No. 2015-1499

In the United States Court of Appeals for the Federal Circuit

AMGEN, INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California, Case No. 3:14-cv-04741-RS.
The Honorable **Richard Seeborg**, Judge Presiding.

BRIEF OF *AMICUS CURIAE* MYLAN INC. IN SUPPORT OF DEFENDANT-APPELLEE'S PETITION FOR REHEARING *EN BANC*

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1. The full name of every party represented by me is: Mylan Inc.

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: None.

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

   Mylan Inc. is indirectly wholly owned by Mylan N.V., a publicly-held company. Abbott Laboratories, a publicly-held company, owns more than 10% of Mylan N.V.'s stock through wholly-owned subsidiaries.

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

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INTEREST OF *AMICUS CURIAE*[1]

Mylan Inc. ("Mylan") is a global pharmaceutical company and one of the world's leading generics and specialty pharmaceutical companies. Mylan, through its subsidiaries, has filed hundreds of approved Abbreviated New Drug Applications for generic small-molecule drugs, and offers a growing portfolio of around 1,400 generic pharmaceuticals and several brand medications. With sales in approximately 145 countries and territories, Mylan, through its subsidiaries, is dedicated to providing greater access to high-quality, lower-priced medicines.

Mylan, through its subsidiaries, also has a robust pipeline of biologic products in development, both for the global marketplace and to be submitted for licensure in the United States as biosimilar products under the Biologics Price Competition and Innovation Act ("BPCIA"). Mylan, through its subsidiaries, is committed to providing patients expanded, *and timely*, access to high-quality and affordable biopharmaceuticals.

Mylan thus has a significant interest in the proper interpretation and application of the BPCIA, including ensuring that the BPCIA is not misinterpreted to extend reference product monopolies contrary to Congressional intent, thereby delaying competition and consumer access to less expensive medicines.

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

I. ARGUMENT SUPPORTING REHEARING EN BANC.

Mylan fully supports Defendant-Appellee Sandoz Inc.'s ("Sandoz") Petition for Rehearing En Banc on the interpretation of the BPCIA's pre-marketing notice provision (42 U.S.C. § 262(l)(8)(A)). Rehearing and reversal are necessary to correct the holding by the fragmented panel's majority that notice, when provided, must come after the biosimilar is licensed by the FDA.

The majority's interpretation distorts the statutory scheme, contradicts the plain language, and would produce "real world" outcomes contrary to Congress' intent. The consequences cannot be overstated: the majority interpretation would necessarily, in every case where notice is provided, extend the reference product's monopoly six months past the 12-year market exclusivity Congress granted. *See* 42 U.S.C. § 262(k)(7)(A). This exclusivity extension, implied from a simple notice provision, disrupts the statutory bargain and improperly delays competition.

Absent rehearing and reversal, patients in need of high-quality, lower-priced biosimilars will be denied access for at least six months longer than Congress intended. This extra-statutory delay would significantly harm consumers and give the brands an economic windfall. The full court should grant Sandoz's petition, and reverse the panel's interpretation of Section 262(l)(8)(A).

A. The Majority Has Improperly Converted a Notice Provision into an Automatic Stay and Exclusivity Windfall.

The majority's interpretation of Section 262(l)(8)(A) reads a simple notice provision as silently extending the statutory market exclusivity for 180 days, or automatically granting a 180-day preliminary injunction against the biosimilar sponsor with no consideration of the merits or equities.

The majority opinion asserts "that [the] extra 180 days will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period . . . ." Opinion at 18. But this statement misunderstands the statute. Under the majority, the effective 180-day extension of market exclusivity would flow inevitably from the plain statutory language barring licensure of any biosimilar until 12 years after the reference product was licensed. *See* 42 U.S.C. § 262(k)(7)(A). FDA interprets this exclusivity provision to mean exactly what it says. *See* U.S. FOOD & DRUG ADMIN., REFERENCE PRODUCT EXCLUSIVITY FOR BIOLOGICAL PRODUCTS FILED UNDER SECTION 351(A) OF THE PHS ACT: DRAFT GUIDANCE at 2 (Aug. 2014) ([42 U.S.C. § 262(k)(7)] states a "period of time in which . . . ***FDA is not permitted to license*** a 351(k) [biosimilar] application . . .") (emphasis added). Because licensure cannot occur until this exclusivity expires, requiring notification *after* licensure effectively extends the market exclusivity.

Both opinions concurring- and dissenting-in-part recognize this outcome, respectively calling this result an automatic "180-day stay of commercial

marketing" (Newman, J., concurrence at 2) or "an extra-statutory exclusivity windfall." Chen, J., dissent at 2. Whatever you call it, the majority interpretation disrupts the BPCIA's complex and careful statutory bargain. Congress granted reference products 12 years of exclusivity regardless of patent protection, in exchange for the biosimilar applicant's reliance on the reference product sponsor's ("RPS") safety and efficacy data. *See* 42 U.S.C. § 262(k)(7)(A). When Congress wanted a longer exclusivity period, it *expressly* granted one. *See, e.g.*, 42 U.S.C. § 262(m)(2)(A) (granting "12 years and six months" of non-patent exclusivity to sponsors providing pediatric data).

