No. 2015-1499

United States Court of Appeals for the Federal Circuit

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
PLAINTIFFS-APPELLANTS,

v.

SANDOZ INC.,
DEFENDANT-APPELLEE.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
IN CASE NO. 3:14-CV-04741, JUDGE RICHARD SEEBORG

BRIEF FOR HOSPIRA, INC., CELLTRION HEALTHCARE CO., LTD, AND CELLTRION, INC. AS AMICI CURIAE SUPPORTING DEFENDANT-APPELLEE AND AFFIRMANCE OF THE DISTRICT COURT'S JUDGMENT

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April 24, 2015

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. has no parent corporation. T. Rowe Price Associates, Inc., which is a subsidiary of T. Rowe Price Group, Inc., a publicly held corporation, owns more than 10% of Hospira, Inc.

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, Andrew C. Nichols, Peter E. Perkowski, Samuel S. Park

Dated: APRIL 24, 2015

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INTRODUCTION AND INTEREST OF AMICUS CURIAE[1]

Amici Hospira, Inc., Celltrion Healthcare Co., Ltd. and Celltrion, Inc. support the district court's construction of the Biologics Price Competition and Innovation Act ("BPCIA") and adopt the arguments of Sandoz and the Generic Pharmaceutical Association. Rather than repeat those arguments, this brief focuses on the narrow role of the notice of commercial marketing in view of the BPCIA as a whole. After all, "[j]ust as Congress' choice of words is presumed to be deliberate, so too are its structural choices." *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2529 (2013). Thus, a court must interpret a statute "as a symmetrical and coherent regulatory scheme," and "fit, if possible, all parts into an harmonious whole." *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000).

The district court did so. Amgen and its amicus Janssen Biotech, Inc. do not. Instead, they invite this Court to rewrite the BPCIA to award branded biologic manufacturers an automatic 180-day injunction—costing consumers hundreds of millions, if not billions, of dollars—even where they assert *no* patent rights to support injunctive relief. Not only would that distort the structure of the BPCIA, it would ignore the plain instruction of *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). The Court should affirm.

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[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.

Hospira and the two Celltrion amici have an interest in this appeal because they are being sued by Janssen for supposedly providing a notice of commercial marketing too soon. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, No. 1:15-cv-10698 (D. Mass.). Like Amgen, Janssen is not seeking an injunction to enforce *any* patent rights. Instead, Janssen purports to sue to enforce the notice of commercial marketing provision itself—forcing Hospira and the Celltrion amici to delay their notice and, with it, their product launch.

As a global pharmaceutical company headquartered in Illinois, Hospira is the world's largest producer of generic injectable drugs—including biosimilars. In the events leading to Janssen's case, Hospira teamed with Celltrion, Inc. ("Celltrion"), a Korean company that develops and manufactures biosimilar antibodies and novel drugs, and Celltrion Healthcare Co., Ltd., which markets and distributes drugs developed by Celltrion in more than 120 countries. Celltrion has applied for approval from the U.S. Food and Drug Administration ("FDA") of a biosimilar version of Janssen's multi-billion-dollar biologic called Remicade®. After FDA approval, Celltrion and/or Hospira intend to market the drug in the United States.

BACKGROUND

In the BPCIA, Congress created an expedited path for licensing biosimilars—which, as their name suggests, are biologic products similar to branded biologics already licensed by FDA. In return for allowing the biosimilar developer

(called the "applicant") to rely on the data of the brand (called the "reference product sponsor" or "sponsor"), Congress barred FDA from approving any biosimilar until 12 years after the sponsor's product was licensed. 42 U.S.C. 262(k)(7)(A). In other words, the sponsor gets a guaranteed 12-year statutory monopoly regardless of patent protection. The statute also offers a method for the parties to determine whether any relevant patents exist and tools to resolve any patent disputes through patent litigation.

A. The BPCIA offers a process to assess which patents will be subject to immediate litigation.

To identify and resolve biosimilar patent disputes, the BPCIA effectively amends the Public Health Service Act and the Patent Act to provide a pathway for the reference product sponsor and applicant to exchange lists of patents to be litigated. Here is how it works.

At the outset, the applicant may provide to the reference product sponsor the application and information describing the applicant's manufacturing process. 42 U.S.C. § 262(*l*)(2)(A). If the applicant does *not* do so (the approach taken by Sandoz), the sponsor 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 Celltrion), the sponsor reciprocates by preparing and 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). By imposing a harsh penalty on the sponsor for not disclosing, the statute creates a strong incentive for the applicant to provide its information.

