Appeal No. 2015-1499

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., 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-RS, JUDGE RICHARD SEEBORG

NON-CONFIDENTIAL REPLY BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED

NICHOLAS 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, New York 10019
(212) 373-3000

VERNON M. WINTERS
ALEXANDER D. BAXTER
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, California 94104
(415) 772-1200

WENDY A. WHITEFORD
LOIS M. KWASIGROCH
KIMBERLIN L. MORLEY
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

April 28, 2015

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

Nicholas 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 D. Baxter
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

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

Nicholas Groombridge

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CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 27(m), materials that were designated as confidential pursuant to the district court's Protective Order have been redacted from the non-confidential version of the brief. Specifically, the material omitted on page 28 contains references to Sandoz's confidential information regarding pricing strategy and marketing and sales strategy.

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COUNTER-STATEMENT OF RELATED CASES

Sandoz asserts that *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Mar. 6, 2015) could be directly affected by this Court's decision. The parties here and in *Janssen* are entirely separate, so this Court's decision would affect that case only as it would any other case, under principles of stare decisis.

STATEMENT OF JURISDICTION

The parties agree regarding this Court's jurisdiction, except Sandoz argues that Amgen's preliminary-injunction appeal is moot. (Red Br. at xi.) That appeal is not moot, *see infra* at 26-27, and mootness goes to the merits, not this Court's jurisdiction.

INTRODUCTION

Sandoz and Amgen agree on this: an applicant seeking FDA approval of a biological product may choose between two alternatives. The parties differ about what those alternatives are, however. Amgen contends that the applicant may choose either (i) to file its BLA under the traditional regulatory pathway of 42 U.S.C. § 262(a) and accept the burdens of time and cost to develop clinical data to demonstrate the safety and efficacy of its biological product, or (ii) to file its BLA under the new, abbreviated pathway of 42 U.S.C. § 262(k) and accept both the benefits of that pathway, including reliance on the RPS's prior demonstration of safety and efficacy to secure a biologics license, and the obligations of that pathway, including disclosure of information to the RPS, limitations on declaratory judgments, and required notice to FDA and the RPS. Choosing the abbreviated pathway requires compliance with the "Patents" provisions of 42 U.S.C. § 262(*l*): "When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide" the RPS with the BLA and manufacturing information "required to be produced pursuant to paragraph (2)." 42 U.S.C. § 262(*l*)(1)(B)(i).

Sandoz says an Applicant that avails itself of the benefits of the subsection (k) pathway may choose either (i) to follow all the patent- and information-exchange provisions of 42 U.S.C. § 262(*l*), or (ii) to disregard them. To "complete the BPCIA's patent-exchange process from beginning to end" is only "[o]ne way,"

while refusing to complete that process and being sued for patent infringement is the other "path." (Red Br. at 10, 13.)

Sandoz's characterization of the BPCIA ignores the fundamental balancing of interests that Congress expressly sought to achieve. If an Applicant does not want to follow the provisions of the statute that benefit the innovator, then it cannot enjoy the provisions that benefit Applicants; it must file its BLA under the traditional, subsection (a) pathway. Sandoz did not do so. Sandoz has enjoyed the benefit of Amgen's data to secure a biosimilar license for ZARXIO® and now wishes to use that license to compete directly with Amgen, while it reneged on its BPCIA-created obligations and denied Amgen the unique information, procedures, and time to identify and act on Amgen's patent rights.

Amgen has thus been harmed by (i) Sandoz's unlawful use of Amgen's property (its biological license for filgrastim) without Amgen's consent, to secure a license for Sandoz's filgrastim product; (ii) Sandoz's use of that biosimilar license, secured in violation of the BPCIA, to compete with Amgen; and (iii) Sandoz's thwarting of Amgen's ability to timely identify and protect against Sandoz's infringement of Amgen's patents. The courts should have and do have broad powers, under federal and state laws, to remediate such harm to the RPS, including an injunction compelling the Applicant to honor its statutory obligations.

ARGUMENT

I. Sandoz's Reading of the BPCIA Guts the Purpose of the Statute

Sandoz acknowledges that Congress "struck a careful balance in the BPCIA between facilitating prompt access to cost-saving biosimilars and promoting innovation in biological products." (Red Br. at 8.) But Sandoz advances a construction of the BPCIA that guts the innovation-protecting provisions in the "Patents" section of the statute, subsection 262(*l*). Sandoz contends that the exclusivity provisions of subsection 262(k)(7) are the only rights given to an RPS that an Applicant may not vitiate at its election.

The BPCIA's "Patents" provisions provide important safeguards for the orderly identification and enforcement of patents that would be infringed by the Applicant's commercial manufacture, importation, use, or sale of the biosimilar product. Those provisions should be construed as they are written, honoring the balance struck by Congress to protect the Applicant and the RPS, irrespective of whether an Applicant files its BLA during the RPS's period of data exclusivity or after.

The "Patents" provisions compel the Applicant and the RPS quickly to identify patent disputes in an informed context, with confidential information protected from disclosure or misuse, and without needlessly encumbering court resources. (Blue Br. at 26-34.) They compel—within 230 days or less—

negotiations and, if necessary, "[i]mmediate" patent litigation, as well as public notice of that litigation and a limitation on the length of interchangeable biosimilar exclusivity based on that litigation. And they serve the public's interest in providing an orderly process and a limited window of time in which the status quo is maintained so the RPS can seek a preliminary injunction on certain patents. *See* 42 U.S.C. § 262(k)(6), (*l*)(3)-(6), (*l*)(8).

