No. 2015-1499

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* SUPPORTING DEFENDANT-APPELLEE AND AFFIRMANCE OF THE DISTRICT COURT'S DECISION

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April 21, 2015

CERTIFICATE OF INTEREST

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Federal Circuit Rules 29(a) and 47.4, Carlos Angulo, counsel for *amicus curiae* the Generic Pharmaceutical Association certifies the following:

1. The full name of every party or *amicus* represented by me is:

   The Generic Pharmaceutical Association

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   N/A

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

   None

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

   ZUCKERMAN SPAEDER LLP: Carlos T. Angulo

Dated: April 21, 2015

/s/ Carlos T. Angulo
Carlos T. Angulo

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INTEREST OF *AMICUS CURIAE*[1]

The Generic Pharmaceutical Association ("GPhA") is a nonprofit voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide Americans with generic drugs that are as safe and effective as their brand-name counterparts, but are substantially less expensive, accounting for roughly 86% of all prescriptions dispensed in the United States but only 27% of spending on prescriptions. In this way, the products sold by GPhA members save consumers over $200 billion on average each year. GPhA regularly participates in litigation as an *amicus curiae*, taking legal positions adopted by its Board of Directors.

Many GPhA members are currently developing "biosimilars," for which Congress established an expedited Food and Drug Administration ("FDA") approval pathway in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA").[2]

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[1] No counsel for any party authored this brief in whole or in part, and no person other than *amicus* and its members made a monetary contribution to the preparation or submission of this brief. All parties have consented to the filing of this brief.

[2] Pub. L. No. 111-148, §§ 7001 *et seq.*, 124 Stat. 119, 804 (2010). The BPCIA was part of the Affordable Care Act.

This case presents issues of first impression regarding the interpretation of certain of the BPCIA's patent dispute resolution provisions and is of critical importance to GPhA and its members, who have a strong interest in (1) seeing this Court construe the statutory language as Congress intended; (2) ensuring that the BPCIA is not used by the brand-name industry to stifle competition from biosimilars; and (3) affording biosimilar applicants the flexibility to address patent issues on a case-by-case basis, in the manner most likely to get affordable medicines to patients as quickly as possible.

INTRODUCTION AND BACKGROUND

GPhA supports the interpretation of the BPCIA successfully advanced in the district court by Defendant-Appellee Sandoz Inc. ("Sandoz") and opposes the contrary interpretation advanced by Plaintiffs-Appellants (collectively, "Amgen").

The context surrounding the BPCIA's enactment is critical to an understanding of the issues in this case. Congress enacted the BPCIA to create an expedited FDA approval pathway for, and speed consumer access to, "biosimilars," which are highly similar or interchangeable versions of FDA-licensed brand company biologic medicines (known in this context as "reference

products" and their licenseholders as "reference product sponsors").[3] Biologics are large-molecule medicines derived from living organisms; they are among the most expensive drug products in the United States and account for an increasing share of money spent in this country on prescription drugs.[4] On average, biologics cost $45 per day, as compared to $2 per day for traditional, small-molecule drugs.[5] Certain

[3] Reference products are licensed under section 351(a) of the Public Health Services Act ("PHSA"), 42 U.S.C. § 262(a). The expedited pathway for biosimilars was added by the BPCIA to the PHSA as section 351(k), 42 U.S.C. § 262(k).

[4] In 2010, spending on biologics was $67 billion, or approximately 20 percent of overall drug spending. IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010*, 4, 6 (Apr. 2011), *available at* http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf. By 2013, spending on biologics in the United States increased nearly 40 percent to $92 billion, or approximately 28 percent (also a 40 percent increase) of overall drug spending. Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry* 4 (Feb. 2015), *available at* http://www.matrixglobaladvisors.com/storage/MGA_biosimilars_2015_web.pdf.

[5] American Consumer Institute Center for Citizen Research ConsumerGram, *Lifesaving Drugs at Lower Costs*, 2 (July 2014), *available at* http://www.theamericanconsumer.org/2014/07/new-consumergram-lifesaving-drugs-at-lower-costs/.

biologics cost tens or even hundreds of thousands of dollars per patient per year.[6] The BPCIA's biosimilars approval pathway, which allows an applicant to rely on FDA's previous findings of safety and effectiveness for a reference product, serves the dual purposes of (1) reducing the costs of developing biosimilars (and therefore their prices); and (2) facilitating quicker FDA review, thus expediting market competition and consumers' access to affordable life-saving medicines.