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). 42 U.S.C. § 262(*l*)(3)(B). By means of 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 list of patents that may give rise to an "immediate" patent infringement lawsuit ("final patent list") is determined either by agreement or, absent agreement, by following 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).

Congress designed these procedures to resolve patent disputes on key patents first, thus speeding competition. For example, Congress recognized that the threat of a lost-profits award against the applicant could deter it from launching its product. So Congress penalized a reference product sponsor for delaying litigation by banning the sponsor from recovering lost profits.

Moreover, nothing in the statute prevents the sponsor from seeking a preliminary injunction on any litigated patents at any time after the lawsuit begins—even if FDA approval were years away. 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 and risk of irreparable harm.

B. The notice of commercial marketing provision merely addresses any patents not subject to immediate litigation.

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 ("non-listed patents")? With limited exceptions (such as where the applicant does not produce its application), neither sponsor nor applicant may sue on any non-listed patent "prior to the date notice [of commercial marketing] is received under paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(A).

In other words, the notice of commercial marketing lifts the bar on litigating non-listed patents—providing a 180-day period during which the sponsor can seek a preliminary injunction blocking the launch of products that allegedly infringe those patents. Under paragraph (8)(A), "[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)." 42 U.S.C. § 262(*l*)(8)(A). But as explained in paragraph (8)(B), this notice grants the sponsor at least 180 days to "*seek* a preliminary injunction" solely "with respect to any [non-listed] patent" before the applicant launches its product. *Id.* § 262(*l*)(8)(A) (emphasis added). This construction is undisputed. As Amgen concedes, the notice is directed solely to the "patents not listed" in the final patent list. Amgen Br. 47.

That said, the notice is not required for FDA approval. Rather, as discussed, Congress addressed the sponsor's exclusivity by barring FDA from approving a biosimilar before a "date that is 12 years after the date on which the [sponsor's biologic] product was first licensed[.]" 42 U.S.C. § 262(k)(7)(A). Nor does the notice alter the sponsor's burden in obtaining preliminary injunctive relief based on an actual patent. It merely allows the sponsor to "seek" such an injunction based on one or more non-listed patents. *Id.* § (*l*)(8)(B); *eBay*, 547 U.S. at 392-93 ("[The Patent Act itself indicates that patents shall have the attributes of personal property

… [such that] injunctive relief 'may' issue only 'in accordance with the principles of equity.'") (citing 35 U.S.C. §§ 261, 283); *see also Apple Inc. v. Samsung Electronics Co.*, 735 F.3d 1352, 1361 (Fed. Cir. 2013) (applying *eBay* factors to a preliminary injunction motion, except requiring "likelihood of success on the merits rather than actual success") (quotation omitted).

C. Janssen's lawsuit against Hospira and Celltrion illustrates how both Janssen and Amgen seek a windfall 180-day injunction.

Though refusing to dispute any of this, Amgen and Janssen ask this Court to construe the phrase "seek a preliminary injunction" in paragraph 8(B) as mandating a preliminary injunction lasting 180 days after FDA approval—regardless of patent rights. They make this argument in two steps. *First*, they say the 180-day prior notice of commercial marketing cannot be provided until after FDA licenses the biosimilar product. *Second*, they say courts must enforce this delay with an injunction banning competition for 180 days after notice is provided (and therefore at least 180 days after FDA approval).

In other words, according to Amgen and Janssen, FDA approval is illusory. No matter what FDA says, the applicant may not launch its product until at least 180 days after FDA approves it—thus extending the sponsor's statutory 12-year exclusivity to 12.5 years (and effectively handing even longer exclusivity to Amgen and Janssen, which have been marketing their products for 24 and 16 years, respectively). The district court forcefully rejected this reading: "Had Con-

gress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." Op. 13-14.

Respectfully, Janssen's lawsuit against Hospira and Celltrion shows why the district court was right, and Amgen and Janssen's statutory construction is wrong. Hospira and Celltrion seek to introduce in the United States a biosimilar version of Janssen's multi-billion dollar drug Remicade® (infliximab) at an affordable cost to patients suffering from debilitating diseases, including rheumatoid arthritis. Together, they have expended significant resources, including well more than $100 million, to research and develop their proposed biosimilar infliximab product. Through this effort, they have obtained approval of the product in over 50 countries worldwide, including Europe, Japan, and Canada. Hospira and Celltrion expect the drug to be approved by the FDA some time this year.