What Sandoz proposes instead of Congress's carefully mapped-out system is an uninformed, possibly unnecessary infringement suit to the detriment of both parties: the RPS may lack the information necessary to protect its rights, while the Applicant may be forced to launch at risk and face ruinous liability. Sandoz says that if an Applicant "declines" to provide its BLA and manufacturing information, the RPS is advantaged because it "ends up with far more control over the scope and timing of the infringement suit." (Red Br. at 1, 34.) It can sue immediately, or wait and force the Applicant to launch at risk. (*Id*. at 34, 35.) To Amgen's point that the RPS might not know which patents to enforce without the BLA and manufacturing information, Sandoz capitalizes on coincidence and notes that because here Amgen happens to have a method-of-treatment patent, it could sue and then seek discovery into what other patents might apply (*id.* at 6, 17), whereas an RPS that had only manufacturing patents could write "pre-suit letters seeking information about manufacturing processes" from the Applicant, and file suit "[i]f

there is no response" (*id.* at 34). An RPS like Amgen, with perhaps 400 potentially applicable patents, would presumably have to distill them into a book-length letter. An Applicant's good-faith response would take longer than would the statutory provisions themselves. Of course, given Sandoz's refrain that Applicants might not want to disclose their confidential information, the response would likely be a refusal to respond at all.

That is exactly the opposite of what Congress wanted. The BPCIA "Patents" provisions, enforced as written, methodically achieve Congress's desired balance, providing predictability to the industry, protection to innovators, swift resolution of patent disputes, and swift access to the market for biosimilars that do not infringe any patents.

That Sandoz wishes the process moved even faster does not permit Sandoz to disregard the process. Sandoz parrots the district court's assertion that the statute offers a "carrot" of a litigation safe harbor for an Applicant that "pursues the patent-exchange process but 'contains no stick to force compliance in all instances.'" (Red Br. at 20, quoting A0010-11.) The carrot-without-a-stick metaphor neatly sums up the error in Sandoz's argument. Congress sought to achieve a balance between competing interests, not to let the Applicant control that balance to its favor and as it chooses. The policy behind the BPCIA confirms this, as does its plain text.

II. The District Court Erred in Holding that the Requirement of 42 U.S.C. § 262(*l*)(2)(A) Is Not Mandatory

A. The BPCIA Does Not Create Two Dispute-Resolution Pathways

Sandoz argues that providing the BLA and manufacturing information under 42 U.S.C. § 262(*l*)(2)(A) is mandatory only if the Applicant wants to follow the dispute-resolution procedures laid out in subsection 262(*l*), and that the Applicant may instead invoke another, "separate path" by "declin[ing]" to provide its subsection 262(*l*)(2)(A) disclosure and facing "patent infringement litigation, with the scope and timing at the sole discretion of the sponsor." (Red Br. at 1, 4.) The core of this argument is 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), which define relevant rights if the Applicant fails to provide its BLA and manufacturing information. Those provisions actually refute Sandoz's argument.

First, neither provision uses the verb "to decline," (*see id.* at 1, 4), or any verb of choice: "choose," "elect," "opt," "decide," etc. Instead, Congress used "fail." Both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) refer to an Applicant that "fails to provide" its BLA and manufacturing information. That is not how one articulates a choice between alternative, permissible options. Sandoz never explains why Congress described not providing the BLA and manufacturing information as a "fail[ure]" rather than a "choice" between two "procedural path[s]," (Red Br. at 5), if in fact Congress intended to authorize such a choice.

Second, both sections describe the BLA and manufacturing information as "required under" subsection 262(*l*)(2)(A). 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). So do two other sections of the BPCIA. *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A). Congress could have said the information "referred to," "referenced in," or "listed in" subsection 262(*l*)(2)(A) instead of "required." It did not. Sandoz has no answer to Congress's use of "required." Indeed, Sandoz says that "the applicant is not required to initiate the patent-exchange process" by providing its BLA to the RPS, but then omits the words "required under" from its supporting quotations from 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). (Red Br. at 27 (emphasis added).)

B. That Congress "Contemplated" Noncompliant Applicants Does Not Mean that Congress Authorized Noncompliance

Again relying on these two provisions, Sandoz repeatedly asserts that the BPCIA "expressly contemplates" or "specifically contemplates" that an Applicant will not provide its BLA and manufacturing information and "expressly provides the consequences for not doing so." (*See, e.g.*, Red Br. at 1, 5, 11, 27.) If the BPCIA specifies a consequence for not completing an action, Sandoz argues, then failing to complete the action and enduring the consequence renders that failing lawful and thus irremediable: "[t]aking a procedural path that the BPCIA expressly laid out cannot be unlawful conduct," (*id.* at 5).

That proves too much. Many statutes—civil and criminal—expressly contemplate and anticipate unlawful conduct, and spell out the consequences of that conduct. The conduct is still unlawful. Sandoz cites no case holding that where Congress requires (or prohibits) a specified act, and provides consequences for noncompliance, a person may elect to incur those consequences rather than complying, and may escape liability for harm caused to others by non-compliance.

