No. 2016-1308

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellees,

v.

APOTEX INC., APOTEX CORP.,

Defendants-Appellants.

Appeal from the United States District Court for the Southern District of Florida in No. 0:15-cv-61631-JIC, Hon. James I. Cohn

BRIEF FOR THE BIOSIMILARS COUNCIL AS *AMICUS CURIAE* SUPPORTING DEFENDANTS-APPELLANTS AND REVERSAL OF THE DISTRICT COURT'S DECISION

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January 6, 2016

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 Biosimilars Council, certifies the following:

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: January 6, 2016

/s/ Carlos T. Angulo
Carlos T. Angulo

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Biosimilars Council is a division of the Generic Pharmaceutical Association, 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. The Biosimilars Council's members are focused on issues relating to biosimilars, which are highly similar or interchangeable versions of Food and Drug Administration ("FDA")-licensed branded biologic medicines. Branded biologics are known in this context and referred to in this brief as "reference products" and their licenseholders as "Reference Product Sponsors" or "RPS's."[2] Congress established an expedited FDA approval pathway for biosimilars in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA").[3]

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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] 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).

[3] 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 critical issues regarding the interpretation of certain of the BPCIA's patent dispute resolution provisions – specifically, whether Congress intended that a biosimilars applicant (hereafter, "applicant") that does not provide notice of commercial marketing of its biosimilar, after having otherwise followed the statute's patent dispute resolution process, could be required by the RPS through an injunction to provide such notice. The answer is "no." Proper resolution of this issue is of great importance to the Biosimilars Council and its members, who have a strong interest in (1) seeing this Court construe the statutory language as Congress intended and in a manner consistent with the BPCIA's overarching goals and (2) ensuring that the BPCIA's notice provisions not be used by the brand-name industry to improperly delay competition from biosimilars.

INTRODUCTION AND BACKGROUND

Biologics are large-molecule medicines derived from living organisms, 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

[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), 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), http://www.matrixglobaladvisors.com/storage/MGA_biosimilars_2015_web.pdf.

average, biologics cost $45 per day, as compared to $2 per day for traditional, small-molecule drugs.[5] Certain biologics cost tens or even hundreds of thousands of dollars per patient per year.[6] The BPCIA's biosimilars approval pathway, which provides for FDA's expedited approval of highly similar or interchangeable versions of reference product biologics based on the agency's previous findings of safety and effectiveness for the 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 patients' access to affordable life-saving medicines. Increased competition from affordable biosimilars holds the potential for enormous savings for the U.S. healthcare

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

[6] The branded biologic Humira®, which treats arthritis and other conditions, costs $50,000/year. The branded biologic Cerezyme®, which treats Gaucher's Disease, costs $200,000/year. Erwin A. Blackstone & Joseph P. Fuhr, *Innovation and Competition: Will Biosimilars Succeed?*, Biotechnology Healthcare 24-27 (Spring 2012), 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, 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).

system.[7] In California alone, potential savings from biosimilars over the next decade are estimated to exceed $27 billion.[8]

When Congress enacted the BPCIA's expedited approval pathway, it also, after extensive negotiation, expressly provided RPS's with 12 additional years of market exclusivity, in an effort to preserve a careful balance between encouraging price competition and promoting innovation. 42 U.S.C. § 262(k)(7)(A). *See also Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015) (noting that the BPCIA "balance[s] innovation and price competition.")

This case concerns whether the BPCIA provides an RPS with a freestanding, automatic injunctive remedy when a biosimilars applicant elects not to provide notice of commercial marketing of its biosimilar under BPCIA section 351 (l)(8)(A) (42 U.S.C. § 262(l)(8)(A)), after the applicant has otherwise followed the BPCIA's patent dispute resolution process. The Biosimilars Council supports the interpretation of the BPCIA advanced by Defendants-Appellants Apotex Inc. and

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[7] In Europe, where biosimilars have been marketed since 2004, savings from biosimilars through 2020 for three particular product classes have been estimated between €11.8 and €33.4, with additional savings expected as more biologics go off-patent and more biosimilars reach the market. Robert Haustein, et al., *Saving Money in the European healthcare systems with biosimilars* 1(3-4) Generics & Biosimilars Initiative J. 120-26 (2012), http://gabi-journal.net/saving-money-in-the-european-healthcare-systems-with-biosimilars.html.

