Nos. 15-1039 and 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner, Cross-Respondent,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents, Cross-Petitioners.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* MYLAN INC. IN SUPPORT OF PETITIONER, CROSS-RESPONDENT SANDOZ INC.

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INTEREST OF THE *AMICUS CURIAE*[1]

Mylan is one of the world's leading pharmaceutical companies. Mylan Inc.'s subsidiaries have filed and received approval for hundreds of Abbreviated New Drug Applications for generic drugs. With sales in approximately 165 countries and territories, Mylan is dedicated to providing greater access to high-quality, lower-priced medicines.

Mylan 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"). Indeed, Mylan subsidiaries have submitted, and will submit, applications for licensure under subsection (k) of the BPCIA. Mylan 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

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[1] All parties have consented to this filing. Correspondence reflecting the parties' consent has been lodged with the Clerk. No counsel for any party authored this brief in whole or in part. No party, counsel for any party, or person other than *amicus curiae* or its counsel made a monetary contribution to the preparation or submission of this brief.

create *de facto* exclusivities for Reference Product Sponsors ("RPS") contrary to the plain language of the statute and Congressional intent, thereby impermissibly delaying competition and consumer access to less expensive medicines.

SUMMARY OF ARGUMENT

The BPCIA reflects a careful and critical balance between innovation and price competition. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, Sec. 7001(b) ("It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established."); *see also* Pet. App. 4a. On one side, Congress created an abbreviated licensure pathway that allows applicants to file a so-called abbreviated biologics licensure application ("aBLA") under 42 U.S.C. § 262(k) for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. In exchange, Congress granted RPSs certain periods of exclusivity which prevent applicants from filing an aBLA for a biosimilar product for four years from the date the reference product was licensed, and which delay ultimate eligibility for licensure of an aBLA product for 12 years from the date the reference product was licensed.

The Federal Circuit's decision regarding BPCIA Section 262(*l*)(8)(A) ignores the critical balance Congress struck by, *inter alia*, effectively extending the reference sponsor's 12-year exclusivity period by 180 days *every time* an aBLA applicant gives notice of commercial marketing under 42 U.S.C.

§ 262(*l*)(8)(A). The Federal Circuit's interpretation of Section 262(*l*)(8)(A) cannot stand: it runs afoul of the statutory language and Congressional intent by converting a simple notice provision into a *de facto* 180-day extension of market exclusivity; and preemptively awards an automatic 180-day preliminary injunction against every biosimilar sponsor without consideration of the merits or equities.

The Federal Circuit also ruled that the notice provision under Section 262(*l*)(8)(A) is a mandatory stand-alone provision, enforceable by an RPS; and that an aBLA applicant's notice of its commercial marketing cannot become effective until *after* FDA licensure. This interpretation fails on several levels. As an initial matter, only Congress can create a private right of action to enforce federal law, and it did not do so here. Even if Congress had created a private right of action (it did not), the Federal Circuit's decision conflicts with the express statutory language—and Congress' intent—which established a statutory mechanism to facilitate early *pre*-licensure patent resolution. The Federal Circuit based its decision on reasoning that reflects a fundamental misunderstanding of the detrimental impact it will have on all future aBLA applicants for years to come. That decision, by creating an automatic 180-day preliminary injunction against biosimilar sponsors without regard to the RPS' patent rights and the traditional requirements for equitable relief, further jettisons this Court's clear precedent.

The Federal Circuit's decision not only hurts aBLA applicants (who must wait 180 days to market their products, even after they have demonstrated biosimilarity to the relevant licensed reference products and all statutory exclusivities have expired), but also consumers and payors (who must wait an extra six months for a competing product to enter the market and drop prices). These costs capsize the balance Congress created in the BPCIA. This Court should reverse the Federal Circuit's decision regarding Section 262(*l*)(8)(A).

Finally, unlike its interpretation of Section 262(*l*)(8)(A), the Federal Circuit's construction of Section 262(*l*)(2)(A) is fully consistent with the express statutory language, as well as Congress' intent for these provisions and the BPCIA as a whole. This Court should thus affirm the Federal Circuit's decision regarding Section 262(*l*)(2)(A).

