for *all* biological products beyond the exclusivity period Congress expressly provided." Pet. Br. at i (emphasis added). But the Federal Circuit expressly disavowed that interpretation of its decision, holding that an "extra 180 days will *not* likely be the usual case" going forward. Pet. App. 22a (emphasis added); *accord Amgen v. Apotex*, 827 F. 3d at 1062. Janssen urges this Court to recognize, as the court did below, that neither party's position in No. 15-1039 requires deciding that 42 U.S.C. § 262(*l*)(8)(A) contemplates an extra 180 days of exclusivity for "all biological products."

INTRODUCTION AND SUMMARY OF ARGUMENT

As indicated by its name—the Biologics Price

Competition *and* Innovation Act—the BPCIA was enacted to create a pathway for approval of biosimilars that "balanc[es] innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). Under the BPCIA, applicants are permitted to rely on research and clinical testing conducted by the innovator, often costing hundreds of millions of dollars, without any compensation to the innovator. Where an applicant chooses to take advantage of the innovator's research and clinical testing under the BPCIA, the statute requires the applicant to engage in a detailed patent dispute resolution process to ensure that the innovator's patent rights can be properly adjudicated. That process involves providing the innovator with full information disclosure at an early stage, negotiating in good faith over which patents should be litigated immediately, and notifying the innovator when the commercial marketing of a licensed product is imminent, so that the innovator has the opportunity to file a preliminary injunction motion prior to launch of the biosimilar. If the applicant does not want to participate in this process, it may forego relying on the innovator's data, conduct its own research, and file an ordinary biological license application.

1. The BPCIA requires that the biosimilar applicant "shall" provide a "notice of commercial marketing" no fewer than 180 days before the first commercial marketing of a "licensed" product, 42 U.S.C. § 262(*l*)(8)(A), so that the innovator may then "seek a preliminary injunction prohibiting the . . . applicant from engaging in the commercial manufacture or sale of such biological product." 42

U.S.C. § 262(*l*)(8)(B). The express statutory purpose of the notice is to trigger the innovator's right to seek a preliminary injunction. To satisfy this purpose, the requisite notice must be given *after* the FDA licenses the product for commercial marketing.

A notice that is issued months or even years before FDA approval of the biosimilar product—for example, contemporaneously with the filing of the applicant's abbreviated biologics license application ("aBLA")—is not a "notice of commercial marketing" in any meaningful sense. This kind of premature notice fails to serve the purpose of a "notice of commercial marketing" because it does not provide the innovator notice that commercial marketing is imminent, a prerequisite to a motion for a preliminary injunction under 42 U.S.C. § 262(*l*)(8)(B). A premature notice of commercial marketing leaves the innovator to guess when commercial marketing will actually begin and when the resulting irreparable harm will actually occur.

A premature notice of commercial marketing also leaves the innovator uncertain of the nature of the product that will finally be approved or whether the product will be approved at all. The diseases that a product will eventually be approved to treat, the methods of manufacture that will ultimately be approved, and even the precise composition of the product can change from those disclosed in the initial aBLA. Manufacturing processes are especially central to innovation in biotechnology because a biosimilar product is never identical to the innovator's product since they are produced from living cell lines. Even small changes in the

manufacturing process can produce significant differences in the safety and efficacy of the end product. Without knowing the indications for which a biological medicine is licensed, its final method of manufacture, or its precise composition, the innovator cannot identify exactly which of its composition, method-of-use, or method-of-manufacturing patents are infringed. In short, giving notice before FDA licensing of a product does not serve the statutory purpose of a "notice of commercial marketing." Indeed, since all biosimilar applicants hope to market their products eventually, such a notice serves no purpose at all.

Separately, and contrary to Sandoz's contention, the Federal Circuit's interpretation of section 262(*l*)(8)(A) does not extend the BPCIA's 12-year marketing exclusivity period by an "additional" 180 days, much less does it do so for "all" biological products. The relationship between statutory exclusivity and the notice of commercial marketing is not at issue here, because Amgen's Neupogen® product was approved more than 12 years before the BPCIA was enacted and therefore never enjoyed *any* statutory exclusivity at all. In a future case addressing the interaction between these two provisions of the BPCIA, the correct interpretation would be that the statutory exclusivity and notice periods can run concurrently. The BPCIA provides that a biosimilar license cannot be "made effective" for 12 years after the reference product was first approved, 42 U.S.C. § 262(k)(7)(A), but it does not prevent FDA from issuing an earlier approval with a delayed effective date, as it routinely does under similarly worded provisions of the Hatch-Waxman

Act. After such an early license decision, the approved product's composition, uses, and method of manufacture would be fixed, and the applicant could serve a notice of commercial marketing that would satisfy the statutory language and purpose. In such a case, the 180-day notice period would occur while the statutory period of exclusivity is still in effect.

2. This Court should also clarify that the information disclosure requirements beginning with 42 U.S.C. § 262(*l*)(2)(A) are mandatory and enforceable. They are not mere options that benefit only biosimilar applicants and can therefore be waived by biosimilar applicants at their sole discretion.

The Federal Circuit's interpretation of section 262(*l*)(2)(A) effectively guts the statute's disclosure provisions, and transforms a carefully orchestrated dispute resolution process into a series of strategic choices available only to biosimilar applicants. Under the Federal Circuit's incorrect reading, a biosimilar applicant can avail itself of the innovator's proprietary data in seeking an FDA license on a biosimilar product under the BPCIA, while ignoring the *quid pro quo* for doing so—i.e., the statutory requirement that the applicant must provide information needed for the innovator to assess potential patent infringement and protect its patent rights.