Therefore, a court may not properly assume Congress intended to silently extend the statutory exclusivity period through a simple notice provision. "Congress . . . 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." *Whitman v. Am. Trucking Ass'ns.*, 531 U.S. 457, 468 (2001). Calling the delay an automatic "180 day stay of commercial marketing" does not change the legal or practical result. Congress knows how to enact automatic stay provisions when it chooses. *See, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) (thirty month stay provision of the Hatch-Waxman Act). It did not do so here—the BPCIA has no such automatic stay. By its express terms, Section 262(l)(8)(A) is a notice provision, not a covert automatic stay or exclusivity extension.

B. Section 262(l)(8)(A) Does Not Limit When Notice Can First Be Given.

The majority's interpretation of the pre-marketing notice provision lacks foundation in the text, and reads Section 262(l)(8)(A) out of context.

1. The Majority's Reading Contradicts the Plain Language.

When interpreting a statute, the Court must "look first to its language, giving the words used their ordinary meaning." *Levin v. United States*, 133 S. Ct. 1224, 1231 (2013). Here, the stautory language contains no qualification on the pre-marketing notice save "[t]he subsection (k) applicant shall provide notice . . . ***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) (emphasis added). The plain language of the BPCIA thus supports Sandoz's reading that pre-marketing notice may come prior to licensure. To find otherwise, the majority dismissed one key word ("applicant") while reading another word ("licensed") out of its statutory context. *See* Opinion at 15-18.

Notably, Section 262(l)(8) refers to an "applicant" when discussing the pre-market notification. This intentional use of the word "applicant" is consistent with Sandoz's position, and inconsistent with the majority opinion, because it indicates that the notification may be sent while the application remains pending. After licensure, the "applicant" is an "applicant" no longer; that company is the sponsor, or holder, of a licensed biosimilar product. "[C]ourts must presume that a

legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). So the Court must presume "applicant" means "applicant."

Similarly, the Court must presume that "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)" also means what it says. *See id.* The natural reading of the word "licensed" in that sentence describes the necessary state of the product when marketed. To find that this word mandates notice after licensure, the majority compared the use of "licensed" in Section 262(l)(8)(A) to the phrase "the subject of [the application]" appearing elsewhere. It concluded "[i]f Congress intended paragraph (l)(8)(A) to permit effective notice before the product is licensed, it would have used the 'subject of' language." *See* Opinion at 16-17.

But the majority reasoning is flawed, not least because each of the seven other subsections cited address the period after filing but *before* licensure, *i.e.* during the so-called "patent dance." *See* Opinion at 16 (citing 42 U.S.C. § 262(l)(1)(D), (l)(2)(A), (l)(3)(A)(i), (l)(3)(B)(i), (l)(3)(B)(ii)(I), (l)(3)(C), (l)(7)(B)). It is not surprising that provisions discussing the period *before* licensure do not use "licensed." It is also unsurprising that Section 262(l)(8)(A) uses the word "licensed," because "the date of the first commercial marketing" comes only *after* licensure of the biologic product. The majority's reading provides a slender

reed at best, which cannot support the weight of an implied automatic stay and effective extension of market exclusivity in every case where notice is provided.

2. The Majority's Reading of Section 262(l)(8)(A) is Inconsistent With Section 262(l)(8)(B).

"[W]e do not . . . construe statutory phrases in isolation[.]" *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010). One purpose of the notice requirement is to trigger the RPS's right to ***seek*** a preliminary injunction based on patents not litigated earlier under Section 262(l)(6). *See* 42 U.S.C. § 262(l)(8)(B). That notice also sometimes allows the RPS to sue immediately. *See* 42 U.S.C. § 262(l)(9). But the majority construes that provision out of context; it must be read as "an integral part of the [BPCIA] procedures for managing patent litigation that arises as a result of a party filing an aBLA." Chen, J., dissent at 10.

"The practical consequence of the majority's interpretation is that (l)(8)(A) provides an inherent right to an automatic 180-day injunction." *Id.* at 9. This reading is squarely inconsistent with the express language of the very next section, which allows the RPS, after receiving the notice, to "***seek*** a preliminary injunction prohibiting the . . . ***applicant*** from engaging in the commercial manufacture or sale of such biological product . . . " based on any patent(s) listed in the initial exchanges during the "patent dance" but not selected for litigation. 42 U.S.C. § 262(l)(8)(B) (emphasis added). First, the word "applicant" again indicates Congress expected the RPS to ***seek*** an injunction while the application remained

pending (impossible under the majority reading). Second, finding "an inherent right to an automatic 180-day injunction" in Section 262(l)(8)(A) is inconsistent with Section 262(l)(8)(B) granting the right to "seek" a preliminary injunction, which the RPS will obtain only by making the required showing on the merits and equities. Third, the majority's interpretation grants an automatic injunction ***even if there is no patent dispute***, which cannot be squared with that provision's purpose. It also runs afoul of Supreme Court authority holding there is no automatic right to an injunction in patent litigation. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 393-94 (2006) (the standard equitable analysis applies to injunctive relief in patent cases).