STATUTORY BACKGROUND

In 2010, Congress enacted the BPCIA to facilitate the entry of biosimilar drugs into the market by allowing for the submission of aBLAs for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. Among other things, the BPCIA added 42 U.S.C. § 262(k) to create the abbreviated regulatory pathway for the licensure of biosimilar and interchangeable products, and separately added 42 U.S.C. § 262(*l*) to provide a patent dispute-resolution process for these abbreviated applications.

Under the regulatory framework created by 42 U.S.C. § 262(k), Congress provided two exclusivity periods for the reference product: the *first* bars the submission of an aBLA for four years from the date the reference product was licensed; the *second* prevents FDA from granting approval to an aBLA product for 12 years from the date the reference product was licensed. 42 U.S.C. § 262(k)(7)(A), (B). These expressly defined periods of exclusivity apply independent of any patent rights held by the RPS.

Separate from creating this new regulatory approval pathway, Congress also created a mechanism for early resolution of patent disputes by allowing an RPS to assert infringement claims based solely on the submission of an aBLA and before FDA licensure occurs. 42 U.S.C. § 262(*l*); 35 U.S.C. § 271(e)(2)(C). This patent resolution mechanism is separate and distinct from the regulatory pathway that permits FDA licensure immediately upon expiration of the statutorily-determined periods of exclusivity. Under this regime, an RPS may seek to enjoin market entry by the competing biosimilar product, but only after filing an infringement action and making the requisite showing for a patent-based injunction.

The filing of an aBLA and notice of acceptance by FDA marks the beginning of the BPCIA's patent resolution procedures governed by 42 U.S.C. § 262(*l*). As detailed by the petitioner, Sandoz Inc., Congress set forth specific timeframes and sequencing prerequisites for each stage of the so-called "patent dance" that allows the aBLA applicant to opt out at any stage. *See* Pet. Br. at 12-16. Congress

recognized that an aBLA applicant may choose to participate in all, some, or none of the information exchanges under Sections 262(*l*)(2)-(8); Congress thus built into the statute specific ramifications for each action or inaction by the RPS or aBLA applicant. In sum, the scope and timing of patent litigation under the BPCIA is dictated by the actions or inactions of the parties at each stage of the information exchange process.

Relevant here, aBLA applicants who elect to disclose the information specified in Section (*l*)(2)(A), and engage in the information exchange, can control whether litigation occurs in one or two stages. More specifically, aBLA applicants may agree to immediately litigate all patents initially identified by both parties as reasonably giving rise to a claim of infringement, or choose to narrow the first stage of litigation to a select number of patents and leave other listed patents to be resolved in a second later stage of litigation. 42 U.S.C. § 262(*l*)(4)-(5). If an applicant chooses not to litigate all patents immediately, the aBLA applicant and RPS will exchange lists of patents that each believes should be litigated immediately, with the remainder to be potentially resolved in a second phase of litigation. 42 U.S.C. § 262(*l*)(5). The aBLA applicant controls the timing of the second stage of litigation, which cannot commence until after the aBLA applicant provides its 180-day notice of commercial marketing under Section 262(*l*)(8)(A). This notice lifts the bar on the parties' ability to litigate previously identified but unlitigated patents; allows the RPS to seek a preliminary injunction based on these patents; and

triggers the start of any second phase of litigation. 42 U.S.C. § 262(*l*)(8)(A). If, however, the aBLA applicant fails, or elects not, to give such notice, the BPCIA provides that the RPS, but not the aBLA applicant, has the right to bring an immediate action for declaratory judgment on any patents previously listed by the RPS. 42 U.S.C. § 262(*l*)(9)(B).

In contrast, where an aBLA applicant elects *not* to participate in the first step of the patent dance by providing its application within 20 days of notice of FDA acceptance, Section 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) give the *RPS* the immediate right to bring an infringement action against the aBLA applicant. Congress ensured that, whether an aBLA applicant elects to complete all, some, or none of the information exchange process, the RPS retains the ability to assert its patents and seek injunctive relief prior to the commercial marketing of the aBLA product.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION REGARDING SECTION 262(*l*)(8)(A) IS WRONG ON THE MERITS.