Unlike the situation at issue in this appeal, Celltrion (the applicant) produced to Janssen its abbreviated Biologics License Application ("aBLA") and has participated in the BPCIA's patent-information exchange.[2] In December 2014, Janssen disclosed its patent list, which identified six patents that it believed could reasona-

[2] According to Janssen, Celltrion has "refused to provide Janssen" with certain manufacturing information "contrary to the BPCIA." Janssen Br. 23 n.12. That is false. Celltrion timely produced *its* pertinent manufacturing information. What Janssen seeks is proprietary *third-party* information that Celltrion has no right—and no obligation under the BPCIA—to disclose. *See*, *e.g.*, 42 U.S.C. 262(*l*)(1)(E) (referring to "confidential information disclosed" under the Act as "the property of the subsection (k) applicant").

bly support a claim of infringement. In February 2015, Celltrion offered no competing patent list, but instead agreed that all six patents identified by Janssen could be the subject of an immediate infringement lawsuit. This meant that Janssen had 30 days to sue to preserve any right to seek lost profits. It also meant there were no "non-listed patents" remaining to be sued upon. That same day, Hospira and Celltrion provided to Janssen their notice of commercial marketing, which said that Hospira and/or Celltrion may launch the biosimilar product as early as 180 days from that notice.

In March 2015, Janssen sued Hospira and Celltrion for purportedly violating the BPCIA by not (1) producing third-party manufacturing information along with the aBLA; (2) agreeing to Janssen's patent list without first engaging in good-faith negotiations; and (3) providing notice of commercial marketing before FDA approved the biosimilar product. Janssen further alleged infringement of each of the six patents identified in its patent list—meaning that all patents identified during the patent exchange are currently being litigated. The entire dispute is in court.

Accordingly, Janssen is not barred from seeking injunctive relief for any of those patents. Thus, in Janssen's situation, the notice of commercial marketing—which, again, addresses only non-listed patents—serves no practical purpose.

Undeterred, Janssen has asked the District of Massachusetts to enter a preliminary injunction barring Hospira and Celltrion from launching their product for

180 days after FDA approval. To support this relief, Janssen has not pointed to any of its six asserted patents. Instead, it says it needs an injunction to enforce the BPCIA, because Hospira and Celltrion notified Janssen of commercial marketing before FDA licensed the drug. According to Janssen, the BPCIA entitles it to an injunction commanding delay of that notice until FDA approves the drug—handing Janssen an automatic, statutory six-month extension on its monopoly. Briefing on Janssen's motion is ongoing, and no hearing has yet been scheduled.

ARGUMENT

Amgen, like Janssen, seeks a windfall 180-day injunction—relief completely divorced from any patent rights—based solely on the BPCIA's notice of commercial marketing requirement. To support this remarkable request, they ignore the structure of the BPCIA and urge the Court to insert language that Congress conspicuously avoided. By contrast, the district court construed the BPCIA according to its structure and plain language. That construction should be affirmed.

Amgen and Janssen misconstrue the notice of commercial marketing provision as authorizing an automatic, 180-day injunction.

The BPCIA's notice requirement serves one purpose: It describes when the sponsor can "seek a preliminary injunction" based on a non-listed patent. 42 U.S.C. § 262(l)(8)(B). By its terms, this requirement does not create an automatic injunction, much less in every case. This conclusion is confirmed by the structure of the statute and the Supreme Court's ruling in *eBay*. We address each in turn,

along with the fact that Congress did not confer a private right of action to enforce this notice provision.

A. The BPCIA does not bar notice of commercial marketing before FDA approval, as plainly shown by the statute's structure.

The notice of commercial marketing provision contains no precondition for providing such notice, saying only that it must be provided "not *later* than 180 days" before commercial marketing. 42 U.S.C. § 262(*l*)(8)(A). According to Amgen and Janssen, however, this Court should add such a precondition—i.e., "not *earlier* than FDA licensing." They argue that this precondition is necessary to "ensur[e] the existence of a fully crystallized controversy regarding the need for injunctive relief." Janssen Br. 23; Amgen Br. 47-48. This argument turns the statute on its head.

