No. 2016-1308

In the United States Court of Appeals for the Federal Circuit

AMGEN, INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellees,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants-Appellants.

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

BRIEF OF AMICUS CURIAE MYLAN INC. IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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Dated: January 6, 2016

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CERTIFICATE OF INTEREST

Counsel for amicus curiae Mylan Inc. certifies the following as required by Federal Circuit Rules 26.1, 29(a), and 47.4:

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

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 misused to create extra-statutory remedies, or misinterpreted to create de facto exclusivities for Reference Product Sponsors ("RPS") contrary to Congressional intent, thereby delaying competition and consumer access to less expensive medicines.

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. Pursuant to Federal Rule of Appellate Procedure 29(a), Mylan states that all parties have consented to this filing.

I. INTRODUCTION.

This appeal raises questions of statutory interpretation under the BPCIA, that have not previously been addressed by this Court, regarding not only the proper scope of certain provisions, but the very ability of a private litigant to enforce such provisions through the injunctive relief appealed from here. Simply put, the Court should reverse the injunction below because Congress did not create a private right of action to enforce the statute's notice provision. And even if it had, the district court's interpretation cannot stand.

As discussed at length in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351-52 (Fed. Cir. 2015), the BPCIA created an expedited approval pathway for applicants seeking to rely on the Food and Drug Administration's ("FDA") prior findings of safety and efficacy for a reference product in support of their own applications for licensure of a biosimilar product (a so-called "abbreviated biologics license application" or "aBLA"). Among other things, the BPCIA creates what this Court has coined a "patent-dispute-resolution regime," which guides the parties' exchange of certain information relating to the aBLA and patents owned or licensed by the RPS, and allows an RPS to commence an infringement action prior to actual commercial marketing of the aBLA product. *See, e.g.*, *Sandoz*, 794 F.3d at 1352; 42 U.S.C. §§ 262(k), (*l*); 35 U.S.C. § 271(e)(2)(C).

In *Sandoz*, this Court considered, among other things, whether the information disclosure requirements under Section 262(*l*)(2)(A) are mandatory; whether the notice of commercial marketing obligations under Section 262(*l*)(8)(A) are mandatory for aBLA applicants (like Sandoz, there) who elect *not* to disclose their applications to the RPS; and relatedly, whether the statutory notice requirements in such instances may be satisfied by providing notice of commercial marketing before FDA licenses the aBLA product. The majority held that the information disclosure requirements under Section 262(*l*)(2)(A) are not mandatory; that where an aBLA applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory"; and that such notice is only effective after the FDA has licensed the aBLA product. *Sandoz*, 794 F.3d at 1358-59.[1]

The facts here are notably distinct from those involved in *Sandoz*. Here, Apotex *did* share its aBLA with the RPS (Amgen) pursuant to Section 262(*l*)(2)(A), but contended that it need not provide Amgen with advance notice of

[1] Mylan disagrees that such notice is mandatory where an applicant fails to provide its aBLA (or that such notice is effective only after licensure), but notes that the Court's consideration of those issues as they relate to an aBLA applicant that has elected not to disclose its aBLA to the RPS is not relevant here since there is no dispute that Apotex elected to comply with the disclosure requirements of Section 262(*l*)(2)(A).

commercial marketing pursuant to Section 262(*l*)(8)(A) after licensure. The majority's decision in *Sandoz* is thus not dispositive of the issue, as framed by Apotex, as to whether the notice of commercial marketing provision under the BPCIA is mandatory when a biosimilar applicant (such as Apotex, here) has chosen to participate in the disclosure requirements pursuant to Section 262(*l*)(2)(A).

Importantly, what *is* dispositive here—and what both the district court and Amgen failed to address—is the fact that *nowhere* in the BPCIA did Congress confer either an express or implied private right of action to enforce the statute's notice provision. Thus, whatever views this Court may have with respect to the mandatory nature of such notice provision as it relates to aBLA applicants who have complied with the statute's disclosure requirements, the Court need not, and indeed should not, reach or decide that issue. No cause of action exists to secure an injunction to compel compliance with that provision.