Under the Federal Circuit's decision, an RPS may privately enforce the BPCIA's notice provision and effectively extend the RPS' statutory market exclusivity for 180 days longer than Congress intended *every time* notice is given or required to be given. This result has no basis in the statute and, in fact, squarely conflicts with one of Congress' primary goals in creating the BPCIA—to facilitate the

resolution of patent disputes *before* aBLA licensure. If not reversed, the Federal Circuit's flawed statutory interpretation will remain unchecked and will continue to be applied by courts throughout the country; RPSs will benefit from an extra-statutory windfall that Congress never intended; and patients will suffer from delayed entry of more affordable biologic products.

A. The Federal Circuit's Decision Violates Clear Supreme Court Precedent By Creating A Private Right Of Action Where None Exists.

Under a plain reading of the statute, Section 262(*l*)(8)(A) is <u>*not*</u> a stand-alone notice provision that can be privately enforced. The Federal Circuit improperly fashioned a private right of action that allows an RPS to run into court to seek an order requiring the aBLA applicant to provide post-licensure notice of commercial marketing. The Federal Circuit's decision ignores the settled rule, repeatedly affirmed by this Court, that "private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). The Federal Circuit's decision on this issue cannot stand.

This Court has recognized that "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 . . . under an implied right of action." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 286 (2002). *No* evidence exists here that Congress intended for an RPS to compel compliance

with the notice provision, let alone through a Federal Circuit-created extra-statutory injunction mandating post-licensure notice by an aBLA applicant. The majority (Judge Lourie joined by Judge Newman) did not even address this fundamental issue, much less identify any supporting authority or evidence that Congress created such an action. In reality, the BPCIA contains no express mechanism for litigants to privately enforce the notice provision under Section 262(*l*)(8)(A). In other words, just as the Federal Circuit found with respect to Section 262(*l*)(2)(A), here too, "the BPCIA has no other provision that grants a procedural right to compel compliance with the [notice] requirement of paragraph [262(*l*)(8)(A)]." Pet. App. 15a-16a. Nor can a private right of action be implied by the language or the structure of the Act. The statutory text suggests just the opposite.

First, the notice provision under Section 262(*l*)(8) "entirely lack[s] the sort of 'rights-creating' language critical to showing the requisite congressional intent to create new rights." *Gonzaga*, 536 U.S. at 287 (quoting *Alexander*, 532 U.S. at 288-89). 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). Separately, Section 262(*l*)(8)(C)

simply provides that the parties will "reasonably cooperate" to expedite any discovery deemed necessary in any such injunction action. *Id.* at § 262(*l*)(8)(C). Nowhere in Section 262(*l*)(8) does the statute provide the RPS with a "right" to notice, let alone a right to *enforce* the notice provision through an injunction proceeding.

Second, the BPCIA already contains express remedies where the aBLA applicant elects *not* to give notice of commercial marketing under Section 262(*l*)(8)(A). As the Federal Circuit acknowledges, where the aBLA applicant has provided its application to the RPS but elects not to provide notice of commercial marketing under Section 262(*l*)(8)(A), an RPS may immediately bring a declaratory judgment action under Section 262(*l*)(9)(B) for patent infringement, validity or enforceability of any patent included in the initial list described in paragraph (3)(A), including as provided under paragraph (7). 42 U.S.C. § 262(*l*)(9)(B); Pet. App. 25a ("[P]aragraph (*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) . . . ."); Pet. App. 51a n.2 (Chen, J. dissenting).

Alternatively, as Judge Chen observes in his dissent, the statute provides that where the aBLA applicant elects *not* to provide its application to the RPS, under Section 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C), an RPS, but not the aBLA applicant, may bring a declaratory judgment action for patent infringement, validity or enforceability of *any* patent that claims the biological product or use of the

biological product. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C); Pet. App. 51a (Chen, J. dissenting) ("Congress created the fallback provision of (*l*)(9)(C) for just these circumstances. An RPS does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action when the (k) applicant fails to comply with (*l*)(2). At this point, the RPS possesses the statutory right to seek a preliminary injunction for any of its patents that 'could be identified pursuant to section [262](*l*)(3)(A)(i).'").