Increased competition from affordable biosimilars holds the potential for enormous savings for the U.S. healthcare system.[7] In Europe, where biosimilars

[6] The branded biologic Humira®, which treats arthritis and other conditions and is made by Abbvie Inc, an *amicus* in this case on behalf of Amgen, costs $50,000/year. The branded biologic Cerezyme®, which treats Gaucher's Disease, costs $200,000/year. Erwin A. Blackstone and Joseph P. Fuhr, *Innovation and Competition: Will Biosimilars Succeed?*, Biotechnology Healthcare, 24-27 (Spring 2012), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351893/. *See also* Bill Berkrot, *U.S. Prescription Drug Spending Rose 13 Percent in 2014: IMS Report*, Reuters, Apr. 14, 2015, *available at* http://www.reuters.com/article/2015/04/14/us-health-spending-medicine-idUSKBN0N508I20150414 (noting that prescription drug price increases in 2014 were due in part to price increases on branded medicines, "particularly insulin products for diabetes," which are biologics),

[7] The analogous expedited approval pathway enacted by Congress for small-molecule generic drugs in the Hatch-Waxman amendments to the Federal Food, Drug and Cosmetic Act (Pub. L. No. 98-417, 98 Stat. 1585 (1984)) ("Hatch-Waxman") has been instrumental in successfully slashing prescription drug prices and healthcare costs. A recent study found that the use of generic drugs saved American consumers, taxpayers, federal and state governments and other payers $239 billion in 2013 alone and over $1.5 trillion between 2004 and 2013. IMS Health & Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, 2 (6th ed. 2014), *available at* http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf

have been marketed since 2004, savings from biosimilars through 2020 for three particular product classes have been estimated between €11.8 and €33.4 billion,[8] with additional savings expected as more biologics go off-patent and more biosimilars reach the market. In the United States, potential savings from biosimilars in California alone over the next decade are estimated to exceed $27 billion.[9]

ARGUMENT

The question here is whether the BPCIA's patent dispute resolution provisions should be interpreted according to the statute's clear structure, which in turn supports Congress's overarching goals of increased competition and consumer access to affordable biologics. The answer, as the district court found, is yes. The contrary readings advanced by Amgen and its *amici* depend on illogical, context-free interpretations of selected individual words that if read as Amgen suggests would render superfluous important sections of the BPCIA, undercut the statute's overarching purposes, and produce results that Congress could not possibly have intended.

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[8] Robert Haustein et al., *Saving Money in the European healthcare systems with biosimilars*, 1(3-4) Generics & Biosimilars Initiative J. 120-26 (2012), *available at* http://gabi-journal.net/saving-money-in-the-european-healthcare-systems-with-biosimilars.html.

[9] Sharon Frazee et al., *Ten-Year Potential Savings from Biosimilars in California*, 3 (Sept. 26, 2013), *available at* http://www.gphaonline.org/media/cms/Biosimilars_CA_white_paper_092613.pdf.

I. Congress Intended the BPCIA's Application-Sharing Provision, and its Patent Information Exchange Provisions in General, to be Non-Mandatory.

The BPCIA includes a patent dispute resolution process, codified at 42 U.S.C. § 262(l), that contemplates the exchange of patent-related information between a biosimilar applicant (hereafter, "applicant") and a reference product sponsor (hereafter, "sponsor"), the first step of which is the applicant's sharing of its application with the sponsor. 42 U.S.C. § 262(l)(2)(A). The question here is whether the BPCIA information exchange provisions, including the application-sharing provision, are mandatory. The answer is no.

a. The Information Exchange Provisions Are One Way, *But Not the Only Way*, of Resolving Patent Disputes under the BPCIA's Flexible Framework.

As the district court pointed out, and as the BPCIA's text and structure make crystal clear, the statute provides a flexible framework with several alternative approaches by which applicants and sponsors may address patent disputes. *See* A0004-05 ("Together, 42 U.S.C. § 262(l) and 35 U.S.C. § 271(e) reflect an integrated scheme that provides consequences for the choice each party makes at each step . . . ."). This clearly articulated legislative framework does not envision that an applicant will be forced to provide its application – which may include confidential development and manufacturing information and/or trade secrets − to the sponsor. Quite the contrary. In the BPCIA, Congress expressly envisioned

that an applicant might *not* share this information and clearly set forth the consequences of this choice. The framework, far from being "opaque" (*e.g.*, Corrected Brief for Abbvie Inc. as Amicus Curiae Supporting Plaintiffs-Appellants ("Abbvie Br.") 13), is quite transparent.

