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, PRESIDING

BRIEF FOR HOSPIRA, INC., CELLTRION HEALTHCARE CO., LTD., AND CELLTRION, INC. AS *AMICI CURIAE* IN SUPPORT OF SANDOZ'S PETITION FOR REHEARING *EN BANC*

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. 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, Steffen N. Johnson, Andrew C. Nichols, Peter E. Perkowski, Samuel S. Park, and Dan H. Hoang.

Dated: SEPTEMBER 2, 2015

/s/ Charles B. Klein

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

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

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION AND INTEREST OF *AMICI CURIAE*[1]

The full Court should review the panel's fractured ruling in this case. That ruling raises critical issues affecting the competitive structure of the biosimilar industry, warranting immediate review. Moreover, price competition in that industry is vital not only to public and private consumers, but to the economy as a whole.

In enacting the Biologics Price Competition and Innovation Act ("BPCIA"), Congress intended to speed competition by enabling branded biologics companies ("sponsors") and biosimilar drug makers ("applicants") to resolve their patent disputes quickly. Congress also handed sponsors a powerful incentive to develop biologics—"up to twelve years of exclusivity … regardless of patent protection." Op. 5. The panel's split decision erroneously requires any "notice of commercial marketing" to await FDA approval. That ruling allows some sponsors to receive not only their twelve-year monopoly, but an "extra-statutory exclusivity windfall"—"a 180-day injunction beyond the express twelve-year statutory exclusivity period." Judge Chen Dissent 2. In so doing, the majority effectively created a private claim and remedy not authorized by Congress—an automatic, bondless injunction barring sales of the biosimilar drug for 180 days.

The panel's decision exceeds the judicial role contemplated by Congress in

[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.

the BPCIA, and calls out for *en banc* review. The decision has major implications for industry and consumers, and split the panel three ways. Indeed, all three panel members described the case as one that "require[d] [the Court] to 'unravel the riddle, solve the mystery, and comprehend the enigma' that is the BPCIA." Op. 3 n.1; Judge Newman Dissent 2 (joining Part A); Judge Chen Dissent 11.

Amici file this brief to emphasize three points. First, review is needed *now*. Although the panel's ruling addresses an issue of first impression, that issue is vital to the competitive structure of the biosimilar industry. Litigation over the meaning of the ruling continues in the lower courts; further percolation will not advance the law; and settling the issue will spur competition.

Second, the ruling flouts the Act's text and Congress's purpose in passing it. In the panel's view, a potential second phase of litigation—which involves patents that only the sponsor deems relevant—cannot even *begin* until after FDA approval. But as even the Biotechnology Industry Organization ("BIO") has noted, the Act is designed "to identify and resolve patent issues before a biosimilar is approved."[2]

Third, the ruling conflicts with a host of cases—such as *Alexander v. Sandoval*, 532 U.S. 275 (2001), and *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)—governing when courts may recognize a private right of action or extra-

[2] *Biologics & Biosimilars: Balancing Incentives for Innovation*, Hr'g of Subcomm. on Courts & Competition Policy of H. Jud. Comm., 111th Cong. 77 (2009).

statutory remedy. That precedent bars the automatic, bondless injunction entered here—one that not only was granted without any findings that satisfy the traditional requirements for equitable relief, but is unmoored from any patent rights.

Amici's interest in this case is not academic. They are being sued by another sponsor, Janssen, for providing a notice of commercial marketing "too soon." *See Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, No. 1:15-cv-10698 (D. Mass.). Unlike Sandoz in this case, *amici* timely produced the biosimilar application and participated in the patent exchange. Like Amgen, however, Janssen says the notice provision authorizes an automatic injunction divorced from any patent rights—delaying consumer access to less expensive medications for 180 days.

Hospira, a global company headquartered in Illinois, is the world's largest producer of generic injectable drugs. In the events leading to Janssen's case, Hospira teamed with Celltrion, Inc. ("Celltrion"), a Korean company that develops biosimilar antibodies and novel drugs, and Celltrion Healthcare Co., Ltd., which markets those drugs worldwide. Celltrion has applied for FDA approval of a biosimilar of Janssen's multi-billion-dollar Remicade® for sale in the U.S.

To that end, and to secure its rights for future products, *amici* support review and reversal of the majority's holdings that (1) the notice of commercial marketing provided for by the BPCIA must await FDA approval; and (2) failing to provide such notice, where mandatory, warrants an automatic, bondless 180-day injunction.

REASONS FOR GRANTING THE PETITION

I. Review is needed now, because resolving this case will establish the competitive framework that governs the biosimilars industry.

How to read the BPCIA's "notice of commercial marketing" provision is a question of exceptional importance under Rule 35; and the Court should not deny review or allow the issue to "percolate" merely because the question is one of "first impression." Op. 3. The question is vital to competition and the functioning of the multi-billion-dollar biosimilars industry, which is rapidly growing. Indeed, the provision at issue here is a key element of a key statute governing an industry at the vanguard of health care delivery in the 21st Century.

