No. 2016-1308

United States Court of Appeals for the Federal Circuit

AMGEN INC. AND AMGEN MANUFACTURING LTD.,
PLAINTIFFS-APPELLEES,

v.

APOTEX INC. AND APOTEX CORP.,
DEFENDANTS-APPELLANTS.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
IN CASE NO. 15-CV-61631, JUDGE JAMES I. COHN

BRIEF FOR HOSPIRA, INC., CELLTRION HEALTHCARE CO., LTD., AND CELLTRION, INC. AS *AMICI CURIAE* SUPPORTING DEFENDANTS-APPELLANTS

SAMUEL S. PARK
DAN H. HOANG
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601
(312) 558-5600

CHARLES B. KLEIN
STEFFEN N. JOHNSON
ANDREW C. NICHOLS
Winston & Strawn LLP
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000

Counsel for Amici Curiae
Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc.

CERTIFICATE OF INTEREST

Counsel for *Amici Curiae* Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc. certify the following:

1. The full name of every party or amicus represented by me is:

Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Hospira, Inc. is an indirect, wholly-owned subsidiary of Pfizer Inc. Pfizer Inc., a publicly held corporation, has no parent corporation and no publicly held corporation holds 10% or more of its stock.

Celltrion Healthcare Co., Ltd. has no parent corporation. The entities that own 10% or more of Celltrion Healthcare Co., Ltd. include Ion Investments B.V., a Netherlands corporation that is 100% owned by Temasek, an investment company based in Singapore, and One Equity Partners IV, L.P., a Cayman Islands company that is 100% owned by JP Morgan.

Celltrion, Inc. has no parent corporation. The entities that own 10% or more of Celltrion, Inc. include Celltrion Holdings Co., Ltd., a Korean corporation, and Ion Investments B.V., a Netherlands corporation that is 100% owned by Temasek, an investment company based in Singapore.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Winston & Strawn LLP: Charles B. Klein, Steffen N. Johnson, Andrew C. Nichols, Samuel S. Park, and Dan H. Hoang

Dated: JANUARY 6, 2016

/s/ Charles B. Klein

CHARLES B. KLEIN
Winston & Strawn LLP
1700 K Street, N.W.
Washington, D.C. 20006
(202) 282-5000
cklein@winston.com

Counsel for Amici Curiae *Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc.*

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*[1]

This appeal raises critical issues affecting the competitive structure of the biosimilar industry, which seeks to provide consumers with lower-cost alternatives to expensive biologic medications. *Amici* Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc. support Apotex's interpretation of the Biologics Price Competition and Innovation Act ("BPCIA"). The district court misread the statute's notice of commercial marketing provision (42 U.S.C. § 262(*l*)(8)(A)) to authorize an automatic, bondless injunction that delays marketing of every biosimilar product until at least 180 days after approval by the FDA.

The BPCIA does not grant Amgen and other reference product sponsors ("RPSs" or "sponsors") such a marketing windfall. In subsection (k) of the statute, Congress *expressly* granted sponsors 12 years of marketing exclusivity independent of their patents. *Id.* § 262(k)(7)(A). Congress did not *impliedly* provide an additional form of marketing exclusivity for every biosimilar application—extending at least another 180 days following FDA approval. In fact, the notice of commercial marketing provision appears in an entirely separate subsection of the statute, entitled "Patents." *Id.* § 262(*l*). As its title suggests, subsection (*l*) creates a process to address whether biosimilar marketing should be delayed beyond 12 years

[1] All parties have consented to the filing of this brief, no part of which was authored by counsel for a party. Nor has any party or party's counsel, or any person or entity other than the *amici*, funded the preparation or submission of this brief.

due to patent rights. According to the statutory patent-exchange process (sometimes called the "patent dance"), paragraph (*l*)(8)(A) provides for 180 days' notice before commercial marketing as one means of allowing the parties to address secondary patent disputes that may (but often will not) arise. Construing the notice provision as imposing a new form of marketing exclusivity—unrelated to patent rights—would distort the statute's text and clear purpose, provide an unwarranted monopoly, and cost consumers billions of dollars.

Our position comports with the Court's ruling this past summer in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). There, the majority found the subsection (*l*) "patent dance" process optional, because the statute provides a remedy if the applicant refuses to disclose timely its abbreviated biologics license application ("aBLA"). Any other statutory reading would render this remedy "superfluous." *Id.* at 1356. According to the Court there, the statute likewise provides a remedy if (1) the applicant "fail[s] to comply with paragraph (*l*)(8)(A)," the 180-day notice provision; and (2) that failure occurs "*after the applicant has [already] complied* with" the provision requiring that the applicant disclose its aBLA to the sponsor. *Id*. at 1359. Thus, as a matter of statutory construction, this 180-day notice is optional so as long as the applicant participates in the patent dance by timely disclosing its aBLA.

