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

EMERGENCY MOTION OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED FOR AN INJUNCTION PENDING EN BANC CONSIDERATON AND REVIEW

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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
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Jennifer H. Wu
Jennifer Gordon
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/s/ Nicholas Groombridge
Nicholas Groombridge

Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") respectfully request that the Court enter a temporary injunction to preserve the status quo—preventing Defendant-Appellee Sandoz Inc. ("Sandoz") from launching its biosimilar product ZARXIO®—while the Court considers whether to grant Amgen's petition for rehearing en banc, and if granted, while the en banc Court decides this appeal. Pursuant to Federal Circuit Rule 27(a)(5), Amgen informed counsel for Sandoz of Amgen's intent to file this motion and sought Sandoz's position. Sandoz indicated that it opposes the motion and will file an opposition.

This appeal involves issues of first impression as to the correct statutory construction of the BPCIA. (Maj. Op. at 3.) On July 21, 2015, this Court issued a fractured panel decision, with three opinions from each of the three Judges. Prior to the panel decision, the Court had granted Amgen's emergency motion for an injunction preventing Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved ZARXIO® biosimilar product during this appeal. (Dkt. No. 105.) In the panel decision, the Court ordered that the injunction extend only through September 2, 2015 consistent with the panel majority's interpretation of the BPCIA. (Maj. Op. at 25.) Thus, Sandoz is poised to begin commercial marketing and sale of its biosimilar product in direct

competition with Amgen's innovative NEUPOGEN® biological product, upon expiry of the injunction. *See* Ex. 1.

Amgen filed a petition for rehearing en banc on August 20, 2015 (Dkt. No. 118 or "Amgen Pet."), and this Court invited Sandoz to file a response on or before September 8, 2015. (Dkt. No. 122.) As stated in Amgen's petition, Amgen requests that the full Court consider whether the aBLA Applicant may avail itself of the benefits of the BPCIA by referencing the Sponsor's license for the reference product, while circumventing the information-exchange provisions of that statute and leaving the Sponsor without a meaningful remedy for the injury caused to it by the Applicant's failure to comply with the statute. (Amgen Pet. at 5.) Amgen believes that the panel majority erred in its holding on this issue, and agrees with Judge Newman's dissent that an Applicant must comply with the required statutory provisions in order to obtain the benefits of the BPCIA. (Newman Op. at 9.) In particular, Amgen seeks review of the panel majority's decision that the exclusive remedy for non-compliance with the BPCIA's statutory information-exchange provisions is a patent-infringement or declaratory judgment action. (*See* Amgen Pet. at 8-15.)

If Amgen is correct that non-compliance with the BPCIA causes injury to statutorily protected legal interests that encourage innovation by the Sponsor, then Amgen may pursue remedies beyond a patent-infringement or declaratory

judgment action for Sandoz's deliberate violation of the BPCIA. For example, Amgen's Complaint alleged that Sandoz's violations of the BPCIA damaged Amgen, and sought equitable, compensatory, and punitive relief. The nature and scope of that relief is left to the district court in the first instance, which may for example decide to enjoin Sandoz from launch or prevent Sandoz from obtaining the benefits of the abbreviated biosimilar pathway absent compliance with the BPCIA. The full scope of Amgen's requested remedy, however, cannot be considered or awarded by the district court if Sandoz has launched its biosimilar product already. As Amgen stated in its prior motion for an injunction, Sandoz's launch will fundamentally and permanently alter the market, causing irreparable harm to Amgen if the en banc Court ultimately decides the issues in favor of Amgen. (Dkt. No. 56 at 16-19.)

