No. 16-332

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

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

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

WILLIAM A. RAKOCZY
Counsel of Record
PETER J. CURTIN
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 Pharmaceuticals Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes

Other Authorites

INTEREST OF THE *AMICUS CURIAE*[1]

Mylan Pharmaceuticals Inc. ("Mylan") is one of the world's leading pharmaceutical companies. Mylan has 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"). 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 create de facto exclusivities for Reference Product Sponsors ("RPS") contrary to Congressional intent,

---

[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.

thereby delaying competition and consumer access to less expensive medicines.

SUMMARY OF ARGUMENT

The BPCIA reflects a carefully crafted and critically important balance between innovation and price competition. *See* Public Law 111-148, sec. 7001(b) ("It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established."). On one side, Congress created an abbreviated pathway to licensure allowing applicants to file a so-called "abbreviated biologics licensure application" or "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 created periods of exclusivity which: (1) prevent aBLA filings for four years from the date the reference product was licensed, and (2) delay licensure of any aBLA product until twelve years from the date the reference product was licensed. 42 U.S.C. § 262(k)(7)(A)-(B). These statutory exclusivities apply regardless of any RPS patents.

The Federal Circuit's decision mandating notification post-licensure upends this balance by effectively extending every RPS's twelve-year market exclusivity by 180 days beginning after the aBLA applicant provides notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A), even if the RPS holds no relevant patents at the time of licensure. This Court should immediately review and correct the Federal Circuit's flawed interpretation of Section 262(*l*)(8)(A), which leads to absurd results.

Setting aside Congressional intent and policy concerns, the Federal Circuit flatly misreads the notice provision as a matter of statutory interpretation. The Federal Circuit extended its erroneous reasoning from the *Sandoz*[2] decision to cover aBLA applicants like Apotex who have engaged in the information exchange and patent dispute resolution procedures established in Sections 262(*l*) (the so-called "patent dance"). The court ruled that Section 262(*l*)(8)(A)—the notice requirement—is a mandatory stand-alone provision enforceable by an RPS, under which the applicant must delay any potential second stage litigation by providing notice of commercial marketing only *after* licensure. (*See* App. 3a). This interpretation fails on several levels.

First, only Congress can create a private right of action to enforce federal law, which it has not done here. Second, the Federal Circuit's reading of Section 262(*l*)(8)(A) contradicts the text, and renders other BPCIA provisions superfluous. Third, by *mandating* that any second stage litigation can only begin *after* licensure, the decision undercuts the BPCIA's purpose and the statutory mechanism promoting early and orderly *pre*-licensure resolution of patent disputes. *See* 35 U.S.C. § 271(e)(2)(C). Fourth, assuming the RPS still holds patent rights at licensure, mandating post-licensure notice effectively creates an automatic 180-day preliminary injunction

---

[2] *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *reh'g denied*, No. 2015-1499, slip. op. at 2 (Fed. Cir. Oct. 16, 2015).

without regard to traditional requirements for equitable relief.

Furthermore, the Federal Circuit's reasoning rests on flawed assumptions that misunderstand the statute, the current regulatory scheme, and the practical effects of its decision. Mandatory post-licensure notice harms all aBLA applicants by forcing them to wait an extra 180 days to market their products even: (a) after proving biosimilarity or interchangeability to the licensed reference product; (b) after all statutory exclusivities have expired; and (c) after all patent disputes are resolved. That delay also harms consumers and payors by delaying the market entry of a competing product, thereby delaying lower prices.

Review is particularly appropriate here because the Federal Circuit's decision is not limited to the facts of this case. Along with *Sandoz*, this decision will 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. This Court can thereby restore the balance Congress created, and correct the Federal Circuit's erroneous and costly misinterpretation of the BPCIA while the Act is still in its infancy.

ARGUMENT

I. THIS COURT SHOULD CORRECT THE FEDERAL CIRCUIT'S MISREADING OF THE BPCIA—MANDATING NOTICE AFTER LICENSURE UPSETS THE STATUTORY BALANCE WITH UNINTENDED NEGATIVE CONSEQUENCES.