As this Court previously has acknowledged, "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) (citing *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. Nat'l Sea Clammers Ass'n*, 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 284 (quoting *Alexander*, 532 U.S. at 286).

Here, Congress created the *sole* remedies for an alleged breach of Section 262(*l*)(8)(A) in Sections 262(*l*)(9)(B) and 262(*l*)(9)(C)—both of which provide the RPS with the right to assert its patents at pre-specified stages before the commercial marketing of the biosimilar. There is no indication whatsoever that Congress ever intended to provide any other remedies, including injunctive relief, for failure to provide effective notice of commercial marketing—particularly where such injunctive relief is divorced entirely from any claim of patent infringement. Indeed, just as the Federal Circuit found with respect to Section 262(*l*)(2)(A), "the BPCIA does not specify any non-patent-based remedies for a failure to comply with [Section 262(*l*)(8)(A)]." Pet. App. 17a. Thus, the Federal Circuit's decision cannot stand.

Finally, even though the Federal Circuit acknowledged "certain similarities" between the goals and procedures of the BPCIA and the Hatch-

Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, Pet. App. 5a, the Federal Circuit's decision here is wholly inconsistent with its prior decisions considering whether a private right of action can be implied under Hatch-Waxman.

In case after case under Hatch-Waxman, the Federal Circuit found that a private right may <u>not</u> be implied. For example, as originally enacted, Hatch-Waxman required a drug company seeking to market a generic drug product prior to expiration of a relevant patent to provide the patentee with "*a detailed statement* of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." 21 U.S.C. § 355(j)(2)(B) (1984) (emphasis added)). In an appeal before the Federal Circuit, the brand drug company sought relief based upon the alleged insufficiency of the generic company's "detailed statement." *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002). There, the Federal Circuit correctly held that "§ 355(j)(2)(B) cannot be enforced by a private party in a patent infringement action . . . ." *Id.* at 777.

As another example, as originally enacted, Hatch-Waxman required brand drug companies to submit "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1) (1984). Because the submission of patent information under the original statutory scheme almost certainly led to delays in generic drug approvals, various brand companies submitted information for patents that did not meet the statutory criteria for submission.

Some generic companies responded to such statutory violations by bringing claims seeking to have improperly submitted patents removed, or "delisted," from FDA's official list of patents. Time after time, the Federal Circuit held that no private right of action existed for delisting a patent that did not meet the statutory criteria for submission to FDA. *See, e.g.*, *Mylan Pharm., 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 Pharm., 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). *See also* United States Amicus Br. at 19-20. For this reason alone, this Court should reverse the Federal Circuit's decision.

B. Even If A Private Right Of Action Existed, The Federal Circuit's Decision Runs Afoul Of The BPCIA's Express Text And Purpose, And Thus Cannot Stand.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A)—requiring mandatory post-licensure notice and effectively imposing an automatic 180-day injunction—cannot be squared with the BPCIA's text or purpose. The statutory text and purpose compel a construction under which notice of commercial marketing can be effective *before* FDA licensure, and the RPS may obtain an injunction to delay biosimilar marketing only *after* the RPS has met the traditional requirements of equitable relief.

1. The Federal Circuit's Decision Is Contrary To The BPCIA's Express Text.

The sole qualification the statute offers with respect to pre-marketing notice is that "[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). The plain language of the BPCIA does not—as the Federal Circuit held—require notice to be sent post-FDA licensure. Congress, rather, established the *latest* date on which a biosimiliar may give notice, not the *earliest* (as the Federal Circuit impermissibly construed it). The "not later than" restriction is the *only* limit that the statute imposes on the timing of pre-marketing notice. Thus, by its express "not later than" terms, Section

262(*l*)(8)(A) directly addresses the timing of pre-marketing notice and explicitly permits *pre*-licensure notice. To find otherwise, the Federal Circuit improperly construed the plain language of the statute, and its interpretation cannot stand. *See* Pet. Br. at 31-32; United States Amicus Br. at 13-20; Pet. App. 18a-21a.