The BPCIA does not offer the biosimilar applicant the choice between participating in or declining to participate in the statutory patent dispute resolution procedures. Instead, Congress offered biosimilar applicants a choice between: (a) using the innovator's

FDA license and underlying research and engaging in the BPCIA's mandatory information exchange process, or (b) foregoing reliance on the innovator's clinical research and instead conducting its own expensive research. The statutory price for using the simpler, less expensive route is compliance with mandatory procedures requiring the applicant to share with the innovator information that otherwise would be private, including the aBLA and details of the applicant's manufacturing processes. This information is needed so that the innovator can assess potential patent infringement and, where appropriate, institute litigation prior to biosimilar launch to protect its patent rights. If the applicant avails itself of the innovator's FDA license and underlying research, then the BPCIA's disclosure requirements are mandatory and enforceable. The Federal Circuit's holding that those requirements are optional and unenforceable is at odds with the BPCIA and upsets the balance that Congress intended.

Section 262(*l*)(2)(A) states that a biosimilar applicant "shall" make the disclosures at issue in this case. The mandatory nature of this obligation is underscored by Congress's use of the permissive "may" in other statutory provisions, when an optional meaning was intended. In Janssen's view, the issue presented is simple: When a biosimilar applicant chooses to use the benefits of the BPCIA and piggyback on the innovator's work, is it bound to play by the rules? Janssen believes the answer is yes.

ARGUMENT

I. AN APPLICANT DOES NOT SATISFY ITS OBLIGATION TO PROVIDE "NOTICE OF COMMERCIAL MARKETING" BY PROVIDING SUCH NOTICE BEFORE ITS BIOSIMILAR PRODUCT IS LICENSED BY THE FDA

The Federal Circuit was correct in holding that an applicant does not satisfy its statutory obligation to provide "notice of commercial marketing" under 42 U.S.C. § 262(*l*)(8)(A) by giving notice before the FDA licenses the applicant's biosimilar product. Pet. App. 20–23a. A notice given earlier is "premature and ineffective." *Id.* 23a.

A. Under Section 262(*l*)(8), a Notice of Commercial Marketing Cannot Precede Licensing

42 U.S.C. § 262(*l*)(8) is entitled "NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION." Under this section, an applicant is obligated to provide a notice of commercial marketing of a "licensed" product, and receipt of that notice entitles the innovator to seek a preliminary injunction to protect against imminent harm from sales of the licensed product.

1. Under Section 262(*l*)(8)(A), a "Notice of Commercial Marketing" Relates to a Product that Has Been Licensed and Can Be Commercially Marketed

The text of section 262(*l*)(8)(A) makes clear that an effective notice of commercial marketing can only be given after the product has been licensed. That

conclusion follows from the use of the term "licensed" in section 262(*l*)(8)(A) and from the term "notice of commercial marketing" in the title of that subsection.

The term "licensed": Section 262(*l*)(8)(A) states that an applicant shall give the innovator 180-days' notice of the "first commercial marketing of the biological product *licensed under subsection (k)*." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). A "biological product licensed under subsection (k)" is one that is licensed—not one that may (or may not) be licensed at some indeterminate time in the future.

Sandoz argues that term "licensed under subsection (k)" in section 262(*l*)(8)(A) "merely refers to the applicant's proposed biosimilar product, which will be 'licensed' by the time of marketing." Sandoz Br. 27. The Government echoes that argument, asserting that "licensed" in section 262(*l*)(8)(A) "describ[es] the biological product as of 'the *date* of [its] first commercial marketing.'" United States *Amicus* Br. 29 (emphasis and bracketed language added by the Government). That interpretation distorts the statutory language. Under this approach, the phrase "licensed under subsection (k)" is a nullity because "first commercial marketing of the biological product *licensed under subsection (k)*" would mean the same thing if the italicized words were not part of the statute. This approach thus violates a "cardinal principle of statutory construction," i.e., the principle that courts must "'give effect, if possible, to every clause and word of a statute.'" *Duncan v. Walker*, 533 U.S. 167, 174 (2001); *see also TRW, Inc. v. Andrew*, 534 U.S. 19, 31 (2001) ("It is 'a cardinal principle of statutory

construction' that 'a statute ought, upon the whole, be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void or insignificant.").

A marketed biosimilar product certainly must be licensed, but it does not follow that Congress would describe an unlicensed product as "licensed" whenever its future commercial marketing is being discussed. On the contrary, other related provisions of the BPCIA referring to the future commercial marketing of a yet-to-be-licensed product do not use the term "licensed product," and instead make clear that the product that will eventually be commercially marketed is not yet licensed.

The provision of the BPCIA that addresses patent disputes, section 262(*l*), refers to future "commercial marketing" three times outside of subsection (*l*)(8). On none of these occasions does the statute use the term "licensed product" to refer to the unlicensed product that may be licensed and marketed in the future. For example, the statute requires the applicant, if it intends to market its biosimilar product before the expiration of a patent, to provide a detailed statement describing its opinion that "such patent is invalid, unenforceable, or will not be infringed by the *commercial marketing of the biological product that is the subject of the subsection (k) application*." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) (emphasis added). If, on the other hand, the applicant does not challenge a patent, it is required to provide a statement that it "does not intend to begin *commercial marketing of the biological product* before the date that such patent

expires." 42 U.S.C. § 262(*l*)(3)(B)(ii)(II) (emphasis added). After the applicant provides these statements, the innovator (if it wishes to assert a disputed patent) must describe its opinion that "such patent will be infringed by the *commercial marketing of the biological product that is the subject of the subsection (k) application*." 42 U.S.C. § 262(*l*)(3)(C) (emphasis added).