Putting that aside, however, even if the issue as framed by Apotex were properly before this Court (and it is not), the district court's decision still cannot stand. The district court's interpretation of the notice provision distorts the statutory scheme, contradicts the plain language, and will produce "real world" outcomes contrary to Congress' intent. Indeed, under that decision, *every* aBLA applicant—even those that comply with the disclosure provisions—must provide

advance notice 180 days prior to commercial marketing, and must do so—under *Sandoz*—only after licensure, thereby effectively extending the reference product's monopoly six months past the 12-year market exclusivity Congress granted under 42 U.S.C. § 262(k)(7)(A). This interpretation is unlawful for a host of reasons: it provides the RPS with a de facto exclusivity windfall and an automatic 180-day injunction implied from a simple notice provision; it grants the RPS an extra-statutory remedy rendering the statute's only express remedy superfluous; and it significantly harms patients in need of high-quality, lower-priced biosimilars who will be denied access for at least six months longer than Congress intended.

For these and all the reasons set forth below, this Court should reverse the district court's decision.

II. ARGUMENT.

The district court acknowledges that its review of Amgen's motion for preliminary injunction boils down to one, and only one, merits-based issue: whether the notice of commercial marketing provision in Section 262(*l*)(8)(A) is "mandatory" in all instances, including where an aBLA applicant provides the required information to the RPS under Section 262(*l*)(2)(A). (Appx2). The district court found that Amgen had established a likelihood of prevailing on the argument that it was mandatory, and enjoined Apotex from marketing its biosimilar Pegfilgrastim product for 180 days after obtaining FDA licensure. (Appx8-9).

Mylan agrees with Apotex that this appeal presents new facts that have not previously been addressed by this Court—namely, a situation where an aBLA applicant has provided the required information under Section 262(*l*)(2)(A) to the RPS, but elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A) after licensure. Yet the critical question that was never raised by the parties or the district court, but should have been, is whether Amgen's claim for injunctive relief based on the BPCIA's notice provision is actionable to begin with. That answer is no. Because the statute neither expressly nor impliedly confers a private cause of action to enforce compliance with the BPCIA's notice provision, and because this fundamental question goes directly to the district court's ability to consider Amgen's claim for injunctive relief, this Court should reverse the district court's decision.

Even if Amgen's claim for injunctive relief were lawfully before the district court, however, Mylan agrees with Apotex that, where an applicant has chosen to provide the aBLA information referenced in Section 262(*l*)(2)(A) but elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A), the statute provides the RPS its sole remedy: a declaratory judgment action on any patents the RPS listed as relevant to the aBLA product. The district court's decision to the contrary improperly imposes an automatic injunction and unconditional 180-day period of de facto market exclusivity that effectively extends the RPS's 12-year

marketing exclusivity period, and ignores the only express statutory remedy to which Amgen is entitled here. The Court should reverse that decision because there is no foundation for this de facto period of exclusivity in the plain language, structure, or public policy objectives of the BPCIA.

A. The BPCIA Does Not Confer A Private Right Of Action To Enforce The Notice Provision.

As a matter of first principles, before this Court can even reach the question of whether the notice provision under Section 262(*l*)(8)(A) is mandatory, it must reverse the district court's decision because the BPCIA creates no private right of action to enforce the notice provision.

"Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Unless congressional intent "can be inferred from the language of the statute, the statutory structure, or some other source, the essential predicate for implication of a private remedy simply does not exist." *Consol. Edison Co. of N.Y. v. O'Leary*, 117 F.3d 538, 543 (Fed. Cir. 1997); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 286 (2002) ("Where the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private suit, whether under § 1983 or under an implied right of action."); *Alexander*, 532 U.S. at 286-87 ("The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a

private remedy. Statutory intent on this latter point is determinative. Without it, a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." (citations omitted)).

Here, there is no evidence that Congress intended for an RPS to compel compliance with the notice provisions through the injunctive relief Amgen sought, and received, below. The BPCIA admittedly contains no express mechanism for litigants to privately enforce the notice provision under Section 262(*l*)(8)(A). Nor can a private right of action be implied by the language or the structure of the Act. Indeed, the statutory text suggests just the opposite.

For one, the notice provisions under Section 262(*l*)(8) "entirely lack the sort of 'rights creating' language critical to showing the requisite congressional intent to create new rights." *Gonzaga*, 536 U.S. at 287. Section 262(*l*)(8)(A) provides instructions to the aBLA applicant to provide advance notice of commercial marketing, while Section 262(*l*)(8)(B) provides that the RPS "may" seek a preliminary injunction where two preconditions to such an action have been met—(1) notice has been provided under subparagraph (A), and (2) the injunction is sought before the aBLA applicant has commercially marketed its biosimilar product. 42 U.S.C. § 262(*l*)(8)(A), (B). Section 262(*l*)(8)(C), meanwhile, does nothing more than provide that the parties will "reasonably cooperate" to expedite

any discovery deemed necessary in any such injunction action. *Id.* at § 262(*l*)(8)(C). Notably, nowhere in Section 262(*l*)(8) does the statute provide the RPS with a "right" to any notice, let alone a right to *enforce* the notice provision through an injunction proceeding.