Moreover, by holding that Section 262(*l*)(8)(A) is a standalone provision requiring mandatory notice after licensure, the majority's interpretation provides, as dissenting Judge Chen explained, "an inherent right to an automatic 180-day injunction," a result wholly at odds with the express language of the immediately succeeding section, Section 262(*l*)(8)(B). Pet. App. 52a (Chen, J., dissenting). Section 262(*l*)(8)(B) allows the RPS, "[a]fter receiving the notice," solely to "*seek* a preliminary injunction prohibiting the [aBLA] 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 (*i.e.*, the so-called "phase-two patents"). 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). These statutory notice provisions may not be construed in isolation. *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010). Congress did not create an automatic right to a 180-day injunction through Section 262(*l*)(8)(A); it granted, through Section 262(*l*)(8)(B), the more limited right for an RPS to "seek" such an injunction only, which the RPS may obtain solely by making the required showing on the merits and equities.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A) as requiring mandatory post-licensure notice runs contrary to the plain language of the statute and should be reversed on this basis alone.

2. The Federal Circuit's Decision Conflicts With The BPCIA's Structure And Purpose.

The Federal Circuit's decision rests on a fundamental misunderstanding of the practical consequences of mandating notice *after* licensure but *before* commercial marketing. The Federal Circuit acknowledges that its mandatory post-licensure notice interpretation grants RPSs 180 days of exclusivity found nowhere in the statute, but asserts "[t]hat [the] extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." Pet. App. 22a. As the petitioner has explained, however, this assertion misunderstands, if not completely ignores, the timing consequences of mandating *post*-licensure notice of commercial marketing. *See* Pet. Br. at 58-60.

The fact is that licensure cannot occur until the RPS' 12-year exclusivity expires. *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). Consequently, the Federal Circuit's decision mandating notification only *after* FDA grants

licensure inevitably and necessarily extends the statutory 12-year exclusivity in *all* instances where notice is given. Judge Chen identified precisely this problem in his dissent, discussing how the majority's mandatory post-licensure notice interpretation gives the RPS "an extra-statutory exclusivity windfall" in the form of "an inherent right to an automatic 180-day injunction," even in instances where no patent issues remain unresolved. Pet. App. 44a, 52a (Chen, J., dissenting).

The Federal Circuit's creation of a 180-day *de facto* exclusivity period disrupts the complex and careful statutory bargain Congress enacted. Congress granted reference products 12 years of exclusivity (regardless of patent protection) in exchange for the biosimilar applicant's reliance on the safety and efficacy of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). If, as Judge Chen correctly observed, Congress had wanted to create an automatic stay of approval, it knew how to do so. Pet. App. 52a-53a (Chen, J., dissenting); *see, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) (thirty-month stay provision under Hatch-Waxman). Congress did <u>not</u>, by the express language of the statute, do so here. Similarly, when Congress wants to grant additional periods of exclusivity, it *expressly* grants 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 seven (7) years of non-patent exclusivity for orphan drugs). Congress did <u>not</u> do so here.

By judicially-creating an additional 180-day exclusivity period for the RPS, the Federal Circuit

runs afoul of the structure of the BPCIA. Again, independent of any patent rights, Congress granted reference products four years of exclusivity before an aBLA may be submitted *and* 12 years of exclusivity before an aBLA may be licensed. *See* 42 U.S.C. § 262(k)(7)(A), (B). These exclusivity provisions under Section (k)(7) (entitled "Exclusivity for reference product") are separate from the patent resolution procedures established in Section (*l*) (entitled "Patents")—the section which includes the notice of commercial marketing provision under paragraph (*l*)(8)(A). Despite Congress' clear intent to have such notice revolve around the resolution of patent disputes by including it in Section (*l*) and tying such notice to the start of the second phase of litigation, the Federal Circuit erroneously converts the notice provision into an extra 180-day period of *de facto* exclusivity regardless of the RPS' patent rights.