For example, in its dispute with *amici*, Janssen argues—contrary to the panel's unambiguous ruling—that notice of commercial marketing is mandatory even when, unlike here, the applicant timely provides its aBLA during the patent information exchange.[3] Janssen thus seeks to expand the ruling to authorize an automatic 180-day injunction following FDA approval for *all* sponsors. This issue affects the whole industry, warranting *en banc* review of the notice provision.

[3] *See* Op. 21 (holding that the notice of commercial marketing is mandatory only when an applicant "completely fails to provide its aBLA and the required manufacturing information to the [sponsor] by the statutory deadline"); *Janssen, Celltrion Brawl Over Fed. Circ. Biosimilar Ruling*, Law360 (Aug. 27, 2015) ("Janssen Biotech Inc. and Celltrion Inc. are squaring off in … federal court with competing views of a recent Federal Circuit interpretation of the [BPCIA]"); Dkt. No. 72 at 6-15 (Janssen Br. filed Aug. 24, 2015), *in Janssen v. Celltrion*, *supra*.

Indeed, the Supreme Court—which rarely decides questions of first impression—has not hesitated to take up similar questions under the Hatch-Waxman Act, where those questions were critical to the incentives and competitive frameworks created by Congress. In *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990), this Court decided a "question of first impression, namely, whether the noninfringement defense of 35 U.S.C. § 271(e)(1) … applies to medical devices." But that did not deter the Supreme Court from granting certiorari, presumably because further percolation was unlikely to generate a split and a definitive ruling was needed.

Similarly, *Caraco Pharm. Labs. v. Novo Nordisk*, 601 F.3d 1359 (Fed. Cir. 2011)—which likewise produced a fractured ruling and three opinions—was this Court's first occasion to address the Hatch-Waxman Act's counterclaim provision, and whether it authorized generics to contest the accuracy of patent information that brands submit to FDA. Again, the Supreme Court did not delay taking up the matter, presumably because the counterclaim was vital to "facilitat[ing] the approval of generic drugs as soon as patents allow." 132 S. Ct. 1670, 1676 (2012).

Here too, Congress has sought to enable brand and generic drug makers to resolve their disputes quickly. The BPCIA is vital to both sides in the disputes, to competition, and to consumers. Review is needed now.

II. Review is needed because the decision conflicts with the BPCIA's purpose of expediting patent disputes, preferably *before* FDA approval.

The full Court should review and reverse the panel's ruling that the notice of commercial marketing—which kick-starts any "phase two" litigation over patents whose relevance the parties dispute—must await FDA approval. That ruling delays certain patent disputes until *after* FDA approves the biosimilar, and thus conflicts with Congress's manifest aim of resolving disputes *before* FDA approval.

If the biosimilar applicant declines to give the sponsor its aBLA (42 U.S.C. § 262(*l*)(2)(A)), the sponsor may bring an immediate declaratory judgment suit for infringement of *any* patent it considers relevant (*id.* § 262(*l*)(9)(C)). But if the applicant provides that information, the sponsor prepares a list of patents that could support an infringement claim. *Id*. § 262(*l*)(3)(A)(i). The applicant responds with its own list and a "detailed statement" of its contentions. *Id*. § 262(*l*)(3)(B). The parties thus try to agree on "which, if any, patents" will be litigated (*id.* § 262(*l*)(4)(A))—an exchange sometimes called the "patent dance." Whether by agreement or statutory procedure, the parties produce a "final" list of patents that may give rise to "immediate" litigation. *Id.* § 262(*l*)(6)(A), (B). And the biosimilar applicant has significant control over which patents are litigated first.

A sponsor has an incentive to file suit on all patents identified on the final list right away. If it fails to sue within 30 days, the sole remedy for infringement is a "reasonable royalty." 35 U.S.C. § 271(e)(6)(A), (B). Congress thus sought to

speed competition by facilitating litigation over the key patents first—and quickly.

The notice of commercial marketing determines when the parties litigate any patents that didn't make the final list ("phase-two patents").[4] Generally, when the parties have participated in the patent dance, neither the sponsor nor the applicant may sue on any phase-two patent "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—providing a 180-day period for the sponsor to "seek" (not automatically obtain) a preliminary injunction barring the launch of products that allegedly infringe those patents. *Id*. § 262(*l*)(8)(A). Amgen admits that the notice is directed solely to "patents not listed." Merits Br. 47. Under a proper reading of the Act, the applicant may begin this second phase of litigation before FDA approval. But according to the panel, this phase-two BPCIA litigation—which involves patents that only the sponsor initially deemed relevant—cannot even *begin* until *after* a biosimilar is approved by FDA. Respectfully, this turns the Act on its head.

[4] In the lawsuit between *amici* and Janssen, *amici* accepted Janssen's patent list and Janssen sued on all listed patents. Thus, there will be no "phase-two" litigation. The notice of commercial marketing—which triggers such litigation—serves no purpose, as the sponsor (Janssen) is aware of the underlying application and already has asserted all identified patents. The *Janssen* litigation illustrates, in part, why—as the panel recognized—notice is not mandatory unless the applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline." Op. 21. After all, why should *amici* be required to provide a notice that serves no statutory purpose? But even if the notice is mandatory in certain cases, it should not have to await FDA approval.

