2015-1499

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

—v.—

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
JUDGE RICHARD SEEBORG
3:14-CV-04741-RS

CORRECTED BRIEF FOR *AMICUS CURIAE* JANSSEN BIOTECH, INC. IN SUPPORT OF PLAINTIFFS-APPELLANTS

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CERTIFICATE OF INTEREST

Counsel for *amicus* Janssen Biotech, Inc. certifies the following:

1. The full name of the amicus represented by me is: Janssen Biotech, Inc.

2. The name of the real party in interest represented by me is: Janssen Biotech, Inc.

3. All parent corporations and any publicly held companies that own 10 percent of more of the stock of the amicus curiae represented by me are: Johnson & Johnson.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court:

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Dated: April 14, 2015

/s/ Gregory L. Diskant
Gregory L. Diskant

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INTERESTS OF *AMICUS CURIAE*

Amicus curiae Janssen Biotech, Inc. ("Janssen") is the maker of the revolutionary biological medicine, Remicade® (infliximab), which has dramatically improved the lives of hundreds of thousands of patients suffering from autoimmune illnesses ranging from rheumatoid arthritis to Crohn's disease. Like Neupogen® (filgrastim), the biological medicine marketed by plaintiffs-appellants Amgen, Inc. and Amgen Manufacturing Limited (together "Amgen") in this appeal, Remicade is the subject of a biosimilar application pursuant to the Biologics Price Competition and Innovation Act ("BPCIA").

Like defendants-appellees Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH (together "Sandoz") here, the makers of the proposed Remicade biosimilar have contended that the patent dispute resolution procedures of the BPCIA are optional and that the statutory "notice of commercial marketing" may be provided at any time, regardless whether the product has been licensed for commercial sale. Like Amgen, Janssen has filed suit contending that the BPCIA procedures are mandatory and that the notice of commercial marketing must pertain to the imminent commercial marketing of a licensed product. *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Mar. 6, 2015) ("*Janssen Biotech*"). Although there are differences between Janssen's and

Amgen's suits that will be addressed below, Janssen's pending claims may be directly affected by the outcome of this appeal.

In addition to Remicade, Janssen markets other biological medicines, and is developing still others, that may someday be subject to biosimilar applications under the BPCIA. Janssen therefore has an interest in seeing that the patent dispute resolution provisions of the BPCIA are interpreted to strike the balance Congress intended between the interests of innovators and biosimilar applicants.[1]

INTRODUCTION

As its name indicates – the Biologics Price Competition *and* Innovation Act – the BPCIA was enacted to create a biosimilar pathway "balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010). But Sandoz and other early biosimilar applicants have advocated, and the district court accepted, an interpretation of the BPCIA's patent dispute resolution provisions that destroys this balance. This Court has not yet construed the BPCIA. It should clarify that the statutory patent dispute resolution procedures are intended to be followed as written, and are not merely optional choices or empty formalities, as Sandoz contends.

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[1] *Amicus* has consent from all parties to file this brief.

No party's counsel authored any part of this brief. No party, party's counsel or other person besides Janssen contributed money to fund the preparation or submission of this brief.

The district court's reading of the statute, if affirmed by this Court, would gut the BPCIA's patent provisions, transforming them from a carefully orchestrated dispute resolution process into a series of strategic options existing for the sole benefit of the biosimilar applicant. Under the district court's reading, the biosimilar applicant may avail itself under the BPCIA of the innovator's proprietary data to obtain an FDA license. But at the same time, it may ignore the BPCIA's procedural provisions – designed to allow the innovator to protect its patent rights – and launch its product without notice to the innovator.

That is not the choice that the BPCIA offers. The choice that Congress offered a biosimilar maker is to use the innovator's FDA license and underlying expensive research *and* engage in the BPCIA process, on the one hand, or to forego the biosimilar approval process altogether and do the research on its own, on the other hand. The price for using the simpler and less expensive abbreviated pathway to market is compliance with a set of mandatory procedures that include sharing key, otherwise private information with the innovator – specifically, the abbreviated biologics license application ("aBLA"), manufacturing information, patent contentions and notice of imminent launch. This information was required in order to allow the innovator to institute litigation under the BPCIA prior to biosimilar launch to protect its patent rights against irreparable harm. The district court's conclusion that none of this is mandatory – that Congress "intended merely

to encourage" compliance with the terms of the statute – is untenable.