In sum, the en banc Court's ability to grant Amgen the relief it seeks—remand to the district court to fashion a remedy for the injury to Amgen from Sandoz's violation of the BPCIA, including injunctive relief—requires that the status quo be preserved. Otherwise, the unique interests Amgen seeks to protect, which include, but go beyond its patents, will have been lost, and the district court will have been deprived of its ability to fashion an appropriate remedy for the full scope of the injury to Amgen. Accordingly, Amgen respectfully requests that this Court continue the injunction— preventing Sandoz from marketing, selling,

offering for sale, or importing into the United States its ZARXIO® biosimilar product—beyond September 2 through the full pendency of this appeal, before the status quo is irrevocably changed. Amgen's requested temporary injunction will be short given the expedited nature of this appeal: this Court issued its panel decision on July 21, less than two months after the June 3 oral argument, Amgen filed its petition for rehearing en banc on August 20, and Sandoz's response to Amgen's petition is due by September 8.

Dated: August 26, 2015

Respectfully submitted,

/s/ Nicholas Groombridge

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INDEX OF EXHIBITS

Ex.	Description	Date
	Declaration of Jennifer H. Wu in Support of Plaintiffs-Appellants' Motion for an Injunction Pending En Banc Consideration and Review	
1.	Press Release, Sandoz, Court Ruling Paves the Way for Launch of Sandoz's Zarxio as First US Biosimilar (July 22, 2015)	7/22/2015
2.	District Court's Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction [Dist. Ct. Dkt. No. 105]	3/19/2015
3.	District Court's Final Judgment Under Rule 54(b) and Order Establishing Schedule for Rule 62(c) Proceedings and Staying All Other Proceedings [Dist. Ct. Dkt. No. 111]	3/25/2015
4.	Amgen's Notice of Appeal [Dist. Ct. Dkt. No. 112]	3/25/2015
5.	District Court's Order Denying Amgen's Motion for Injunction Pending Appeal [Dist. Ct. Dkt. No. 129]	4/15/2015
6.	Federal Circuit's Order Granting Motion for an Injunction Preventing Sandoz from Marketing, Selling, Offering for Sale, or Importing into the United States its FDA-Approved ZARXIO® Biosimilar Product Until this Court Resolves the Appeal [Dkt. No. 105]	5/5/2015
7.	Federal Circuit's Opinion and Judgment [Dkt. No. 116]	7/21/2015

Appeal No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LTD.,

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

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DECLARATION OF JENNIFER H. WU IN SUPPORT OF PLAINTIFFS-APPELLANTS' MOTION FOR AN INJUNCTION PENDING EN BANC CONSIDERATION AND REVIEW

I, Jennifer H. Wu, declare and state as follows:

1. I am an attorney admitted to the bar of this Court, and a partner of the law firm, Paul, Weiss, Rifkind, Wharton & Garrison LLP. I am one of the attorneys of record in Appeal No. 2015-1499 for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"). I have personal knowledge of the facts set forth in this Declaration, and if called upon as a witness, I could and would testify competently as to these facts.

2. Attached hereto as Exhibit 1 is a true and correct copy of Sandoz's press release entitled "Court Ruling Paves the Way for Launch of Sandoz's Zarxio as First US Biosimilar" dated July 22, 2015.

3. Attached hereto as Exhibit 2 is a true and correct copy of the District Court's Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction (Dist. Ct. Dkt. No. 105) dated March 19, 2015 from *Amgen Inc. v. Sandoz Inc.*, No. 3:14-CV-04741-RS (N.D. Cal.) (the "District Court Action").

4. Attached hereto as Exhibit 3 is a true and correct copy of the District Court's Final Judgment Under Rule 54(b) and Order Establishing Schedule for Rule 62(c) Proceedings and Staying All Other Proceedings (Dist. Ct. Dkt. No. 111) dated March 25, 2015 from the District Court Action.

5. Attached hereto as Exhibit 4 is a true and correct copy of Amgen's Notice of Appeal (Dist. Ct. Dkt. No. 112) dated March 25, 2015.

6. Attached hereto as Exhibit 5 is a true and correct copy of the District Court's Order Denying Amgen's Motion for Injunction Pending Appeal (Dist. Ct. Dkt. No. 129) dated April 15, 2015 from the District Court Action.