Furthermore, the Federal Circuit's interpretation is at odds with the BPCIA's broader purpose. As the majority acknowledges, "[t]he BPCIA amended the Patent Act to create an artificial 'act of infringement' and to allow infringement suits based on a biosimilar application *prior to FDA approval* and prior to the marketing of the biological product." Pet. App. 6a. (emphasis added). Yet, the Federal Circuit's decision now creates a mandatory 180-day *post*-licensure waiting period to purportedly provide the RPS with a "defined statutory window" during which the RPS may assert any remaining patent claims. Pet. App. 21a. If Congress wanted biosimilar patent suits postponed until *after* FDA licensure, Congress would

not have needed to create an artificial act of infringement under 35 U.S.C. § 271(e)(2)(C), which it did indeed do. Moreover, there already is a statutory mechanism to resolve patent disputes post-licensure: the RPS may bring a declaratory judgment action and/or seek a preliminary injunction under other sections of the Patent Act such as 35 U.S.C. § 271(a) and/or (g). 35 U.S.C. § 271(a), (g). By including Section 262(*l*)(8)(A)'s pre-commercial marketing notice, Congress afforded the parties a mechanism to engage in *pre*-licensure patent litigation over patents that had been previously identified by the parties but were not a part of the phase-one litigation—a mechanism which RPSs and would-be biosimilar applicants alike endorsed. During Congressional testimony presented during enactment of the BPCIA, a representative of the Biotechnology Industry Organization, which includes among its members RPSs like Amgen, confirmed this, testifying that:

> Nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues <u>*before*</u> *a biosimilar is approved* and placed on the market. . . . Providing a way to start patent litigation before the biosimilar product is on the market (*i.e.*, during the data exclusivity period of the innovator and while the biosimilar product cannot be marketed because it is undergoing review by the FDA) will benefit patients, physicians, insurers, follow-on manufacturers and innovators alike.

(Jeffrey P. Kushan, Prepared Statement On Behalf Of Biotechnology Indus. Org. on *Biologics and Biosimilars: Balancing Incentives for Innovation, Before the H.R. Subcomm. on Courts & Competition Policy, Comm. on the Judiciary*, 111th Cong. (July 14, 2009), http://judiciary.house.gov/_files/hearings/pdf/Kushan090714.pdf) (emphasis added).

Interpreting Section 262(*l*)(8)(A)'s notice provision to delay litigation until *after* licensure frustrates Congress' goals of facilitating early patent resolution. Moreover, regardless of whether notice is given after licensure or at least 180 days before licensure, there still exists a "defined statutory window" within which any so-called "phase-two" patent claims may be asserted. Pet. App. 21a.

The Federal Circuit defends its decision by asserting that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Pet. App. 21a. According to the Federal Circuit, Congress meant for notice to follow licensure so that "the product, its therapeutic uses, and its manufacturing processes are fixed." *Id.* But this explanation contradicts the Federal Circuit's own statements, made just seven months earlier in another BPCIA dispute involving the same parties and Amgen's patents covering its Enbrel® product. There, the Federal Circuit stated that the aBLA application itself "circumscribes and dominates the assessment of potential infringement." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014).

The statute provides no basis for holding an RPS' injunction efforts at bay until after licensure, given that Congress *created* the pathway by which an RPS may initiate suit—*pre*-licensure—after the parties engage in the "patent dance" (or immediately after an aBLA applicant reveals that it will not disclose its application or otherwise participate in the "patent dance"). In fact, following the Federal Circuit's reasoning to its logical end, if a crystalized controversy only exists after the biosimilar product, its therapeutic uses, and manufacturing processes are fixed by way of licensure, then all pre-licensure litigation is premature. This view—which flows directly from the Federal Circuit's reasoning—is, of course, as illogical as it is unsupported. No one disputes that a federal court has jurisdiction to hear a case brought under the BPCIA and to issue appropriate injunction(s) if the RPS and the aBLA applicant engage in the patent dance and agree to immediately litigate patents identified pursuant to the patent exchange process—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). Indeed, to date, Amgen has initiated several independent BPCIA actions, all filed prior to aBLA licensure, to assert various patent claims. *See Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. filed Oct. 24, 2014); *Amgen Inc. v. Apotex Inc.*, No. 15-cv-61631 (S.D. Fla. filed Aug. 6, 2015); *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del. filed Sept. 18, 2015); *Amgen Inc. v. Apotex Inc.*, No. 15-cv-62081 (S.D. Fla. filed Oct. 2, 2015); *Immunnex Corp. v. Sandoz, Inc.*, No. 16-cv-01118 (D.N.J. filed Feb. 26, 2016).