Petitioner raises issues critical to the biosimilars industry and to the proper application of the BPCIA. The Federal Circuit has extended its flawed interpretation of the BPCIA's pre-marketing notice provision first adopted in *Sandoz*. By interpreting Section 262(*l*)(8)(A) to mandate notice *after* licensure but 180 days *before* commercial marketing, the court extends every RPS's statutory market exclusivity 180 days past the twelve years set by Congress, thus providing the RPS with an anti-competitive, extra-statutory windfall ***even if no patent rights remain***.

This absurd but inevitable result flows directly from the Federal Circuit's misunderstanding of the practical consequences of its decision. Examining the flawed assumptions underlying the Federal Circuit's justifications for mandatory post-licensure notice highlights its errors and illuminates the reason for granting *certiorari* and reversal.

A. The Federal Circuit Engages In Pure Speculation When It Assumes Post-Licensure Notice Will Extend RPS Market Exclusivity Past The Twelve Year Mark Less And Less As Time Goes By.

The Federal Circuit wishes away the creation of the 180-day extra-statutory windfall by assuming no real windfall exists, or that this windfall will occur less often over time. (App. 17a). But the court cites nothing to support these assumptions, which do not reflect reality. In *Sandoz* the court claimed "[t]hat 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." *Sandoz*, 794 F.3d at 1358. That statement is a classic *non sequitur*. FDA grants licensure only after RPS market exclusivity expires, so mandatory post-licensure notice effectively extends an RPS's exclusivity in every case.

Rather than correct its error, the Federal Circuit has doubled down. This decision endorses the *Sandoz* panel's faulty reasoning, asserting that any "delay beyond 12 years should occur less and less as time goes by," and that the court sees "no reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." (App. 17a). These statements are pure speculation. As Petitioner notes, no language in the Public Health Service Act, or in the Federal Food, Drug, and Cosmetic Act, expressly authorizes FDA to grant pre-effective date licensure for biosimilar applications. (*See* Pet. 13-14). FDA has issued no regulations or guidance on pre-effective date licensure, and has announced no plans to develop any. Any

rule-making process to create such a "tentative licensure" scheme could take many years with no guarantee of a final result.

The court in *Sandoz* wrote that "[a] statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case." *Sandoz*, 794 F.3d at 1358. Very well, but the Federal Circuit's interpretation of Section 262(*l*)(8)(A) must be judged in the world as it exists, not in light of speculation about how FDA might someday change its regulations. In the real world, the post-licensure notice requirement extends an RPS's market exclusivity by six months in every case.

B. The Federal Circuit's Justifications For Requiring Second Stage Patent Litigation To Begin After Licensure Are Unmoored From The Statute And The Realities Of Practice.

Here and in *Sandoz*, the Federal Circuit justified its interpretation of Section 262(*l*)(8)(A) in part by asserting that mandating notice of marketing post-licensure would benefit the second stage litigation because "the applicant's product, uses, and processes are fixed by the license." (App. 18a (citing *Sandoz*, 794 F.3d at 1358, 1360)). Even assuming that is true, the court's decisions fundamentally altered the patent dance in a manner inconsistent with the statute and not contemplated by Congress.

The BPCIA "affirmatively contemplates two stages of litigation . . . ." (App. 18a). The filing of an aBLA application and notice of acceptance by FDA

triggers the beginning of the BPCIA's patent resolution procedures under which aBLA applicants may choose to participate in the information exchange under Sections 262(*l*)(2)-(6). Applicants who disclose the information specified in paragraph (*l*)(2)(A), and engage in the information exchange described in paragraphs (*l*)(3)-(*l*)(5), control whether litigation occurs in one or two stages.

Applicants may agree to immediately litigate all listed patents, or may narrow the first stage litigation while leaving other patents to be resolved in the second stage. 42 U.S.C. § 262(*l*)(4)-(5). If an applicant chooses not to litigate all patents immediately, the Section 262(*l*)(8)(A) notice triggers a second litigation stage; the applicant controls that timing. 42 U.S.C. § 262(*l*)(8)(A); *see also* App. 7a, 18a-19a. To allow the applicant and RPS to litigate these patent disputes pre-licensure, the BPCIA creates an artificial act of infringement based on filing an aBLA. 35 U.S.C. § 271(e)(2)(C). Finally, to properly interpret the statute, one must read the patent dance provisions (Section (*l*)) in light of the exclusivity provisions (Section (*k*)). The statute mandates a four year delay before any applicant may file an aBLA for a biosimilar product, and delays biosimilar licensure until twelve years after reference product licensure. 42 U.S.C. § 262(k)(7).

