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

[PROPOSED] BRIEF FOR THE BIOSIMILARS COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR REHEARING EN BANC BY DEFENDANT-APPELLEE SANDOZ INC.

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September 3, 2015

CERTIFICATE OF INTEREST

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

   The Biosimilars Council. The Biosimilars Council is a division of the Generic Pharmaceutical Association ("GPhA").

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: September 3, 2015

/s/ Carlos T. Angulo
Carlos T. Angulo

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INTEREST OF *AMICUS CURIAE*[1]

The Biosimilars Council, a division of the Generic Pharmaceutical Association ("GPhA"), consists of companies and other stakeholders focused on issues relating to biosimilars, which are highly similar or interchangeable versions of Food and Drug Administration ("FDA")-licensed "reference product" branded biologic medicines. Congress established an expedited FDA approval pathway for biosimilars in the 2010 Biologics Price Competition and Innovation Act ("BPCIA") in order to reduce the costs of, and expedite patient access to, biologic medicines, which are among the most expensive drugs in the United States and account for an increasing share of our prescription drug costs. GPhA Amicus Br. n.4. Competition from biosimilars could lead to enormous savings for our healthcare system. *See id.* 5 & n.8 (projecting savings from biosimilars in Europe), & n.9 (projecting savings from biosimilars in California).

Amicus has an interest in ensuring courts' fidelity to the BPCIA's pro-consumer, pro-competition goals, and that patients have the quickest possible access to biosimilars. It therefore supports the petition for en banc review filed by Defendant-Appellee Sandoz Inc., agreeing with Sandoz that the panel incorrectly concluded that biosimilars applicants cannot provide 180-day notice of commercial marketing under BPCIA section (l)(8)(A) until *after* FDA licensure. The panel's

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

incorrect reading of (l)(8)(A) converts notice into the trigger for an automatic six-month injunction against the marketing of a licensed biosimilar, *sub silentio* extending to 12 ½ years Congress's carefully crafted 12-year reference product exclusivity. This automatic, extra-statutory delay, if left uncorrected, would broadly undercut Congress's goal of greater competition in biologics markets and dramatically reduce savings to the U.S. healthcare system from biosimilars. This Court en banc must correct a reading of the BPCIA that Congress could not have intended and that will delay millions of patients' access to needed treatments.

BACKGROUND

Under the BPCIA, a biosimilars applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the [biosimilar] licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A). This provision is part of the statutory web Congress enacted in BPCIA subsection (l) to expedite resolution of patent disputes between biosimilars applicants and reference product sponsors. One of roles of the notice provision in this web is to trigger the sponsor's right to seek a preliminary injunction against the applicant related to patents not part of earlier litigation under subsection (l)(6). 42 U.S.C. § 262(l)(8)(B). Notice may also allow the sponsor to bring a declaratory judgment action based on the applicant's "artificial infringement" of any of the sponsor's patents. 42 U.S.C. § 262(l)(9).

The issue before the panel relating to the notice provision was: *when* can a biosimilars applicant first give the 180-day notice. A majority of the panel, reversing the district court, held that notice under (l)(8)(A) must occur *after* FDA licenses the biosimilar. Slip. op. 15-21 (July 21, 2015). This holding is incorrect and if left unaltered would broadly undercut the BPCIA's overarching purposes in a manner Congress could not possibly have intended.

ARGUMENT

I. The Statute's Plain Language Permits Notice Before FDA Licensure.

The clear meaning of 42 U.S.C. § 262(l)(8)(A) is that notice provided under that subsection must occur *at least* six months "before the date of the first commercial marketing" of the relevant biosimilar, without limiting when notice can *first* be given. However, the majority effectively rewrote this straightforward notice requirement to dictate both the earliest *and* the latest possible time for notice. This error rested on the majority's incorrect interpretation of the phrase "the biological product licensed under subsection (k)." The majority reasoned that because (l)(8)(A) required notice before commercial marketing of *licensed* products, *notice itself* could only be given after licensure. *Id. at* 16-17. The majority explained that because BPCIA subsection (l) refers elsewhere to "the biological product that is the subject of" a biosimilars application, rather than to the "licensed" product, (*e.g.*, 42 U.S.C. § 262(l)(3)(B)(ii)(I), 42 U.S.C.