The same is true where the aBLA applicant refuses to disclose its application. In that instance, as the Federal Circuit recognizes, the RPS is entitled under Section 262(*l*)(9)(C) to file an immediate declaratory judgment action on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(*l*)(9)(C). There is no indication that Congress believed the issues for purportedly relevant patents that were not initially selected for immediate litigation during the patent exchange process (*i.e.*, the so-called "phase-two" patents) are any less "crystallized," and must be resolved after licensure. Nor is there any indication that Congress intended for the parties to wait—possibly years—to conclude litigation over these phase-two patents, which only delays patent certainty for the aBLA applicant.

Finally, another inherent problem with the Federal Circuit's decision is that, under its interpretation, an aBLA applicant's launch will necessarily be delayed by 180 days even where there are *no* relevant patents, all patents have *expired* by the time of licensure, or the parties have fully *resolved* their patent dispute before licensure. Indeed, it could easily be the case that, by the time an aBLA applicant is eligible for licensure, all relevant patents have expired, or such patents have already been fully litigated and all disputes resolved. Such impermissible launch delays become all the more likely as new aBLAs are filed immediately after the four-year data exclusivity period expires, where the parties have up to eight years to resolve disputes

over the RPS' patents before the aBLA may be eligible for licensure.

This Court should reverse the Federal Circuit's decision, thus ensuring that the BPCIA's early patent resolution mechanism is allowed to work as Congress intended.

C. Even If A Private Right Of Action Existed, The Federal Circuit's Decision Violates This Court's Precedent By Creating An Automatic 180-Day Injunction, Without Consideration Of The Equities.

The Federal Circuit's decision must also be set aside because it effectively grants an automatic 180-day injunction in all circumstances, without any findings that satisfy the traditional requirements for equitable relief, in blatant violation of this Court's precedent in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006), which rejects any kind of "general rule" for an automatic injunction under the Patent Act. 547 U.S. at 393-94. As this Court held, "a major departure from the long tradition of equity practice should not be lightly implied." *Id.* at 391 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982)). This Court cautioned against "broad classifications" or "categorical rule[s]" when applying the traditional principles of equity and "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows" a statutory violation. *eBay*, 547 U.S. 392-93.

The Federal Circuit previously has recognized this Court's directive when it overruled its general practice of issuing permanent injunctions, without consideration of the traditional principles of equity, upon adjudication of infringement and validity under the Patent Act. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1148 (Fed. Cir. 2011); *see also SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 807 F.3d 1311, 1332 (Fed. Cir. 2015) ("Likewise, *eBay* clarifies that a patentee is not automatically entitled to an injunction—the patentee must prove that the equities favor an injunction." (citing *eBay*, 547 U.S. at 392)). Despite understanding and applying this Court's precedent in other circumstances, the Federal Circuit, here, effectively rewrote the notice provision as imposing an automatic injunction without any consideration of the equities.

There is no basis in the BPCIA, equity, or common sense to delay patient access to lower-cost biosimilars for even a day—much less 180 days—without a full consideration of the equities and justification on the merits of a patent claim. As discussed above, under the majority's interpretation, this automatic injunction would apply in all circumstances, independent of any evaluation of infringement and, indeed, independent of the existence of any patent protection whatsoever. This Court should, and indeed must, reverse the Federal Circuit to ensure that this Court's precedent is followed and injunctive relief against an aBLA applicant is awarded only where the traditional requirements for equitable relief are met.