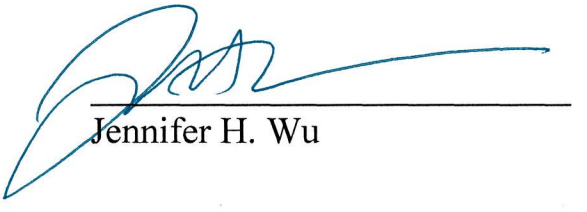
7. Attached hereto as Exhibit 6 is a true and correct copy of the Federal Circuit's Order Granting Motion for an Injunction Preventing Sandoz from Marketing, Selling, Offering for Sale, or Importing into the United States its FDA-

Approved ZARXIO® Biosimilar Product Until this Court Resolves the Appeal (Dkt. No. 105) dated May 5, 2015 from this Court in this appeal.

8. Attached hereto as Exhibit 7 is a true and correct copy of the Federal Circuit's Opinion and Judgment dated July 21, 2015 (Dkt. No. 116) from this Court in this appeal.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on August 26, 2015 in New York, New York.



Jennifer H. Wu

EXHIBIT 1

MEDIA CENTER
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COURT RULING PAVES THE WAY FOR LAUNCH OF SANDOZ'S ZARXIO AS FIRST US BIOSIMILAR

Holzkirchen, Germany, July 22, 2015 - The US Court of Appeals for the Federal Circuit issued a ruling on July 21 that paves the way for Sandoz to launch Zarxio (filgrastim) after September 2, as the first US biosimilar.

The court, which ruled following an appeal hearing on June 3, found that provision of the biosimilar application to the originator company within 20 days of filing – the so-called "patent dance" component of the US biosimilar approval pathway, or BPCIA -- is optional.

However, it also ruled that the required notice of commercial marketing can only be provided to the brand company following FDA product approval, but must be at least 180 days before commercial marketing. Sandoz gave a further notice of commercial marketing when it received FDA approval of Zarxio on March 6, so it can launch 180 days from then, i.e. after September 2.

Carol Lynch, Global Head of Sandoz Biopharmaceuticals & Oncology Injectables, said: "We welcome the Federal Circuit's finding that the BPCIA's patent dance is optional.

"As we have argued all along, the decision of a biosimilar applicant not to provide its dossier as one step in the patent dance entitles the brand under the BPCIA to commence patent infringement proceedings, which Amgen has done here.

"We look forward to launching Zarxio after September 2 as the first US biosimilar."

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "launches," "introduction," "will," or similar terms, or by express or implied discussions regarding potential revenues from guanfacine extended release tablets. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and

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uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that guanfacine extended release tabletswill be commercially successful in the future. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; competition in general, including potential approval of additional versions of guanfacine extended release tablets; national trends toward health care cost containment, including ongoing pricing pressures; unexpected patent litigation outcomes; unexpected manufacturing issues; general economic and industry conditions, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz
Sandoz, a division of Novartis, is a global leader in generic pharmaceuticals, driving sustainable access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable products to patients and customers around the globe.

The Sandoz global portfolio comprises approximately 1,100 molecules, which accounted for 2014 sales of USD 9.6 billion. Sandoz holds the global #1 position in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines. Sandoz also holds leading global positions in key therapeutic areas ranging from generic injectables, dermatology and respiratory to cardiovascular, metabolism, central nervous system, pain and gastrointestinal.

Sandoz develops, produces and markets finished dosage form (FDF) medicines as well as intermediary products including active pharmaceutical ingredients (APIs) and biotechnological substances. Nearly half of the Sandoz portfolio is in differentiated products – medicines that are scientifically more difficult to develop and manufacture than standard generics.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has consistently driven growth in selected geographies and differentiated product areas through a series of targeted acquisitions, including Hexal (Germany), EBEWE Pharma (Austria), and Fougera Pharmaceuticals (US).

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global.