County of Ramsey v. MERSCORP Holdings, Inc., 962 F. Supp. 2d 1082 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014), provides Sandoz no support. The mortgage statute in that case "creates no obligations" at all, and any harm from non-compliance is visited on only the non-compliant party. (*See* Blue Br. at 42-43.) Neither does *National Federation of Independent Business v. Sebelius*, 132 S.Ct. 2566 (2012), which Sandoz cites in response to amicus AbbVie's brief. (Red Br. at 31-32.) There, the Supreme Court determined that the Affordable Care Act's "individual mandate" to require individuals to obtain health insurance or pay a "shared responsibility payment" should be read as a tax, not a penalty, "for constitutional purposes" and "to give practical effect to the Legislature's enactment." 132 S.Ct. at 2595-96, 2598 (*citing New York v. United States*, 505 U.S. 144, 169 (1992)). There are no constitutional-avoidance implications here, nor has Sandoz so argued. And *NFIB* did not hold that Congress's thousands of

statutory commands throughout the U.S. Code may be disregarded by electing specified statutory consequences.

Sandoz also tries to support its argument that Congress "contemplated" nondisclosure of the subsection 262(*l*)(2)(A) information by describing subsection 262(*l*) as a "reticulated" structure in which every "shall" command is accompanied by a "defined, patent litigation consequence" for the Applicant's or RPS's "decision to continue the process (or not) at every step." (Red Br. at 3, 11-12 (emphasis added).) Sandoz is incorrect, and its diagram is incomplete, omitting several "shall" commands that have no corresponding "consequences." *E.g.*, 42 U.S.C. § 262(*l*)(3)(A)(ii), (*l*)(3)(B)(iii), (*l*)(3)(C), (*l*)(8)(C). To the extent that the BPCIA imposes what Sandoz calls "consequences," it penalizes an Applicant or RPS, as the case may be, that fails to comply with the statute. Those penalties are not Congressional permission for the Applicant to do what Congress itself termed a "fail[ure]" or to cause irreparable harm to others. If anything, those consequences underscore the significance Congress placed on compliance.

C. By Sandoz's Own Argument, FDA Acceptance of its BLA Under Subsection (k) Mandated a Timely Subsection 262(*l*)(2)(A) Disclosure

In an effort to explain why each provision of subsection 262(*l*) uses the mandatory word "shall," Sandoz argues that the use of "shall" "simply establishes a mandatory condition precedent that *must* be taken for the patent-exchange

process to continue." (Red Br. at 5 (emphasis in original); *accord, e.g.*, *id.* at 10, 22.)

While it is correct that many of the steps of subsection 262(*l*) depend on the performance of a prior step, this statutory structure of successive obligations triggered by the fulfillment of a condition precedent explains why Sandoz's subsection 262(*l*)(2)(A) disclosure was mandatory not optional.

Sandoz characterizes subsection 262(*l)*(2)(A) as the first step in the process. There is, however, a "condition precedent" to that step: "Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review . . ." 42 U.S.C. § 262(*l*)(2)(A). And the subsection is phrased in mandatory language: "the subsection (k) applicant— (A) shall provide to the" RPS a copy of its BLA and manufacturing information (emphasis added). Once the condition precedent was met—and here there is no factual dispute that it was satisfied on July 7, 2014—then the disclosure became a mandatory obligation that Sandoz was required to fulfill within 20 days. This is reinforced by 42 U.S.C. § 262(*l*)(1)(B)(i): "When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii) [*i.e.*, the RPS's inside and outside counsel], subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2)," *i.e.*, the BLA and manufacturing information.

As described above, a would-be seller of a biologic product need not follow the subsection (k) pathway, but can instead choose the traditional, subsection (a) approval pathway. Indeed, Teva is currently marketing its own version of filgrastim, GRANIX®, for which it secured approval under the traditional subsection 262(a) pathway. But if the would-be seller chooses to avail itself of the advantages of the biosimilar (k) pathway—as Sandoz did—then it must comply with the Patent provisions of subsection 262(*l*).

D. The Subsection 262(*l*)(6) Lawsuit Is Mandatory

To blunt the impact of the "shall" in subsection 262(*l*)(2)(A), Sandoz argues that the "shall" in "[o]ther provisions" of subsection 262(*l*) is optional. (Red Br. at 28.) Despite the plural, Sandoz cites only one provision: the command in subsection 262(*l*)(6) that the RPS "*shall* bring an action for patent infringement" on the patents listed for inclusion in that suit. Sandoz argues that "[i]t cannot seriously be contended that this 'shall' mandates that the sponsor *must* sue the applicant *in all circumstances*, or else it has violated the BPCIA," and that "it is not rational to believe that Congress mandated that private parties sue other private parties." (*Id.* at 5, 28 (emphases in original).) Notably, Sandoz cites no support for this premise other than to hypothesize that an RPS might want to "avoid litigation expense until learning whether the biosimilar will be approved." (*Id.* at 28.)

It would be a violation of the BPCIA to fail to bring the "Immediate patent infringement action" specified in subsection 262(*l*)(6). The statute commands that suit be brought—"shall bring an action for patent infringement"—within 30 days. If the Applicant is harmed by the RPS's violation of that mandate, the Applicant may petition the courts to remedy that harm.