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

Apotex Corp. (collectively, "Apotex") and opposes the contrary interpretation advanced by Plaintiffs-Appellees Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen") and erroneously adopted by the district court. Correctly interpreted, the BPCIA *does not* provide a free-standing injunctive remedy against biosimilars applicants that elect not to provide notice of commercial marketing after having otherwise followed the statute's patent dispute resolution procedures. This result is mandated by the plain language of the BPCIA – which specifies the exclusive remedies available to RPS's in these circumstances. It also flows directly from this Court's recent analysis of the statute in *Amgen v. Sandoz*, although, as the district court recognized (Appx5), that decision did not decide the precise question at issue here.

Moreover, the district court's and Amgen's view of the BPCIA, if upheld by this Court, would fundamentally distort, in a manner Congress could not possibly have intended, the careful balance struck in the statute between encouraging price competition in biologics markets and promoting the development of innovative new medicines. Congress provided RPS's with 12 years of exclusivity in exchange for agreement on an expedited biosimilars pathway. But providing RPS's with an extra-statutory injunctive remedy to address lack of notice would effectively add six additional months of exclusivity to this express 12-year statutory exclusivity period for *each and every* biosimilar application. Congress could not possibly

have intended to extend RPS exclusivity, and thereby to further delay patients' access to affordable medicines, by six additional months through the backdoor mechanism of the BPCIA's notice provisions.

ARGUMENT

Although the BPCIA's framework is unquestionably complicated, the question at the heart of this case is, at bottom, a simple one:

> If the BPCIA *expressly* provides an RPS with a specific patent litigation remedy in cases where an applicant elects not to provide notice of commercial marketing to the RPS, may the RPS also seek additional, extra-statutory relief in the form of a preliminary injunction requiring the applicant to provide the notice?

The answer to this question, under the plain terms of the BPCIA and this Court's recent decision in *Amgen v. Sandoz*, is "no." Amgen is therefore not entitled to an extra-statutory injunction requiring Apotex to provide notice of commercial marketing under BPCIA section 351(l)(8)(A), and the district court's award of such an injunction to Apotex must be vacated.

I. BPCIA section 351(l)(9)(B) provides an express remedy for an applicant's failure to provide notice under section 351(l)(8)(A), and an extra-statutory injunctive remedy is not available to Amgen.

This Court has cautioned that "'[w]here a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.'" *Albright v. United States*, 10 F.3d 790, 794 (Fed. Cir. 1993) (quoting *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989)). Yet this is exactly what the

district court did in this case, creating in its own words "another remedy" (Appx7), beyond what Congress expressly provided in the BPCIA, to address lack of notice. But the district court had no authority – statutory or otherwise – to create a remedy that Congress did not, much less a private right of action to enforce that remedy through an injunction.[9]

Both the notice provision and the remedial provision addressing lack of notice are part of the BPCIA's integrated framework for the resolution of patent disputes between an RPS and an applicant – a framework discussed at length in Apotex's brief (pp. 4-7). Congress's chosen remedy for lack of notice under BPCIA section 351(l)(8)(A) appears in the very next section of the BPCIA, section 351(l)(9)(B), and could not be clearer:

> If a [biosimilars] applicant fails to complete an action required of the . . . applicant under paragraph 3(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), *or paragraph (8)(A)* [*i.e.*, the notice provision], the reference product sponsor, but not the . . . applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

42 U.S.C. § 262(l)(9)(B) (emphasis added).

[9] In fact, Amgen, which at all times bears the burden of establishing jurisdiction, has not even attempted to show, much less establish, that the BPCIA necessarily creates a private right of action to enforce the remedy it secured in the first instance.

In other words, if an applicant fails to provide notice under BPCIA section 351(l)(8)(A) (referred to in the remedial provision as "paragraph (8)(A)"), the *express* remedy prescribed by Congress is that the RPS may bring an immediate patent declaratory judgment action against the applicant regarding patents the RPS identified under BPCIA section 351(l)(3)(A) (42 U.S.C. § 262(l)(3)(A)).