In *Sandoz*, however, the biosimilar applicant did *not* timely disclose its aBLA. In that specific circumstance, the majority found the 180-day notice mandatory. Thus, a biosimilar applicant must wait 180 days after FDA approval to market its biosimilar product only if it "*completely fails to provide its aBLA* … by the statutory deadline." *Id.* at 1360 (emphasis added).

Sandoz encourages compliance with the statutory patent dance because only those applicants that fail to provide their aBLA timely will face a 180-day injunction. But this case is different. As Judge Chen noted in his dissent in *Sandoz*, without contradiction by the majority: "nothing in the majority opinion suggests that this automatic [180-day] injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A)." *Id.* at 1371 (Chen, J., dissenting-in-part). Judge Chen was correct, and this Court should now so hold.

In short, neither the BPCIA nor *Sandoz* supports the automatic 180-day marketing exclusivity imposed by the district court. This Court should reverse, vacate the underlying injunction, and confirm that: (1) notice is not mandatory when the aBLA is timely disclosed; (2) the statute confers no private right of action to enforce the 180-day provision; and, even if it did, (3) reading into that provision an automatic injunction would flout *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

Amici have a vital interest in these issues. Hospira, a wholly-owned subsidiary of Pfizer Inc., has an interest in developing biosimilars, among other pharmaceutical products. Hospira has teamed with Celltrion, Inc., which is a Korean company that independently develops and manufactures biosimilar antibodies and novel drugs, along with Celltrion Healthcare Co., Ltd., which markets and distributes drugs developed by Celltrion, Inc. in more than 120 countries.

Amici seek to introduce in the United States a biosimilar version of Janssen Biotech, Inc.'s multi-billion dollar drug Remicade® (infliximab) at an affordable cost to patients suffering from debilitating diseases, including rheumatoid arthritis. Janssen sued *amici* under the BPCIA for, among other things, allegedly violating the 180-day notice provision. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, No. 1:15-cv-10698 (D. Mass.).

Like Apotex here, and unlike the situation in *Sandoz*, Celltrion timely produced its aBLA to Janssen and participated in the patent dance. With *amici*'s agreement, Janssen sued to enforce all six patents it identified during the patent dance (three of which are no longer at issue). Like Amgen here, Janssen has not sought an injunction based on patent rights.[2] Rather, Janssen says the Court must

[2] Janssen has moved to stay the case as to one of the remaining three patents pending a reexamination, the second patent expires in a few months, and Janssen concedes that the third patent is not literally infringed.

force all biosimilar applicants to wait at least 180 days after FDA approval to launch their biosimilar products, regardless of patent rights. That would dramatically delay biosimilar competition, to the ultimate detriment of consumers. But Amgen and Janssen are wrong. An automatic injunction is not required by the BPCIA or this Court's decision in *Sandoz*. This Court should reverse and vacate the underlying injunction.[3]

BACKGROUND

In the BPCIA, Congress created an expedited path for licensing biosimilars—which, as their name suggests, are biologic products similar to branded biologics previously licensed by the FDA. Subsection (k) addresses "Licensure of biological products as biosimilar or interchangeable." 42 U.S.C. § 262(k). This subsection allows the biosimilar applicant to rely on data submitted by the sponsor of a new biologic drug. In return, the sponsor gets 12 years of marketing exclusivity regardless of whether any patents cover the biosimilar. *Id.* § 262(k)(7)(A).

A. The subsection (*l*) patent process

The separate subsection (*l*), entitled "Patents," sets forth a process to identify relevant patents so that any patent disputes may be resolved efficiently through litigation. *Id.* § 262(*l*). To identify and resolve biosimilar patent disputes, the

[3] Hospira is litigating a similar dispute against Amgen in *Amgen Inc. v. Hospira, Inc.*, C.A. No. 15-839 (RGA), pending in the District of Delaware.

BPCIA amends the Public Health Service Act and the Patent Act to provide a pathway for the reference product sponsor and biosimilar applicant to exchange lists of patents to be litigated, and to prioritize the most important patent disputes. Although the statutory patent processes are not mandatory, Congress provided incentives for each party to participate in the "patent dance" by imposing penalties for non-participation.