This may be one of the few places in American law where Congress commanded one party to sue another, *accord*, *e.g.*, mandatory counterclaims under Fed. R. Civ. P. 13, but its rarity confirms only that Congress meant exactly what it wrote. To the extent that Sandoz analogizes the "shall" in subsection 262(*l*)(2)(A) to the "shall" in subsection 262(*l*)(6), the comparison proves only that providing the BLA and manufacturing information is mandatory.

The immediate, mandatory infringement action plays a vital role in the statutory mechanism, as it allows an Applicant to obtain pre-licensure judicial resolution of a dispute and thereby avoid having to launch at risk and incur potentially ruinous damages liability. If, as Sandoz posits, an RPS can simply decline to bring the subsection 262(*l*)(6) lawsuit at this stage, it leaves the Applicant at risk for infringement damages if the Applicant wants to enter the market before patent expiry. And while the BPCIA limits those damages to a reasonable royalty, 35 U.S.C. § 271(e)(6)(B), in this industry those royalties can be very high. *See*, *e.g.*, *AstraZeneca AB v. Apotex, Corp.*, No. 14-1221, 2015 WL

1529181, at *10 (Fed Cir. Apr. 7, 2015) (50% royalty rate for at-risk generic launch).

A central purpose of the patent-exchange mechanism is to privately resolve patent disputes or seek judicial intervention to clarify rights before licensure, for the benefit of the RPS, the Applicant, and the public. That purpose was achieved by making the immediate subsection 262(*l*)(6) lawsuit mandatory, and permitting an Applicant harmed by the RPS's noncompliance to seek relief from the courts, including a remedy to rectify the harm caused by the RPS's delay.

E. The Immediate Patent Infringement Action Is the Lynchpin of the Patent-Exchange Provisions

Sandoz also tries to downplay the importance of the subsection 262(*l*)(6) lawsuit, and to do so wrongly equates "pre-launch infringement lawsuits" with an action for patent infringement under subsection 262(*l*)(6). (Red Br. at 36.) Neither an action seeking a declaration of patent infringement in accordance with subsection 262(*l*)(9)(B) or (C) nor a patent infringement action under 35 U.S.C. § 271(e)(2)(C)(ii) triggers the same statutory rights and obligations as does a subsection 262(*l*)(6) patent infringement action.

The mandatory injunction Congress created in 35 U.S.C. § 271(e)(4)(D) is triggered by only a subsection 262(*l*)(6) lawsuit, and Sandoz has no response for why an Applicant should be permitted to escape this remedy by preventing filing

of a subsection 262(*l*)(6) lawsuit. (Blue Br. at 40.) Likewise, notice to FDA and publication of the complaint are triggered by only a subsection 262(*l*)(6) lawsuit.

Nor can Sandoz explain away the Applicant's ability to game the interchangeability exclusivity provisions of subsection 262(k)(6) by preventing a subsection 262(*l*)(6) lawsuit. (Blue Br. at 40-41; Red Br. at 37.) That exclusivity ends with the soonest-to-occur of five events, three of which require a subsection 262(*l*)(6) lawsuit to have been filed. Sandoz says that because the remaining two provisions do not require a subsection 262(*l*)(6) lawsuit, Congress contemplated the absence of such a suit. But that gets the statute wrong again. There might well be no subsection 262(*l*)(6) lawsuit if, for example, the RPS listed no patents in subsection 262(*l*)(3)(A), or the RPS licensed all relevant patents to the Applicant. The system-gaming comes not if a subsection 262(*l*)(6) lawsuit proves unnecessary but if, as Sandoz would have it, the Applicant can cause the RPS to file some kind of infringement lawsuit other than a subsection 262(*l*)(6) lawsuit.

Finally, Sandoz argues that a subsection 262(*l*)(6) lawsuit cannot be the lynchpin of the BPCIA because the Applicant "has the unilateral right to limit that suit to a single patent." (Red Br. at 37.) That misses the point; as explained above, the significance of the subsection 262(*l*)(6) lawsuit is evidenced by its triggering other statutory rights and obligations throughout the BPCIA—in 35 U.S.C. § 271(e), 42 U.S.C. § 262(k), and 42 U.S.C. § 262(*l*)—not by the number of

patents that could be included. All of these provisions further confirm why the statute must be construed according to its plain terms, requiring the Applicant to provide its BLA and manufacturing information under subsection 262(*l*)(2)(A) so that the subsection 262(*l*)(6) lawsuit can occur.

III. The District Court Erred in Holding that Notice Under 42 U.S.C. § 262(*l*)(8)(A) Is Optional and May Be Provided Before FDA Licensure

The 180 days' notice of commercial marketing required by 42 U.S.C. § 262(*l*)(8)(A) may not be given until the FDA has licensed the biosimilar. (Blue Br. at 45-52.) This is true because the statute refers to notice of commercial marketing of a "product licensed," whereas in every other instance the statute refers to the "product that is the subject of" the BLA. And it is true because notice as of licensure is the only way to give effect to the preliminary-injunction provisions with which the notice provision is paired, 42 U.S.C. § 262(*l*)(8)(B), (C).