To be sure, the notice of commercial marketing is designed to provide the sponsor with 180 days before the biosimilar launch to seek a preliminary injunction on any phase-two patents. But notice is *not* tied to, or required for, FDA approval. Rather, Congress addressed the sponsor's exclusivity by barring FDA from approving any biosimilar until "12 years after … the [sponsor's] product was first licensed"—even where *no* patents protect that product. 42 U.S.C. § 262(k)(7)(A). In return, Congress gave applicants substantial control over the timing of litigation. If the applicant provides notice of commercial marketing before FDA approval, the notice enables the sponsor to sue immediately on all phase-two patents (and allows the applicant to bring a declaratory judgment suit). As Congress recognized, many applicants will prefer to litigate phase-two patents well before FDA approval. By setting no conditions on providing the notice, the BPCIA allows that to happen.

Amgen cannot explain why Congress would want to delay the sale of drugs that do not infringe, or suits over drugs that might not infringe, beyond the twelve-year exclusivity period. Indeed, as even BIO has noted, the Act seeks "to identify and resolve patent issues before a biosimilar is approved." *Supra* at 2 & n.2.

III. Review is needed because the decision improperly creates an implied private right of action and an extra-statutory remedy, in conflict with numerous Supreme Court decisions, including *Alexander* and *eBay*.

Finally, even if the panel had correctly held that phase-two BPCIA litigation cannot begin until after FDA approval, review would still be needed because the

ruling conflicts with extensive precedent restricting when courts may imply private rights of action or remedies, and when courts may grant automatic injunctions.

Congress provided a remedy for noncompliance with the notice provision—sponsors may immediately bring declaratory judgment actions, asserting infringement. 42 U.S.C. § 262(*l*)(9)(B). And the majority recognized, where the applicant timely produces its aBLA, "paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with [the notice provision]." Op. 20. But where the applicant does not timely produce its aBLA, the majority created the remedy of a "windfall" (Judge Chen Dissent 2)—an automatic bondless injunction barring the sale of biosimilar products for 180 days—even if the sponsor lacks patent rights. Respectfully, creating that extra-statutory remedy exceeded the Court's authority.

As the Supreme Court has repeatedly held, "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Alexander*, 532 U.S. at 290. As discussed, Congress provided a remedy if the applicant fails to provide proper notice—one that does not include an automatic 180-day injunction without regard to any patent rights.

Even if the BPCIA conferred a private right of action for injunctive relief, the Act provides that sponsors may only "seek" such relief to protect actual patents (42 U.S.C. § 262(*l*)(8)(B)), and in those circumstances *eBay* requires satisfying the traditional four-factor test. Nothing in the Act alters the longstanding rules 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*, 547 U.S. at 394. And 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.

A rule providing for an automatic injunction is especially hard to reconcile with the BPCIA. As other provisions of that Act confirm, Congress knew how to create a presumption favoring injunctions. In paragraph (*l*)(1)(H), Congress stated that the unwarranted disclosure of any confidential information "shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy." 42 U.S.C. § 262(*l*)(1)(H). Further, Congress amended the Patent Act to state, in circumstances not at issue here, that "the court shall order a permanent injunction … ." 35 U.S.C. § 271(e)(4)(D).

No language authorizing injunctions appears in paragraph 8. 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). Thus, there is no basis to extend sponsors' marketing exclusivity to 12.5 years. Full Court review is needed to make that clear.

Respectfully submitted,

/s/ Charles B. Klein

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

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

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

SEPTEMBER 2, 2015

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 2, 2015, I caused true copies of the foregoing BRIEF FOR HOSPIRA, INC., CELLTRION HEALTHCARE CO., LTD., AND CELLTRION, INC. AS *AMICI CURIAE* IN SUPPORT OF SANDOZ'S PETITION FOR REHEARING *EN BANC* to be served upon the following counsel listed below, by the CM/ECF system:

<table>
<tr>
<td>

Nicholas P. Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
Alexander David Baxter
SIDLEY AUSTIN LLP
20th Floor
555 California Street
San Francisco, CA 94104-1715
(415) 772-1200

</td>
<td>

Deanne Maynard
Marc A. Hearron
Joseph R. Palmore
MORRISON & FOERSTER LLP
Suite 6000
2000 Pennsylvania Avenue, NW
Washington, DC 20008
(202) 887-1500

Rachel Krevans
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105
(415) 268-7000

Julie Park
MORRISON & FOERSTER LLP
Suite 100
12531 High Bluff Drive
San Diego, CA 92130
(858) 720-5100

Attorneys for Defendant-Appellee

</td>
</tr>
</table>

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin L. Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

/s/ Charles B. Klein

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

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

SEPTEMBER 2, 2015