At the outset, the applicant may provide to the sponsor the biosimilar application and information describing the applicant's manufacturing process. 42 U.S.C. § 262(*l*)(2)(A). If the applicant does *not* do so (as in *Sandoz*), the sponsor—but not the applicant—may bring an immediate declaratory judgment action for patent infringement. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

If the applicant *does* provide the information (the approach taken by Apotex and *amici*), the sponsor reciprocates by providing a list of patents under which it "believes a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(*l*)(3)(A)(i). If the sponsor does not respond by providing its patent list, or omits some patents, the sponsor may not sue for infringement of "a patent that should have been included." 35 U.S.C. § 271(e)(6)(C). The statute thus imposes a harsh penalty on the sponsor for not disclosing relevant patents.

If the sponsor provides its patent list, the applicant may respond with its own list of patents that reasonably could be asserted (and also responds by providing a

"detailed statement" of the applicant's factual and legal patent contentions for each patent listed by the sponsor). 42 U.S.C. § 262(*l*)(3)(B). Through this information exchange, the BPCIA encourages the parties to agree upon "which, if any, patents" will be the subject of an "action for patent infringement." *Id.* § 262(*l*)(4)(A).

A final patent list that may give rise to an "immediate" patent infringement lawsuit is determined either by agreement or by following the steps described in the statute. *Id.* § 262(*l*)(6)(A),(B); 35 U.S.C. § 271(e)(2)(C). If the sponsor sues right away on a patent appearing on the final patent list (within 30 days), it may seek the full complement of infringement remedies for that patent—including injunctive relief and damages for lost profits. 42 U.S.C. § 262(*l*)(6)(A),(B); 35 U.S.C. § 271(e)(4). But if the sponsor does not file an infringement lawsuit for a patent appearing on the final patent list within this 30-day period, or if its suit "[is] dismissed … or [is] not prosecuted … in good faith," "the sole and exclusive remedy" is a "reasonable royalty." 35 U.S.C. § 271(e)(6)(A), (B). That is, Congress punishes sponsors for waiting to sue on a patent that makes the final list by limiting their remedy. This process encourages the parties to resolve key patent disputes expeditiously, thus speeding competition.

Importantly, nothing in the statute prevents the sponsor from seeking a preliminary injunction on any litigated patents after the lawsuit begins. As with any injunction, the only restriction is satisfying the traditional four-factor injunctive-

relief test—which, of course, considers the strength of the sponsor's patent claims, the risk of irreparable harm, the balance of hardships, and the public interest.

B. The 180-day notice provision in paragraph (*l*)(8)(A)

All of this leaves a question of timing: When can the parties litigate any patents that appeared in an initial patent list but were omitted from the final patent list—i.e., "phase-two patents"? Subject to an exception described below, neither the sponsor nor the applicant may sue on any of these secondary, phase-two patents "prior to the date notice [of commercial marketing] is received under paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(A).

Under the BPCIA, the bar on litigating phase-two patents can be lifted in one of two ways. First, as discussed in paragraph (*l*)(9)(A), the applicant can provide a notice of commercial marketing. This notice is described in paragraph (8)(A), which says "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A). If provided, this notice creates a 180-day period during which either the sponsor or the applicant can file a claim seeking declaratory relief. As explained in paragraph (8)(B), the sponsor may then "*seek* a preliminary injunction … with respect to any [phase-two] patent." *Id.* § 262(*l*)(8)(B) (emphasis added). The injunction, therefore, is not automatic.

The statute also creates a second way to lift the bar on litigating phase-two patents—the applicant can refuse to provide the 180-day notice. In that instance, the "sponsor, but not the subsection (k) applicant," may file an immediate declaratory judgment action on any phase-two patents:

> If a subsection (k) applicant *fails to complete* an action required of the subsection (k) applicant under ... *paragraph (8)(A)* [i.e., fails to provide the 180-day notice], the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

Id. § 262(*l*)(9)(B) (emphasis added). In other words, an applicant that fails (or refuses) to provide the 180-day notice may never initiate its own action for declaratory judgment of non-infringement, invalidity, or unenforceability to obtain patent certainty before the product launch (but still could assert defenses to an action by the sponsor).

The statute thus gives the applicant a choice: provide the 180-day notice or lose its right to sue. Either way, the notice is not a requirement for FDA approval. Nor does it guarantee the sponsor market exclusivity. Instead, paragraph (8)(A) merely creates an optional process that allows the sponsor, after receiving the notice, to "seek" an injunction based on any phase-two patents. *Id.* § 262(*l*)(8)(B). Indeed, as discussed below, most cases that go through the statutory patent process—including this case as well as *amici*'s—do not involve any phase-two pa-

tents, because all relevant patents will be addressed in the first litigation phase. In those cases, the 180-day notice serves no purpose.