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EXHIBIT 2

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER ON CROSS MOTIONS FOR JUDGMENT ON THE PLEADINGS AND DENYING MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

This dispute arises from conflicting interpretations of the Biologics Price Competition and Innovation Act ("BPCIA"), which established an abbreviated pathway for producers of biologic products deemed sufficiently similar to products already on the market ("biosimilars") to receive Food and Drug Administration ("FDA") license approval. *See* 42 U.S.C. § 262(k), (*l*). The BPCIA allows a drug maker who demonstrates the biosimilarity of its product to one which has already received FDA approval (the "reference product") to rely on studies and data completed by the reference product producer ("reference product sponsor"), saving years of research and millions in costs. Through its amendments to both 42 U.S.C. § 262 and 35 U.S.C. § 271, the BPCIA also enabled a process for resolving patent disputes arising from biosimilars, whereby applicants and sponsors may participate in a series of disclosures and negotiations aimed at narrowing or eliminating the prospect of patent litigation. While engagement in the process creates a temporary safe harbor from declaratory judgment actions, a party's failure to participate

permits the opposing party to commence patent litigation.

Plaintiffs Amgen, Inc. and Amgen Manufacturing, Ltd. (collectively "Amgen") have produced and marketed the biologic product filgrastim under the brand-name Neupogen since 1991. They aver that defendants Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH,[1] who in July 2014 applied to the FDA to receive biosimilar status for their filgrastim product in order to begin selling it in the United States, behaved unlawfully under 42 U.S.C. § 262 by failing to comply with its disclosure and negotiation procedures. Amgen alleges these transgressions give rise to claims under California's Unfair Competition Law ("UCL") and for conversion, as well as patent infringement as to U.S. Patent No. 6,162,427 ("'427 patent"). Sandoz counterclaims for declaratory judgment adopting its interpretation of the BPCIA and finding its conduct permissible as to Amgen's UCL and conversion claims; and for noninfringement and invalidity of the '427 patent. The parties each filed cross-motions for partial judgment on the pleadings.[2] Amgen, in addition, requests a preliminary injunction to forestall Sandoz's market entry until a disposition on the merits has issued.[3]

While there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process, its decision not to do so was within its rights. Amgen's motion for partial judgment on the pleadings or partial summary judgment in the alternative is, accordingly, denied, and its UCL and conversion claims are dismissed with prejudice. As the BPCIA does not bar Sandoz's counterclaims for noninfringement and invalidity of the '427 patent, these claims may advance. In addition, Amgen's motion for preliminary injunction is, accordingly, denied.

[1] Of the named defendants, only Sandoz, Inc. has responded to Amgen's suit thus far. Sandoz, Inc. will be referred to herein simply as "Sandoz."

[2] Amgen notes that, while the standards under these rules are similar, it brings its motion under both Rule 12(c) and Rule 56 to account for conflicting case law as to whether a court may rule only as to certain claims, but not others, on a motion for judgment on the pleadings.

[3] Since then, however, the parties stipulated that Sandoz would not market its product until the earlier of either a partial judgment on the pleadings in its favor, or April 10, 2015. Sandoz further agreed that, should it receive a favorable ruling before April 10, 2015, it will give Amgen five days' notice before launching its product.

II. BACKGROUND

A. Relevant Provisions of the BPCIA

The dispute presented in the pending motions exclusively concerns questions of law—specifically, of statutory interpretation, as to several provisions in 42 U.S.C. § 262 and 35 U.S.C. § 271(e), both amended in 2010 via Congress's enactment of the BPCIA. The Act's stated purpose was to establish a "biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010). At issue in particular are two central provisions of 42 U.S.C. § 262: (1) paragraphs (*l*)(2)-(*l*)(6), which lay forth the disclosure and negotiation process that commences with an applicant sharing its Biologic License Application ("BLA") and manufacturing information with the reference product sponsor within twenty days of receiving notice that the FDA has accepted the application for review; and (2) paragraph (*l*)(8), requiring an applicant to give the sponsor at least 180 days' advance notice of the first commercial marketing of its biosimilar. Understanding these particular provisions requires a review of the statutory context.