Congress provided that the applicant "shall" undertake the procedures at issue in this appeal, and it underscored the mandatory nature of this provision by using the permissive "may" for other provisions, when an optional meaning was intended. 42 U.S.C. § 262(*l*). These BPCIA procedures are mandatory components of a statute that, in its totality, benefits not only the biosimilar applicant, but also the innovator, the courts, and eventually the public. Legislative requirements that benefit others are not optional and may not be unilaterally waived by one beneficiary.

Likewise, in the BPCIA, Congress required that the biosimilar applicant "shall" provide a 180-day notice "before" the commercial marketing of a "licensed" product for the express purpose of permitting the innovator to "seek a preliminary injunction" prior to commercial launch. *Id.* § 262(*l*)(8). Contrary to the district court's conclusion, the applicant cannot opt out of providing notice. Nor can it satisfy the requirement by providing a meaningless notice for a product that may never be licensed and that cannot be commercially marketed for some (indefinite) time.

The BPCIA is a new statute and its meaning is now being tested in the district courts. Janssen submits this amicus brief because the BPCIA is extremely important to its ability to compete in the present and to plan for the future.

Moreover, the facts of its case differ significantly from those of Amgen's case, and the Court should be aware of other situations that will be affected by its decision. In Janssen's view, the issue presented is simple: when a biosimilar applicant opts to use the benefits of the BPCIA and piggyback on the work of the innovator, is it bound to play by the rules? Janssen believes the answer is yes.

BACKGROUND

The BPCIA has not yet been construed by this Court, and it has generated only six lawsuits to date: this appeal; a prior dispute between Amgen and Sandoz involving a different biologic;[2] three now-dismissed declaratory judgment actions concerning the proposed biosimilar version of Janssen's Remicade;[3] and *Janssen Biotech*. In all of these cases, the biosimilar applicants have contended that the BPCIA's patent dispute resolution procedures are optional and not mandatory.

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[2] *See Sandoz Inc. v. Amgen Inc*., No. C-13-2904, 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013), *aff'd* 773 F.3d 1274 (Fed. Cir. 2014) ("*Sandoz*").

[3] *See Celltrion Healthcare Co. v. Kennedy Trust for Rheumatology Research*, 14-cv-2256, 2014 U.S. Dist. LEXIS 166491 (S.D.N.Y. Dec. 1, 2014); *Hospira, Inc. v. Janssen Biotech, Inc*., 113 U.S.P.Q.2d 1260 (S.D.N.Y. 2014); *Celltrion Healthcare Co. v. Janssen Biotech, Inc*., No. 14-cv-11613 (D. Mass. filed Mar. 31, 2014).

A. The Pre-Application Declaratory Judgment Actions

The first round of BPCIA litigation involved declaratory judgment actions brought by biosimilar applicants before their aBLAs were accepted by FDA.[4] The biosimilar applicants contended that they were not barred from bringing a pre-application declaratory judgment action because the BPCIA did not prohibit doing so, and even if it did, the applicants were released from any such prohibition by providing a "notice of commercial marketing," even before FDA accepted their aBLAs. *See* 42 U.S.C. § 262(*l*)(9)(A).

The district courts rejected the applicants' arguments and dismissed their actions on two grounds. First, the courts held that there was no justiciable case or controversy prior to the filing of an aBLA.[5] Second, they held that in any event, a biosimilar applicant could not file a declaratory judgment action without first exhausting the BPCIA patent dispute resolution procedures.[6]

Only one of these cases was appealed. In that case, this Court affirmed dismissal on justiciability grounds and expressly declined to address the BPCIA. *Sandoz*, 773 F.3d at 1275, 1278-79. Although the Court did not "adopt[] a

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[4] *See supra* notes 2-3.

[5] *See Celltrion*, 2014 U.S. Dist. LEXIS 166491, at *9-12; *Sandoz*, 2013 U.S. Dist. LEXIS 161233, at *6-8.

[6] *See Hospira*, 113 U.S.P.Q.2d at 1262; *Celltrion*, 2014 U.S. Dist. LEXIS 166491, at *12-16; *Sandoz*, 2013 U.S. Dist. LEXIS 161233, at *6.

categorical rule," it observed that it was "aware of no decision in which we have found a case or controversy when the only activity that would create exposure to potential infringement liability was a future activity requiring an FDA approval that had not yet been sought." *Id*. at 1279. The Court thus largely closed off pre-application declaratory judgment actions under the BPCIA on justiciability grounds, without addressing the biosimilar applicants' statutory arguments.