C. The *Sandoz* decision and the decision below

In *Sandoz*, the biosimilar applicant (Sandoz) refused to produce its aBLA and manufacturing information in a timely manner, arguing that the statute does not require such production. 794 F.3d at 1360. Amgen sued to enforce the BPCIA provision and sought injunctive relief, which the district court denied. Amgen appealed, and sought an injunction pending appeal under the traditional four-factor test. This Court granted the injunction (*id.* at 1362), and, in a split decision on the merits, addressed three issues of statutory interpretation.

First, the majority recognized that, under the BPCIA, the biosimilar applicant "shall provide" its application within the 20-day timeframe prescribed by paragraph (*l*)(2)(A), but this language does not impose a mandatory requirement. As the panel explained, the BPCIA's "'shall' provision … cannot be read in isolation," and Congress later "specifically sets forth the consequence" for failing to disclose the application on time—namely, "the RPS may bring an infringement action." *Id*. at 1355. Because "the BPCIA explicitly contemplates that a subsection (k) applicant might fail" to provide its aBLA and "specifically sets forth the consequence for such failure," it follows that "'shall' … does not mean 'must.'" *Id.* Otherwise, "mandating compliance [with the "shall" provision] in all circumstanc-

es would render [the consequence provisions] superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Id*. at 1356.

Second, all three panelists "conclude[d] that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." *Id.* at 1358. As a result, Sandoz's notice provided before FDA licensure was deemed legally ineffective.

Third, the majority held that the notice is mandatory only when the applicant "completely fails" to participate in the statutory information-exchange procedures:

> We therefore conclude that, where, as here, a subsection (k) applicant *completely fails* to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory.

Id. at 1360 (emphasis added). Here again, where the BPCIA "explicitly contemplate[] that a [biosimilar] applicant might fail to comply … and further specifies the consequence for such failure," the statute must be construed to allow for non-compliance to avoid rendering those provisions superfluous. *Id.* at 1359. Further, the panel found that, as discussed above, "paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with" the 180-day notice provision—"*after the applicant has complied* with paragraph (*l*)(2)(A)." *Id.* Because Sandoz did not comply with paragraph (*l*)(2)(A) by timely producing its aBLA, the Court turned to whether the 180-day notice was mandatory in that circumstance.

The Court found that "[p]aragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*)"—that is, "nothing in subsection (*l*) excuses [Sandoz] from its obligation to give notice of commercial marketing to [Amgen] after [Sandoz] has chosen not to comply with paragraph (*l*)(2)(A)." *Id.* at 1359-60. The Court further held, however, that the remedy for noncompliance in paragraph (*l*)(9)(B) "does not apply in this case," because "Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id.* at 1359. That is, the Court did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A) *here*"—where Sandoz refused to participate in the BPCIA patent exchange and thus never "complied with paragraph (*l*)(2)(A)." *Id.* (emphasis added).

Viewed collectively, these holdings establish that (1) any notice of commercial marketing must await FDA licensure, *but* (2) such notice is not mandatory unless the applicant "completely fails" to participate in the BPCIA patent-exchange process. *Id.* at 1360. In applying *Sandoz* here, however, the court below held that the 180-day notice provision creates a "defined statutory window" that "exists for *all* biosimilar products that obtain FDA licenses, regardless of whether the subsection (k) applicant complies with § 262(*l*)(2)." ADD-006 at 6 (emphasis added). The Court did not reconcile this holding with the reasoning in *Sandoz*.

ARGUMENT

The decision below misconstrues the BPCIA and this Court's decision in *Sandoz*. It also assumed a private right of action that does not exist. Even if this Court were to read the BPCIA both to require 180 days' notice in all cases, and to confer a private right of action to enforce that notice, reading the statute to provide an automatic injunction would violate *eBay*. This Court should reject the district court's statutory analysis and vacate its injunction—which, if upheld, would potentially hand branded biologic companies an additional 180-day exclusivity windfall and cause billions of dollars in harm to consumers.

I. The district court misread the 180-day notice provision as mandatory for all biosimilar applicants.

A. Under *Sandoz*, the 180-day notice is optional unless the applicant "completely fails" to initiate the patent dance.

Although the 180-day notice provision says the "applicant shall provide notice," this Court has recognized that the use of "shall" in the BPCIA "cannot be read in isolation"—and does not necessarily mean "must." *Sandoz*, 794 F.3d at 1355. Indeed, the statutory language instructing that the applicant "shall provide" its aBLA within a particular time period "does *not* mean 'must.'" *Id*. (emphasis added). The reason is that the statute provides a remedy for statutory noncompliance. Thus, when the applicant fails to comply with the statute, it does "not violate the BPCIA"—it simply triggers the available remedy, which otherwise would be rendered "superfluous." *Id*. at 1356-57.