Subsection (a) of 42 U.S.C. § 262 sets forth standards for FDA approval of biologic products. Among other requirements, applicants must demonstrate that their products are safe, pure, and potent. Subsection 262(k) establishes an abbreviated pathway by which a product "biosimilar" to one previously approved under subsection (a) (a "reference product") may rely on the FDA's prior findings of safety, purity, and potency to receive approval. According to subsection (k), any entity which demonstrates its biologic product is sufficiently similar to a reference product may apply for an FDA license to market its biosimilar product. Applications must include publicly available information as to the FDA's prior determination of the reference product's safety, purity, and potency, and may include additional publicly available information. 42 U.S.C. § 262(k)(2)(A).

The FDA may not approve a biosimilarity application until twelve years after the date on which the reference product was first licensed under subsection (a); in other words, reference products are entitled to twelve years of market exclusivity. Biosimilarity applicants are precluded

from even submitting applications under subsection (k) until four years after the licensing of the reference product. 42 U.S.C. § 262(k)(7)(A), (B).

Subsection 262(*l*) sets forth a process and timeline by which an applicant and reference product sponsor "shall" participate in a series of informational exchanges regarding potential disputes over patent validity and infringement. As long as both parties continue to comply with these disclosure and negotiation steps, neither may bring a declaratory action regarding patent validity, enforceability, or infringement against the other until the applicant provides notice of its upcoming first commercial marketing. 42 U.S.C. § 262(*l*)(9)(A)-(C).

The BPCIA also added to 35 U.S.C. § 271, which governs patent infringement, a provision rendering it "an act of infringement to submit" a subsection (k) application based on a patent the reference product sponsor identified (or could have identified) as infringed by the applicant's biosimilar product under subsection (*l*)'s disclosure and negotiation procedures. 35 U.S.C. § 271(e)(2)(C). In addition to enabling a reference product sponsor to initiate an infringement action for an applicant's reliance on its product, subsection 271(e) sets forth remedies for instances in which liability for infringement is found. Where the sponsor identified or could have identified the infringed patent on its initial disclosure to the applicant under 42 U.S.C. § 262(*l*)(3), injunctive relief may be granted to prevent such infringement, while damages or other monetary relief may only be awarded if there has been commercial manufacture, use, offer to sell, or sale within the United States of an infringing product. Other than attorney fees, these are "the only remedies which may be granted by a court for [infringement of such a patent]." 35 U.S.C. § 271(e)(4)(B)-(D). Where, however, the infringed patent appears on the parties' agreed-upon list of patents that should be subject to an infringement action, 42 U.S.C. § 262(*l*)(4), or their respective lists of such patents, 42 U.S.C. § 262(*l*)(5)—and the sponsor did not sue within the time frame prescribed in subsection (*l*), had its suit dismissed without prejudice, or did not prosecute its suit to judgment in good faith—the "sole and exclusive remedy" for infringement "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6).

Together, 42 U.S.C. § 262(*l*) and 35 U.S.C. § 271(e) reflect an integrated scheme that

provides consequences for the choice either party makes at each step of subsection (*l*)'s information exchange to carry on the process, or end it and allow patent litigation to commence. At one step in this series of tradeoffs, for example, the applicant has sixty days to respond to a list of patents the sponsor flagged in the prior step as potential grounds for an infringement suit. The applicant, according to 42 U.S.C. § 262(*l*)(3)(B)(ii), must provide the factual and legal basis for its beliefs that any patents flagged by the sponsor are invalid, unenforceable, or not infringed by its biosimilar. If the applicant does not complete this step, however, the sponsor may bring a declaratory judgment action for any patents it flagged in the prior step. 42 U.S.C. § 262(*l*)(9)(B). Conclusion of the process yields a list of patents on which a sponsor may bring suit within thirty days. 42 U.S.C. § 262(*l*)(6). Should the sponsor elect not to do so, it may collect only a reasonable royalty. 35 U.S.C. § 271(e)(6)(A). Thus, to continue the process or to terminate it confers advantages and disadvantages the parties must weigh at each step.

B. Procedural Background

Since 1991, Amgen has produced and marketed the biologic product filgrastim under the brand-name Neupogen as a result of the FDA's approval of Amgen's application for a license to market the product pursuant to BLA No. 103353. Neupogen was originally approved for decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The FDA subsequently approved additional therapeutic indications for the drug, such as aiding faster engraftment and recovery for bone marrow transplant patients.