§ 262(l)(3)(C)), Congress's use of the latter term evinced an intent that licensure predate notice. Slip. op. 17.

The panel's reading is incorrect because the word "licensed" is clearly intended to modify "the product" that is *the subject* of notice and not to circumscribe *the timing* of notice. Congress used the past-tense "licensed" because the right to commercially market a product, regardless of when notice is given, only exists after FDA licensure. In other words, the statute simply provides for notice that the applicant intends to market its product *once it has been* "licensed," not to limit the earliest date notice can be provided. This is the reading adopted by the district court in this case (A12-14), and it is correct.

This straightforward reading also addresses the panel's concern that Congress did not use a different BPCIA formulation, "the biological product that is the subject of the application under subsection (k)," in the notice provision. A biosimilar that is merely the "subject of [an] application" *cannot be* commercially marketed. As the district court pointed out, "[i]t 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." A13 (emphasis added).

Of course, in analyzing statutory language, courts cannot look at the text in a vacuum, but must interpret it to reflect the overall purposes of the statute and to

avoid results contrary to those purposes. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355 (Fed. Cir. 2003) (noting that courts interpreting statutes "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 . . . and the objects and policy of the law, as indicated by its various provisions, and give it such a construction as will carry into execution the will of the Legislature.") (citation omitted). The district court's reading of (l)(8)(A) squares with the BPCIA's "objects and policy" and avoids results contrary to the statute's purpose. The majority's reading, conversely, undercuts the statutory structure and purposes, producing results that Congress could not have possibly intended.

II. Congress Did Not Intend for Notice to Trigger an *Automatic* Six-Month Injunction Against Marketing of FDA-Licensed Biosimilars.

The majority's holding that any notice of commercial marketing must follow FDA licensure gives reference product sponsors "an inherent right to an automatic 180-day injunction" blocking access to approved biosimilars. Slip. op. 44 (Chen, J., dissenting). Congress did not intend this extreme and absolute result.

A preliminary injunction "is a drastic and extraordinary remedy that is not to be routinely granted," *Intel Corp. v. ULSI System Technology, 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 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 demonstrate entitlement to preliminary relief."); *eBay Inc. v. MercExchange*, 547 U.S. 388, 392-93 (2006) (emphasizing that the Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation) (citations omitted). Nothing suggests that Congress intended through the notice provision to take the extraordinary step, *sub silentio*, of relieving sponsors of the usual heavy burden accompanying a request for a preliminary injunction.

Indeed, in BPCIA subsection (l)(8) itself, Congress expressly provided that the (l)(8)(A) notice triggers the reference product sponsor's right to *seek—not* automatically obtain—a preliminary injunction based on patents not already the subject of litigation under subsection (l)(6). 42 U.S.C. § 262(l)(8)(B). Under this approach, a reference product sponsor cannot obtain an injunction without the usual showing of, *inter alia*, a likelihood of success on the merits of its infringement claim. Congress, having expressly employed the traditional approach to preliminary injunctions in (l)(8)(B), could not have intended at the same time to use the notice provision in (l)(8)(A) as an end-run around those same principles.

Had Congress wanted notice to create an automatic 180-day injunction, it "understood how to do so." Slip op. 44 (Chen, J., dissenting). As part of the Hatch-Waxman expedited approval regime for small-molecule generic drugs, Congress enacted a 30-month automatic stay of FDA approval of generic drug applications during patent litigation, providing that approval "shall be made effective upon the expiration of" the 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii). Congress could have used similar language in (l)(8)(A), providing that FDA licensure "shall be made effective upon the expiration of" the notice period, but chose not to do so, a clear signal that, unlike in Hatch-Waxman, it did not intend to create a new statutory injunction. *Cen. Bank of Denver N.A. v. First Interstate Bank of Denver N.A.*, 511 U.S. 164, 176 (1994) (Congress did not impose aiding and abetting liability under the Securities Exchange Act and its use of "aid" and "abet" in other statutes showed that "Congress knew how to impose aiding and abetting liability when it chose to do so.") (citations omitted)).