A. Sandoz Has Identified No Statutory Basis to Permit Notice To Be Given Prior to FDA Approval

Sandoz argues that Congress's use of "biological product licensed" simply reflects that the product cannot be commercially marketed until it is "licensed." (Red Br. at 39.) That cuts the wrong way. Commercial marketing would require licensure even if Congress had instead written that notice must be given "not later than 180 days before the date of the first commercial marketing of the biological

product that is the subject of the subsection (k) application." The fact that licensure is a prerequisite for marketing cannot explain Congress's wording.

Sandoz also argues that other BPCIA provisions using the phrase "the product that is the subject of" the application do not refer to "a future date when the product will be 'licensed,'" and seeks thereby to explain why that phrase was not used in subsection 262(*l*)(8)(A). (Red Br. at 39.) That premise is incorrect, however. At least five provisions using such wording refer to future dates by which the product will have been licensed. *See* 42 U.S.C. § 262(*l*)(3)(B)(ii)(I); (*l*)(3)(C); *accord* (*l*)(1)(D); (*l*)(3)(A)(i); (*l*)(7)(B).

Next, Sandoz says that because the notice is to be given by the "subsection (k) *applicant*," Congress intended for notice to be given before FDA licensure, because "[a]fter approval is granted, the party is no longer an 'applicant.'" (Red Br. at 39 (emphasis in original).) But "subsection (k) applicant" is not a descriptive term, it is a defined term. Subsection 262(*l*) begins by stating the "person that submits an application under subsection (k)" is "referred to in this subsection as the 'subsection (k) applicant.'" 42 U.S.C. § 262(*l*)(1)(A). Congress's use of that defined term in subsection 262(*l*)(8)(A) signifies nothing about the timing of notice, only who has to give that notice: the Applicant.

Finally, Sandoz says that "notice" at the time of licensure would be "superfluous," since FDA's approval of a biosimilar is public. (Red Br. at 40.)

But FDA's product-approval announcement does not provide the date on which the Applicant will in fact begin commercial marketing of the licensed product. Advance notice of that date is important because it sets the outer boundary (not less than 180 days) by which the RPS may seek a pre-marketing preliminary injunction under subsection 262(*l*)(8)(B). That date might not be 180 days after FDA approval: an Applicant might delay commercial marketing after licensure for commercial reasons, supply reasons, or even to wait for the expiration of a patent held by someone other than the RPS. Thus, requiring the Applicant to give notice on or after FDA approval is not superfluous.

B. The 180-Day Period After Licensure Does Not Extend the RPS's Market or Data Exclusivity

Sandoz makes much of Amgen's having enjoyed 24 years of "exclusivity" for filgrastim, conflating data exclusivity and market exclusivity to serve its advocacy. While it is true that Amgen, based on its investments in clinical trials and its securing of FDA licensure for five clinical indications, has met filgrastim demand for 24 years, any data exclusivity Amgen enjoyed during that period did not and could not confer on Amgen filgrastim "market exclusivity." Anyone has been free to obtain an FDA license for a filgrastim product under the traditional, subsection 262(a) pathway, as Teva did for GRANIX® in 2013.

Sandoz's assertion that the 180-day period extends the BPCIA's 12-year data exclusivity period is wrong. When that 12-year period expires, it expires.

The 180-day notice provision will become applicable to each biosimilar as of the time of its licensing, but the fact that a given biosimilar is in that 180-day waiting period does not preclude others from getting FDA approval or entering the market with their own biologic, whether biosimilar or not. Sandoz recognizes this, cabining its complaint about extra "market" exclusivity to only the "first-approved biosimilar" for a given reference product. (Red Br. at 41.) But even for that first-approved biosimilar's 180-day-post-licensure period, the RPS's "exclusivity" is quite narrow. Consider this case, for example: Sandoz's 180-day notice period for its filgrastim product confers no exclusivity to Amgen with respect to Teva's filgrastim product, which is already on and will presumably remain on the market.

Next, Sandoz argues that a 180-day notice period amounts to an automatic, "standardless, bondless injunction," conflicting with the preliminary-injunction provisions of subsection 262(*l*)(8)(B) itself. (Red Br. at 40-41.) Not so. The 180-day notice period gives the RPS time to seek a preliminary injunction on, for example, patents issued or in-licensed after the "[i]mmediate" infringement action was commenced. (*See* Blue Br. at 47.) It gives effect to subsection 262(*l*)(8)(B) by giving the court an orderly procedure and time to consider such a motion.

Finally, Sandoz offers no valid answer to Amgen's observation that the interchangeability exclusivity provisions of 42 U.S.C. § 262(k)(6) support the notion that the 180 days should follow FDA licensure. Two of the five soonest-to-

occur events are (i) one year from commercial marketing of the biosimilar, and (ii) 18 months from approval of that biosimilar (if there has been no subsection 262(*l*)(6) lawsuit), and this timing suggests that commercial marketing would follow approval by 180 days. (*Id.* at 48-49.) Sandoz argues that if notice must be given only after FDA licensure, these two dates would always be the same, and thus it would make no sense for Congress to speak of the sooner-to-occur of them. (Red Br. at 43.) But that again assumes that commercial marketing will occur as soon as the 180-day notice period expires. It might not: the Applicant might wait to commence commercial marketing for any number of reasons. Thus, eighteen months from approval could happen before one year from commercial marketing, even if the Applicant gives 180 days' notice of commercial marketing as soon as it gets FDA approval. The overarching point, however, and one that Sandoz fails to address, is that subsection 262(k)(6)—the only part of the BPCIA that addresses both product approval and first commercial marketing—clearly contemplates that those events would be different in time, and different by approximately 180 days.