Congress's use of different terminology in section 262(*l*)(8)(A)—referring to the "commercial marketing of the biological product *licensed* under subsection (k)"—indicates that Congress was referring to a product that already has been licensed by the FDA.[2]

The term "notice of commercial marketing": Congress's use of the term "notice of commercial marketing" in the title of section (8)(A) confirms that the notice in question refers to a product that has been licensed and could be marketed. In any meaningful sense of the words, a "notice of commercial marketing" can only be given *after* a biological product is licensed, because a biological

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[2] *See Abbott v. Abbott*, 560 U.S. 1, 33 (2010) ("In interpreting statutory text, we ordinarily presume that the use of different words is purposeful and evinces an intention to convey a different meaning."); *Sebelius v. Cloer*, 569 U.S. __, __, 133 S. Ct. 1886, 1894 (2013) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (alteration and internal quotation marks omitted).

product cannot be commercially marketed before it is licensed. It would be superfluous for an applicant to give "notice," prior to obtaining a license, that it intends to commercially market its product once it obtains a license; that is the sole purpose of submitting a license application. If the notice required by section 8(A) was not intended to describe a product that could be commercially marketed, as Sandoz contends, then Congress would not have described that notice as a "notice of commercial marketing."

2. The Purpose of a Notice of Commercial Marketing is Defeated If the Notice Is Served Before a Product is Licensed

Sandoz's interpretation also violates another basic principle of statutory interpretation, i.e., the principle that courts must interpret statutes "'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations omitted).

The other subsections of section 262(*l*)(8) confirm that a notice of commercial marketing must follow licensing, not precede it. A notice of commercial marketing of "the biological product licensed under subsection (k)," 42 U.S.C. § 262(*l*)(8)(A), triggers the innovator's right under section 262(*l*)(8)(B) to "seek a preliminary injunction" prohibiting the applicant from "engaging in the commercial manufacture or sale of such biological product" while the suit is pending. 42 U.S.C. § 262(*l*)(8)(B). Section 262(*l*)(8)(C) requires the parties to "reasonably cooperate" to expedite further discovery "in

connection with the preliminary injunction motion." 42 U.S.C. § 262(*l*)(8)(C).

As its name indicates, a "notice of commercial marketing" under section 262(*l*)(8)(A) is designed to inform the innovator that the applicant will soon begin commercial marketing of a licensed product. Armed with that information, the innovator is then in a position to move for a preliminary injunction under section 262(*l*)(8)(B). Any other reading is contrary to section 262(*l*)(8)'s language and structure.

In general, a preliminary injunction is not available unless the harm in question—in this case, the harm from commercial marketing—is imminent. It is not available "simply to prevent the possibility of some remote future injury." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Rather, a plaintiff "must show that the injury complained of is of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Wis. Gas Co. v. FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985) (emphasis removed); *see also Connecticut v. Massachusetts*, 282 U.S. 660, 674 (1931) ("Injunction[s] issue[] to prevent existing or presently threatened injuries. One will not be granted against something merely feared as liable to occur at some indefinite time in the future."). The requirement under section 262(*l*)(8)(A) that the product has been licensed ensures the imminence necessary to vindicate the right to move for a preliminary injunction under section 262(*l*)(8)(B).

Treating a pre-license notice as an effective "notice of commercial marketing" under section

262(*l*)(8) would sever that section's explicit linkage between the notice and the innovator's ability to seek a preliminary injunction. If an applicant could file an effective notice of commercial marketing prior to licensing, for example at the time it filed its aBLA (which may be years before approval), then the notice would serve no purpose at all because the time of commercial launch would be entirely speculative and not imminent. The notice would not serve its statutory purposes of announcing an imminent launch and the accompanying need to consider a preliminary injunction, and the innovator would be deprived of the benefit the notice was intended to provide.

In addition, a "notice of commercial marketing" that is served before FDA licensing does not give the innovator any information that the innovator does not already have. The applicant's aBLA, which must be supplied to the innovator within 20 days of FDA's acceptance of the aBLA for review, *see* 42 U.S.C. § 262(*l*)(2), already puts the innovator on notice that the applicant has applied for FDA approval and intends to market a biosimilar if an FDA license is obtained. A "notice of commercial marketing" that is served before the product is actually licensed does not provide any additional information.

3. Requiring a Notice of Commercial Marketing to Come After Licensing Ensures that the Nature of the Controversy Will Be Concrete

The requirement that a notice of commercial marketing must follow licensing also serves another important purpose. As the Federal Circuit

recognized, it ensures the existence of a "fully crystallized controversy regarding the need for injunctive relief" at the time the reference product sponsor is faced with the decision whether to move for a preliminary injunction. Pet. App. 21a. In particular, "[t]he 180-day period gives the [innovator] time to assess its infringement position for the final FDA-approved product as to yet-to-be-litigated patents." *Amgen v. Apotex*, 827 F.3d at 1063. Until the aBLA is approved, the innovator cannot know which of its patents will be infringed by the marketed product. Without a post-licensing window in which to assess the need for injunctive relief, innovators will be obliged to bring protective preliminary injunction motions that could have been avoided.