II. THE BPCIA'S EXPRESS LANGUAGE REQUIRES THE CONSTRUCTION OF SECTION 262(*l*)(2)(A) ARTICULATED BY THE FEDERAL CIRCUIT.

After an exhaustive review of the relevant BPCIA provisions, the Federal Circuit correctly concluded that, under a plain reading of the statute, an aBLA applicant that fails to provide the RPS with information under Section 262(*l*)(2)(A) does "not violate the BPCIA," but rather takes "a path expressly contemplated by the BPCIA . . . ." Pet. App. 18a. Further, when an aBLA applicant does not provide the RPS with information under Section 262(*l*)(2)(A), the Federal Circuit held that "42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide *the only remedies* as those being based on a claim of patent infringement." Pet. App. 18a (emphasis added). The Federal Circuit could reach no other lawful result given the express statutory language.

Section 262(*l*)(2)(A) provides that:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.

42 U.S.C. § 262(*l*)(2)(A). The RPS here, Amgen, makes much of the "shall" language in this statutory provision to support its contention that failing to provide the identified information constitutes a statutory violation. *See, e.g.*, Amgen Cond. Cross-Pet. at 4-6. But as the Federal Circuit found, the "shall" language in Section 262(*l*)(2)(A) does not render an aBLA applicant's decision to withhold the specified information a statutory violation. Indeed, the Federal Circuit recognized that the BPCIA expressly contemplates that an aBLA applicant may elect to withhold the information identified in Section 262(*l*)(2)(A). Pet. App. 12a-18a.

In those instances where an aBLA applicant elects to withhold the information identified in Section 262(*l*)(2)(A), the BPCIA expressly specifies patent-based remedies as the sole remedies available to the RPS. In the Federal Circuit's words: "the BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It 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)." Pet. App. 15a. Section 262(*l*)(9)(C) provides:

> If a subsection (k) applicant *fails to provide the application and information required under paragraph (2)(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* that claims

> the biological product or a use of the biological product.

42 U.S.C. § 262(*l*)(9)(C) (emphases added). And 35 U.S.C. § 271(e)(2)(C)(ii), as amended by the BPCIA, provides:

> It shall be an act of infringement to submit . . . if the applicant for the application *fails to provide the application and information required* under section 351(*l*)(2)(A) of such Act [*i.e.*, 42 U.S.C. § 262(*l*)(2)(A)], an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act.

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added). In addition, 35 U.S.C. § 271(e)(4) expressly identifies "the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2) . . . ." 35 U.S.C. § 271(e)(4) (emphasis added); *see also* Pet. App. 18a.

As the Federal Circuit acknowledged, "both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and *the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (l)(2)(A)*." Pet. App. 17a (emphasis added); *see also* Pet. App. 15a-16a ("[T]he BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A).").

Thus, as the Federal Circuit pointed out, mandating compliance with Section 262(*l*)(2)(A) in all instances "would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." Pet. App. 17a (citing *Marx v. Gen. Revenue Corp.*, 568 U.S. ——, 133 S. Ct. 1166, 1178, (2013); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (cited quotations omitted)).

Because the BPCIA on its face expressly contemplates that an aBLA applicant may elect to withhold the information identified in Section 262(*l*)(2)(A), and because the statute contains patent-based remedies as the sole remedy available to RPSs that do not receive the information identified in Section 262(*l*)(2)(A) from the aBLA applicant, the Federal Circuit's decision on these issues should stand.

CONCLUSION

With respect to Section 262(*l*)(8)(A), the Federal Circuit's decision runs afoul of the plain language of the statute, as well as the purpose of the BPCIA. If left in place, that decision inevitably will deny patients lower-priced biologic medications, *in all cases*, longer than Congress intended, thus upsetting the careful balance of the BPCIA. The Federal Circuit's decision should be reversed. With respect to Section 262(*l*)(2)(A), the Federal Circuit correctly concluded that the BPCIA expressly contemplates that aBLA applicants may elect not to provide the RPS with information under Section 262(*l*)(2)(A), and in such instances, "42 U.S.C. § 262(*l*)(9)(C) and 35

U.S.C. § 271(e) expressly provide the only remedies" available to the RPS. Its decision on this issue should be affirmed.

Respectfully submitted,

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