According to congressional testimony by the Biotechnology Industry Organization ("BIO"), which supports Amgen as an amicus here, the BPCIA was designed to impose "patent review procedures that will *precede approval of a biosimilar[.]*" *Biologics and Biosimilars: Balancing Incentives for Innovation*, Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. at 39 (2009) (emphasis added). BIO had it right the first time. Congress crafted the BPCIA to resolve patent disputes *before* FDA approval—not 180 days after approval.

The statute, read as a whole, confirms this congressional intent. For example, the BPCIA bans the filing of biosimilar applications for four years and forbids FDA from approving biosimilars for 12 years after sponsor approval. 42 U.S.C. § 262(k)(7). It allows a sponsor to seek preliminary injunctions based on the traditional four-factor showing, even years before FDA approval. And it allows injunctions on patents subject to a declaratory judgment action. 42 U.S.C. § 262(*l*)(9). Nobody questions whether those disputes are "fully crystallized" before FDA approval.[3]

Thus, there is no reason to think that the BPCIA bans such pre-approval traditional injunctions, and instead commands an automatic injunction, solely as to non-listed patents. Why should FDA approval be needed to "crystallize" disputes over non-listed patents? Neither Amgen nor Janssen has any answer.

In short, Janssen is wrong to say that notice of commercial marketing must await FDA approval to "provide[], in effect, a statutory 180-day injunction in which to litigate before launch." Janssen Am. Br. 17. That would certainly help Janssen delay competition in its case (relief it is seeking without pointing to any of

[3] Moreover, courts have routinely entertained preliminary injunction motions even though the generic drug manufacturer was merely *seeking* FDA approval. *See, e.g., Glaxo Group Ltd. v. Ranbaxy Pharms, Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001); *Apotex Inc. v. Eisai Inc.*, 2010 WL 3420470, at *4 (M.D.N.C. Aug. 27, 2010); *The Research Found. v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 644 (D. Del. 2010).

its patents). But it is not the law. The BPCIA provides no automatic injunction. Unlike the Hatch-Waxman Act (*see* 21 U.S.C. § 355(j)(5)(B)(iii)), the BPCIA does not even provide for an automatic stay of approval if such a lawsuit is brought.

Indeed, often parties will not need to seek a preliminary injunction based on a non-listed patent. That is true in this very case, where the applicant (Sandoz) did not provide its aBLA to the reference product sponsor (Amgen). In that instance, the Act authorizes the sponsor to bring a declaratory judgment action and seek a preliminary injunction based on patent rights immediately—potentially years before FDA approval. 42 U.S.C. § 262(*l*)(9)(C). It also is true in the case of Hospira and Celltrion, where all the patents were listed and sued upon, and, therefore, Janssen may seek an injunction on any of the patents it listed now—even before FDA approval.

It defies logic to read the notice of commercial marketing provision essentially to delay FDA approval by six months given these real-world examples in which such notice serves no purpose. Such a delay accomplishes nothing—other than to provide sponsors with windfall protection from competition.

B. Reading the notice of commercial marketing provision to require an automatic 180-day injunction would flout *eBay*.

If that were not enough (and it is), the notion of an implied, automatic, statutory injunction runs headlong into *eBay*, which rejects any kind of "general rule" for an automatic injunction under the Patent Act. 547 U.S. at 393-94 (citations

marks omitted). As the Court stated: "We hold … that … whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id*. at 394. After all, "[a]s this Court has long recognized, a major departure from the long tradition of equity practice should not be lightly implied." *Id*. at 391 (quotation omitted).

So too here. Amgen and Janssen invite this Court to imply from the BPCIA such a "major departure" from the "long tradition of equity practice." *Id*. at 392. The notice of commercial marketing provision says nothing about an automatic injunction. Here is how they would rewrite the provision to impose an automatic injunction (with the underlined language added to the actual statutory language):

> **(B) Preliminary injunction**
>
> <u>The court shall order an injunction prohibiting commercial marketing of the biological product licensed under subsection (k) for 180 days beginning on the date notice of commercial marketing was provided under subparagraph (A).</u> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing … the reference product sponsor may seek a preliminary injunction prohibiting the section (k) applicant from engaging in the manufacture or sale of such biological product until the court decide the issue of patent validity, enforcement, and infringement with respect to any [non-listed] patent[.]"

42 U.S.C. § 262(*l*)(8)(B) (underlined language not in statute).

As in *eBay*, such a dramatic change in the law imposing an automatic injunction must not be "lightly implied." 547 U.S. at 392. There is no basis in the statute, equity, or common sense to delay commercial marketing for even a day—much less 180 days—unless an injunction is justified on the merits of a patent claim. That is why the actual language of the statutory provision merely allows the "sponsor [to] *seek* a preliminary injunction" based on certain patent rights. 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). If no preliminary injunction is sought and justified, none is merited.