Not only is the remedy of a free-standing injunction clearly absent from the BPCIA. The district court's decision adding this "[]other remedy" (Appx7) *effectively reads Congress' chosen remedy out of the statute*. If an RPS can simply obtain an injunction requiring notice under BPCIA section 351(l)(8)(A), there would never be any reason for the RPS to go to the trouble of following the remedial path set out in BPCIA section 351(l)(9)(B). Thus, the district court's decision violates not only the rule of statutory construction against inferring remedies beyond those chosen by Congress; it also violates the equally central interpretive rule 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 TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void or insignificant." (citation and internal quotation marks

omitted)); *Heinzelman v. HHS*, 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).[10]

The BPCIA's exclusive remedial provision addressing lack of notice makes eminent sense in light of the overarching framework of the patent dispute resolution provisions in BPCIA section 351(l), of which the notice provision and the remedial provision is each a part. If exercised, the section 351(l) framework is intended to expedite the identification and resolution of patent disputes. The (l)(8)(A) notice provision is part and parcel of this framework. As the district court itself recognized, the very purpose of notice is tied to patent litigation: Notice gives an RPS "'a period of time to seek a preliminary injunction based on patents that the parties initially identified during [the BPCIA's process for patent] information exchange but were not selected for the immediate infringement action, as well as any newly listed or licensed patents (collectively, "non-listed

[10] The district court suggested that the remedial provision remains an option for a RPS and that requiring notice through an injunction simply adds "another remedy" and does not read the BPCIA's language out of the statute. Appx7. Putting aside the issue of whether a court can add remedies beyond those chosen by Congress (it cannot), the district court failed to identify any instance where the remedy expressly provided under the BPCIA for lack of notice would be necessary or desirable if an RPS could simply require notice through an injunction.

patents").'" Appx3 (citing 42 U.S.C. § 262(l)(7)-(8) and *Amgen v. Sandoz*, 794 F.3d at 1352).

Because the BPCIA's patent dispute resolution provisions, of which the notice provisions are part, are generally intended as a patent litigation roadmap, and because the notice provision itself is designed to trigger the right to litigate certain patent disputes, it stands to reason that the failure to provide notice should similarly trigger a procedural right to initiate patent litigation. Indeed, nothing in the 351(l) framework generally, or in the express statutory language of section 351(l)(9)(B) specifically, suggests that the notice provision confers an independent statutory private right of action on the RPS to require notice through an injunction.

In short, the district court erred by failing to read the BPCIA notice provision as part of an integrated patent dispute resolution framework that includes specific, patent litigation-based remedies for the failure to take certain actions, including the failure to provide notice. As this Court has pointed out, "[w]hen 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." *Warner-Lambert Co.*, 316 F.3d at 1355 (citation and internal quotation marks omitted). The district court instead (and erroneously)

read the notice provision in total isolation, untethered from the patent dispute resolution process of which it is a part, and improperly converted the notice provision from the procedural mechanism that Congress intended into a substantive, independently-enforceable right and further created a private right of action to enforce that supposed right that is nowhere found, either explicitly or implicitly, in the BPCIA.

The district court's failure to read the notice provisions in the proper context of the BPCIA patent dispute resolution provisions as a whole becomes apparent when the facts of this case are considered. As Apotex explains in its brief (*e.g.*, pp. 9, 34), Amgen and Apotex have *already* identified through the BPCIA's information exchange provisions *all* patents that are relevant to Apotex's biosimilars applications: There are in this case no "non-listed patents" (*Amgen v. Sandoz*, 794 F.3d at 1352) to be swept into the case through the provision of notice, and therefore no legitimate purpose to be served by an injunction requiring notice. While the district court emphasized that requiring notice helps "crystallize[]" the parties' patent disputes (Appx7), here those patent disputes are *already* fully crystallized. Requiring notice in this context in no way advances the objectives Congress sought to achieve through the BPCIA section (l) framework of which the notice provisions are part and parcel and has only one effect: To give the RPS an additional six months of marketing exclusivity beyond what Congress

expressly provided as part of the statute's careful-crafted balance between innovation and competition.

II. This Court's decision in *Amgen v. Sandoz* supports reversal of the district court's decision in this case.

This Court's recent decision in *Amgen v. Sandoz* compels reversal of the district court's decision in two related, but distinct, respects.

a. *Amgen v. Sandoz*'s interpretation of the BPCIA's application-sharing provisions compels a similar interpretation of the statute's notice provisions and compels reversal of the district court's decision granting Amgen an injunction.