In sum, Congress structured the BPCIA to allow the parties—and particularly the applicant—to control the timing of litigation. The statute's plain language allowed the parties to begin both litigation stages pre-licensure, if they chose, thus perhaps resolving all relevant patent disputes *within the eight*

year statutory window between the earliest possible aBLA filing date and the earliest possible aBLA product licensure. Put simply, the law *allowed* the parties to begin the second stage of litigation post-licensure, but did not *require* it. 42 U.S.C. § 262(*l*)(2)-(9).

But now, because the notice provision triggers the second litigation stage, the Federal Circuit's decision *requires* the applicant to delay any potential second stage litigation until after its biosimilar product is licensed whether the parties like it or not. Under this interpretation of Section 262(*l*)(8)(A), if the first stage litigation begins several months after the aBLA filing and reaches final judgment years later, the parties must wait to begin the second litigation stage (perhaps for years) until the twelve year market exclusivity expires. This result makes no practical or policy sense, wastes judicial resources, and undercuts the BPCIA mechanisms designed to permit and encourage the parties to resolve patent disputes before licensure. Nothing in the statute or its legislative history justifies the Federal Circuit's radical change to the timing of the litigation.

The Federal Circuit also justifies its decision by hypothesizing that its 180-day post-licensure delay would provide time to adjudicate patent rights without "the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury." (App. 20a). But this too is speculation. Allowing the parties to begin—and possibly complete—the second litigation stage before licensure would provide much more time for discovery and analysis, and do far more

to reduce mad rushes to the courthouse, while remaining faithful to the statute's text and purpose.

Finally, though the Federal Circuit's concern for "the existence of fully a crystallized controversy" might seem logical in the abstract, *Sandoz*, 794 F.3d at 1358, this concern is again divorced from reality. As the Federal Circuit has acknowledged, under the BPCIA the application itself "circumscribes and dominates the assessment of potential infringement." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014). No one disputes that federal courts have jurisdiction to hear patent cases brought under the BPCIA even if those cases begin and end years before licensure. The BPCIA is structured to allow and encourage pre-licensure litigation. 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); 42 U.S.C. § 262(*l*)(4), (*l*)(6). The Federal Circuit cannot justify rewriting the BPCIA's notice provision based on abstract concerns that different timing might work better.

C. The Federal Circuit's Interpretation Of Section 262(*l*)(8)(A) Will Lead To Absurd Results That Harm Applicants And Consumers While Providing No Added Incentives To Innovate.

The Federal Circuit seemingly overlooks the broader anti-consumer impact of mandatory post-licensure notice. If this decision stands, licensed biosimilars will always be held off the market for 180 days, *even when all relevant patents have expired or been defeated*.

The facts here show this absurd result is not merely hypothetical. A district court has already concluded that Apotex's manufacturing process does not infringe the last unexpired patent Amgen asserted against Apotex. (Pet. 13). But Apotex's aBLA product has not yet been licensed, so Apotex cannot trigger the 180-day notice period. It is therefore possible, even likely, that all patent issues will be resolved before Apotex can provide the pre-marketing notice. So even though Apotex successfully cleared Amgen's patents, the Federal Circuit's decision will force Apotex to wait 180 days after licensure before entering the market.

Other aBLA holders may soon face this same situation. For example, Amgen has asserted only two patents in an ongoing dispute involving Hospira's proposed biosimilar for Amgen's Epogen®, and both have now expired. *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del. filed Sept. 18, 2015). Nonetheless, the Federal Circuit's decision will force Hospira to delay commercial marketing by 180 days after licensure even though all relevant patents and exclusivities have expired. This absurd result will not "occur less and less as time goes by." Instead, it may well become more common as time passes, because more applicants will file more aBLAs immediately after the four-year data exclusivity period expires. The BPCIA then provides up to eight years before the aBLA products can be licensed—more than enough time to complete the first litigation stage resulting from the patent dance. 42 U.S.C. § 262(k)(7)(A).