It would be particularly inappropriate to read automatic injunction language into the notice provision—i.e., "the court shall order an injunction"—because Congress used similar phrasing elsewhere in the BPCIA itself. 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). And elsewhere in the BPCIA, Congress provided that the unauthorized disclosure of confidential information "shall be deemed to cause [the applicant] irreparable harm," and thus "the court shall *consider* immediate injunctive relief. …" 42 U.S.C. § 262(*l*)(1)(H) (emphasis added). Further, as explained in Sandoz's brief (at 48), Congress also expressly provided an exclusive, *non*-injunction remedy for a failure to provide the notice of commercial marketing.

Id. § 262(*l*)(9)(B). 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. The Court should affirm.

As the Supreme Court has explained as to liability in patent disputes, "when Congress wishes to impose [liability] … it knows precisely how to do so. The courts should not create … liability … where Congress has elected not to[.]" *Limelight Networks, Inc. v. Akamai Tech., Inc.*, 134 S. Ct. 2111, 2118 (2014). So too here. Amgen and Janssen offer no basis for the Court to read into the BPCIA's notice provision language Congress knew how to use and conspicuously avoided.

Rather, as *eBay* underscores, a sponsor can rely on this notice of commercial marketing provision to support an injunction *only* if the sponsor can show: (1) it has been barred from bringing a patent lawsuit on a non-listed patent (neither Amgen nor Janssen has been barred from suing on any patent or seeking a preliminary injunction); (2) it is likely to succeed on the merits of its claim that the applicant will infringe that patent; (3) it faces irreparable harm sufficiently tied to such infringement; and (4) the balance of hardships and public interest favor an injunction. Amgen has made no such showing in this appeal, and Janssen has made no such showing in its lawsuit against Hospira. Thus, neither should receive an in-

junction—much less an implied, automatic injunction where Congress declined to create one.

C. The BPCIA does not confer a private right of action to enforce purported violations of the patent-exchange process.

Finally, as Sandoz rightly emphasizes, the BPCIA contains no "rights-creating language" entitling sponsors such as Amgen and Janssen to a private right of action enforcing the statute. Sandoz Br. 53 (quoting *Alexander v. Sandoval*, 532 U.S. 275, 288 (2001)). This, too, is dispositive.

After all, Congress knows how to create a right of action when it wants to. For example, in the Hatch-Waxman Act, which addresses small-molecule drugs (as opposed to biologics), Congress enacted a "counterclaim" that "enables a generic competitor to obtain a judgment directing a brand to 'correct or delete' certain patent information that is blocking the FDA's approval of a generic product." *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012). Specifically, a generic may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

In the BPCIA, Congress just as easily could have provided that a sponsor may "assert a claim seeking an order requiring" an applicant to comply with the requirement of the patent exchange or, more specifically, requiring the applicant to stay off of the market until 180 days after FDA approval. It did not do so—even though it expressly provided a remedy for statutory violations elsewhere in the

BPCIA, such as the "effect of violation" provision addressing injunctive relief to remedy unauthorized disclosure of confidential information. 42 U.S.C. § 262(*l*)(1)(H). Once again, "the courts should not create … liability … where Congress has elected not to[.]" *Limelight Networks, Inc.*, 134 S. Ct. at 2118.

CONCLUSION

Granting automatic injunctions to sponsors such as Amgen and Janssen has no basis in the text of the BPCIA and would thwart its purpose of expediting non-infringing competition. Nor would it make logical sense to award automatic injunctions, especially in cases like Janssen's, where all patents are being litigated and Janssen is free to move for a preliminary injunction any time. And it flies in the face of *eBay*. Still further, it would harm consumers far beyond this case. If Amgen and Janssen had their way, every biosimilar launch would be delayed by at least 180 days beyond the statutorily prescribed 12 years (and much longer for drugs like Amgen's and Janssen's that have enjoyed a monopoly for well more than 12 years)—costing the healthcare system billions and potentially harming sick patients. The district court's well-reasoned decision should be affirmed.

Respectfully submitted,

/s/ Charles B. Klein

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APRIL 24, 2015

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/s/ Andrew C. Nichols
(Signature of Attorney)

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