B. This Appeal and Janssen's Pending Lawsuit

The second round of BPCIA litigation comprises the present appeal and *Janssen Biotech*. They show, in different ways, how biosimilar makers are attempting to take advantage of the benefits of the BPCIA, while ignoring its obligations.

In this action, Sandoz refused to supply required information to Amgen prior to litigation, undermining Amgen's ability to determine which patents to assert. This is particularly problematic with respect to manufacturing patents, for which infringement cannot be properly evaluated without access to the applicant's proprietary information. Recognizing that problem, Congress required that the biosimilar applicant provide not only its aBLA, but also "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).

Sandoz decided to ignore this requirement and did not disclose its aBLA or its manufacturing processes. This has been a particular problem for Amgen because most its product patents on filgrastim have apparently expired. Without access to Sandoz's aBLA or its manufacturing information, Amgen was unable to learn through the BPCIA process whether its many manufacturing patents were infringed. Even after it finally brought suit, Amgen has obtained only limited access to this information. Meanwhile, Sandoz obtained its FDA license and is now on the eve of launch. By ignoring the disclosure required by the BPCIA, Sandoz has been able to reap the rewards of the statute while hamstringing Amgen's ability to institute patent litigation, defeating the basic *quid pro quo* of the BPCIA.

The facts alleged in the *Janssen Biotech* lawsuit show another way in which the district court's misreading of the BPCIA skews the statute. Like Sandoz, the makers of the proposed Remicade biosimilar provided a purported "notice of commercial marketing" before their product was licensed in order to trigger the 180-day statutory period for bringing a preliminary injunction motion. But unlike Sandoz's Neupogen biosimilar, the proposed Remicade biosimilar is still not licensed, and it remains unclear whether it will be licensed and, if it is licensed, when it will be licensed and what the scope of its license will be. For a variety of

reasons, discussed further below, Janssen cannot decide whether to seek a preliminary injunction on any of its patents without knowing that information.

As Janssen contends in a motion currently pending in the district court, it should not have to face this dilemma. *Janssen Biotech*, No. 15-cv-10698 (D. Mass. Apr. 8, 2015), ECF No. 34-1 ("*Janssen Biotech* Br.").[7] The statute requires a notice of commercial marketing to be made after the FDA has made its licensing decision. That would provide Janssen what the statute promised: a 180-day window prior to market launch to permit an injunction to be sought on patents that are actually implicated by the FDA license. The premature notice that the biosimilar applicants intend to launch one day – hardly a surprise to Janssen – is useless and denies Janssen one of the core benefits of the BPCIA.

The facts of Amgen's and Janssen's cases present just two examples of the opportunities for gamesmanship inherent in the district court's decision.

ARGUMENT

I. THE BPCIA'S PATENT DISPUTE RESOLUTION PROCEDURES ARE NOT OPTIONAL AND MAY BE ENFORCED BY THE COURTS

In ruling that the patent dispute resolution procedures of the BPCIA are optional, the district court concluded that "Congress intended merely to encourage

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[7] Available at http://www.fdalawblog.net/REMICADE%20-%20Janssen%20Partial%20SJ%20%26%20PI.pdf.

use of the statute's dispute resolution process in favor of litigation" and that in most instances it provided "no stick to force compliance." A10-11. In so ruling, the court conflated two different questions: (1) whether the procedures of the BPCIA are mandatory or permissive; and (2) if the procedures are mandatory, what are the consequences of a violation. When the questions are addressed separately, a different answer emerges.

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 the choice of complying with its terms or suffering the consequences. But that reductive mode of analysis skips over the critical first step. Does the law on its face permit a choice, or is a choice available only to those who are willing to violate the law? That predicate question must be answered before it is possible to analyze the consequences of one choice or another.

A. The BPCIA's Patent Dispute Resolution Procedures Are Mandatory and Not Optional

The district court's conclusion that Congress intended "merely to encourage" compliance with the BPCIA is indefensible. Reflecting their importance to the BPCIA's balance of competition and innovation, most of the

statutory patent dispute resolution procedures are expressly mandatory, not optional: the parties "shall" undertake them. *See* 42 U.S.C. § 262(*l*)(2)(A), (*l*)(3)(A), (*l*)(3)(B), (*l*)(3)(C), (*l*)(4)(A). Where a specific step is optional or conditional, the statute states that the parties "may" take such action. *See id.* § 262(*l*)(2)(B), (*l*)(3)(B)(i). Amgen's brief explains the district court's error in concluding that the BPCIA's mandatory provisions are optional. Amgen Br. 35-41.

