No. 15-1039

IN THE

# Supreme Court of the United States

SANDOZ INC.,

*Petitioner,*

*v.*

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

*Respondents.*

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

## BRIEF OF *AMICUS CURIAE* MYLAN INC. IN SUPPORT OF THE PETITION FOR CERTIORARI

WILLIAM A. RAKOCZY
*Counsel of Record*
LARA E. FITZSIMMONS
TRANG D. HOANG
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654
(312) 527-2157
wrakoczy@rmmslegal.com

*Counsel for Amicus Curiae Mylan Inc.*

264584

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

### Federal Cases





### Federal Statutes



### Other Authorities

## INTEREST OF THE *AMICUS CURIAE*[1]

Mylan Inc. ("Mylan") is a global pharmaceutical company and one of the world's leading generics and specialty pharmaceutical companies. Mylan, through its subsidiaries (collectively, "Mylan"), has filed hundreds of approved Abbreviated New Drug Applications for generic small-molecule drugs, and offers a growing portfolio of more than 1,400 generic pharmaceuticals and several brand medications. 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"). 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

---

[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 Congressional intent, thereby 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. 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 (4) 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 ignores this critical balance and effectively extends 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—and should be immediately reviewed by this Court—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.



Not only is immediate review necessary to ensure that the balance struck by the BPCIA is respected, the Federal Circuit's interpretation is simply wrong. The Federal Circuit ruled that the notice provision under Section 262(*l*)(8)(A) is a mandatory stand-alone provision, enforceable by an RPS like Amgen, under which an aBLA applicant like Sandoz, here, must wait to give notice of commercial marketing until *after* licensure. This interpretation fails on several levels. For one, only Congress can create a private right of action to enforce federal law, and it did not do so here. Adding to that, the Federal Circuit's decision is contrary to the express statutory language and goals of Congress, which established a statutory mechanism to facilitate early *pre*-licensure patent resolution. The Federal Circuit's decision is based on reasoning that reflects a fundamental misunderstanding of the detrimental impact it will have on all future aBLA applicants for years to come. And the Federal Circuit's decision ignores clear precedent from this Court by creating an automatic 180-day preliminary injunction against biosimilar sponsors without regard to the traditional requirements for equitable relief.

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 payers—who are forced to wait an extra six (6) months for a competing product to enter the market and drop

prices. These costs capsize the balance Congress sought so hard to create.

Review is particularly appropriate here because the reach of the Federal Circuit's decision is not limited to the facts of this case. While Sandoz, in this case, elected not to disclose its filgrastim aBLA to Amgen or participate in the patent exchange process set forth in Section 262(*l*) (the so-called "patent dance"), the Federal Circuit's decision already has been applied in at least one other biosimilar case involving an aBLA applicant that *did* disclose its application and participate in the patent dance. Thus, the Federal Circuit's decision has the potential to delay the market entry of *every* aBLA product by at least 180 days after licensure.

Mylan urges this Court to grant Petitioner's request and review the Federal Circuit's decision, to restore the balance Congress created and immediately correct the Federal Circuit's erroneous and costly misunderstanding and misapplication of the BPCIA while the Act is still in its infancy.



## ARGUMENT

### I. THIS CASE PRESENTS AN OPPORTUNITY FOR THIS COURT TO CORRECT THE FEDERAL CIRCUIT'S FUNDAMENTAL MISUNDERSTANDING OF THE BPCIA AND PREVENT THE UNINTENDED CONSEQUENCES OF MANDATORY POST-LICENSURE NOTICE.

The issues raised by Petitioner are critical to the proper application of the BPCIA and operation of the biosimilars industry as a whole. Under the Federal Circuit's decision, an RPS may privately enforce the notice provision of the BPCIA and effectively extend the RPS's statutory market exclusivity for 180 days longer than Congress intended *every time* notice is given or required to be given. This result, as Petitioner has explained, and as discussed further below, has no basis in the statute and, in fact, squarely conflicts with one of Congress's primary goals in creating the BPCIA—the establishment of an early patent dispute mechanism for the RPS and aBLA applicant. If certiorari is not granted, the Federal Circuit's flawed statutory interpretation will remain unchecked and will be applied by courts throughout the country; RPSs will benefit from an extra-statutory windfall that Congress never intended; and patients and biosimilar companies will suffer from delayed entry of more affordable biologic products.

At the heart of the Federal Circuit's decision is a fundamental misunderstanding of the practical consequences of requiring notice *after* licensure but

*before* commercial marketing. In an attempt to downplay the anti-consumer effects of its decision, the Federal Circuit 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." App. 22a. But this statement misunderstands, if not completely ignores, the timing consequences of mandating post-licensure notice of commercial marketing. Because licensure cannot occur until the RPS's 12-year exclusivity expires, the Federal Circuit's decision requiring notification after licensure inevitably and effectively extends this market exclusivity in *all* instances where notice is given.