As the Federal Circuit pointed out, prior to licensing, key features of the proposed product may be unknown and subject to change, *e.g.*, the approved therapeutic uses for the product, the approved dosage regimen, the approved method of administration, and the approved methods of manufacture. *See* Pet. App. 21a. Even the precise structure of the biosimilar product is potentially subject to change.[3] Until the patentee knows this

[3] *See, e.g.*, Nana Kawasaki et al, *The Significance of Glycosylation Analysis in Development of Biopharmaceuticals*, Biol. Pharm. Bull. 32(5) 796, 798 (2009) (noting that "changes in manufacturing processes for biopharmaceuticals are often attempted during the development phase and after marketing authorization" and that "changes in the manufacturing process possibly cause the alteration of glycosylation in . . . glycoprotein products," which include many biologics).

information, it will not know the relevance of certain patents—*e.g.*, patents on methods of using the product for therapeutic purposes that may or may not be approved, or on processes that may or may not be used in the ultimate commercial product, or even on the composition of the product. There may also be patents that will expire before licensing or within 180 days of licensing, which need not be litigated if notice of commercial marketing is provided after a license is obtained. The 180-day post-licensing "statutory window" enables the innovator to wait until licensing to decide whether to bring a motion for injunctive relief—and thus potentially avoid the need for such a motion altogether. Pet. App. 21a.

Janssen's experience in *Janssen v. Celltrion* illustrates that these considerations are not speculative, but real. In that case, Janssen filed suit asserting a number of patents based on Celltrion's application to market a biosimilar version of Janssen's Remicade (infliximab) biologic. Like Sandoz here, Celltrion served a premature notice of commercial marketing (in February 2015), before the biosimilar product was licensed and at a time when the date of eventual licensing, if any, was unknown. One month later, before the Federal Circuit issued its decision below, Janssen moved for a preliminary and permanent injunction to enforce section 262(*l*)(8)(A), contending (as Amgen did here) that the statute requires a mandatory, post-approval 180-day period to assess patent rights. Janssen felt compelled to bring the motion because Celltrion claimed the right, based on its pre-license notice of commercial marketing, to launch commercially in as few as 180 days should its biosimilar product be

approved by then. Had a claim under section 262(*l*)(8)(A) not been available, Janssen likely would have been forced to protect its rights by moving prematurely for a preliminary injunction on one or more of its patents.

As it turned out, an unforeseeable delay in the approval process, coupled with the defendants' agreement to observe a 180-day post-license notice period in light of the Federal Circuit's decisions in this case and in *Amgen v. Apotex*, *supra*, made such a motion for a preliminary injunction unnecessary. The unnecessary motion was avoided for the very reasons identified by the Federal Circuit in this case.

For example, as the Federal Circuit pointed out, a post-approval window for patent assessment is important because the "therapeutic uses" for a proposed biosimilar are not "fixed" prior to FDA licensing. Pet. App. 21a. In *Janssen v. Celltrion*, Celltrion sought approval for its biosimilar for use in treating many therapeutic indications, including Crohn's disease. For a variety of reasons, it was uncertain whether Celltrion's biosimilar would be approved for treating Crohn's disease (it had not been in Canada), and there was no reason for Janssen to allege infringement of a patent covering methods of treating Crohn's disease unless the FDA approved Celltrion's biosimilar for treating Crohn's disease. Before Celltrion's biosimilar product was licensed, there was no way for Janssen to assess the need to assert that patent, much less rely on it in seeking a preliminary injunction under section 262(*l*)(8)(A).

Ultimately, the FDA did approve Celltrion's biosimilar for use in treating Crohn's disease, but that approval did not come until April 2016, only two months before the Crohn's disease patent expired. When Celltrion served its initial notice of commercial marketing—over a year before FDA licensing—the timing of that approval could not have been predicted. In view of the Federal Circuit's holding in this case and *Amgen v. Apotex* that section 262(*l*)(8)(A) creates a 180-day post-license window before commercial marketing can commence, Celltrion agreed to delay launching its product until after the patent expired and Janssen did not need to move for a preliminary injunction. As a result, the Federal Circuit's holding in this case spared the parties and the district court the wasted time of an unnecessary preliminary injunction motion.

Another patent asserted in *Janssen v. Celltrion* similarly illustrates the importance of a notice of commercial marketing coming after FDA licensing. One of Janssen's patents expired on September 15, 2015, within the earliest post-approval 180-day period anticipated at the time that Janssen filed suit. Under Janssen's reading of the BPCIA, there was never any need to seek emergency relief on this patent because commercial launch could not occur before patent expiration. If Sandoz's reading of the BPCIA were to prevail, however, future innovators in similar circumstances may be obliged to seek a premature preliminary injunction to protect against the possibility of FDA approval and commercial launch, even if it were also possible that the patent would expire by the time of actual FDA approval.

For Janssen to have moved for a preliminary injunction would have been a burden on the judicial system and a waste of resources for all involved. Yet if Celltrion had been permitted to serve a pre-license notice of commercial marketing, Janssen would likely have been forced to do so. Under the interpretation put forth by Sandoz, a biosimilar applicant could launch its product on the very same day that it receives FDA approval, leaving the innovator no "period of time to assess and act upon its patent rights." Pet. App. 26a. The innovator would thus find itself between a rock and a hard place, having to choose between a burdensome and potentially unnecessary pre-launch motion for a preliminary injunction or accepting the irreparable harm of a biosimilar launch. As the Federal Circuit correctly held, the purpose of section 262(*l*)(8)(A) was to avoid this dilemma.