The district court's error is particularly glaring because the procedures, as construed by the court, are not only optional, but are optional in a grossly one-sided way. The only party given any significant choice, under the district court's analysis, is the biosimilar applicant. 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. A11. Once the applicant initiates the BPCIA process, the innovator must participate as well or risk losing its right to seek lost profit damages, potentially worth billions of dollars. *See* 35 U.S.C. § 271(e)(6). The district court's interpretation effectively transforms the BPCIA process into a one-sided option available only to the applicant.

This result is contrary to the structure and purpose of the statute. As Amgen explains, the BPCIA procedures are not intended to benefit the applicant alone, but

rather to benefit both parties and the courts by creating an orderly process for identifying and litigating potentially infringed patents prior to the marketing of a proposed biosimilar. Amgen Br. 24, 29, 33, 43-44. Because of this, the applicant does not have the right to waive its provisions unilaterally. Although "[a] party may waive any provision, either of a contract or of a statute, intended for his benefit," *United States v. Mezzanatt*o, 513 U.S. 196, 201 (1995) (quoting *Shutte v. Thompson*, 82 U.S. 151, 159 (1873)), this rule does not apply to a "provision that benefits both sides." *Citadel Equity Fund Ltd. v. Aquila, Inc.*, 168 F. App'x 474, 476 (2d Cir. 2006).[8] Since it is apparent from the face of the statute and its legislative history that the BPCIA is intended to benefit both biosimilar applicants and innovators, it follows that the district court was incorrect in finding that the biosimilar applicant could opt out of its provisions.

B. The Courts May Enforce Compliance With the BPCIA

Once it is concluded that Congress set forth mandatory procedures in the BPCIA, the question is then presented what remedies are available to enforce those procedures. The district court failed to recognize that this question focuses on how to treat Justice Holmes' "bad man," not a citizen who is simply making an

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[8] *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).

acceptable choice offered by the law. As a result, the court effectively eschewed its judicial obligation to require Sandoz to do what the BPCIA says it "shall" do. Rather, the court concluded that the sole remedy for non-compliance – the "choice" available to the biosimilar applicant – was a restriction on the right to seek a declaratory judgment under 42 U.S.C. § 262(*l*)(9)(C). Nothing in the law supports this conclusion.

As Amgen demonstrates, this conclusion is contrary to the language, structure, and purpose of the BPCIA. Amgen Br. 52-59. When Congress wanted to identify a sole remedy for a violation of the BPCIA, it said so clearly. Thus, 35 U.S.C. § 271(e)(6)(B), which was enacted as part of the BPCIA, expressly identifies "the sole and exclusive remedy that may be granted by a court" for a failure to bring a timely suit. Similarly, 35 U.S.C. § 271(e)(4), which the BPCIA made applicable to biologics, identifies "the only remedies which may be granted by a court" under certain circumstances. By contrast, 42 U.S.C. § 262(*l*)(9)(C) identifies one consequence for violating the BPCIA's procedures, but does nothing to make that an exclusive remedy.

The district court's reading of the BPCIA is also contrary to the "well settled" principle 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."). While the BPCIA does not expressly provide for an injunction to enforce its terms, that does not mean that one 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 also Plata v. Schwarzenegger*, 603 F.3d 1088, 1093-94 (9th Cir. 2010) ("absent the clearest command to the contrary" a "statute should not be construed to displace" the "recognized equitable tools available to the courts to remedy otherwise uncorrectable violations of the Constitution or laws") (alteration and internal quotation marks omitted).

The district court's failure to recognize this principle may have been affected by Amgen's decision to sue under California state law, rather than the BPCIA itself. Nonetheless, there are at least two separate sources of federal judicial power to enforce the provisions of the BPCIA.