One of the key issues in *Amgen v. Sandoz* was whether under the BPCIA section 351(l)(2)(A) application-sharing provision (42 U.S.C. § 262(l)(2)(A)), a biosimilars applicant is *required* to share its application with the RPS and whether, accordingly, the RPS may enforce that "requirement" through an injunction – just as the issue here is whether under the *351(l)(8)(A) notice provision*, the applicant is required to provide notice and whether *that* requirement is enforceable through an injunction. And in *Amgen v. Sandoz*, this Court held that the application-sharing provision was *not* mandatory/enforceable through an injunction, *on the grounds that the BPCIA in section 351(l)(9)(C)* (42 U.S.C. § 262(l)(9)(C)) *provided an exclusive patent-based remedy for the applicant's failure to share its application with the RPS*. 794 F.3d at 1355-57. This Court emphasized that (1) the information-sharing provision "cannot be read in isolation" from the rest of the

BPCIA (*id.* at 1355); (2) in section 351(l)(9)(C), Congress specified the patent-based consequences for the applicant's failure to share its application (*id.* ("[the BPCIA] *specifically sets forth the consequence for such failure*: the RPS may bring an infringement action under 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)."") (emphasis added)); (3) the BPCIA "does not specify any non-patent-based remedies for a failure to comply with [the application-sharing provisions]" (*id.* at 1356); and (4) allowing Amgen to obtain an injunction to enforce the application-sharing provisions would "render [the section 351(l)(9)(C) remedial provision] superfluous" (*id.* (citations omitted)). Accordingly, this Court concluded that Amgen could not avail itself of an injunction to enforce the application-sharing provisions.

That analysis applies foursquare in this case. BPCIA section 351(l)(9)*(B)*, which specifies the consequences attending an applicant's election to not provide notice under section 351(l)(8)(A), is parallel to and serves a purpose analogous to BPCIA section 351(l)(9)*(C)*, which specifies the consequences attending an applicant's election to not share its application with the RPS under section 351(l)(2)(A). Both subsections of 351(l)(9) provide patent litigation-based remedies to an RPS in situations where the applicant has elected not to follow certain of the patent dispute resolution procedures set forth in section 351(l). This Court's holding in *Amgen v. Sandoz* that an injunction enforcing the application-

sharing provision was unavailable because of the exclusive patent-based remedy set forth in 351(l)(9)*(C)* compels the conclusion here that an injunction enforcing the notice provision is *equally unavailable* because of the exclusive patent-based remedy set forth in 351(l)(9)*(B)*. Indeed, 351(l)(9)(B) would be rendered no less superfluous by the district court's injunction in this case than 351(l)(9)(C) would have been rendered had this Court allowed an injunction in *Amgen v. Sandoz*.

b. The *Amgen v. Sandoz* Court's analysis of the notice provisions also supports reversal of the district court's decision here.

In *Amgen v. Sandoz*, this Court also examined the BPCIA notice provisions themselves and whether they were mandatory/enforceable through an injunction, concluding that Amgen could enforce the notice provisions through an injunction against Sandoz. The Biosimilars Council believes this holding to have been erroneous and reserves the right to continue to contest it, but in any event, the holding was limited to the facts of that case, where Sandoz, unlike Apotex in this case, had elected *not* to comply with the information sharing provisions or any of the other information exchange provisions of 351(l): "We therefore conclude that *where, as here, a [biosimilars] applicant completely fails to provide its [application] and the required manufacturing information to the RPS by the statutory deadline,* the requirement of paragraph (l)(8)(A) is mandatory." *Id.* at 1360 (emphasis added).

Indeed, Judge Lourie's majority opinion explicitly distinguished between situations where, as in the *Sandoz* case, the applicant did not follow the application sharing provision and situations where, as in this case, the applicant did follow those provisions, indicating that in the latter instance, the 351(l)(9)(B) remedy was the specified statutory remedy for lack of notice: "While it is true that *paragraph (l)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (l)(8)(A) after the applicant has complied with paragraph (l)(2)(A)*, it does not apply in this case, where Sandoz did not comply with paragraph (l)(2)(A) in the first place." *Id.* at 1359 (emphasis in original).