If the applicant provides its application to the sponsor and both sides otherwise participate in the BPCIA patent information exchange process, neither party may bring a declaratory judgment action against the other regarding patent validity, enforceability, or infringement until the applicant serves notice of intent to commercially market its product. 42 U.S.C. § 262(l)(9)(A).

But *if* the applicant does not provide its application to the sponsor, the sponsor – but not the applicant – may immediately bring an action 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. § 262(l)(9)(C). *See also* 42 U.S.C. § 262(l)(9)(B) (allowing the sponsor to bring a patent declaratory judgment action if the applicant chooses not to participate in any of the other information exchange provisions found in 42 U.S.C. § 262(l)). The BPCIA's amendments to the Patent Act confirm that Congress envisioned that an applicant might not share its application, providing that such a choice creates an act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii).

In short, sharing a biosimilar application with the sponsor provides the applicant with a safe harbor from immediate litigation; a decision not to share the application eliminates that safe harbor, with consequences that Congress clearly spelled out. These consequences do not include the remedy of an injunction requiring the applicant to participate in the information-sharing process, or any other penalty against the applicant for its choice not to participate – *e.g.*, restitution. Instead, Congress merely provided a *procedural* avenue that the sponsor may follow in the event of the applicant's choice – an avenue that, ironically, Amgen itself used in this case. This Court cannot read other consequences into the statute. *See Albright v. United States*, 10 F.3d 790, 794 (Fed. Cir. 1993) ("[W]here a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.") (citation and internal quotation marks omitted).[10]

Indeed, if sponsors could force applicants to share their applications, the BPCIA's provision for immediate patent litigation in the event that the applicant chooses *not* to share the application would become completely superfluous.

[10] Amgen's *amici* contend that "the district court's reading of the BPCIA is . . . contrary to the 'well-settled' principle that 'federal courts may use any available remedy' to enforce federal rights." *See, e.g.*, Corrected Brief for Amicus Curiae Janssen Biotech, Inc. in Support of Plaintiff-Appellants with Appendix ("Janssen Br.") 13 (citations omitted). But this argument presupposes, incorrectly, that the BPCIA's information exchange provisions created substantive "federal rights" to "enforce." They did not, and the procedural "remedy" that Congress chose – the option to initiate immediate patent litigation − is the only one available to Amgen.

Amgen's reading of the BPCIA therefore violates the cardinal rule of statutory construction that courts must "'give effect, if possible, to every clause and word of [the]statute.'" *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355 (Fed. Cir. 2003) (quoting *United States v. Menasche*, 348 U.S. 528, 538-39 (1955)). *See also Heinzelman v. Sec'y of Health & Human Servs.*, 681 F.3d 1374, 1379 (Fed. Cir. 2012) ("[W]e must give effect, if possible, to every clause and word of a statute and should avoid rendering any of the statutory text meaningless or as mere surplusage.") (citation and internal quotation marks omitted).

Amgen and its *amici* rely on the same canon of construction to support *their* interpretation of the BPCIA, arguing that if an applicant could merely refuse to share its application, courts would not be giving effect to the information-exchange provisions of 42 U.S.C. § 262(l). *See, e.g.*, Abbvie Br. 13 ("It is impossible to read subsection (l) from beginning to end and conclude that Congress went through all of that effort, provided all of those details, and considered all of the potential alternatives, only to conclude by saying in (l)(9): 'but do whatever you want.'") The flaw in this reasoning is that, as discussed *infra* section I.b, there are some situations in which an applicant *would* choose to avail itself of that information-exchange process, in which case a detailed exposition of that process is absolutely necessary, but there are other situations where it might choose not to do so. Congress's flexible, multi-layered approach covers both these possibilities, such

that neither provision in the statute is superfluous. Amgen's reading of the statute, by contrast, ensures that 42 U.S.C. § 262(l)(9)(C) would *never* come into play.

b. Requiring All Applicants to Participate in the Patent Information Exchange Would Frustrate the BPCIA's Overall Purposes and Produce Absurd Results.

Congress included a range of patent dispute resolution options in the BPCIA for a reason − this layered framework was the approach most suited to advancing the overall objective of the BPCIA of expediting access to affordable medicines. The District Court's interpretation of the BPCIA stays true to this purpose. Amgen's alternative interpretation, by contrast, would frustrate the BPCIA's objectives and produce absurd results that Congress clearly did not intend.