First, the BPCIA creates a private right of action that may be judicially

enforced.[9] Under the case law, this conclusion follows, *inter alia*, from the following: (1) The BPCIA's information exchange and notice provisions "expressly identif[y] the class Congress intended to benefit," namely, the biosimilar applicant and the reference product sponsor. *Cannon v. Univ. of Chicago*, 441 U.S. 677, 690 (1979). (2) Congress expressly provided in the BPCIA that the statutory procedures would lead to private federal-court litigation between these parties. *See* 42 U.S.C. § 262(*l*)(6), (*l*)(8)(B); 35 U.S.C. § 271(e)(2)(C). (3) There is no administrative agency or other entity besides the parties that is responsible for enforcing the BPCIA's procedures. *See, e.g.*, *Ind. Prot. & Advocacy Servs. v. Ind. Family & Soc. Servs. Admin.*, 603 F.3d 365, 375-79 (7th Cir. 2010) (implied right of action where, *inter alia*, statute "lack[ed] separate administrative enforcement mechanisms").

Second, and separately, the district court may issue an injunction requiring compliance with the procedures of the BPCIA under its inherent powers to supervise BPCIA patent litigation before it and under the All Writs Act, 28 U.S.C. § 1651(a) (federal courts may "issue all writs necessary or appropriate in aid of their respective jurisdictions"). *See Klay v. United Healthgroup, Inc.*, 376 F.3d

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[9] Because Amgen pleaded its claims under California state law rather than directly under the BPCIA, the court expressly did "not . . . address[]" whether the BPCIA is directly enforceable by federal courts through a private right of action. A8.

1092, 1098 (11th Cir. 2004) (All Writs Act is "codification" of courts' "inherent power and the constitutional obligation to protect their jurisdiction from conduct which impairs their ability to carry out Article III functions").

Requiring compliance with the procedures of the BPCIA is both necessary and appropriate in aid of the district court's jurisdiction over the patent infringement action created by the statute. The purpose of the statutory procedures is to identify, and narrow, issues for eventual patent litigation through pre-litigation disclosure and discovery. The court has every right to order compliance with these procedures so as to assure itself that any eventual litigation before it has been sharpened for resolution, as Congress intended, and to reduce any unnecessary burdens on the judiciary 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.").

II. A NOTICE OF COMMERCIAL MARKETING CANNOT BE PROVIDED UNTIL A BIOSIMILAR PRODUCT IS LICENSED

The district court's conclusion that a "notice of commercial marketing" may be provided before a biosimilar product is licensed also distorts the BPCIA. The language, structure and purpose of the BPCIA all require a product to be licensed

before a notice of commercial marketing so that the notice may provide an opportunity for a preliminary injunction to be sought prior to launch to protect against imminent irreparable harm. This provides, in effect, a statutory 180-day injunction in which to litigate before launch. Under the district court's interpretation, a notice of commercial marketing would sever the connection to a preliminary injunction motion that the statute requires.

A. Section 262(*l*)(8) Provides for a Preliminary Injunction Motion Upon Notice That a Licensed Product Will Imminently Be Marketed

As is clear from its title, "[n]otice of commercial marketing and preliminary injunction," and its text, 42 U.S.C. § 262(*l*)(8) creates a right to seek a preliminary injunction that is triggered by a notice of commercial marketing of a "licensed" product. Subsection (A) requires the biosimilar applicant to provide 180 days' notice before the commercial launch of a "biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Subsection (B) permits the innovator to "seek a preliminary injunction" based on patents that were not subject to immediate litigation once the notice of commercial marketing is provided. *Id.* § 262(*l*)(8)(B). This combination indicates that the function of the notice of commercial marketing is to permit the innovator to initiate a second phase of patent litigation once the scope of the FDA license is known and the marketing of the proposed biosimilar product is imminent, and to do so by a motion for a

preliminary injunction before the launch of the biosimilar causes irreparable injury.

The statutory requirement that a biosimilar product be "licensed" before the notice of commercial marketing follows directly from the notice's function as a trigger for a preliminary injunction motion. In general, a preliminary injunction will not be an option unless commercial launch is imminent. A preliminary injunction 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). To be entitled to a preliminary injunction, a plaintiff "must show that the injury complained of is of such imminence that there is a 'clear and present' need for relief to prevent irreparable harm." *Wis. Gas Co. v. FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985) (emphasis removed). The license requirement of subsection (A) ensures the imminence necessary to vindicate the right to move for a preliminary injunction under subsection (B).