The very same analysis applies to the 180-day notice provision, which states that the applicant "shall provide" such notice "not later than 180 days before" commercial marketing. 42 U.S.C. § 262(*l*)(8)(A). Here, too, the statute provides a remedy. This Court has recognized as much, noting "that paragraph (*l*)(9)(B) specifies the consequences for a subsequent failure to comply with paragraph (*l*)(8)(A) after the applicant has complied with paragraph (*l*)(2)(A)." *Sandoz*, 794 F.3d at 1359. The Court in *Sandoz* held that this remedy "does not apply" if the applicant does "not comply with paragraph (l)(2)(A) to begin with." *Id.* But that is not the situation here (or in *amici*'s dispute with Janssen), where the aBLA has been timely provided.

When applicable (as here), the paragraph (*l*)(9)(B) remedy effectively preserves any phase-two patent rights by ensuring that the sponsor may seek injunctive relief on those patents before the biosimilar launch. By authorizing "an action … for a *declaration* of infringement," Congress obviously contemplated lawsuits before the biosimilar is marketed (that is, before *actual* infringement). 42 U.S.C. § 262(*l*)(9)(B) (emphasis added). Thus, unless the applicant commits to providing the 180-day notice, the statute allows the sponsor to file a declaratory judgment action and seek a preliminary injunction whenever the issue becomes ripe under Article III—for example, after the FDA announces or holds its public advisory committee meeting on whether to recommend approval of the biosimilar application.

This remedy allows the sponsor to attempt to enforce any phase-two patents months before the biosimilar launch. (For example, the FDA publicly announced its advisory committee meeting addressing the biosimilar application at issue in *Sandoz* in December 2014 and did not approve the product until March 2015.)

Here, the district court improperly rendered this express statutory remedy "superfluous." *Sandoz*, 794 F.3d at 1356. The court also ignored Supreme Court precedent holding that "when legislation expressly provides a particular remedy or remedies, courts should not expand the coverage of the statute to subsume other remedies." *Nat'l R. R. Passenger Corp. v. Nat'l Ass'n of R. R. Passengers*, 414 U.S. 453, 458 (1974); *Consol. Edison Co. of N.Y. v. O'Leary*, 117 F.3d 538, 544 (Fed. Cir. 1997) (same); *see also* 35 U.S.C. § 271(e)(4) (providing that the statutory remedies are "the *only* remedies which may be granted by a court for an [artificial] act of infringement" under the BPCIA) (emphasis added).

Both Amgen and Janssen read too much into the following passage from *Sandoz*: "A question exists ... concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory [in light of paragraph (*l*)(9)(B)]. We conclude that it is." 794 F.3d at 1359. The Court did not stop there. It limited this conclusion to the facts before it—where Sandoz "completely fail[ed] to provide its aBLA and the required manufacturing information to [Amgen] by the statutory deadline." *Id.* at 1360. Again, this is precisely how Judge Chen read the majority decision. *Id.* at

1371 (Chen, J., dissenting-in-part). And rightly so. As the majority explained, "[w]hile it is true that paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id*. at 1359.

In sum, under *Sandoz*, an applicant that participates in the patent dance but fails to provide a notice of commercial marketing does "not violate the BPCIA"—it merely takes "a path expressly contemplated by the BPCIA." *Id.* at 1357, 1360. Unlike Sandoz, Apotex took this path, and that is dispositive under both the plain language of the BPCIA and this Court's holding in *Sandoz*.

B. The district court's injunction, if upheld, would destroy the incentive under *Sandoz* to participate in the patent dance.

As discussed, the Court in *Sandoz* found the 180-day notice provision mandatory only if the applicant "completely fails" to initiate the patent dance by timely providing its aBLA. *Id.* at 1360. By imposing a 180-day injunction under those circumstances, the Court prevented Sandoz from marketing its product upon FDA approval because Sandoz did not timely produce its aBLA to the sponsor. *See id.* (noting that "paragraph (*l*)(8)(A) ... require[s] notice of commercial marketing be given to allow the [sponsor] a period of time to assess and act upon its patent rights"). This statutory interpretation encourages applicants to disclose their applications on time and to participate in the patent dance.

By contrast, to hold that the 180-day notice is *always* mandatory—even if the applicant participates in the patent dance—would remove this strong incentive to follow the statutory patent-exchange process. If the injunction forbidding marketing will be imposed no matter what, many applicants may elect to sit out the patent dance. Neither Amgen nor Janssen have explained why Congress would have intended such a result, especially given the legislative history encouraging statutory "procedures to identify and resolve patent issues before a biosimilar is approved and placed on the market." *Biologics & Biosimilars: Balancing Incentives for Innovation,* Hr'g of Subcomm. on Courts & Competition Policy of H. Jud. Comm., 111th Cong. 77 (2009); *see also id.* at 39, 105-6, 200.