The goal of the patent provisions is to expedite disputes over patents that might be claimed to block the biosimilar, thereby (1) paving the way for more immediate competition in cases where those patents are found to be invalid, unenforceable, or not infringed, and, in any event, (2) providing the parties with greater certainty regarding the patent landscape facing a particular biosimilar, so that it can be marketed as quickly as possible.[11] Congress enacted the information exchange provisions in 42 U.S.C. § 262(l) because it anticipated that *in certain cases*, adherence to that process would serve these ends. For example, where there

[11] We address *infra* section I.d Amgen's claim that Congress intended the patent dispute provisions as a counterweight to the BPCIA's expedited biosimilar approval pathway.

is genuine uncertainty about the strength of patent protections asserted by the sponsor, an extensive exchange of patent-related information might clarify the parties' positions and help determine the earliest possible date on which a biosimilar can become available. *See* Non-Confidential Opening Brief for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited ("Amgen Br.") 30 (noting that through the patent information exchange provisions, "each party learns the other's detailed contentions regarding infringement, validity, and enforceability, and can make judgments about the litigation risks associated with each patent.").

But as the district court noted, and as Congress clearly recognized, there are other cases in which following these procedures might in fact *delay* resolution of the patent dispute, and where immediate litigation of this dispute, as provided for in 42 U.S.C. § 262(l)(9)(B) & (C), would best serve the BPCIA's overall goals. This is one such case. Here, Sandoz strongly believes that Amgen has no valid patents that could block Sandoz's biosimilar version of Neupogen and therefore concluded that the goal of access to Sandoz's product would best be served by immediate patent litigation, not by the information exchange contemplated in 42 U.S.C. § 262(l). Congress gave Sandoz and biosimilar applicants generally the right to make that judgment. As the district court carefully explained:

> Sandoz's decision not to comply with subsection (l) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords a [biosimilars] applicant many benefits: it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product launch to protect the investment it made in developing its biosimilar.
>
> *On the other hand*, subsection (l) lays out a process that could take up to 230 days – just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged in an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

A0011 (emphasis added).

Amgen and its *amici* are incorrect when they suggest that reading the information exchange provisions as non-mandatory will mean that no applicant will ever choose to engage in the information-sharing process. *See* Abbvie Br. 11 (noting that "[t]o the best of [its] knowledge, not a single [biosimilars] applicant to

date has complied with the notice-and-exchange process set forth in the BPCIA" and suggesting that there will never be "compliance" if the district court's decision is upheld). Only a handful of biosimilar applications have been filed to date, starting in late summer 2014, and the application in this case is the only one that has been approved by FDA. GPhA fully believes and expects that its members will often, in appropriate instances, choose to engage in the information-sharing process. At the same time, the fact that some applicants have already chosen not to share their applications demonstrates exactly why Congress chose to leave that option open in the BPCIA.

Requiring that the applicant adhere to the BPCIA information exchange procedures, even in cases where doing so would delay the resolution of patent disputes, would turn those procedures into ends unto themselves, rather than a means of advancing the BPCIA's overarching purposes. Moreover, this reading of the statute would produce the absurd results that an applicant would be required to share its application, containing confidential information and/or trade secrets, and engage in a time-consuming dispute resolution process *even where there are no disputes that need to be resolved*, for example where: (1) all relevant patents are expected to expire before FDA completes its review of the application; (2) all relevant patents will expire before the expiration of the 12-year statutory exclusivity period provided reference product sponsors under the BPCIA (42

U.S.C. § 262(k)(7)(A)); or, most absurdly, (3) there are no relevant, unexpired patents even at the time the application is submitted. Congress carefully structured the BPCIA to avoid these nonsensical results, which directly undercut the purposes of the statute. *See Heinzelman*, 681 F.3d at 1379 ("We are . . . mindful that we should 'avoid construing a statute in a way which yields an absurd result.'") (citation omitted)).

c. The Word "Shall" Cannot Bear the Weight that Amgen's Interpretation Places on it.

This Court has made clear that "[w]hen interpreting a statute, [it] will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute (or statutes on the same subject) and the objects and policy of the law, as indicated by its various provisions, and give it such construction as will carry into execution the will of the Legislature." *Warner-Lambert Co.*, 316 F.3d at 1355 (quoting *Kokoszka v. Belford*, 417 U.S. 642, 650 (1974)). *See also Deal v. United States*, 508 U.S. 129, 132 (1993) (noting the "fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used.") (citation omitted). Viewed against the clear structure and overall objectives of the BPCIA in general, and the information exchange provisions in particular, Amgen's reliance on a single word, "shall," to support its reading of the statute is thoroughly misplaced.