Judge Chen's dissent correctly recognized – and took issue with − the distinction drawn by the majority, pointing out that under the Judge Lourie's analysis, an automatic injunction to enforce the notice provisions would be unavailable where, as here, the applicant shared its application under (l)(2)(A) and arguing that the majority should not arrive at a different view where, as in Sandoz' case, the applicant did not share its application:

> [N]othing in the majority opinion suggests that this automatic injunction remedy would be available in cases where the applicant complied with (l)(2)(A) by providing its [application] to the RPS, but later failed to provide notice under (l)(8)(A). In fact, the majority's opinion creates an uncomfortable result in which the language of (l)(8)(A) is interpreted in two different ways based on the [] applicant's actions. In a situation like the present case, the . . . applicant cannot refuse to provide the 180-days' notice, because under the majority's reading, (l)(8)(A)

> authorizes an automatic entitlement to a 180-day injunction. *But if [an applicant] complies with all the requirements specified in (l)(2)-(l)(7), then the . . . applicant may still refuse to comply with the 180-day notice provision. In this scenario, there would be no automatic injunction because (l)(9)(B) provides the RPS with the authorization to immediately file suit on any patent it listed under (l)(3)* . . . While the result in the latter scenario comes from the plain language of the statute, not so with the former. Nothing in the statute supports this peculiar outcome.

Id. at 1371 (Chen, J., dissenting) (emphasis added). In other words, for present purposes, Judges Lourie and Chen essentially agreed that if an applicant complied with the application-sharing provisions and other features of BPCIA section 351(l)(2)-(7), as Apotex has done here, the statute afforded RPS's an express, exclusive remedy for lack of notice under section 351(l)(8) and precluded the use of a free-standing injunction requiring notice.

In this case, the district court's decision fundamentally misreads Judge Chen's dissent. The district court incorrectly interpreted Judge Chen's statement that "[n]othing in the statute supports this peculiar outcome" (794 F.3d at 1371 (Chen, J., dissenting) as *supporting* the availability of an automatic injunction where the applicant otherwise abided by the information-sharing provisions. *See* Appx5. In fact, however, the "peculiar outcome" that Judge Chen was referring to was the availability of an injunction where an applicant like Sandoz had not shared its application – an outcome Judge Chen viewed as "peculiar" because under the

plain language of the statute and under the majority's opinion, an injunction would clearly and indisputably be *unavailable* because of the exclusive remedies set forth in 351(l)(9). That was the outcome that in his view "comes from the plain language of the statute" (794 F.3d at 1371 (Chen, J. dissenting) and should govern *any* situation where notice was not provided.

In short, Judge Chen's analysis essentially *confirms and shares* Judge Lourie's view that where, as here, the applicant otherwise abided by the section 351(l) information exchange provisions, the applicant's failure to provide notice could be addressed *only* through the remedial provisions of section 351(l)(9)(B) and not through an automatic injunction.[11] This shared view of *Amgen v. Sandoz*'s majority and dissent opinions alike supports reversal of the district court's decision in this case.

III. The effect of the District Court's decision would be to confer 180 days of extra-statutory exclusivity on RPS's and to distort the BPCIA's careful balance between innovation and competition.

Amgen's reading of the notice provisions, in addition to being contrary to the plain statutory language and this Court's interpretation of that language in *Amgen v. Sandoz*, would also produce results that Congress clearly did not intend, frustrating both the overall statutory goal of expediting access to affordable

[11] As noted above, the Biosimilars Council shares Judge Chen's view that the majority's decision granting Amgen an automatic injunction to address Sandoz's lack of notice was error.

medicines and Congress's chosen way of balancing that goal with preserving incentives to innovate.

Specifically, the overarching effect of the district court's decision, if upheld, would be to confer an automatic six-month preliminary injunction after FDA licensure of, and delay patient access to, *each and every* biosimilar. In *Amgen v. Sandoz*, this Court – incorrectly, in *amicus*'s view − held that notice of commercial marketing under section 351(l)(8)(A) may only be given after FDA's licensure of the biosimilar. *Id.* at 1357-58. Therefore, if this Court were to affirm the district court in this case and hold that each RPS may obtain an injunction requiring notice from its respective biosimilars applicant , it would mean that *every applicant* – not just those who under the (incorrect) holding of *Amgen v. Sandoz* must provide notice after having failed to follow the rest of the information exchange process – could be enjoined to provide notice. This outcome would effectively delay patient access to every biosimilar by an additional six months after FDA would otherwise be able to license the new product. This interpretation of the statute would produce two related results that cannot be squared with Congress's intent.

a. Congress did not intend to use the notice provisions to grant sponsors an automatic six-month preliminary injunction blocking the marketing of each and every FDA-licensed biosimilar.