A proper construction of the notice provision allows the patentee to seek a preliminary injunction on any or all of its relevant patents based on the facts available at the time of FDA license, while providing a protected statutory window in which the court and the parties can fairly assess the parties' rights prior to launch. Sandoz's position would thwart that opportunity.

4. The Correct Interpretation of Section 262(*l*)(8) Does Not Extend the Statutory Exclusivity Period

Sandoz and its *amici* contend that requiring licensing to precede a notice of commercial marketing under § 262(*l*)(8)(A) would "mean[ ] that sponsors receive 12 and one-half years of exclusivity

from biosimilar competition, rather than the 12 years Congress intended." Sandoz Br. 7. According to Sandoz "[t]his would be true for every single biosimilar." *Id.* But this case does not present the question whether section 262(*l*)(8)(A) extends exclusivity beyond the 12 years provided by 42 U.S.C. § 262(k)(7)(A), much less whether it does so for "every single biosimilar." If that question were to arise in the future, the answer would likely be that the exclusivity period of section 262(k)(7)(A) and the notice period of section 262(*l*)(8)(A) can run concurrently.

The interaction between the 12-year exclusivity provision and the 180-day notice is not at issue in this case because Amgen never had the opportunity to receive *any* period—much less 12 or 12½ years—of statutory exclusivity for Neupogen. The reason is that Neupogen (like the other biologics that are currently subject to biosimilar applications) is an older biologic which was on the market more than 12 years before the biosimilar application was filed. Such products do not enjoy any statutory period of non-patent exclusivity under the BPCIA; indeed, biosimilar applications for Neupogen and similarly situated products could be filed immediately once the statute went into effect. For such products, the only protection provided by the BPCIA is the modest 180-day period after licensing for an innovator to bring a potential preliminary injunction motion.

The issue here is whether a notice of commercial marketing must follow licensing of the biosimilar product, not whether the 180-day notice period runs consecutively with the statutory exclusivity period.

If that question arises in a future case, the better reading of the statute is that the two periods typically can run concurrently, since the statute indicates that a license may be *approved* (although not *made effective*) while the statutory exclusivity is still in effect. During the statutory period of market exclusivity, "[a]pproval of a[] [biosimilar] application . . . may not be *made effective*." 42 U.S.C. § 262(k)(7)(A) (emphasis added); *see also id.* § 262(a)(1)(A) (providing that no person may sell a biologic in the United States unless a "biologics license under this subsection or subsection (k) *is in effect*") (emphasis added). This language indicates that FDA may approve the application before the 12-year mark, effective upon the expiration of the market exclusivity period. If the product is approved while the statutory exclusivity period is in effect, the condition precedent to a notice of commercial marketing is met, and the market exclusivity and the 180-day notice period may run concurrently.

Two panels of the Federal Circuit, including the panel in this case, have endorsed this reading of the statute and rejected Sandoz's argument that a post-license notice entails extending the statutory exclusivity period. The court of appeals in this case reasoned (correctly) that "requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the 12-year exclusivity period of § 262(k)(7)(A)." Pet. App. 22a. "It is true that in this case . . . Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. . . . That 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." *Id.*

Similarly, in *Amgen v. Apotex*, a different panel held that the BPCIA does not provide any "reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date—a possibility suggested by [42 U.S.C] § 262(k)(7)'s language about when the FDA approval may 'be made effective.'" *Amgen v. Apotex*, 827 F.3d at 1062. The 180-day notice of commercial could be sent "as soon as the license issues, even if it is not yet effective." *Id.* A notice sent in this fashion would not extend the 12-year exclusivity period and would not delay commercial launch.

Sandoz's arguments against the Federal Circuit's reasoning are unpersuasive. Sandoz Br. 58-60. Sandoz cites a draft guidance document in which FDA states in passing that it cannot license biosimilar products during the statutory exclusivity period, *id.* at 58-59, but this document does purport to deny that an early license can be issued with a later effective date. To the contrary, it echoes the statutory language, stating that "[s]pecifically, approval of a 351(k) application may not be *made effective* until 12 years after the date of first licensure of the reference product."[4]

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[4] Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351 of the PHS Act* (Aug. 2014) at 2 (emphasis added), available at https://www.fda.gov/downloads/drugs/guidancecompliance%20regulatoryinformation/guidances/ucm407844.pdf.

Sandoz also points to the Hatch-Waxman Act, contending that since that statute expressly refers to "tentative approvals," the BPCIA cannot allow for early license decisions with delayed effective dates without using that term. Sandoz Br. 59-60. But the Hatch-Waxman Act supports the Federal Circuit's reading of the BPCIA. The statutory provision Sandoz cites is merely the definition of "tentative approval," a term that is used in connection with forfeiture of the exclusivity period for the first generic applicant. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd); *id.* §§ 355(j)(5)D)(i)(I)(bb) & 355(j)(5)D)(i)(IV). The provisions that affirmatively authorize FDA to issue approvals with delayed effective dates do not use the term "tentative approval." Rather, they use language virtually identical to that in the BPCIA: They refer to the dates that "approval of an application . . . shall be made effective." *E.g.,* 21 U.S.C. § 355(c)(3). Given that the BPCIA was modeled on the Hatch-Waxman Act, its drafters would have understood that referring to when a license may (or may not) or "be made effective" means that there can be a separation between the license decision and the effective date.

So construed, the 180-day period would not delay commercial marketing unless a license issues after the 12-year period has expired. In that situation, the only one presented here, the 180-day notice period is the only window available to the innovator to avoid irreparable harm by litigating its patents before market launch. There is no basis in the statute to deny that modest protection to the innovator.