IV. The District Court Erred in Holding that 42 U.S.C. § 262(*l*)(9) Provides the Exclusive Remedies for Violating 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(8)(A)

Amgen showed that district courts should have a broad range of remedies, under State and federal law, to remedy non-compliance with the BPCIA, and that the district court here erred in holding that an RPS's only recourse in the face of

non-compliance is a declaratory judgment action under 42 U.S.C. § 262(*l*)(9). (Blue Br. at 52-61.) Sandoz has identified no basis to affirm the district court.

A. 35 U.S.C. § 271(e)(4) Does Not Provide Any Remedies, Much Less Exclusive Remedies, for Violating 42 U.S.C. § 262(*l*)(2)(A)

The district court was quite clear in holding that the "only" consequence, the "exclusive consequence[]," for an Applicant's failure to provide the BLA and manufacturing information is for the RPS to bring a declaratory judgment action under 42 U.S.C. § 262(*l*)(9)(C), not a claim for "injunctive relief, restitution, or damages." A0018.

Sandoz abandons this, and argues instead that an RPS's "sole recourse" is a "patent infringement" suit under 35 U.S.C. § 271(e)(2)(C). (*See, e.g.*, Red Br. at 1, 2, 4, 5-6.) Sandoz asserts that the artificial act of infringement in section 271(e)(2)(C) "would allow either the sponsor or the applicant to invoke the Declaratory Judgment Act." (*Id*. at 9). That is wrong. An artificial act of infringement does not invoke declaratory-judgment jurisdiction. Rather, "section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)). The dictum in the case Sandoz cites, *Glaxo Group. Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), does not change this settled law. Nor does

subsection 262(*l*)(9)(C) provide for an affirmative patent infringement suit for an artificial act of infringement. It permits the RPS to bring a declaratory judgment action for anticipated future infringement under section 271(a), (b), (c), or (g). *Accord Novopharm*, 110 F.3d at 1569-71 (bringing section 271(e) infringement claim under 28 U.S.C. § 1338(a), and section 271(g) infringement claim under the Declaratory Judgment Act). Indeed, Sandoz fails to reconcile how a declaratory judgment under subsection 262(*l*)(9)(C) can be based on a section 271(e)(2) infringement, when the remedies prescribed in section 271(e)(4) are the "only remedies which may be granted by a court for an act of infringement described in" section 271(e)(2) and, notably, declaratory judgment is not among the listed remedies.

Sandoz tries to use the limitations in 35 U.S.C. § 271(e)(4), arguing—four times—that this section provides "the 'only remedies' for the failure to provide the application" and manufacturing information, and represents "affirmative congressional intent" to foreclose other remedies. (Red Br. at 51; *see also id.* at 7, 55, 59.) But each time, Sandoz leaves out the most important words from the statute: What section 271(e)(4) actually says is that the remedies set forth therein "are the only remedies which may be granted by a court <u>for an act of infringement</u> described in paragraph (2)." (emphasis added.) The "act of infringement" in paragraph (2) is not the failure to give the RPS a copy of the BLA and

manufacturing information, it is the submission of the BLA to FDA. The remedies in section 271(e)(4) are the exclusive remedies for that patent infringement, not for violating the BPCIA.

B. 42 U.S.C. § 262(*l*)(9)(B) Is Not a Remedy for Untimely Notice of Commercial Marketing

Sandoz argues that a declaratory judgment under subsection 262(*l*)(9)(B) is the exclusive remedy for failure to provide notice of commercial marketing. (Red Br. at 15, 48.) But Sandoz has no answer to the point in Amgen's Blue Brief (at 56-57) that this is no remedy at all: If the Applicant does not provide notice of commercial marketing and simply launches its product, the RPS will sue for patent infringement under 35 U.S.C. § 271(a)—or, depending on the patent, (b) or (c) or (g)—and seek emergency relief. A declaratory judgment would not protect the RPS's rights or remedy the harm caused by the Applicant's failure to give notice.

C. Sandoz Cannot Contend There Should Be No Implied Federal Right of Action

Sandoz argues that there should be no implied federal cause of action to compel compliance with the BPCIA (Red Br. at 49-54), citing *Alexander v. Sandoval*, 532 U.S. 275 (2001). But Sandoz itself brought three federal-law counterclaims seeking declarations that its conduct under the BPCIA is lawful, and it prevailed on them. Unwinding those declaratory judgment counterclaims implies a cognizable claim that could be brought by an RPS under the BPCIA to

remedy the conduct in which Sandoz engaged, if that conduct is indeed unlawful. Otherwise, Sandoz's counterclaims presented no justiciable case or controversy. It cannot now argue that the BPCIA forecloses a federal remedy.