Thus, the majority's reading of Section 262(l)(8)(A) not only disrupts the statutory balance and disregards the statutory text, but also makes Section 262(l)(8)(A) inconsistent with Section 262(l)(8)(B). It should be reversed.

3. The Filing of the Abbreviated Biologic License Application Itself Fully Crystallizes the Dispute.

The majority justifies its interpretation of Section 262(l)(8)(A) in part by noting the purported uncertainty of the biosimiliar product, its therapeutic uses, and manufacturing process before licensure—requiring notice after licensure allegedly "ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Opinion at 17. But this concern is misplaced. The BPCIA makes the filing of the aBLA an artificial act of infringement providing jurisdiction and

imminence for a declaratory judgment action. 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); *see* Opinion at 5. So, filing the aBLA "fully crystallizes" the dispute under the BPCIA, just as filing an Abbreviated New Drug Application creates a fully crystallized, litigation-ready dispute under the Hatch-Waxman Act.

No one disputes that a federal court has the jurisdiction to hear a case brought under the BPCIA and to issue appropriate injunction(s) if the RPS and the aBLA applicant agree to immediately litigate all relevant patents—even if that litigation begins and ends years before licensure. *See generally* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); 42 U.S.C. § 262(l)(4), (l)(6). There is no reason to believe the issues for purportedly relevant but not agreed-upon patents (*see* 42 U.S.C. § 262(l)(8)(B)) are any less "crystallized," and must be resolved after licensure. No litigation-related reason requires or supports the majority's reading of the notice provision.

C. The Majority's Reading of Section 262(l)(8)(A) Frustrates Congressional Intent, and Would Harm the Public.

The BPCIA creates an expedited path for licensing biosimilar products (Opinion at 3-4), and one of its goals was to facilitate early resolution of patent disputes. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(l)(2)-(9). If Congress wanted biosimilar patent suits filed after licensure, there was no need to create an artificial act of infringement. After licensure and marketing, the RPS can sue under 35 U.S.C. § 271(a). Interpreting

the notice provision to delay litigation until after licensure contradicts Congressional intent.

Finally, U.S. consumers spend many billions of dollars each year on biologic medicines, which occupy a rapidly-growing proportion of health-care spending.[2] Biologic medicines are also on average much more expensive than small-molecule pharmaceuticals ($45 per patient/day vs. $2 per patient/day).[3] Adding six months to the 12-year market exclusivity for biologic reference products for which notice is provided would impose significant, unjustified costs upon patients and upon our healthcare system that Congress never intended.

II. CONCLUSION.

For at least the reasons set forth above, Mylan respectfully requests that the Court grant Sandoz's Petition for Rehearing En Banc and reverse the majority's interpretation of Section 262(l)(8)(A) of the BPCIA.

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[2] In 2013, roughly $92 billion, or about 28 percent of U.S. drug spending, was spent on biologic products. ALEX BRILL, THE ECONOMIC VIABILITY OF A U.S. BIOSIMILARS INDUSTRY 4 (Feb. 2015), http://www.matrixglobal advisors. com/storage/MGA_biosimilars_2015_web.pdf. That figure, and the percentage of drug spending on biologics, jumped by almost 40% between 2010 and 2013. *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2010 4, 6 (Apr. 2011) http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf.

[3] *See* AM. CONSUMER INST. CTR. FOR CITIZEN RESEARCH, CONSUMERGRAM: LIFESAVING DRUGS AT LOWER COSTS 2 (July 2014), http://www.theamericanconsumer.org/wp-content/uploads/2014/07/Biosimilars-ConsumerGram-Final.pdf.

Dated: September 3, 2015

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On September 3, 2015, Mr. Rakoczy authorized me to electronically file the foregoing Brief of *Amicus Curiae* Mylan Inc. In Support of Defendant-Appellee's Petition for Rehearing *En Banc* with the Clerk of the Federal Circuit using the CM/ECF System, which will serve e-mail notice of such filing on the following:

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Sixteen paper copies will be filed with the Court via Federal Express within the time provided in the Court's rules.

/s/ Gary Y. Chyi
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September 3, 2015

CERTIFICATE OF COMPLIANCE

This brief complies with the page limitation of Fed. Cir. R. App. P. 35(g), as it does not exceed 10 pages.

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