C. The 180-day notice has limited application and should not be construed as providing windfall marketing exclusivity.

The district court's injunction also ignores the limited purpose of the 180-day notice provision—namely, to initiate a second litigation phase that addresses any remaining disputed patents. Many (perhaps most) BPCIA lawsuits, including this case and *amici*'s case, will have only one phase, because the applicants often will agree to litigate all relevant patents put at issue by a sponsor in the first litigation phase. Thus, there is no reason to make such notice mandatory in *all* cases.

As discussed, the 180-day notice determines when the parties may litigate any patents that did not make the final patent list, or were issued or licensed after the BPCIA patent process—i.e., the phase-two patents. Generally, when the par-

ties have participated in the patent dance, neither the sponsor nor the applicant may sue on any of these phase-two patents "prior to the date [such] notice is received." 42 U.S.C. § 262(*l*)(9)(A). The notice thus lifts the bar on litigating phase-two patents. If provided, the notice triggers a 180-day period for the sponsor to "seek" (not automatically obtain) a preliminary injunction barring the launch of products that allegedly infringe one or more phase-two patents. *Id*. § 262(*l*)(8)(A), (B).

Indeed, the *Sandoz* majority confirmed that the 180-day notice concerns only phase-two patents when the patent process is followed. That is, the notice "allows the [sponsor] a period of time to seek a preliminary injunction *based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action*, as well as any newly issued or licensed patents." 794 F.3d at 1352 (emphasis added). The Court held that this 180-day period can begin no earlier than FDA approval. *Id.* at 1358. But there is no reason to impose a 180-day injunction after FDA approval in all cases. In most cases, all key patents will be addressed in the first litigation phase—during which there is no statutory bar to seeking a preliminary injunction. No second litigation phase triggered by the 180-day notice would be necessary in those cases.

Why should biosimilar applicants be required to provide a notice that serves no statutory purpose—particularly if the effect of such unnecessary notice delays competition for 180 days, thus harming consumers who stand to benefit from a

lower-priced biosimilar? And why would an automatic 180-day injunction be necessary even when the notice serves a statutory purpose (i.e., if phase-two patents need to be litigated)? After all, the statute authorizes a declaratory judgment action on such patents before the biosimilar is launched. Neither Amgen nor Janssen provides persuasive answers to these questions.

II. Even if the 180-day notice were mandatory here, Congress did not create a private right of action to enforce that notice.

The district court inexplicably sidestepped Apotex's argument that Congress never created a private right to seek injunctive relief enforcing the 180-day notice. D.I. 55 at 13. As the Supreme Court has repeatedly emphasized, "courts should not create liability . . . where Congress has elected not to." *E.g.*, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014). "When Congress intends private litigants to have a cause of action to support their statutory rights, the far better course is for it to specify as much when it creates those rights." *Cannon v. Univ. of Chicago*, 441 U.S. 677, 717 (1979) (emphasis added). As Congress here created no claim for the injunction entered below, it should be vacated.

Although the BPCIA confers a private right to seek declaratory relief as to patent rights if the applicant refuses to provide the 180-day notice (42 U.S.C. § 262(*l*)(9)(B)), the statute does not confer a private right to enforce the notice provision itself. There certainly is no such express right, as Amgen conceded in its earlier lawsuit against Sandoz—which did not allege a private right of action under

the BPCIA but, instead, sought to enforce California law. *See Sandoz*, 794 F.3d at 1350-51; Transcript of Oral Argument at 16:3-6, *Amgen, Inc. v. Sandoz, Inc.*, No. C 14-4741 (N.D. Cal. Mar. 13, 2015).

Although a private right of action may be implied in certain circumstances, the standard is very strict: "The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Absent such intent, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-87. "[U]nless this 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." *Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 94 (1981).

There is no evidence that Congress intended to create a private right of action to enforce paragraph (*l*)(8)(A). Indeed, the BPCIA explicitly provides the remedy for failing to provide the 180-day notice—authorizing an immediate declaratory judgment action. *See* 42 U.S.C § 262(*l*)(9)(B). And again, as *Sandoval* confirmed, "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." 532 U.S. at 290. Indeed, it is an "elemental canon" of statutory construction that where a statute expressly pro-

vides a remedy, courts must be "especially reluctant to provide additional remedies." *Karahalios v. Nat'l Federation of Federal Empl., Local 1263*, 489 U.S. 527, 533 (1989).

Had Congress intended to create an entirely different private right of action authorizing a 180-day injunction here, it could have said that a court "shall order an injunction," or at least "consider immediate injunctive relief," to enforce the notice. But Congress used no such language in paragraph (*l*)(8), even though it used this precise language elsewhere in the BPCIA.