B. The 180-Day Notice Is Not Optional and May Be Enforced by the Courts

The obligation to provide 180-day notice of commercial marketing is framed in language that is mandatory and imperative. *See* 42 U.S.C. § 262(l)(8)(A) ("The subsection (k) applicant *shall* provide notice . . . .") (emphasis added). The duty to provide such notice is not optional.

District courts plainly have authority to enforce compliance with the notice provision by issuing an appropriate preliminary injunction. The notice requirement requires the applicant to provide notice no later than 180 days "before the date of the first commercial marketing." 42 U.S.C. § 262(l)(8)(A). If an applicant attempts to launch a biosimilar product fewer than 180 days after an effective notice is given, a federal court in an appropriate action has the power to maintain the status quo by preliminarily enjoining commercial marketing during the 180-day notice period. It would defeat section 262(*l*)(8)(A)'s basic purpose, and be directly contrary to its terms, if a biosimilar applicant could not be prevented from marketing before the expiration of the 180-day period. Clearly, for example, an applicant that served a 180-notice of commercial marketing and then sought to launch on day 90 could be enjoined from doing so. So too can an applicant that seeks to commercially market its product before providing an effective notice of commercial marketing.

Indeed, the premise of the statute is that the innovator will be irreparably harmed if denied that 180-day period window after licensing to bring a preliminary injunction. That premise can only be

enforced with an injunction. *See, e.g.*, *City of New York v. Golden Feather Smoke Shop,* 597 F.3d 115, 120 (2d Cir. 2010) ("In certain circumstances, [courts] . . . employ a presumption of irreparable harm based on a statutory violation."); *Miller ex rel. S.M. v. Bd. of Educ.*, 565 F.3d 1232, 1252 n.13 (10th Cir. 2009) (statutory provision requiring maintenance of status quo during pendency of proceedings imposes "an automatic statutory injunction" on parties) (quoting *Norman K. ex rel. Casey K. v. St. Anne Cmty. High Sch. Dist. No. 302*, 400 F.3d 508, 510-11 (7th Cir. 2005)).

Although the BPCIA permits the innovator to commence a declaratory judgment action if the applicant "fails to complete" any of several steps, including the 180-day notice required by section 262(*l*)(8)(A), "there is no [statutory] language that excludes other remedies for the conduct described." *Amgen v. Apotex*, 827 F.3d at 1064. As part of its power to protect its jurisdiction and supervise BPCIA patent litigation, a court can properly require compliance with the notice provision to provide an opportunity for the innovator to move for a preliminary injunction before the biosimilar product is commercially marketed, as contemplated by the statute. *See, e.g., FTC v. Dean Foods Co.*, 384 U.S. 597, 604 (1966) (the All Writs Act creates "power to issue injunctions to preserve the status quo").[5]

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[5] Because courts in BPCIA patent infringement actions have the power to enforce section 262(*l*)(8)(A), Janssen agrees with Amgen that the Court need not address whether that provision provides a private right of action. Amgen Br. 25, 43-45.

II. SECTION 262(*l*)(2)(A)'S DISCLOSURE REQUIREMENT IS MANDATORY AND ENFORCEABLE BY THE COURTS

Section 262(*l*)(2)(A) of the BPCIA uses mandatory language in stating that an applicant "*shall provide* to the [innovator] a copy of the [aBLA] . . . and such other information that describes the process or processes used to manufacture the biological product" that is the subject of an application for approval under the statute. 42 U.S.C. § 262(*l*)(2)(A) (emphasis added). By statute, the applicant must provide this information at the outset of the approval process, "[n]ot later than 20 days" after the applicant is notified that its application has been accepted for review. 42 U.S.C. § 262(*l*)(2). Although Congress framed this disclosure requirement in "language of an unmistakably mandatory character," *Hewitt v. Helms*, 459 U.S. 460, 471 (1983), the Federal Circuit concluded that "'shall' in section 262(*l*)(2)(A) does not mean 'must,'" but means that the applicant may optionally disclose the required information. Pet. App. 15a. The BPCIA does not support that conclusion.

As Justice Holmes famously observed, compliance with the law is *always* optional. A party may choose to honor a contract, but a "bad man" may choose to breach the contract and pay damages instead. Oliver W. Holmes, *The Path of the Law*, 10 Harv. L. Rev. 457, 459-62 (1897). In that sense, the BPCIA is like any other law: It presents biosimilar makers with a choice between complying with the statute or suffering the consequences. But that reductive mode of analysis skips over the critical first step. Does the

law on its face invite a choice, or is the real choice between following the law or violating it? That predicate question must be answered before considering the consequences of one choice or another.

A. The Disclosures Required by Section 262(*l*)(2)(A) Are Mandatory

Section 262(*l*)(2)(A)'s disclosure requirement is expressed in language that is mandatory and imperative: The disclosures described in that section "shall [be] provide[d]." 42 U.S.C. § 262(*l*)(2)(A). "The word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive." *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661–62 (2007) (citation omitted). Other sections of the BPCIA reinforce the mandatory nature of this obligation by referring to "the information that is *required* to be produced pursuant to paragraph [*l*](2), 42 U.S.C. § 262(*l*)(1)(B)(i), and "information *required* under paragraph [*l*](2)(A)," 42 U.S.C. § 262(*l*)(9)(A) (all emphases added). *See also* 42 U.S.C. § 262(*l*)(9)(C) (same). "Congress could not have chosen stronger words to express its intent that [disclosure] be mandatory in cases where the statute applied . . . ." *United States v. Monsanto*, 491 U.S. 600, 607 (1989). Congress also used the mandatory "shall" in other sections of the BPCIA that address patent dispute resolution provisions. *See*, *e.g.*, 42 U.S.C. § 262(*l*)(3)(A), (*l*)(3)(B), (*l*)(3)(C), (*l*)(4)(A).