The far-reaching implications of this erroneous decision support granting *certiorari*. The public harm and anti-competitive effects from the Federal Circuit's post-licensure notice requirement will multiply as time passes and more applications are filed. The Federal Circuit is simply wrong about the negative effects and potential for absurd results arising from its interpretation of Section 262(*l*)(8)(A), which will always delay patient access to biosimilar products regardless of patent protection.

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

A. The Federal Circuit's Interpretation Of Section 262(*l*)(8)(A) Conflicts With The Text And Purpose Of The BPCIA.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A) to require mandatory post-licensure notice in all cases—even when the applicant provides its aBLA and manufacturing information to the RPS—cannot be squared with the text or purpose 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, the BPCIA's plain language and structure, viewed in the proper context, show that Congress contemplated that applicants might not always provide pre-marketing notice, but could do so before licensure.

The BPCIA qualifies the timing of pre-marketing notice only by saying "[t]he subsection (k) applicant shall provide notice . . . *not later than 180 days before* the date of the first commercial marketing of the bio-

logical product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). This language sets the latest date on which a biosimiliar may give notice, not the earliest. So, by its express terms, Section 262(*l*)(8)(A) permits pre-licensure notice. But the Federal Circuit added an "earliest date" to that paragraph—no earlier than licensure—without acknowledging the conflict with the rest of the statute or recognizing the impact of its decision.

As discussed above, the structure of the BPCIA's patent dance and exclusivity provisions show Congress intended to permit and encourage the orderly, pre-licensure resolution of patent disputes by allowing the parties to begin, and perhaps resolve, *all* patent disputes in the *eight-year window* between the earliest possible aBLA filing and the earliest possible biosimilar licensure. 42 U.S.C. § 262(k)(7); 42 U.S.C. § 262(*l*)(2)-(9). As written, the BPCIA allowed the parties, and particularly the applicant, to control the timing of litigation. The notice provision's "not later than" language *allowed* the applicant to trigger the second litigation stage post-licensure, but did not *require* such delay. 42 U.S.C. § 262(*l*)(8)(A). By interpreting that paragraph to both require the applicant to deliver the notice and to do so post-licensure, the Federal Circuit severely limited the applicant discretion provided by statute, delayed any second stage patent litigation for years, and created an automatic 180-day post-licensure marketing delay whether or not the RPS still holds any patents relevant to the biosimilar product.

The Federal Circuit's interpretation of Section 262(*l*)(8)(A) conflicts with the statutory language,

and with the structure and broader purpose of the BPCIA's dispute resolution mechanism. It also leads to absurd results. The statutory language and legislative history do not support such radical revisions to the patent dance, and particularly not an automatic 180-day stay of commercial marketing.

This Court should grant *certiorari* and review this decision to allow the BPCIA's early patent resolution mechanism to work as intended.

B. The Federal Circuit Improperly Created An Extra-Statutory Remedy To Enforce The Pre-Marketing Notice Provision Beyond The Remedies Specified In Paragraphs (*l*)(8)(B) And (*l*)(9)(B).

The Federal Circuit's decision requires all aBLA applicants to provide pre-marketing notice, even those who complied with the information disclosure under paragraph (*l*)(2)(A) and engaged in the patent dance. The decision also allows the RPS to seek an injunction to enforce the notice provision. (App. 26a). By doing so, as Petitioner notes, the court rendered superfluous the specified statutory remedy. (Pet. 12). Congress had already provided a potential remedy to the RPS when an aBLA applicant complied with paragraph (*l*)(2)(A) but chose not to provide pre-marketing 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 prod-

> uct 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).

So if an applicant (like Apotex) has participated in the patent dance by providing its aBLA and manufacturing information to the RPS (like Amgen), but chooses not to provide pre-marketing notice under Section 262(*l*)(8)(A), the statute expressly allows the RPS to bring a declaratory judgment action asserting any or all patents on the RPS's initial list. 42 U.S.C. § 262(*l*)(9)(B). These are essentially the same patents the RPS could assert in a preliminary injunction action under Section 262(*l*)(8)(B) if the applicant *had* provided pre-marketing notice.[3] *Compare* 42 U.S.C. § 262(*l*)(8)(B)(i)-(ii); 42 U.S.C. § 262(*l*)(9)(B).