Sandoz's arguments fare no better in the details. They rest on the premise that 35 U.S.C. § 271(e)(4) provides exclusive remedies for failure to provide the BLA and manufacturing information, citing *Touche Ross & Co. v. Redington*, 442 U.S. 560 (1974), when, as addressed above, that statute provides no remedy for that failure. And while Amgen did not plead a federal private right of action under the BPCIA, Sandoz's assertion that the district court found Amgen to have waived such a claim is wrong; the district court found only that the motions before it involved no such claim. A0008 n.8. And while Sandoz cites *Northwest Airlines, Inc. v. Transport Workers Union of America, AFL-CIO*, 451 U.S. 77 (1981) for the unremarkable proposition that an implied right of action should benefit the class that the statute benefits, the BPCIA benefits both the Applicant and the RPS despite Sandoz's protestations otherwise.

D. Amgen Properly Sought Relief Under State Law for Sandoz's Unlawful Conduct

Sandoz offers a litany of one- or two-sentence attacks on Amgen's state-law claims. None provides any reason to affirm the district court's Order.

First, Sandoz argues that Amgen cannot bring a UCL claim or a conversion claim if Sandoz's reading of the BPCIA is correct. (Red Br. at 54, 57.) That is

true as far as it goes, but for all the reasons set forth in the Blue Brief and above, Sandoz's reading of the BPCIA is wrong.

Second, Sandoz argues that UCL remedies are not available where the underlying statute alleged to have been violated—here, the BPCIA—"expressly provide[s]" that its remedies are exclusive. (*Id.* at 54.) But the BPCIA does not expressly provide exclusive remedies for violation of the notice and disclosure provisions of subsection 262(*l*). Sandoz relies on 35 U.S.C. § 271(e)(4), (*id.* at 55), but, as noted above, that provision sets forth exclusive remedies "for an act of infringement" under section 271(e)(2), not a remedy, much less an exclusive one, for failing to provide the BLA and manufacturing information or for giving untimely notice of commercial marketing.

Third, Sandoz argues that a UCL remedy should not be available because "Congress already balanced" the equities between an Applicant and the RPS. (*Id.*) That, too, assumes that Sandoz is correct that the BPCIA provisions are not mandatory and that notice of commercial marketing is not required. If Sandoz is in breach of those provisions, the UCL provides a remedy for that breach.

Fourth, Sandoz argues that Amgen can have no conversion claim because the BPCIA allows Applicants to rely on the RPS's license and because California conversion claims cannot interfere with the balance struck in the BPCIA. (*Id.* at 57-58.) But that argument, too, assumes its own conclusion. Sandoz's referencing

of Amgen's license is an act of conversion if Sandoz has, in fact, failed to comply with the very statute it argues shelters it from liability. And if the BPCIA requires Sandoz to do what Sandoz refused to do, treating that obstinacy as tortious does not upset the balance that Congress created.

E. Sandoz Deliberately Waived its Preemption Argument

Finally, Sandoz argues that while it "did not affirmatively argue preemption in its motion for judgment on the pleadings," it is does so now in response to AbbVie's amicus brief. (*Id.* at 58.)

Sandoz did more than "not affirmatively argue preemption." Sandoz deliberately disclaimed any reliance on preemption. Neither party addressed preemption in the district court briefing, but the issue came up at oral argument. Sandoz's counsel was emphatic: "[L]et me be clear. We have not argued preemption of the state law claims." A1854. When confronted with Sandoz's sixth affirmative defense, which asserts preemption, A1869, Sandoz's counsel reiterated that it had abandoned preemption:

> First, it is true that in our answer we said this was preempted, but then we looked farther at the issue when we wrote our briefs -- and you'll notice in our briefs we did not argue preemption, because having looked very closely at the law, we decided that was really not the right analysis to put before the Court. So we did not argue that in our motions. We are not arguing it today. We are not relying on it.

A1876 (emphasis added).

Preemption is an affirmative defense. It is waivable unless it affects subject-matter jurisdiction, which it does not here: the parties agree that the district court and this Court have subject-matter jurisdiction, under 28 U.S.C. §§ 1331 and 1338 and 28 U.S.C. § 1295(a), respectively. Rather, Sandoz makes a choice-of-law preemption argument. This Court follows regional circuit law regarding waiver of that defense. *See Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005). The Ninth Circuit holds that choice-of-law preemption arguments are waived if raised for the first time on appeal, *see Brannan v. United Student Aid Funds, Inc.*, 94 F.3d 1260, 1266 (9th Cir.1996), including where raised for the first time by a defendant-appellant in its responsive brief, *see Williams v. Gerber Products Co.*, 552 F.3d 934, 937 (9th Cir. 2008).

Sandoz waived its preemption defense. The issue is not before this Court.

V. The District Court Abused Its Discretion in Denying Amgen's Motion for a Preliminary Injunction

A. Amgen's Appeal Is Not Moot

Sandoz asserts that Amgen's appeal from the denial of its preliminary injunction motion is moot because Amgen sought preliminary relief only until the district court resolved the parties' motions for judgment on the pleadings. (Red Br. at 60.) That is untrue. Amgen also sought a preliminary injunction against Sandoz's commercial activity until Sandoz completes the acts required by the BPCIA, if the district court were to agree that those acts are required. A0469;

A0598-604. Whether the injunction motion is now moot depends on the outcome of this appeal: If the Court affirms the district court's construction of the BPCIA, then Amgen's motion for an injunction is moot. If the Court reverses, either by ruling in Amgen's favor on its own UCL claim or by entering judgment in Amgen's favor on Sandoz's counterclaims, then an injunction is necessary while Sandoz complies with the BPCIA and the district court conducts further proceedings consistent with this Court's ruling.