In contrast, where Congress wanted a particular step to be optional or conditional, the BPCIA states that a party "may" take such action. For example,

the section immediately following section 262(*l*)(2)(A) states that the applicant "*may provide* to the reference product sponsor additional information requested by or on behalf of the [innovator] . . . ." 42 U.S.C. § 262(*l*)(2)(B); *see also* 42 U.S.C. § 262(*l*)(3)(B)(i) (stating that the applicant "*may provide* to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted . . . .") (all emphases added). "[W]hen a statute distinguishes between 'may' and 'shall,' the latter generally imposes a mandatory duty," *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1972 (2016), and there is "no reason to depart from the usual inference here." *Id.* at 1977. "[Where] the word 'may' is used in special contradistinction to the word 'shall,'" there can be no reason for taking "a liberty . . . with the plain words of the statute." *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359–60 (1895).

In the Federal Circuit's view, a failure to meet section 262(*l*)(2)(A)'s disclosure requirements "did not violate the BPCIA" because the BPCIA "explicitly contemplate[s]" the possibility of noncompliance. Pet. App. 15a. That is a *non sequitur*. Obligations imposed by statute do not become optional merely because the statute contemplates the possibility of a violation. For example, the obligation to file income tax returns under 26 U.S.C. § 6012 does not become optional because Congress addressed the consequences of failing to file. *See* 26 U.S.C. § 7203. Likewise, the obligations of security issuers to disclose certain information to the public and the S.E.C. do not become optional merely because a

failure to disclose the required information has statutory consequences. *See* 15 U.S.C. § 78m. By the same token, the disclosures required by the BPCIA do not become optional merely because the statute contemplates the possibility that an applicant may violate the statute.

Under the Federal Circuit's reasoning, the disclosures required by section 262(*l*)(2)(A) are optional in a way that is grossly one-sided: only the biosimilar applicant is given any meaningful option. Because the statutory process begins with the applicant's provision of information to the innovator, 42 U.S.C. § 262(*l*)(2)(A), it is the applicant, not the innovator, who supposedly may opt to forego the process. If the applicant initiates the BPCIA process and completes it, the innovator must participate or risk losing its right to seek lost profit damages, potentially worth billions of dollars. *See* 35 U.S.C. § 271(e)(6). The Federal Circuit's interpretation effectively transforms the BPCIA's carefully balanced process into a one-sided option that favors only the applicant.

The disclosure provisions set forth in section 262(*l*)(2)(A) are intended to benefit both parties and the courts by allowing innovators to assess an applicant's documentary evidence first and then file suit asserting infringement of patents where the documentary evidence provides a reasonable basis for that assertion. That purpose is frustrated if an applicant violates section 262(*l*)(2)(A)'s disclosure provisions. If the applicant does not provide the disclosure that section 262(*l*)(2)(A) requires, then the innovator is left in the situation of having to sue first

and obtain documentary evidence concerning the applicant's product and manufacturing process later. In that scenario, suit would be brought on *all* patents where there is a possibility of infringement and the action subsequently would be winnowed down to only those patents where the initial allegations are consistent with later-provided facts.

That is exactly what happened in the *Janssen v. Celltrion* case. Because the applicants there did not provide all the information required under section 262(*l*)(2)(A) at the outset, Janssen initially was forced to assert several manufacturing process patents that Janssen ultimately dropped from the case when it later turned out that Celltrion was using a different process. This was because, as is almost always the case, an owner of a manufacturing process patents cannot determine if they are being infringed until the defendant discloses information specifying the details of its manufacturing process, as required under section 262(*l*)(2)(A). Janssen would have had no need to assert those patents if the applicant had provided the required disclosures at the outset. *Janssen v. Celltrion* thus illustrates how violations of section 262(*l*)(2)(A)'s disclosure requirements harm the public and unnecessarily burden the courts and the innovator by leading to litigation that could have and should have been avoided or minimized if the applicant had met section 262(*l*)(2)(A)'s disclosure requirements at the outset.

The *Amgen v. Hospira* case, currently on appeal to the Federal Circuit, further illustrates the problem. In that case, the biosimilar applicant

(Hospira) failed to provide manufacturing information to the innovator (Amgen) at the outset. Appellant's Br. 8-10, Dkt. 28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). In subsequent litigation, the district court denied Amgen's request for discovery concerning Hospira's manufacturing process as not relevant to any patent on which Amgen had sued. The only way Amgen could have avoided that result would have been by asserting patents before having the information needed to assess whether they are infringed. If Hospira had complied at the outset with section 262(*l*)(2)(A), Amgen would have had all the information and been able to assess which of its patents are infringed before bringing suit.

The BPCIA procedures are not intended to benefit the applicant alone, but rather to benefit the courts and the innovators as well by creating an orderly process for identifying and litigating potentially infringed patents before a proposed biosimilar is marketed. Failing to provide the required disclosures at the outset defeats that statutory purpose.