The district court's reading of the BPCIA would sever section 262(*l*)(8)'s explicit linkage between the notice and the ability to bring a preliminary injunction motion. If, as the court concluded, a notice of commercial marketing could be provided at any time, biosimilar applicants could (and, based upon experience so far, would) effectively eliminate the right to seek a preliminary injunction upon receipt of the notice by providing a premature notice at a time when commercial launch is not imminent. Unable to seek injunctive relief during the 180-day period

following the notice, innovators would be left to guess when commercial marketing was actually going to begin and would lose the benefits of the notice period before commercial launch.

B. Subsection (A) Requires that a Notice of Commercial Marketing Relate to a "Licensed" Product

The language selected by Congress in subsection (A) of section 262(*l*)(8) makes its meaning clear. As Amgen demonstrates, subsection (A) states that a product must be "licensed" to be the subject of a notice of commercial marketing and this plain language should be enforced. 42 U.S.C. § 262(*l*)(8)(A); Amgen Br. 46-47. That was the conclusion of the only other district court expressly to address the issue. In *Sandoz*, the district court concluded that a biosimilar applicant "cannot, as a matter of law, have provided a 'notice of commercial marketing'" prior to obtaining a biological license because until that time the biosimilar "product is not 'licensed under subsection (k).'" 2013 U.S. Dist. LEXIS 161233, at *6.

The district court here rejected this conclusion – chiding the *Sandoz* court for "looking only to the language of the statute itself" – by reasoning that it "would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its 'first commercial marketing' a biosimilar must, in all instances, be a 'licensed' product." A13. It is true that a product must be licensed in order to be marketed, but it does not follow that an

unlicensed product must be called a licensed product whenever its future commercial marketing is being discussed.

On the contrary, when Congress wanted to refer to the future "commercial marketing" of a biological product that was not yet licensed, it used the precise formulation the district court considered "nonsensical." On multiple occasions in the BPCIA, Congress accurately refers to 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), (*l*)(3)(C) (emphasis added); *see also id*. § 262(*l*)(1)(D), (*l*)(3)(A)(i), (*l*)(7)(B) (similar).

Congress' use of the past form of the verb "license" in subsection (A) was advertent. If a product has not yet been "licensed under subsection (k)," a notice of commercial marketing is premature. *See, e.g.*, *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.").[10]

[10] *See also, e.g.*, *Sebelius v. Cloer*, 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).

C. Subsection (B) Confirms That a License is a Condition Precedent to a Notice of Commercial Marketing

The existence of a license as a condition precedent to notice is a necessary part of the structure of the statutory scheme. *See*, *e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (courts must interpret statutes "'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole'") (citations omitted). If, as the district court held, an FDA license were not a condition precedent to notice and a notice of commercial marketing could be served at any time, the statute would make no sense.

Under the district court's reading of the statute, the notice of commercial marketing would not advise the innovator of anything at all. The biosimilar applicant's aBLA, which must be supplied to the reference product sponsor within twenty days of FDA's acceptance of the aBLA for review, already notifies the innovator of the applicant's intention to begin commercial marketing if an FDA license is obtained. The provision of the aBLA triggers the first round of disclosures and permits the initial round of patent litigation, which would be pointless if the applicant did not intend to begin commercial marketing upon licensure. The notice of commercial marketing, in subsection (A) of section 262(*l*)(8), does not inform the innovator that the applicant intends to market its product one day, but rather that the commercial marketing of a licensed product is

imminent – as few as 180 days away. If the license requirement were read out of the statute, as the district court held, the notice of commercial marketing would not tell the innovator anything it did not already know.

Furthermore, subsection (B) of section 262(*l*)(8) makes it explicit that there must be a condition precedent to a notice of commercial marketing. Under subsection (B), receipt of a notice of commercial marketing allows the reference product sponsor immediately to move for injunctive relief on patents that were "included" on its list of patents for which a reasonable claim of patent infringement could be brought, but "not included" among the patents selected for immediate litigation in the immediate litigation phase. 42 U.S.C. § 262(*l*)(8)(B). But no list will exist on which patents are "included" or "not included" unless the applicant has first provided notice via its aBLA and the parties have gone through the statutory pre-litigation procedures. If a notice of commercial marketing could be provided before these procedures are complete, subsection (B) would be meaningless. It would include no patents at all.

Subsection (B) of section 262(*l*)(8) thus presupposes that a notice of commercial marketing under subsection (A) cannot be provided until *after* the information exchanges required by the BPCIA have occurred, and patents have been "included" or "not included" on the list for immediate litigation. In symmetry, subsection (A) specifies that a notice of commercial marketing cannot

be given at any time, but only after the biosimilar product is first "licensed" by the FDA.