Second, the BPCIA already contains a remedy where the aBLA applicant elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A). Under Section 262(*l*)(9)(B), where the aBLA applicant has provided its application to the RPS and engaged in the patent exchange, but elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A), an RPS may bring a declaratory judgment action for patent infringement, validity or enforceability of any patent included in the initial list provided by the RPS:

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph (8)(A), the reference product sponsor, but not the subsection (k) 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).

Id. at § 262(*l*)(9)(B). Section 262(*l*)(9)(B) provides the ***sole*** remedy for an alleged breach of Section 262(*l*)(8)(A). Amgen has not shown that Congress ever intended to provide any other remedy, including injunctive relief, for failure to provide notice of commercial marketing. The district court thus erred in finding that "an

injunction to compel compliance with the 180-day notice provision of Section 262(*l*)(8)(A) is *another remedy*." (Appx7) (emphasis added).

It is "an 'elemental canon' of statutory construction that where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps., Local 1263*, 489 U.S. 527, 533 (1989) (quoting *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979)). In such cases, absent strong evidence of contrary congressional intent, courts "are compelled to conclude that Congress provided precisely the remedies it considered appropriate." *Karahalios*, 489 U.S. at 533 (quoting *Middlesex Cty. Sewerage Auth. v. Sea Clammers*, 453 U.S. 1, 15 (1981)); *Alexander*, 532 U.S. at 290 ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others."). This is true even where the statute may be interpreted as providing a benefit to those seeking to enforce it. *California v. Sierra Club*, 451 U.S. 287, 294 (1981) ("The question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon those beneficiaries."); *Transamerica*, 444 U.S. at 24 ("[T]he mere fact that the statute was designed to protect advisers' clients does not require the implication of a private cause of action for damages on their behalf. The dispositive question remains whether Congress intended to create any such remedy." (citations omitted)). Indeed, "even where a statute is phrased in such

explicit rights-creating terms, a plaintiff suing under an implied right of action still must show that the statute manifests an intent 'to create not just a private *right* but also a private *remedy*.'" *Gonzaga*, 536 U.S. at 286 (quoting *Alexander*, 532 U.S. at 286).

Here, the statute does not provide a private enforcement remedy when an aBLA applicant chooses not to provide advance notice of commercial marketing. However, this is not a case where the aggrieved complainant lacks a remedy or is otherwise without a procedural mechanism to pursue—far from it. The statute expressly provides a patent remedy: judicial recourse under Section 262(*l*)(9)(B), where the RPS may bring a declaratory judgment action on *any* of the patents included in the sponsor's initial list described in Section 262(*l*)(3)(A)—essentially the same patents that could have been raised in a preliminary injunction action brought pursuant to Section 262(*l*)(8)(B).

Finally, because this Court has acknowledged "certain similarities" between the goals and procedures of the BPCIA and the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *Sandoz*, 794 F.3d at 1351, this Court's decisions considering whether a private right of action can be implied under Hatch-Waxman may be instructive. In case after case, this Court has found that such a private right may not be implied. *See Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002) (holding that "§ 355(j)(2)(B) cannot

be enforced by a private party in a patent infringement action"); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001) (holding that no private right of action existed for delisting a patent from the Orange Book because there is "nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FFDCA that 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States'"), *superseded by statute*, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (codified at 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2003)); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (holding that "the district court ha[d] no authority in the infringement action . . . to shorten the thirty-month stay because of allegedly improper conduct before the FDA"). The facts presented here compel the same result—the BPCIA does not expressly or implicitly create a private right of action to enforce the notice provision of Section 262(*l*)(8)(A). For this reason alone, this Court should reverse the district court's decision.

B. The District Court's Decision Provides The RPS With An Exclusivity Windfall And Improperly Converts The Notice Provision Into An Automatic Injunction.

Even if this matter were properly before the Court (it is not), the district court's interpretation of Section 262(*l*)(8)(A) must be reversed because it converts a simple notice provision into a de facto 180-day extension of market exclusivity,

and provides for an automatic 180-day preliminary injunction against every biosimilar sponsor with no consideration of the merits or equities.

1. Requiring Mandatory Notice After Licensure From Every aBLA Applicant Unlawfully Creates A 180-Day Period Of De Facto Exclusivity.