At least one district court in Florida already has blindly adopted and extended the Federal Circuit's interpretation, and the reasoning behind it, beyond the situation when an aBLA applicant elects not to disclose its aBLA or participate in the patent exchange process. In holding that notice after licensure is required even when an aBLA applicant has disclosed its application and manufacturing information and engaged in the patent exchange process, the district court latched onto the Federal Circuit's misunderstanding of how often biosimilar marketing would be delayed, and assumed, as the Federal Circuit did, that such a result will not necessarily occur when aBLA applicants file their applications during the 12-year exclusivity period. *See Amgen Inc. v. Apotex Inc.*, No. 15-cv-61631, slip op. at 6-7 (S.D. Fla. Dec. 9, 2015), appeal docketed, No. 16-1308 (Fed. Cir. Dec. 11, 2015). This example places into sharp focus the need for immediate review



to correct the Federal Circuit's error and to ensure that this mistake is not perpetually carried over from court to court, thereby denying the public timely access to lower-priced biosimilars.

Indeed, RPSs are currently exploiting the Federal Circuit's error in BPCIA actions in Massachusetts and Delaware over biosimilar versions of Janssen's Remicade® (infliximab) and Amgen's Epogen® (epoetin alfa) products, respectively. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Sept. 18, 2015); *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del. filed Mar. 6, 2016). The Federal Circuit's decision also raises the prospect of gamesmanship in future proceedings, in which RPSs will likely seek to improperly extend exclusivity to the detriment of patients in need of lower-priced biosimilar medicines.

The judicial creation of a 180-day de facto exclusivity period disrupts the BPCIA's complex and careful statutory bargain. Congress granted reference products 12 years of exclusivity regardless of patent protection, in exchange for the biosimilar applicant's reliance on the safety and efficacy of the reference product. *See* 42 U.S.C. § 262(k)(7)(A). As Judge Chen aptly pointed out in his dissent, mandatory post-licensure notice gives the RPS "an extra-statutory exclusivity windfall" or, put differently, "an inherent right to an automatic 180-day injunction." App. 44a, 52a (Chen, J., dissenting). But, as Judge Chen acknowledged, if Congress had wanted to create an automatic stay of approval, it knew how to do so. *Id.* at 52a-53a; *see, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii) (thirty-month stay provision under

Hatch-Waxman). And 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 seven (7) years of non-patent exclusivity for orphan drugs). It did neither here.

Another inherent (and unaddressed) problem with the Federal Circuit's decision is that, under its interpretation, an aBLA applicant's launch will necessarily be delayed by 180 days *regardless* of whether there are patents in dispute at the time notice is given. 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. This is a real possibility as more and more future aBLAs are filed immediately after the four (4)-year data exclusivity period expires, where the parties have up to eight (8) years to resolve disputes over the RPS's patents before the aBLA may be eligible for licensure.

This case presents an ideal opportunity for this Court to resolve a critical issue of first impression, while the BPCIA is still in its infancy and the impact of the Federal Circuit's erroneous decision is relatively limited. The Federal Circuit has denied rehearing *en banc*, and no other court of appeals is likely to hear these issues as the interpretation of the notice provision is tied directly to the patent resolution regime created under the BPCIA, and the Federal Circuit has exclusive appellate jurisdiction over patent infringement claims and disputes. 28



U.S.C. § 1295(a)(1). If the decision below stands, patient access to biosimilars will always be unnecessarily delayed by 180 days—regardless of patent protection—and the Federal Circuit's mistaken view of the far-reaching detrimental impact of its decision will stand uncorrected.

## II. THE FEDERAL CIRCUIT'S DECISION IS WRONG ON THE MERITS.

### A. The Federal Circuit Has Created A Private Right Of Action That Does Not Exist, In Violation Of Clear Supreme Court Precedent.

Under a plain reading of the statute, Section 262(*l*)(8)(A) is not a stand-alone notice provision that can be privately enforced. The Federal Circuit improperly fashioned a private right of action to enforce compliance with this provision—ignoring 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). This Court should grant review to correct this judicial overreaching.

This Court has recognized "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). Here, there is no evidence that Congress intended for an RPS to compel compliance with the notice provision through the extra-statutory injunctive relief created by the Federal Circuit. The

majority (Judge Lourie joined by Judge Newman) did not even address this fundamental issue, much less identify any supporting authority or evidence for such an action. The fact is that the BPCIA 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 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 any notice, let alone a right to *enforce* the notice provision through an injunction proceeding.

Second, the BPCIA already contains remedies where the aBLA applicant elects not to provide 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); 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) . . . ."); App. 51a n.2 (Chen, J. dissenting).