D. The Requirement of Licensure Before a Notice of Commercial Marketing Ensures that the Nature of the Controversy Will Be Known

The requirement that a product be licensed before a notice of commercial marketing also ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. Until the aBLA is approved, many features of the proposed product remain unknown and subject to change, *e.g.*, approved uses, dosage regimen, or route of administration. Without that knowledge, there will be large numbers of patents whose relevance is unknown – because, *e.g.*, they cover indications that may or may not be approved,[11] or implicate processes that may or may not be used in the ultimate commercial product.[12] There may even be patents

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[11] For example, one of the patents at issue in the *Janssen Biotech* case is Janssen's U.S. Patent No. 7,223,396 ("the 396 patent"), which covers specific methods of using Remicade to treat Crohn's disease. Janssen alleges that the biosimilar applicants' proposed product will infringe the patent only if it is approved for such use. The applicants have applied for such an indication, but there is considerable doubt whether FDA will grant a license for Crohn's disease. In Canada, where the proposed product has already been approved, the health authorities did not approve an indication for Crohn's disease. If FDA were to take the same view, the 396 patent would not be infringed. A preliminary injunction motion before the scope of the license is known could be a waste of court and party resources.

[12] For example, in *Janssen Biotech*, Janssen has asserted three manufacturing patents, U.S. Patent Nos. 7,598,083, 6,900,056, and 6,773,600. Janssen alleges that, like Sandoz and contrary to the BPCIA, the Remicade biosimilar applicants

that will expire within 180 days of the license and that would not be litigated if the biosimilar must wait 180 days after license to launch.[13]

A proper construction of the notice provision allows the patent owner to determine 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. That is the opportunity that the BPCIA provided and that the district court's construction of the statute thwarts.

The allegations in the *Janssen Biotech* case provide concrete example of this issue. As Janssen alleges, because the proposed Remicade biosimilar product has not been approved, a motion for a preliminary injunction is premature, and

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refused to provide Janssen with information describing "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). Instead, they insisted that they would provide such information only if they were sued on these patents. Janssen has now instituted a patent infringement action, but defendants have not yet provided the manufacturing information. In light of the uncertainty about whether the manufacturing patents are infringed, a motion for a preliminary injunction is premature.

[13] For example, one patent at issue in the *Janssen Biotech* case is U.S. Patent No. 5,807,715 ("the 715 patent"), an early patent on methods of producing functional antibodies. Janssen alleges that it will expire on September 15, 2015 – less than 180 days from today. Yet, based on the meaningless notice provided to Janssen, the biosimilar may begin sales on August 4, 2015, an unlikely event since the product has not been licensed, but one that would cause Janssen irreparable harm. With a proper 180-day notice provided *after* FDA license, Janssen could drop the 715 patent.

possibly unnecessary, for *each* of Janssen's patents.[14] *Janssen Biotech* Br. 15-18. See notes 11-14 supra. A pre-license notice of commercial marketing is meaningless on the facts of Janssen's case. On the other hand, a proper notice after FDA license would provide Janssen with the protected six-month window in which to vindicate its rights in court.

E. Applying Section 262(*l*)(8) As Written Would Not Extend the Statutory Exclusivity Period

The district court here believed it necessary to read the requirement of an FDA license out of the BPCIA's notice provision in order to avoid adding an extra 180 days of market exclusivity onto the twelve years the BPCIA expressly provides. A13-14. This is incorrect. As Amgen points out, the 180-day notice provision applies only to a given biosimilar applicant and does not confer market exclusivity on the innovator. Amgen Br. 51-52.

In any event, the interaction of the twelve-year exclusivity provision and the 180-day notice is not at issue in this case because Amgen never did – and never will – receive twelve years of exclusivity under the BPCIA for Neupogen. For

[14] As a final example, one patent at issue in *Janssen Biotech* is U.S. Patent No. 6,284,471 ("the 471 patent"), which covers the Remicade antibody. Janssen alleges that the 471 patent is in reexamination at the PTO and its claims now stand rejected. But the reexamination is not over. Although Janssen believes the patent is valid, so long as there is uncertainty over its validity, Janssen will not be in a position to move for a preliminary injunction. But by the time the biosimilar product is approved, if it is, the 471 patent may have emerged from reexamination, and in that case Janssen would be able to seek an injunction prior to any launch.

older biologics like Neupogen and Remicade, which were on the market more than twelve years before the BPCIA was enacted, the BPCIA provides only a modest 180-day time period after approval of a biosimilar in which to adjudicate a potential preliminary injunction motion. For these products, there is no twelve years, let alone twelve and a half years, of non-patent exclusivity, as the district court wrongly concluded.