In holding that notice under Section 262(*l*)(8)(A) is mandatory and must be given after licensure, even for aBLA applicants that have provided the RPS with information under Section 262(*l*)(2)(A), the district court effectively extends the RPS's 12-year marketing exclusivity period and creates a 180-day period of de facto exclusivity in *all* circumstances. Rejecting Apotex's argument to this effect, the district court quotes from *Sandoz* and asserts "[t]hat [the] extra 180 days will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period . . . ." (Appx6 (quoting *Sandoz*, 794 F.3d at 1358)). But this statement misunderstands, if not completely ignores, the timing consequences of requiring notice *after* licensure but *before* commercial marketing can occur. Because licensure cannot occur until the RPS's 12-year exclusivity expires, the district court's determination that notification after licensure is mandatory, even where the aBLA applicant has engaged in the information exchange under Section 262(*l*)(2)(A), inevitably and effectively extends this market exclusivity in all instances.

The district court's interpretation disrupts the BPCIA's complex and careful statutory bargain. Congress granted reference products 4 years of exclusivity before an aBLA may be submitted and 12 years of exclusivity before an aBLA may be approved, regardless of patent protection, in exchange for the biosimilar applicant's reliance on FDA's finding of safety and efficacy. *See* 42 U.S.C. §§ 262(k)(7)(A), (B). When Congress wanted to grant additional periods of exclusivity, it *expressly* granted them. *See, e.g.*, 42 U.S.C. § 262(m)(2)(A) (granting "12 years and 6 months" of non-patent exclusivity to sponsors providing pediatric data); 21 U.S.C. § 360cc (granting 7 years of non-patent exclusivity for orphan drugs).

Courts should not assume, as the district court essentially did, that Congress intended to create a de facto exclusivity period through a simple notice provision. *Whitman v. Am. Trucking Ass'ns.*, 531 U.S. 457, 468 (2001) (recognizing that there must be a clear textual commitment by Congress to alter fundamental details of a regulatory scheme); *see also MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 (1994) (stating that it is "highly unlikely" that Congress would modify a central statutory scheme through a subtle or ambiguous device). 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 under Hatch-Waxman). 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 marketing exclusivity extension.

2. The Statute Does Not Support The Automatic Injunction Resulting From The District Court's Interpretation.

The mandatory notice interpretation urged by Amgen and adopted by the district court also improperly grants an automatic 180-day injunction in all instances regardless of the circumstances or whether the RPS successfully demonstrates the need for emergency relief. This result is equally unlawful. First, an inherent right to an automatic 180-day injunction is inconsistent with the plain language of Section 262(*l*)(8)(B), which provides only that an RPS "*may seek*" a preliminary injunction if notice is given. 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). The statute does not exempt the RPS from having to make the required showing of patent validity, enforcement and infringement on the merits and equities. Second, the district court's interpretation grants an automatic injunction ***even if, at the end of the 12-year period, there is no remaining patent dispute***. This cannot be squared with the purpose of Sections 262(*l*)(8)(A) or (B), which function together to enable the parties to resolve issues of validity, enforcement or infringement with respect to patents that were initially identified by the RPS for which a claim of infringement could be asserted. Third, 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 district court's interpretation 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 the objectives of the BPCIA.

In a nod to this Court's *Sandoz* decision, the district court attempts to justify its interpretation of Section 262(*l*)(8)(A) by claiming that the "extra" 180 days will "result in a more crystallized patent litigation before this Court." (Appx7). 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 Sandoz*, 794 F.3d at 1352. Thus, filing the aBLA "fully crystallizes" the dispute under the BPCIA, just as filing an Abbreviated New Drug Application (with a so-called paragraph IV certification) creates a fully crystallized, litigation-ready dispute under Hatch-Waxman.

No party disputes that a federal court has jurisdiction to hear a case brought under the BPCIA and to issue appropriate injunction(s), after the requisite findings on likelihood of success on the merits and the equities, with respect to patents the RPS and the aBLA applicant agree are in dispute during the patent exchange process. *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 concerning purportedly

relevant patents that were *not* agreed-upon during the patent exchange process are any less "crystallized," and must be resolved after licensure.

Indeed, the facts here amply demonstrate that the patent dispute between Amgen and Apotex is already fully crystalized. As explained more fully in Apotex's brief, Amgen and Apotex have already identified and are currently litigating all patents purportedly relevant to Apotex's aBLA. Thus, the *only* effect of imposing mandatory notice in this instance is to deny the public access to affordable medicines for an additional 180 days beyond the express 12-year exclusivity period. As Judge Chen noted in his dissent in *Sandoz*, nothing in the BPCIA supports this reading of the notice provision. *See Sandoz*, 794 F.3d at 1370-71 (Chen, J., dissenting) ("I do not find support in the statutory language to create an automatic 180-day injunction."). The district court's decision should be reversed.