Even Amgen and its *amici* acknowledge that the word "shall" does not always denote a mandatory obligation. The most they can say, and the most the cases and other authorities say, is that it *generally* can have that meaning in certain circumstances and contexts. *See, e.g.*, Amgen Br. 37 (noting that "'[s]hall is, *generally*, mandatory language") (emphasis added and citing cases); Abbvie Br. 5 (citing *Gilda Indus., Inc. v. United States*, 446 F.3d 1271, 1282 (Fed. Cir. 2006) for the proposition that "[s]tatutory instructions using the term 'shall' are *ordinarily* treated as mandatory") (emphasis added)).

Here, however, where Congress has clearly specified as part of a complex and comprehensive regulatory framework exactly what consequences follow a biosimilar applicant's decision to forego the information exchange process, "shall" does not impose a mandatory obligation, as it might in other circumstances. Indeed, the courts often recognize that in particular contexts, "shall" can be read as non-mandatory. *E.g.*, *see Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n.9 (1995) ("Though 'shall' generally means 'must,' legal writers sometimes use . . . 'shall' to mean 'should,' 'will,' or even 'may.'") (citations omitted). And the BPCIA itself contains the word "shall" in several instances where it could not possibly be interpreted to impose a mandatory obligation. *See, e.g.*, 42 U.S.C. § 262(l)(6) (noting that sponsor "shall" bring a patent action after agreement on a patent list under the information exchange provisions, even though the option to

bring such an action clearly resides with the sponsor and may be unnecessary because of, for example, a licensing agreement between the parties).

The Supreme Court's treatment of "shall" in *Barnhart v. Peabody Coal Co.*, 537 U.S. 149 (2003), is particularly instructive in this regard. In that case, the majority of the Court held that language in the Coal Industry Retiree Health Benefit Act of 1992 ("CIRHBA") requiring that the Social Security Administration ("SSA") "shall" take certain actions before a certain date did not prevent the SSA from taking action after that date because the statute did not specify the consequences of inaction. *Id.* at 158-59. Justice Thomas' dissent took the position that the CIRHBA's use of "shall" was mandatory but then proceeded to explain exactly how Congress could have acted to deprive "shall" of its usual mandatory meaning: "If Congress desires for this Court to give 'shall' a non-mandatory meaning, *it must say so explicitly by specifying the consequences for noncompliance* or explicitly defining the term 'shall' to mean something other than a mandatory directive." *Id.* at 184-85 (Thomas, J., dissenting) (emphasis added).

In *Barnhart*, Congress had taken neither of the steps prescribed by Justice Thomas, leading him to conclude that the word "shall" should be given its usual meaning – even though the majority concluded that even where Congress specified no consequence, "shall" could be treated as non-mandatory. But in this case, Congress did exactly what Justice Thomas indicated it should do to "give 'shall' its

nonmandatory meaning," *id.* at 185, setting forth clear consequences for any applicant who chooses not to engage in the application-sharing process or the BPCIA's other patent information exchanges.

Finally, contrary to the position taken by the *amicus* Abbvie, the legislative history of the BPCIA in no way supports Amgen's reliance on the word "shall." Abbvie argues principally that because a 2007 bill (S. 623 in the 110th Congress) pertaining to what were then known as "follow-on biologics" made certain patent information exchanges optional, Congress's use several years later of "shall" in the BPCIA signifies a clear legislative intent to move to a mandatory information exchange system. Abbvie Br. 14-15. There are two problems with this analysis.

First, in general, legislation that did not pass an earlier Congress is not a guide to interpreting legislation that passed a later Congress. *See Red Lion Broad. Co. v. FCC*, 395 U.S.367, 381 n.11 (1969) ("[U]nsuccessful attempts at legislation are not the best of guides to legislative intent") (citations omitted); *Waterkeeper Alliance, Inc. v. EPA*, 399 F.3d 486, 508 (2d Cir. 2005) ("[P]rior legislative history is a hazardous basis for inferring the intent of a subsequent Congress.").

Second, as a matter of fact Congress did not, as Abbvie implies, simply change "may" to "shall" and leave everything else alone. Rather, S. 623, which was not even considered by a congressional committee, neither provides for the sharing of biosimilar applications nor specifies the consequences of not sharing

applications – it merely provides that the applicant has the option of providing notice of its application (not the application itself) to the sponsor "with respect to any one or more patents identified by the sponsor" in an earlier notification. S. 623, 110th Cong. § (3)(a)(2)(k)(17)(B). In short, Abbvie compares apples to oranges, and the use of "may" in the easily distinguishable context of S. 623 provides absolutely no evidence of what Congress intended in the BPCIA.