III. Congress Did Not Intend for the Notice Provisions to Extend the 12-Year Reference Product Sponsor Exclusivity Period to 12 ½ years.

The majority not only grafted onto the BPCIA an automatic injunctive remedy unintended by Congress. It also compounded its error by replacing what Congress *had* expressly done, effectively interpreting notice to extend the 12-year exclusivity expressly conferred on sponsors in section (k)(7)(A) (42 U.S.C. § 262(k)(7)(A)) to 12 years *and six months*. Slip Op. 37 (Chen, J., dissenting)

(noting that majority has given Amgen "an extra-statutory exclusivity windfall.") Again, this cannot be what Congress intended. Twelve-year exclusivity was a key component of the overall BPCIA balance struck by Congress between innovation and competition. Negotiations over the length of the exclusivity were particularly hard-fought, with sponsors prevailing over the Federal Trade Commission, the Obama administration, and others who sought a shorter period. GPhA Amicus Br. 27-28 & n.13. Congress cannot have intended to disrupt the BPCIA's delicate exclusivity compromise, or to further delay patients' access to needed 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).

The majority suggests that its reading of (l)(8)(A) "does not necessarily conflict with" 12-year exclusivity where, unlike in Sandoz's case, the exclusivity runs concurrent with FDA review of the biosimilars application. Slip op. 18 (noting that the "extra 180 days will not likely be the usual case, as [biosimilars applications] will often be filed during the 12-year exclusivity period"). But even when FDA review is concurrent with exclusivity, *FDA cannot license a biosimilar until after the exclusivity expires*. FDA, *Guidance for Industry: Reference Product*

Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act 2 (Aug. 2014). Under the majority's reading of (l)(8)(A), notice *must* follow licensure. And because licensure *must* follow the exclusivity, the majority's holding means that notice by definition *must* follow expiration of the 12-year period exclusivity, and operates to extend that period, in the case of *every licensed biosimilar* for which notice is given, regardless of when exclusivity runs.

IV. Congress Intended the Notice Provision, as Part of Subsection (l), to Expedite, Not Delay, the Resolution of Patent Disputes.

The (l)(8)(A) notice provision is "part and parcel of the integrated litigation management process contemplated in" subsection (l) as a whole. Slip. op. 37 (Chen, J., dissenting). Subsection (l)'s basic purpose is to expedite resolution of patent disputes between sponsors and biosimilars applicants *before* FDA is prepared to license the biosimilar, to serve the overall BPCIA goal of speeding patient access to affordable medicines. *Id.* at 38 (noting that subsection (l) is designed to "lead[] up to [ ] expected patent infringement suit that comes *during the pendency of* a [biosimilars] application" (emphasis added)). The majority's reading of (l)(8)(A), however, frustrates the purpose of subsection (l) and the statute as a whole by delaying the onset of patent litigation until *after* FDA licensure of the relevant biosimilar and reducing the period available to the parties to resolve patent disputes after the filing of an application.

The majority justifies its reading of (l)(8)(A) on the grounds that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." *Id.* at 17. But the majority misses the point that the entire subsection (l) framework is premised on resolution of patent disputes before, and is in no way predicated on, FDA licensure. *Id.* at 39 (Chen, J., dissenting) ("Importantly, subsection (l) does not relate to the FDA approval process (for that see subsection (k)."). No other provision of subsection (l) is triggered by FDA licensure, and there is no reason why (l)(8)(A) should be read differently, outside the context of subsection (l) generally, and of the statute's overarching goals.

CONCLUSION

The Court should rehear en banc, and reverse the panel decision on, the "notice of commercial marketing" issue.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of September, 2015, I electronically filed the foregoing **[PROPOSED] BRIEF FOR THE BIOSIMILARS COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR REHEARING EN BANC BY DEFENDANT-APPELLEE SANDOZ INC.** 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
Carlos T. Angulo