All that is at issue on this appeal is whether a notice of commercial marketing requires the biosimilar product to be "licensed," not whether the 180-day notice period runs consecutively with the statutory exclusivity period. If that question arises in a future case, it is far from clear that the 180-day notice period and the twelve-year statutory exclusivity period would run consecutively under a proper interpretation of the BPCIA. The better reading of the statute is that the two periods would typically run concurrently, since the statute allows for a license to be approved (although not made effective) while the marketing exclusivity is still in effect.[15] The biosimilar applicant, having obtained approval, would be able to

[15] During the statutory period of market exclusivity, "[a]pproval of a[] [biosimilar] application . . . may not be made effective," but FDA may approve the application, effective upon the expiration of the market exclusivity period. 42 U.S.C. § 262(k)(7)(A); *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). If the product is approved while the statutory exclusivity period is in effect, the condition precedent to a notice of

provide its notice of commercial marketing 180 days before the expiration of the twelve-year exclusivity period, and the notice provision would not delay commercial launch.

So construed, on a going-forward basis the 180-day period would delay commercial marketing only when the FDA, for one reason or another, does not issue any approval for a biosimilar applicant – tentative or otherwise – until after the twelve-year period has expired. In such cases, the 180-day notice period is the only protected window available to the innovator to avoid irreparable injury by litigating its patents before market launch. There is no basis in the statute to deny that modest protection to the innovator.

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

In a footnote, the district court stated even if Sandoz violated the notice of commercial marketing provision, the obligation that the applicant "shall" give notice was just another optional choice under the BPCIA, subjecting Sandoz only to the limitations on an declaratory judgment action in 42 U.S.C. § 262(*l*)(9)(B). A14. In fact, a prohibition on a declaratory judgment action is an all-but-meaningless penalty on a biosimilar maker that has elected to ignore the provisions of the BPCIA and launch at risk. The notice provision, like the other patent

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commercial marketing is met, and the market exclusivity and the 180-day notice period may run concurrently.

dispute resolution provisions discussed above, is mandatory and for the same reasons.

Moreover, the district court plainly has the power to enforce compliance with the notice provision. As demonstrated above, all of the BPCIA patent dispute resolution provisions are enforceable in court. But that conclusion applies with particular force to the notice provision. As noted, the notice provision is effectively a statutory 180-day injunction. It would defeat the purpose of this provision – and be directly contrary to its terms – if the biosimilar applicant could begin marketing during the 180-day period. Rather, the premise of the statute is that the innovator will be irreparably harmed if denied that 180-day period window after FDA license to bring a preliminary 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, 511 (7th Cir. 2005)).

As part of its power to protect its jurisdiction and supervise BPCIA patent litigation, a court can properly require compliance with the notice provision in

order to ensure that the preliminary injunction motion contemplated by the statute may be properly adjudicated, irreparable harm avoided and the status quo maintained. *See FTC v. Dean Foods Co*., 384 U.S. 597, 604 (1966) (All Writs Act creates "power to issue injunctions to preserve the status quo"); *Klay*, 376 F.3d at 1098 (courts may issue orders to "safeguard not only ongoing proceedings, but potential future proceedings") (footnote omitted). Otherwise, the court would be forced to decide preliminary injunction motions after a product is licensed on a truncated schedule not contemplated by Congress, dealing with unnecessary TRO's and other motion practice as the innovator attempts to protect itself from the irreparable injury of a market launch. There is no reason for a court to tolerate such an imposition on its jurisdiction by a biosimilar applicant seeking to avoid the 180-day litigation period for its own private benefit.

CONCLUSION

The district court's construction of the BPCIA should be reversed.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that I served a copy of the foregoing corrected *amicus* brief to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

Dated: April 14, 2015

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). The brief contains 6,843 words, as calculated by the word count of the word processing system used in preparing it, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The brief has been prepared in Microsoft Word 2010 in Times New Roman 14 point font.

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