The language cited by Abbvie from the House Report on the BPCIA (Abbvie Br. 16) gets it no further. That language merely provides that under the BPCIA, *all* biological product applications (not just biosimilar applications) are governed by the provisions of the PHSA, not the drug approval provisions of the Federal Food, Drug, and Cosmetic Act (as were some biologics applications prior to enactment of the BPCIA). *See* H.R. Rep. No. 111-299, pt. 1, at 742 (2009) (noting that "*all* biological product applications would have to be submitted under the requirements of PHSA section 351" and that "[f]or the small number of biological products that have been approved under FFDCA section 505, the approved application would be deemed to be a license for the biological product under PHSA section 351 as of 10 years after the date of the enactment of this legislation.") (emphasis added). The House Report in no way addresses the provisions at issue here, much less suggests that Congress intended them to be mandatory.

d. Congress Did Not Intend the Patent Dispute Resolution Provisions to Benefit Reference Product Sponsors as a *Quid Pro Quo* for the Expedited Approval Pathway.

Amgen repeatedly alludes in its brief to Congress's intention to establish "a biosimilars pathway balancing innovation and consumer interests" (Amgen Br. 3, 20, 26 (quoting the BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804)), and argues that mandatory information-exchange requirements were Congress's way of "protect[ing] the public's interest in ensuring innovation and preserving the purpose of patents." Amgen Br. 4. *See also id.* at 5 (noting that requiring mandatory sharing of biosimilar applications preserves the BPCIA's "foundational interdependency between abbreviated approval and preservation of patent-protected innovation"). Amgen's efforts to link the BPCIA's patent information exchange provisions to the statute's pro-innovation goals are baseless.

As the district court noted, the BPCIA evinces no congressional intent to enhance sponsors' substantive rights through the patent information exchange provisions. A0010 ("[W]hile Amgen contends persuasively that use of subsection (l)'s procedures can serve important public interests . . . , nowhere does the statute evidence Congressional intent to enhance innovators' substantive rights."). As discussed *supra* section I.b, these provisions provide a procedural mechanism designed to advance the statute's general pro-competition purposes by allowing for the efficient resolution of patent disputes. They are not in and of themselves

intended to confer new rights on sponsors to balance the benefits afforded applicants under the statute.

To the extent Congress sought to achieve the balance between innovation and competition that Amgen describes, it did so by providing sponsors with additional statutory exclusivity periods during which FDA cannot approve and/or consider a biosimilar application. *See* 42 U.S.C. § 262(k)(7)(A). (FDA may not approve a biosimilar application until 12 years after the licensure of the reference product); 42 U.S.C. § 262(k)(7)(B) (FDA may not accept a biosimilar application until four years after such licensure); 42 U.S.C. § 262(m)(2)(A) (adding an additional six-month exclusivity period to the 12- and four-year exclusivity periods if the sponsor conducts certain pediatric studies.) Although Amgen studiously avoids mentioning them, these straightforward intellectual property protections – not mandatory access to an applicant's confidential manufacturing and development information and/or trade secrets − are commonly recognized as the *quid pro quo* for the BPCIA's expedited approval pathway and as Congress's chosen way of encouraging sponsors to continue innovating. *See, e.g.*, Thomas M. Burton, *Biosimilar Drugs Face U.S. Test: FDA Panel Will Decide Whether to Recommend Approval*," Wall Street J., Jan. 6, 2015, *available at* http://www.wsj.com/articles/biosimilar-drugs-face-u-s-test-1420590926 ("The 2010 Affordable Care Act created an abbreviated pathway for

biosimilars to enter the U.S. market . . . . *As a tradeoff for the industry, the law gave biologic drugs a 12-year period of exclusivity that protected them from competition from a biosimilar*.") (emphasis added).

In any event, Amgen fails to explain how its rights or Congress's desire to encourage innovation would be jeopardized under the district court's reading of the patent information exchange provisions. If an applicant chooses not to share its application with the sponsor, or otherwise chooses not to participate in the information exchange process after it begins, the sponsor may immediately bring litigation against the applicant regarding "any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(l)(9)(B), 42 U.S.C. § 262(l)(9)(C). This procedural option provides the sponsor with immediate recourse where the sponsor believes any such patent to exist (while depriving the applicant of the benefit of patent resolution certainty prior to FDA's approval and the applicant's launch of its product) and enables it to receive the application at issue through discovery. Thus, the patent provisions of the BPCIA fully protect sponsors' rights by affording them procedural avenues to protect those rights, but *not* by gifting them an additional entitlement.