C. The District Court's Decision Improperly Grants An Extra-Statutory Remedy, Rendering The BPCIA's Express Remedy Superfluous.

In granting an injunction to enforce what Amgen argued was a "mandatory" notice provision, the district court created an extra-statutory remedy that is unsupported by, if not directly contrary to, the plain language and objectives of the BPCIA.

It is well established that courts "do not . . . construe statutory phrases in isolation . . . ." *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010). Here, when viewed in the proper context, the plain terms of the BPCIA demonstrate that Congress contemplated that notice may not be given in all instances. More specifically, Congress expressly established a single remedy under paragraph (*l*)(9)(B) for when an aBLA applicant has complied with paragraph (*l*)(2)(A) and elects not to give notice under paragraph (*l*)(8)(A):

> ***If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph (8)(A)***, the reference product sponsor, but not the subsection (k) 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).

The district court determined that the remedy provided in Section 262(*l*)(9)(B) is "not an exclusive remedy" and that an injunction to compel compliance with the notice provision "is another remedy." (Appx7). But, just as "the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A))," *Sandoz*, 794 F.3d at 1356, the BPCIA also does not specify any non-patent-based remedies for failure to comply with paragraph (*l*)(8)(A).

The district court's "optional" reading of the remedies provision in Section 262(*l*)(9)(B) not only ignores Congress' election to provide a singular remedy, but renders that statutory remedy superfluous as a result. Where Congress expressly provides the remedy for a statutory violation, an aggrieved party's relief is limited to that statutory remedy. *See, e.g.*, *Bruce's Juices v. Am. Can Co.*, 330 U.S. 743, 755 (1947) ("'[W]here a statute . . . gives a new right and declares the remedy . . . the remedy can be only that which the statute prescribes.'" (quoting *D.R. Wilder Mfg. Co. v. Corn Prods. Ref. Co.*, 236 U.S. 165, 174-75 (1915)). Additionally, as this Court noted in *Sandoz*, "statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Sandoz*, 794 F.3d at 1356 (citation omitted). Here, by mandating compliance with Section 262(*l*)(8)(A)'s notice provision through an injunction, the district court rendered the declaratory judgment remedy granted to the RPS under Section 262(*l*)(9)(B) superfluous.

The district court had no basis to manufacture a remedy that Congress itself did not create—particularly when Congress exercised its authority on the precise subject. For this additional reason, the district court's decision should be reversed.

D. The District Court's Decision Frustrates Congressional Intent and Harms the Public.

As the district court recognized, Congress sought to preserve the careful balance between encouraging price competition and promoting innovation when it enacted the expedited approval pathway for biosimilars. (Appx2 (citing *Sandoz*,

794 F.3d at 1351)). After lengthy negotiations, Congress determined that the 4-year exclusivity barring aBLA submission and 12-year exclusivity barring aBLA approval provided a sufficient benefit to an RPS in exchange for allowing a biosimilar applicant to rely on the reference product under the expedited biosimilars pathway. It is thus directly contrary to the purpose and intent of the statute to extend, through an automatic injunction, the reference products' monopolies when Congress has already considered the public's interest of fostering innovation in granting these periods of non-patent exclusivity. This is particularly true here, where Amgen's 12-year marketing exclusivity has long since expired.

It is also important not to overlook the cost to consumers of this 180-day period of de facto exclusivity. 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

[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.matrixglobaladvisors.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) https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf.

small-molecule pharmaceuticals ($45 per patient/day vs. $2 per patient/day).[3] Adding six months of additional marketing delay to the 12-year market exclusivity for biologic reference products through a purportedly "mandatory" notice provision would impose significant, unjustified costs and delays upon patients and upon our healthcare system that Congress never intended.

III. CONCLUSION.

For at least the reasons set forth above, Mylan respectfully requests that the Court reverse the decision below granting Amgen's motion for preliminary injunction.

Dated: January 6, 2016

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[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.

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This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7)(B). This brief contains 4,737 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b). Microsoft Word 2010 was used to calculate the word count.

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I, Gary Y. Chyi, being duly sworn according to law and being over the age of 18, upon my oath deposes and states that:

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/s/ Gary Y. Chyi
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January 6, 2016