B. The District Court Abused Its Discretion in Denying Amgen's Motion For a Preliminary Injunction

The district court abused its discretion in denying Amgen's motion for a preliminary injunction and finding the harm to Amgen to be "highly speculative." A0018. (Blue Br. at 62-64.)

Sandoz's principal response is that there can be no irreparable harm without a showing of patent infringement. (Red Br. at 61.) Not so. Amgen has been and will be irreparably harmed if Sandoz's product enters the market without affording Amgen the process due it under the BPCIA. By refusing to provide the required BLA and manufacturing information, Sandoz converted Amgen's property and is poised to compete directly with Amgen. Sandoz materially prejudiced Amgen, depriving it of the time—up to 230 days—and information needed to detect Sandoz's infringement and commence a subsection 262(*l*)(6) action. (*See* Blue Br. at 62.) By refusing to provide 180-day advance notice after FDA licensure,

Sandoz further denied Amgen the statutory period to seek a preliminary injunction on the licensed product under patents identified in the BPCIA process. (*See id.*)

Sandoz also argues that the harms it has wrought are speculative, but in fact they are immediate and real. Amgen will face price erosion, patent uncertainty, and harm to its goodwill and customer relationships, which cannot be remediated by a later-issued injunction or by money damages. (*Id*. at 63-64.)

Despite urging that biosimilars will lower prices, Sandoz says that Amgen's witnesses testified only that Amgen "might" or "may" have to lower its own prices in response to competition, and that price erosion was therefore uncertain. (Red Br. at 61.) That testimony was given after Sandoz had said publicly it might price at parity to Amgen's price (A0478, A0591), and before [redacted], confirming the price erosion and loss of goodwill that Amgen will suffer. A0477-80; A0516-17.

Sandoz also argues that Amgen delayed or was not diligent in bringing suit or accepting Sandoz's BLA. (*See, e.g*., Red Br. at 16, 34.) This issue is not before the Court, as the district court made no findings of delay, and thus Amgen does not respond here to all of Sandoz's many accusations. Suffice it to say that Amgen disagrees. By way of only two examples, Sandoz omits that (i) Amgen consistently stated it was ready to receive Sandoz's BLA and manufacturing

information under the BPCIA's confidentiality provisions, but Sandoz was unwilling to provide the material on that basis; and (ii) Sandoz's supposedly "industry-standard" offer for confidential access, (Red Br. at 16), was limited to the BLA, did not include "other information that describes the process or processes used to manufacture" as required by subsection 262(*l*)(2)(A), and would have precluded Amgen from bringing suit under 35 U.S.C. § 271(e) or 271(g). A1465-68, A1481-82, A1484, A1505-07. That Amgen insisted on the rights provided to it by the BPCIA cannot support Sandoz's accusations of delay.

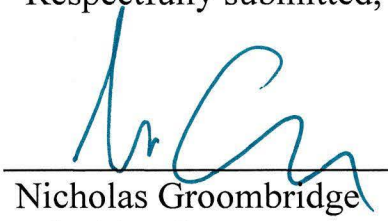
Sandoz next argues that any harm Amgen faces could be remediated with money. The "fact that one could, if pressed, compute a money damages award does not always preclude a finding of irreparable harm." *Celsis In Vitro, Inc. v. CellzDirect, Inc*., 664 F.3d 922, 930 (Fed. Cir. 2012). This Court has repeatedly affirmed findings that price erosion is irreparable harm. Here, the ability to calculate monetary damages is only further complicated by the fact that other biosimilar filgrastim products are expected within a year. (Red Br. at 62.)

CONCLUSION

For the reasons set forth above and in the Blue Brief, Amgen respectfully requests that the Court (i) reverse the district court's entry of judgment in favor of Sandoz on Amgen's UCL and conversion claims; (ii) reverse the district court's entry of judgment on Sandoz's counterclaims; (iii) reverse the district court's denial of Amgen's motion for preliminary injunction; and (iv) remand for further proceedings based on the correct interpretation of the BPCIA, including entry of judgment in Amgen's favor on its claims and Sandoz's counterclaims and entry of an appropriate injunction.

Dated: April 28, 2015

Respectfully submitted,



Nicholas 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 D. Baxter
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104-1503
(415) 772-1200

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

CERTIFICATE OF SERVICE

I hereby certify that on this 28th of April, 2015, I caused the foregoing Non-Confidential Reply Brief of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the foregoing Non-Confidential Reply Brief of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

Deanne E. Maynard
(dmaynard@mofo.com)
Marc A. Hearron
(mhearron@mofo.com)
Joseph R. Palmore
(jpalmore@mofo.com)
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Suite 6000
Washington, D.C. 20006

Rachel Krevans (rkrevans@mofo.com)
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105

COUNSEL PRESS

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). The brief contains 6,930 words, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b). The word count includes the words counted by the Microsoft Word 2010 function.

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Nicholas Groombridge