II. The BPCIA Does Not Require that an Applicant's Notice of Commercial Marketing Be Sent After the Product is Licensed.

The BPCIA requires an applicant to "provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing

of the biological product licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A). Amgen's reading of this requirement is that such notice can *only* be given *after* the application has been approved and that Sandoz acted prematurely when it provided notice the day after FDA accepted its application. The district court rejected this argument, and so too should this Court.

a. Under the Plain Language of the Notice Provisions, the Word "Licensed" Describes the Product to Be Marketed, Not the Timing of the Notice.

Once again, Amgen's entire argument hinges on a single word – this time, "licensed." Amgen claims that because the statute refers to notice of intent to commercially market a biosimilar that has already been "licensed," the notice itself can only be given after licensure. Amgen Br. 46. But the plain meaning of the statute, as found by the district court, is that the past-tense "licensed" is used because the right to commercially market a product would only exist if the product were already "licensed" by FDA. The statute merely provides for notice by an applicant that it intends to market its product *after* (and *if*) the product has been "licensed" by FDA. "Licensed" relates to the product to be marketed, not to the timing of notice.

This straightforward reading disposes of Amgen's claim that Congress's use elsewhere in the BPCIA of "the biological product that is the subject of the application under subsection (k)," instead of "the biological product licensed under

subsection (k)," supports Amgen's interpretation of the notice provisions. Amgen. Br. 46 (citing, *inter alia*, 42 U.S.C. § 262(l)(1)(D)). As the district court pointed out, Congress referred to "licensed" products in the notice provision, instead of to products that were "subject[s] of an application" because a biosimilar that is merely the "subject of an application" *cannot be* commercially marketed. A0013 ("It would be nonsensical for [the notice provision] 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. 'Before' modifies 'first commercial marketing'; 'licensed' refers only to 'biological product' – not the appropriate time for notice.") (emphasis added).[12]

[12] As the district court in this case noted, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904 MMC, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013), *aff'd*, 773 F.3d 1274 (Fed. Cir. 2014), offers Amgen no assistance. In that case, involving a different product from the one at issue here, the district court's two-page dismissal of Sandoz's claim for a declaratory judgment of patent non-infringement/invalidity/unenforceability merely addressed the notice issue in dicta, without any briefing on the issue by the parties, any substantive analysis of the statutory language much less its context or purpose, or any sense of the dramatic implications of its interpretation. And this Court's affirmance of the district court's decision on standing grounds, which expressly declined to interpret any of the information-sharing provisions of the BPCIA, gets Amgen and its *amici* no further. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1275 (Fed. Cir. 2014) ("We do not address the district court's interpretation of the BPCIA."). *See* A0012-13 (noting that *Sandoz* decisions carried "little persuasive authority over the present dispute.")

b. Amgen's Reading of the Notice Provisions Would Confer Benefits on Sponsors that Congress Clearly Did Not Intend.

Amgen's reading of the notice provisions, in addition to being illogical on its face, produces results that Congress clearly did not intend and that would frustrate the overall statutory goal of expediting access to affordable medicines. *Warner-Lambert Co.*, 316 F.3d at 1355 ("When interpreting a statute, [a] court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute (or statutes on the same subject) and the objects and policy of the law, as indicated by its various provisions, and give it such construction as will carry into execution the will of the Legislature.") (citation and internal quotation marks omitted).

The purpose of the notice provisions is to give sponsors enough advance warning of the applicant's intent to commercially market the biosimilar that the sponsor has time to try to enjoin such marketing in connection with patents that were not included on any patent list filed in connection with the information exchange process. This objective can be met in different ways depending on the context. Where 12-year exclusivity will expire sometime after the FDA review process is expected to be complete, then it may make sense for notice to be issued *at or around the time* of approval, since the approval would not signal that the product can be launched. But where, as in this case, exclusivity has already expired or is about to expire at the time FDA review is complete, such that product

launch can immediately follow FDA review, it makes sense for the applicant, as Sandoz did here, to issue notice *well before* approval, so that litigation can conclude in time to allow the product to be launched when FDA approves it. In either situation, the purpose of the notice provision – and the statute's overarching goal of expeditious patent dispute resolution − is served as long as the applicant notifies the sponsor no less than 180 days before the biosimilar is marketed, which Sandoz indisputably did here. Amgen seems to argue, ironically, that it received *too much* notice, but Congress quite clearly did not see this as a problem.

As in the context of the information-sharing provisions, Amgen seeks to convert a procedural provision into a direct entitlement – this time, to an additional and automatic 180 days of freedom from competition from an FDA-licensed biosimilar. This interpretation of the statute, however, would produce two related results that cannot be squared with Congress's intent.

i. Congress Did Not Intend to Use the Notice Provisions to Grant Sponsors an Automatic Six-Month Preliminary Injunction Blocking the Marketing of an FDA-Licensed Biosimilar.