When amending the Patent Act, Congress provided that, "[f]or an act of infringement, … [*t*]*he court shall order a permanent injunction* prohibiting any infringement of the patent by the biological product" under certain circumstances not relevant here. 35 U.S.C. § 271(e)(4) (emphasis added). Elsewhere in the BPCIA, Congress provided that the unauthorized disclosure of confidential information "shall be deemed to cause [the applicant] to suffer irreparable harm," and thus "the court *shall consider immediate injunctive relief*." 42 U.S.C. § 262(*l*)(1)(H) (emphasis added). In short, Congress knew how to address injunctive relief in the BPCIA when it wanted to—whether by commanding that "the court shall order" the injunction, or that "the court shall consider" an injunction. Here it did neither. And, "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress

acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation omitted).

Similarly, Congress expressly created a private counterclaim in the Hatch-Waxman Act, which this Court noted contains "certain similarities in its goals and procedures" to the BPCIA. *Sandoz*, 794 F.3d at 1351. In particular, 21 U.S.C. § 355(j)(5)(C)(ii)(I) authorizes "a counterclaim seeking an order requiring the [brand] to correct or delete [certain] patent information" submitted to the FDA. Thus, Congress obviously knows how to create a private right of action and remedy in this arena, yet it chose not to do so to enforce the 180-day notice provision.

The framework created by subsection (*l*) of the BPCIA creates a streamlined process designed to allow a biosimilar applicant and a sponsor to determine which patents should be part of patent litigation. Congress also specifically created a remedy for any failure to act under any provision of subsection (*l*)—namely, the initiation of a suit for patent infringement. Viewing the BPCIA framework as a whole, it is clear that Congress did not intend to create (and, in fact, did not create) a private right of action to enforce compliance with paragraph (*l*)(8)(A). As the Federal Circuit recognized in the Hatch-Waxman context, to the extent a private right of action is needed to enforce the patent disclosures and exchange provisions of the BPCIA, it is the responsibility of Congress, not the courts, to create one.

See, e.g., *3M v. Barr Labs., Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002); *Mylan Pharms, Inc. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001).

Ultimately, Amgen's claim for a 180-day injunction fails because paragraph (8)(A) contains no "rights-creating language" entitling it to bring a private right of action to enforce the 180-day notice provision, as opposed to its patent rights. *See Alexander*, 532 U.S. at 288 (quotation omitted); *see also Touche Ross & Co. v. Redington*, 442 U.S. 560, 571-76 (1979) ("[I]mplying a private right of action on the basis of congressional silence is a hazardous enterprise, at best."). Far from it: Subsection 262(*l*) of the BPCIA, entitled "Patents," merely provides a framework to ensure that patent disputes are addressed efficiently. As discussed above in Section I, that subsection creates no additional layer of marketing exclusivity.

III. Imposing an automatic injunction would violate *eBay*.

Even if this Court were to find that the BPCIA's notice provision is mandatory and Congress implied a private right of action to enforce that provision, it still would be inappropriate to enter an *automatic* 180-day injunction as a remedy for failure to provide the 180-day notice. Nothing in the BPCIA alters the longstanding rule that "whether to grant or deny injunctive relief rests within the equitable discretion of the district courts," or that "such discretion must be exercised consistent with traditional principles of equity." *eBay Inc.*, 547 U.S. at 394. Moreover, the Supreme Court "has consistently rejected invitations to replace traditional

equitable considerations with a rule that an injunction automatically follows" a statutory violation. *Id*. at 392-93.

Importantly, Apotex has stipulated that three of the four *eBay* factors favor injunctive relief, contesting only likelihood of success on the merits. ADD-001 at 1. *Amici* have made no such concession in their litigation with Janssen. Thus, if the Court were inclined to affirm the injunction here, we respectfully request that it be mindful of the four-factor *eBay* test and avoid holding that an injunction, which is an extraordinary remedy, automatically issues if the applicant refuses to provide the 180-day notice.

After all, the majority in *Sandoz* did not so rule. Instead, the panel relied on its earlier decision granting an injunction pending appeal, which applied the four-factor test. As the majority explained, shortly after noticing its appeal, "Amgen ... filed an emergency motion in [the Federal Circuit] for an injunction pending appeal" based on the four-factor test, and the Court "granted the motion." 794 F.3d at 1362. The Court went on to state that, "[i]n light of what we have decided concerning … the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015." *Id.* In other words, the panel found that it need not *re-apply* the four-factor test to justify extending a previously issued injunction.