Because the disclosure requirements in section 262(*l*)(2)(A) are not for the sole benefit of the applicant, an applicant does not have the right to unilaterally waive the requirements of that paragraph. It is true that a "party may waive any provision, either of a contract or of a statute, *intended for his benefit*." *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995) (quoting *Shutte v. Thompson*, 82 U.S. 151, 159 (1873)) (emphasis added). But logically, this rule cannot

apply to a "provision that benefits both sides." *Citadel Equity Fund Ltd. v. Aquila, Inc.*, 168 F. App'x 474, 476 (2d Cir. 2006).[6] The Federal Circuit erred in concluding that the biosimilar applicant may opt out of its provisions.

B. Courts May Enforce Compliance With Section 262(*l*)(2)(A)'s Disclosure Requirements

Once one recognizes that section 262(*l*)(2)(A)'s disclosure provisions are mandatory, not optional, the next question is what remedies are available to enforce those provisions. This question focuses on how to treat Justice Holmes' "bad man," i.e., an entity that has violated an obligation imposed by statute—not a citizen who is simply making an acceptable choice offered by the law.

As the Federal Circuit recognized, if an applicant does not disclose the information identified in section 262(*l*)(2)(A), the BPCIA authorizes the innovator to bring suit "under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)."[7] Pet. App. 15a. The

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[6] *Accord Shared Imaging, Inc. v. Campbell Clinic, Inc.*, No. 98-5366, 1999 U.S. App. LEXIS 6356, at *13 (6th Cir. Apr. 2, 1999) ("Of course, one party cannot unilaterally waive a provision that benefits the other party to the contract."); *LeaseAmerica Corp. v. Norwest Bank Duluth, N.A.*, 940 F.2d 345, 348 (8th Cir. 1991) (same).

[7] Under the first provision, the innovator (but not the applicant) "may bring an action under section 2201 of title 28 for a declaration of infringement,, validity or enforceability of any patent that claims the biological product or a use of the biological product." 42 U.S.C.

Government recognizes an additional avenue of relief when it states that an innovator could "immediately bring suit under 35 U.S.C. § 281 for patent infringement." *Amicus* Br. of the United States at 13.

Where an innovator brings an action under any of these provisions, the district court is well within its authority to order the applicant to provide the disclosures required by section 262(*l*)(2)(A). It is "well settled" that "federal courts may use any available remedy" to enforce federal rights. *Barnes v. Gorman*, 536 U.S. 181, 189 (2002) (quoting *Bell v. Hood*, 327 U.S. 678, 684 (1946)); *see also Franklin v. Gwinnett Cnty. Pub. Sch.*, 503 U.S. 60, 71 (1992) ("[T]he federal courts have the power to award any appropriate relief in a cognizable cause of action brought pursuant to a federal statute."). Although the BPCIA does not expressly authorize such relief, that does not mean it is not available. "[W]hen all that a plaintiff seeks is to enjoin an unlawful act, there is no need for express statutory authorization; 'absent the clearest command to the contrary from Congress, federal courts retain their equitable power to issue injunctions in suits over which they have jurisdiction.'" *Sterk v. Redbox Automated Retail, LLC*, 672 F.3d 535, 539 (7th Cir. 2012) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 705 (1979)); *see*

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§ 262(*l*)(9)(C). The second provision treats the failure to disclose the required information under section 262(*l*)(2)(A) as "an artificial 'act of infringement' of 'a patent that could be identified' pursuant to paragraph (*l*)(3)(A)(i)." Pet. App. 16a (quoting 35 U.S.C. § 271(e)(2)(C)(ii)).

also Holland v. Florida, 560 U.S. 631, 645 (2010) ("[W]e will not construe a statute to displace courts' traditional equitable authority absent the clearest command") (alteration and internal quotation marks omitted).

Requiring compliance with the BPCIA's procedures is both necessary and appropriate in aid of the district court's jurisdiction over the patent infringement or declaratory action authorized by the statute. The purpose of the statutory disclosure procedures is to identify, and narrow, issues for eventual patent litigation through pre-litigation disclosure and discovery. A district court has every right to order compliance with these procedures to assure itself that the dispute has been sharpened for resolution, as Congress intended, and to reduce any unnecessary burdens on the court caused by non-compliance. *See, e.g.*, *Zenith Elecs. Corp. v. United States*, 884 F.2d 556, 562 (Fed. Cir. 1989) (authority under All Writs Act to enjoin conduct that "would impinge upon and interfere with" court's review of case before it); *Virgin Islands v. Fahie*, 419 F.3d 249, 258 (3rd Cir. 2005) ("[C]ourts' supervisory powers are broad and include implementing remedies for violations of recognized rights.").

Ultimately, an applicant cannot avoid having to provide the disclosures that section 262(*l*)(A)(2) requires. As a result, the question is not *whether* those disclosures must be provided, but *when*. Under the BPCIA, the applicant has a mandatory obligation to provide those disclosures "[n]ot later than 20 days" after learning that its application has been accepted for review. 42 U.S.C. § 262(*l*)(2). If

the applicant violates section 262(*l*)(A)(2) by failing to provide the requisite disclosures, the innovator can then bring suit under the BPCIA and/or the patent statute, and in such an action the court can order the applicant to provide the disclosures required under section 262(*l*)(2)(A).

CONCLUSION

This Court should hold: (1) that a "notice of commercial marketing" under 42 U.S.C. 262(*l*)(8)(A) must be provided after a biological product has been licensed under subsection (k) and that courts may enforce this requirement by enjoining the sale of a biosimilar product for 180 days after effective notice is provided; and (2) that section 262(*l*)(2)(A)'s disclosure requirements are mandatory and may be judicially enforced.

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