The Federal Circuit cites no direct evidence that Congress intended to provide any remedy beyond Section (*l*)(9)(B) when an applicant does not provide

---

[3] As a practical matter, of course, the RPS can pursue declaratory judgments only as to patents that have not yet expired, or were not already adjudicated or settled. So, the BPCIA's express remedies avoid the absurd result the Federal Circuit's decision creates—an automatic 180-day stay to accommodate nonexistent patent rights.

pre-marketing notice. Yet the court created an extra-statutory remedy by allowing the RPS to compel the notice, and justified its creation by stating "we do not find that paragraph (9) establishes that a declaratory-judgment action is the sole remedy for violating 8(A)," and paragraph (9)(B) "plainly does not imply exclusivity of that remedy." (App. 22a-23a). The court erred by doing so, because the law does not allow courts to add additional extra-statutory remedies whenever Congress does not expressly forbid it.

"[W]here 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." *Id.* at 533 (quoting *Middlesex Cty. Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 15 (1981)); *Alexander v. Sandoval*, 532 U.S. 275, 290 (2001) ("The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others."). This principle applies 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."). The law is clear that Congress establishes the remedies and the enforcement rights:

> [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***.

Transamerica, 444 U.S. at 24 (citations omitted) (emphasis added). "[E]ven 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 Univ. v. Doe*, 536 U.S. 273, 284 (2002) (quoting *Alexander*, 532 U.S. at 286). The Federal Circuit cites no direct evidence of such Congressional intent, and none exists. The court's arguments supporting its additional remedy also fall flat.

The Federal Circuit stated that Apotex did not show that "(9)(B), when it applies, implicitly negates 35 U.S.C. § 271(e)(4)'s provision of damages and injunctive remedies." (App. 23a). But this argument conflates two distinct issues–paragraph (9)(B) provides the exclusive remedy for an applicant's failure to follow the patent dance procedures set forth in Section 262(*l*), whereas Section 271(e)(4) provides the exclusive remedies when a court finds infringement. These two provisions remedy very different alleged "violations," so Section 262(*l*)(9)(B) logically need not "negate" Section 271(e)(4) to serve as the exclusive remedy when an applicant fails to provide pre-marketing notice.

The Federal Circuit also defends its extra-statutory remedy by arguing, in essence, that the remedy specified in paragraph (9)(B) does not suffice to enforce paragraph 8(A). "A declaratory-judgment action on the patent merits in the ordinary case would not serve (8)(A)'s essential purpose or, therefore, be a meaningful remedy *for the (8)(A) violation*." (App. 24a). First, Congress, not the courts, establishes and determines the sufficiency of remedies for statutory violations. Second, this argument hinges on the court's reading of paragraph (8)(A) as a "categorical, 'standalone,' 'mandatory'" provision granting the RPS an "(8)(A) notice right." (App. 24a (quoting *Sandoz*, 794 F.3d at 1359-60)). So, the Federal Circuit here presumed that Congress *both* granted the RPS a private notice right in paragraph 8(A), *and* intended that the RPS have a private remedy to enforce that right. But the court cannot assume away those critical underlying questions, and this circular "insufficient remedy" argument does not justify its decision.

Moreover, as discussed, the Federal Circuit's holding that Section 262(*l*)(8)(A) is a standalone provision mandating post-licensure notice effectively grants every RPS a right to an automatic 180-day preliminary injunction. This outcome squarely conflicts with the express language of the very next section. Section 262(*l*)(8)(B) allows the RPS, "[a]fter receiving the notice," to "*seek* a preliminary injunction prohibiting the subsection (k) 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 "stage-two patents"). 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). This passage confirms Congress did not intend that the notice provision create an automatic right to a 180-day injunction in every case. Instead, Section 262(*l*)(8)(B) grants the RPS the more limited right to immediately "seek" such an injunction after receiving notice. To obtain that injunction, the RPS must make the required showing on the merits and equities, in keeping with this Court's precedent. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 393-94 (2006).

C. The Federal Circuit's Decision Creates An Automatic 180-day Injunction After Licensure, Contrary To This Court's Precedent.