Thus, *Sandoz* does not impose an automatic 180-day injunction if an applicant fails to provide a mandatory notice of commercial marketing. Nor should this Court. Instead, under *eBay*, the four-factor injunction test still must be satisfied.

CONCLUSION

Neither the text of the BPCIA nor the *Sandoz* decision supports a claim for 180-day injunctions by sponsors such as Amgen and Janssen. Nor would it make legal or logical sense to award automatic injunctions that do not satisfy the requirements of *eBay*—especially in cases like this, where all patents are being litigated and the plaintiff is free to move for a preliminary injunction to enforce relevant patent rights. Still further, affirming the underlying injunction could have far-reaching implications that hurt consumers. If Amgen and Janssen had their way, every biosimilar launch would be delayed by at least 180 days after the FDA has approved the product for marketing—costing the healthcare system billions of dollars and potentially harming sick patients.

The decision below should be reversed, and the injunction vacated.

Respectfully submitted,

/s/ Charles B. Klein

CHARLES B. KLEIN
STEFFEN N. JOHNSON
ANDREW C. NICHOLS
Winston & Strawn LLP
1700 K Street, N.W.
Washington, D.C. 20006
(202) 282-5000
cklein@winston.com
sjohnson@winston.com
anichols@winston.com

SAMUEL S. PARK
DAN H. HOANG
Winston & Strawn LLP
35 West Wacker Drive
Chicago, Illinois 60601-9703
(312) 558-5600
spark@winston.com
dhoang@winston.com

Counsel for Amici Curiae *Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc.*

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Nicholas P. Groombridge
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: ngroombridge@paulweiss.com

John F. O'Sullivan
Hogan Lovells US LLP
600 Brickell Avenue, Suite 1900
Miami, Florida 33131
305-459-6500
Email: john.osullivan@hoganlovells.com

Jennifer Gordon
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: jengordon@paulweiss.com

Allen P. Pegg
Hogan Lovells US LLP
600 Brickell Avenue, Suite 2700
Miami, Florida 33131
305-459-6550
Email: allen.pegg@hganlovells.com

Lois M. Kwasigroch, Senior Counsel
Amgen Inc.
Law Department
One Amgen Center Drive
Mailstop 28-2-C
Thousand Oaks, CA 91320
805-447-6265
Email: loisk@amgen.com

Peter Sandel
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3198
Email: psandel@paulweiss.com

Kimberlin L. Morley
Amgen Inc.
One Amgen Center Drive
Mailstop 28-2-C
Thousand Oaks, CA 91320
805-447-1000
Email: kmorley@amgen.com

Jason Sternberg
Hogan Lovells US LLP
Suite 2700
600 Brickell Avenue
Miami, FL 33131
305-459-6500
Email: Jason.sternberg@hoganlovells.com

Catherine Nyarady
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-757-3990
Email: cnyarady@paulweiss.com

Eric Alan Stone
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
212-373-3000
Email: estone@paulweiss.com

Wendy A. Whiteford
Amgen Inc.
One Amgen Center Drive
Mailstop 28-2-C
Thousand Oaks, CA 91320
805-447-1008
Email: wendy@amgen.com

Counsel for Amgen, Inc. and Amgen Manufacturing Ltd.

Kerry Brendan McTigue
Cozen O'Connor
1200 19th Street, NW
Washington, DC
202-912-4810
Email: kmctigue@cozen.com

Barry P. Golob
202-912-4815
Cozen O'Connor
1200 19th Street, NW
Washington, DC 20036
Email: bgolob@cozen.com

William Blake Coblentz
Cozen O'Connor
1627 I Street, NW
Washington, DC 20006
202-776-7800
Email: wcoblentz@cozen.com

David Charles Frederick
Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC
Suite 400
1615 M Street, NW
Sumner Square
Washington, DC 20036
202-326-7900
Email: dfrederick@khhte.com

Donald R. McPhail
202-776-7894
Cozen O'Connor
1627 I Street, NW
Washington, DC 20006
Email: dmcphail@cozen.com

Aaron S. Lukas
202-912-4823
Cozen O'Connor
1200 19th Street, NW
Washington, DC 20036
Email: alukas@cozen.com

Miles Sweet
202-236-7974
Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC
Suite 400
1615 M Street, NW
Sumner Square
Washington, DC 20036
Email: msweet@khhte.com

John Christopher Rozendaal
202-326-7985
Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC
1615 M Street, NW
Sumner Square
Washington, DC 20036
Email: jrozendaal@khhte.com

Counsel for Apotex, Inc. and Apotex Corp.

Dated: January 6, 2016

/s/ *Dan H. Hoang*
Dan H. Hoang
Winston & Strawn LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600
dhoang@winston.com

Counsel for Amici Curiae *Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc.*