Amgen's interpretation of the notice provisions would, by the admission of its supporting *amici*, effectively grant sponsors an automatic six-month preliminary injunction against commercial marketing of an FDA-licensed biosimilar. *See, e.g.*, Janssen Br. 17 ("[The notice provision] provides, in effect, a *statutory* 180-day injunction in which to litigate before launch.") (emphasis added). A preliminary

injunction "is a drastic and extraordinary remedy that is not to be routinely granted," *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (citations omitted), and generally requires that the movant show (1) likelihood of success on the merits; (2) irreparable harm from the lack of an injunction; (3) that the balance of hardships tips toward the movant; and (4) that the public interest favors an injunction. *See, e.g.*, *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994). *See also, e.g.*, *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.3d 384, 388 (Fed. Cir. 1987) (noting that "[t]he burden is always on the movant to show entitlement to a preliminary injunction."). There is nothing to suggest that Congress intended through the notice provision to relieve sponsors of the usual heavy burden accompanying a request for a preliminary injunction.

Indeed, if Congress had intended for notice to be allowed only after licensure of a biosimilar and to trigger an automatic 180-day injunction, it would have provided in the notice provisions that FDA's licensure of a biosimilar application "shall be made effective upon the expiration of 180 days from the receipt of the notice." This is the language Congress used in Hatch-Waxman to establish a 30-month automatic stay of FDA approval of a small-molecule generic drug application (known as an "ANDA") while patent litigation ensued. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Congress's choice not to use that language here is a

clear sign that it did not intend to create a new "statutory injunction." *See, e.g.*, *Central Bank of Denver N.A. v. First Interstate Bank of Denver N.A.*, 511 U.S. 164, 176 (1994) (holding that Congress did not intend to impose aiding and abetting liability under the Securities Exchange Act of 1934 and relying on statutes that use the words "aid" and "abet" to reason that "Congress knew how to impose aiding and abetting liability when it chose to do so.") (citation omitted).

ii. Congress Did Not Intend for the Notice Provisions to Add Six Months to the 12-Year Statutory Exclusivity Period.

As the district court pointed out, another effect of Amgen's reading of the notice provisions would be to extend the 12-year statutory exclusivity period conferred on sponsors by the BPCIA (42 U.S.C. § 262(k)(7)(A)) to 12 years *and six months*. A0013.

Again, this cannot possibly be what Congress intended. The 12-year exclusivity period was indisputably a central component of the overall compromise struck by Congress in the BPCIA between innovation and competition. *See supra* section 1.d. Moreover, negotiations over the length of the exclusivity period were particularly hard-fought, with sponsors prevailing over the Federal Trade Commission, the Obama administration, and others who argued that a much

shorter exclusivity period was appropriate.[13] It defies logic to suggest that Congress intended to undercut the BPCIA's delicate balance by *de facto* extending the 12-year exclusivity period, and further delaying patients' access to affordable medicines, through the indirect means of the notice provisions. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes.") (citations omitted).

Ironically, even the *amici* supporting Amgen concede that "a biosimilar would want to be able to launch immediately on the expiration of the exclusivity period." *See* Brief of Amicus Curiae Biotechnology Industry Organization in Support of Reversal or Remand 6. And of course, by its very definition and as Congress intended, the 12-year exclusivity period should operate to prevent a biosimilar's launch for only that length of time, *and no more*. Yet Amgen's reading of the statute would frustrate this objective by making the end of the exclusivity period an essentially meaningless event, and the end of the notice

[13] *See generally* Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 787-91 (2010) (describing FTC and Obama Administration views on exclusivity period, and the industry response thereto); *id.* at 816-17 (noting that the exclusivity provisions were "vetted exhaustively" and were the product of "a genuinely bipartisan Member-level compromise.")

period the true relevant trigger for marketing. Congress clearly did not intend this result.[14]

CONCLUSION

For the foregoing reasons, this Court should affirm the decision below.

Respectfully submitted,

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[14] The fact that Amgen is itself not entitled to additional exclusivity is beside the point, since its reading of the statute is of course not limited to its own case and would clearly extend by 180 days any exclusivity award that in other cases blocks FDA licensure.

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 6,740 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ Carlos T. Angulo
Carlos T. Angulo

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of April, 2015, I electronically filed the foregoing **BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* SUPPORTING DEFENDANT-APPELLEE AND AFFIRMANCE OF THE DISTRICT COURT'S DECISION** with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system in this case.

/s/ Carlos T. Angulo
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