Immediate review is also warranted because the Federal Circuit decision grants every RPS the right to an automatic 180-day post-licensure injunction, contrary to binding precedent. In *eBay*, this Court rejected any kind of "general rule" for an automatic injunction under the Patent Act. *Id.* at 393-94. This Court should step in to ensure that its precedent is followed.

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 using "broad classifications" or "categorical rule[s]" when applying the traditional principles of equity. *eBay*, 547 U.S. at 392-93.

The Federal Circuit recognized this directive when it overruled its longstanding practice of issuing permanent injunctions, without considering traditional principles of equity, whenever it found a patent valid and infringed 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). But here and in *Sandoz*, the Federal Circuit reverted to old errors by effectively rewriting Section 262(*l*)(8)(A) to impose an automatic injunction without considering the merits or equities.

There is no basis in the BPCIA, no basis in equity, and no basis in logic or common sense to delay patient access to lower-cost biosimilars for even a day—much less 180 days—without fully considering the equities and requiring the RPS to justify the merits of its patent claims. Moreover, there can be no good reason for such delay when the RPS can assert no relevant patents.

D. The Federal Circuit's Decision Improperly Creates A Private Right of Action That Is Currently Being Applied By The District Courts And Will Unnecessarily Delay The Availability Of Biosimilar Products.

The BPCIA contains no express mechanism allowing the RPS to privately enforce Section 262(*l*)(8)(A). Nor can a private right of action be implied by the language or structure of the Act. Despite the lack of evidence that Congress intended any

such thing, the Federal Circuit created a private right of action allowing an RPS to compel notice. This Court must intervene to correct the Federal Circuit's overreach.

"Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Alexander*, 532 U.S. at 286. 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) (quoting *Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO*, 451 U.S. 77, 94 (1981); *Gonzaga*, 536 U.S. at 286 ("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.").

The commercial notice provision "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). Specifically, Section 262(*l*)(8)(A) instructs 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 have been met—(1) the applicant has provided notice under subparagraph (A), and (2) the RPS seeks the injunction before the applicant has commercially marketed its biosimilar product. 42 U.S.C. § 262(*l*)(8)(A)-(B). Section 262(*l*)(8)(C) simply pro-

vides that the parties will "reasonably cooperate" to expedite any necessary discovery in such an injunctive proceedings. *Id.* at § 262(*l*)(8)(C). Nothing in Section 262(*l*)(8) provides the RPS a legal "right" to notice, much less the right to *enforce* the notice provision by seeking an injunction.

The Federal Circuit side-steps the private right of action analysis by stating that "Apotex has not asserted that (8)(A) creates no privately enforceable right . . . ." (App. 21a). But, at least one district court has adopted and extended the Federal Circuit's decision to deny a motion for partial dismissal arguing that the BPCIA provides no private right of action to enforce the notice provision. *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839, 2016 WL 4183748, at *3 (D. Del. Aug. 5, 2016). The district court reasoned that the rationale behind the Federal Circuit's conclusion that mandatory post-licensure notice is "enforceable by injunction" (*id.* at *2 (quoting *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1055 (Fed. Cir. 2016))), must apply with "equal force to the declaratory judgment claim at issue here" (*Hospira*, 2016 WL 4183748, at *3). More specifically, the district court reasoned that since the Federal Circuit has allowed an RPS to seek an injunction to compel notice, an RPS must also have the right to seek a declaration of its right to receive such notice. *Id.* at *3. In other words, since "[t]he Federal Circuit has already recognized the availability of injunctive relief for violations of [the notice provision,] [i]f presented with the question raised by [Hospira's] motion, it would make sense to come to the same conclusion regarding the availability of declaratory relief." *Id.*

This Court should intervene immediately to correct the Federal Circuit's decision creating a private right of action to enforce the extra-statutory remedy imposing an automatic 180-day post-licensure injunction, and thereby allow safe and more affordable biosimilar products to reach the market without needless delay.

III. THE ISSUES RAISED IN THE PETITION ARE RECURRING AND CRITICAL TO THE PROPER APPLICATION OF THE BPCIA, AND SHOULD BE CONSIDERED ALONG WITH THE CLOSELY-LINKED ISSUES IN THE *SANDOZ* CASE NOW AWAITING A *CERTIORARI* DECISION.