Alternatively, as Judge Chen observes in his dissent, 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); 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. 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 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). There is no indication that Congress ever intended to provide any other remedies, including injunctive relief, for failure to provide effective notice of commercial marketing.

### B. The Federal Circuit's Decision Does Not Comport With The Text Or Purpose Of The BPCIA.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A)—requiring mandatory post-licensure notice—cannot be squared with the text or purpose of the BPCIA.

First, the stautory language contains no qualification on the pre-marketing notice save "[t]he subsection (k) applicant shall provide notice . . . not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The plain language of the BPCIA thus supports Petitioner's argument that pre-marketing notice may come prior to licensure. To find otherwise, as Petitioner explains, the Federal Circuit dismissed one key word ("applicant") while reading another word ("licensed") out of its statutory context. *See* Pet. at 24-25; App. 18a-21a.

Second, by holding that Section 262(*l*)(8)(A) is a standalone provision requiring mandatory notice after licensure, the majority's interpretation provides, in dissenting Judge Chen's words, "an inherent right to an automatic 180-day injunction,"

which is at odds with the express language of the immediately succeeding section, Section 262(*l*)(8)(B). 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.

Third, the Federal Circuit's decision imposes an extra 180-day period of exclusivity, contrary to the structure and purpose of the BPCIA. As noted above, independent of any patent rights, Congress granted reference products four (4) 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 "[e]xclusivity for reference product") are separate from the patent resolution procedures established in Section (*l*) (entitled "[p]atents")—the section which includes the notice of commercial marketing provision under Section § 262(*l*)(8)(A). Despite Congress's clear



intent to have such notice revolve around the resolution of patent disputes by including it in Section (*l*), the Federal Circuit erroneously converts the notice provision into an extra 180-day period of de facto exclusivity regardless of the RPS's patent rights.

The Federal Circuit's interpretation is at odds with the broader purpose of the BPCIA, too. As the court 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." App. 6a. (emphasis added). Nevertheless, the Federal Circuit has created 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. App. 21a.

If Congress wanted biosimilar patent suits filed after licensure, there would have been no need to create an artificial act of infringement under Section 271(e)(2)(C). After licensure, a mechanism to resolve patent disputes already exists: 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); *see MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

But Congress specifically created a mechanism for early *pre*-licensure patent resolution through the BPCIA—a mechanism which RPSs and would-be biosimilar applicants alike endorsed. In fact, in

Congressional testimony presented during enactment of the BPCIA, a representative of the Biotechnology Industry Organization, which includes among its members RPSs like Amgen, testified that:

> Nearly all stakeholders in the biosimilar debates support inclusion of procedures to identify and resolve patent issues before 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).

Interpreting the notice provision to delay litigation until after licensure frustrates Congress's 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 phase-two patent claims may be asserted.



The Federal Circuit defends its decision by explaining 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." 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 (7) 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).

It is precisely this type of inherent contradiction that requires this Court's review. There is no statutory reason to hold an RPS's 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 extreme, 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 absurd. No one disputes that a federal court has the jurisdiction to hear a case brought under the BPCIA and to issue appropriate injunction(s) if the RPS and the aBLA applicant 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 five (5) different 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.

The Federal Circuit's interpretation proves even more illogical in situations 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. As noted above, this could happen with some frequency in the future, when the time between aBLA filing and licensure may extend eight (8) years or beyond. Nevertheless, under the Federal Circuit's decision, patient access will automatically be delayed by an additional 180 days post-licensure despite the lack of controversy over the RPS's patent rights.

This Court should grant review to ensure that the BPCIA's early patent resolution mechanism is allowed to work as intended.

### C. The Federal Circuit's Creation Of An Automatic 180-Day Injunction Without Consideration Of The Equities Violates This Court's Precedent.

Review is required for the added reason that the Federal Circuit's decision to grant an automatic 180-day injunction in all circumstances, without any findings that satisfy the traditional requirements for equitable relief, runs afoul 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 itself 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 majority effectively rewrites 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 patent protection. This Court should, and indeed must, step in to ensure that its precedent is followed and injunctive relief is awarded only where the traditional requirements for equitable relief are met.



## CONCLUSION

This case presents critical issues of first impression that can be addressed and corrected only by this Court. Absent review, the Federal Circuit's decision will inevitably deny patients lower-priced biologic medications, *in all cases*, longer than Congress intended, thus upsetting the careful balance of the BPCIA. The petition for certiorari should be granted.

Respectfully submitted,

MARCH 21, 2016

WILLIAM A. RAKOCZY
*Counsel of Record*
LARA E. FITZSIMMONS
TRANG D. HOANG
RAKOCZY MOLINO
MAZZOCHI SIWIK LLP
6 West Hubbard Street
Suite 500
Chicago, IL 60654
(312) 527-2157
wrakoczy@rmmslegal.com
*Counsel for* Amicus Curiae
*Mylan Inc.*