Amgen's interpretation of the notice provisions would effectively grant *each and every* RPS an automatic six-month preliminary injunction against commercial

marketing of an FDA-licensed biosimilar. It is inconceivable that Congress intended through such broad, indirect strokes to alter the well-established standards for granting preliminary injunctive relief. 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, e.g.*, *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 388 (Fed. Cir. 1987) (noting that "[t]he burden is always on the movant to demonstrate entitlement to preliminary relief."). There is nothing in the statute to suggest that Congress intended through the notice provision to permit automatic injunctions relieving sponsors of the usual heavy burden accompanying a request

for a preliminary injunction *for each and every biosimilar*.[12]

b. Congress did not intend for the notice provisions to add six months to the 12-year statutory exclusivity period.

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*.

Again, this cannot possibly be what Congress intended. The 12-year exclusivity period was an indisputably central component of the overall compromise struck by Congress in the BPCIA between innovation and competition – the key *qui pro quo* provided RPS's in exchange for agreement on an expedited biosimilars approval pathway. *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, http://www.wsj.com/articles/biosimilar-

[12] 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 more akin to 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., Cent. 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).

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). 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] Congress could not possibly have intended to undercut the BPCIA's delicate balance by *de facto* extending the 12-year exclusivity period for each and every biosimilar, further delaying patients' access to all these essential, 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).

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,

[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.")

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 period the true relevant trigger for marketing – again, for each and every biosimilar. Congress clearly did not intend this result. This Court's extension of its (erroneous) decision in *Amgen v. Sandoz* would have the additional effect of disincentivizing use of the section 351(l) patent dispute resolution provisions altogether – another consequence Congress could not have intended.

c. The District Court's rationales for requiring notice do not apply where, as here, all relevant patents have been identified and full patent litigation is underway.

The district court's rationales for requiring notice – rationales which fly in the face of the BPCIA's express language, this Court's prior decision in *Amgen v. Sandoz*, and the overarching structure and objectives of the statute – also make no sense on their own terms.

The district court, invoking this Court's decision in *Amgen v. Sandoz*, emphasized that requiring notice "allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court" and "ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Appx6 (quoting 794 F.3d at 1358). But as noted above and in Apotex's brief, in this case Amgen has *already* sued Apotex on all patents identified by Amgen, and no additional "non-listed" patents have surfaced in the

course of the information exchange. In other words, the *only* effect of requiring notice in this case is to extend by six additional months the 12-year exclusivity, and to deny patients for this additional, extra-statutory period the access to affordable medicines Congress intended them to receive on an expedited basis.

The District Court also pointed to the fact that one or more of Amgen's patents might expire before the patent litigation is complete as a basis for requiring notice. Appx7. But the fact that a patent, or patents, might expire during litigation is a commonplace feature of patent litigation generally. It is not affected one way or another by requiring notice and certainly cannot serve as a basis for delaying biosimilar marketing beyond the period provided by Congress. Indeed, there is absolutely no basis on which to believe that Congress intended to require notice to address the potential for patent expiration during litigation.

Finally, the District Court also had it wrong when it suggested that an extra 180 days of exclusivity would not be the usual case because biosimilars applications are often filed during the 12-year exclusivity period. Appx6-7. But the fact of the matter is that even when FDA review is concurrent with exclusivity, *FDA cannot license a biosimilar until after the exclusivity expires*. FDA, [*Draft*] *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinform

ation/guidances/ucm407844.pdf. In other words, licensure *must* follow the exclusivity, and since under *Amgen v. Sandoz*, notice *must* follow licensure, requiring notice for *each and every* biosimilar *de facto* extends the 12-year exclusivity period for *each and every* biosimilar by the 180-day notice period, regardless of whether exclusivity runs during FDA's review of the biosimilars application.

CONCLUSION

The district court's decision, if upheld by this Court, would effectively rewrite Congress' carefully-calibrated patent dispute resolution framework for biosimilars and in so doing would delay patients' access to affordable life-saving medicines in a manner Congress could not possibly have intended. This Court should reverse the decision below.

Respectfully submitted,

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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 5,624 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
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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of January, 2016, I electronically filed the foregoing **BRIEF FOR THE BIOSIMILARS COUNCIL AS *AMICUS CURIAE* SUPPORTING DEFENDANTS-APPELLANTS AND REVERSAL 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.

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