This case presents an ideal opportunity for this Court to resolve an issue critical to the biosimilars industry and important to the public while the BPCIA is still in its infancy. The adverse impacts and unintended consequences of the Federal Circuit's erroneous decision here and in *Sandoz* threaten to undermine the delicate balance Congress crafted between innovation and competition in the BPCIA. The growing, multibillion-dollar biosimilars industry needs this Court to resolve these disputed issues surrounding pre-marketing notice and commercial marketing. Until this Court reverses the decision below, patient access to biosimilars will always be unnecessarily delayed by an additional 180 days, whether or not an RPS has any patent rights and whether or not an aBLA applicant participates in the information exchange and patent resolution provisions of Section 262(*l*).

The Federal Circuit's decisions here and in *Sandoz* have set dangerous precedents that will delay commercial availability of licensed biosimilars by at least 180 days after licensure *in all circumstances* regardless of the actions by the aBLA applicant or any RPS patent rights. The Federal Circuit's decisions apply even where an RPS no longer has any patent rights to enforce because its patents expired, it lost all patent litigation, or it has settled the patent disputes. The Federal Circuit's flawed interpretation of the BPCIA is hindering public access to biosimilars right now and will continue to do so until this Court intervenes.

The consequences of these Federal Circuit decisions are far-reaching, and will steadily grow as applicants file more aBLA applications. Since January 2013, FDA has received at least 29 biosimilar investigational new drug applications.[4] Among these applications, there are currently four licensed biosimilars and at least six other publicly known aBLA submissions pending before FDA.[5]

---

[4] FDA-TRACK, *Number of Biosimilar Investigation New Drug Applications (INDs)*, (Oct. 10, 2016), http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cder&status=public&id=CDER-RRDS-Number-ofbiosimilar-INDs&fy=All.

[5] Pink Sheet, Pending Biosimilars, (Mar. 7, 2016), http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cder&status=public&id=CDER-RRDS-Number-of-biosimilar-INDs&fy=All.

Increasing patient access to more affordable biosimilar medicines will likely generate enormous savings. As Petitioner also points out, the industry "project[ed] that the United States would save $250 billion between 2014 and 2024 if just the 11 likeliest biosimilars would enter the market" and "[t]he savings from a biosimilar pathway [are] likely to grow significantly greater when an additional set of major biologic drug patents expire between 2026 and 2028." (*The $250 Billion Potential of Biosimilars*; *see also* Pet. 23-27).[6]

Only this Court can correct the Federal Circuit's flawed interpretation of the BPCIA, which binds subsequent Federal Circuit panels and district courts nationwide. No other court of appeals will likely hear these issues given the close ties between the notice provision and the patent dance, which falls under the Federal Circuit's exclusive appellate jurisdiction over patent infringement claims. 28 U.S.C. § 1295(a)(1); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993).

This Court should grant *certiorari,* and review together the Federal Circuit's decisions here and in *Sandoz* given their similar and often overlapping questions of the proper interpretation of the BPCIA and its process for resolving patent disputes. Con-

---

[6] Steve Miller, *The $250 Billion Potential of Biosimilars*, EXPRESS SCRIPTS (Oct. 10, 2010), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars #sthash.mjIFLF1s.dpuf

sidering and resolving the two factual scenarios presented in those cases will dispel uncertainty and inform the biosimilar industry of its options under the BPCIA. Moreover, since this Court has invited the views of the Solicitor General in *Sandoz*, Mylan urges this Court to seek the Solicitor's views here as well. Both cases raise important issues concerning competition and health care policy.

CONCLUSION

The Federal Circuit's decision conflicts with the text and purpose of the BPCIA, and with equity, logic, and common sense. Requiring mandatory post-licensure notice produces absurd results, and there is no reason to extend RPS market exclusivity by 180 days in every case regardless of the circumstances, delaying patient access to every lower-priced biosimilar product. This Court should intervene to protect patient interests by correcting the Federal Circuit's statutory interpretation, and to ensure that awards of equitable relief meet traditional requirements. This Court should grant the petition for *certiorari*.

Respectfully submitted,

OCTOBER 14, 2016

WILLIAM A. RAKOCZY
Counsel of Record
PETER J. CURTIN
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 Pharmaceuticals Inc.