On July 7, 2014, Sandoz received notice that the FDA had accepted for review its BLA for approval of a biosimilar filgrastim product under subsection (k). The next day, it mailed a letter to Amgen offering to share a copy of its BLA under the protection of a proposed Offer of Conditional Access; notifying Amgen that it believed it would receive FDA approval in the first or second quarter of 2015; and stating its intent to market its biosimilar product immediately thereafter. Sandoz sent Amgen a second letter on July 25 again offering conditional access to its

BLA. It also asserted therein that the BPCIA entitled it to opt out of subsection (*l*)'s procedures, and that Amgen could instead procure information via an infringement action. Amgen, it appears, declined both offers to view Sandoz's biosimilarity BLA under Sandoz's proposed terms. Only after a protracted dispute did the parties, on February 9, 2015, enter a stipulated protective order providing Amgen protected access to Sandoz's BLA and related application materials. They did not engage in any further patent information exchanges.

Amgen initiated this action on October 24, 2014, asserting claims of (1) unlawful competition under Cal. Bus. & Prof. Code § 17200 et seq. based on two alleged violations of the BPCIA; (2) conversion; and (3) infringement of Amgen's '427 patent. According to Amgen, failure to comply with subsection (*l*)'s disclosure and negotiation procedures and its interpretation of subparagraph (*l*)(8)(A)'s 180-day notice requirement each comprise an unlawful business practice actionable under the UCL. In addition, Amgen contends, Sandoz's use of Amgen's FDA license for Neupogen in its biosimilarity BLA without abiding by subsection (*l*)'s procedures rises to an act of conversion.

Alongside its answer, the following month Sandoz asserted seven counterclaims seeking declaratory judgments in favor of its interpretation of the BPCIA, as well as non-infringement and invalidity of the '427 patent. Specifically, these counterclaims are for the following declaratory judgments: (1) subsection (k) applicants may elect not to provide their applications to the reference product sponsor, subject to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) the BPCIA does not provide for injunctive relief, restitution, or damages for failure of a subsection (k) applicant to share its BLA; (3) the BPCIA sets forth exclusive consequences for failure to comply with 42 U.S.C. § 262(*l*)'s disclosure, negotiation, and notification provisions; (4) the BPCIA renders remedies under UCL and conversion claims unlawful and/or preempted; (5) a reference product sponsor does not maintain exclusive possession or control over its biologic product license; (6) noninfringement of the '427 patent; and (7) invalidity of the '427 patent.

Amgen now moves for partial judgment on the pleadings, or partial summary judgment in the alternative, as to the two bases in the BPCIA for its UCL claim, and for declaratory judgment

barring Sandoz's sixth and seventh counterclaims. Sandoz cross-moves for partial judgment on the pleadings granting declaratory judgment in favor of its first through fifth counterclaims, for dismissal with prejudice of Amgen's UCL and conversion claims, and for denial of Amgen's motion.

III. LEGAL STANDARDS

While the Federal Circuit is the court of appeal for all cases raising claims under patent law, it defers to regional circuit courts on non-patent issues. *See* 28 U.S.C. 1338(a); *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002); *Research Corp. Techs. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008). Ninth Circuit law therefore governs the disposition of the parties' cross-motions.

Rule 12(c) of the Federal Rules of Civil Procedure provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Such a motion, like one brought under Rule 12(b)(6), challenges the "the legal sufficiency of the opposing party's pleadings." *Qwest Communications Corp. v. City of Berkeley*, 208 F.R.D. 288, 291 (N.D. Cal. 2002). Accordingly, "a plaintiff is not entitled to judgment on the pleadings when the answer raises issues of fact that, if proved, would defeat recovery." *General Conference Corp. of Seventh–Day Adventists v. Seventh–Day Adventist Congregational Church*, 887 F.2d 228, 230 (9th Cir. 1989). A defendant's sufficient pleading of an applicable affirmative defense likewise will defeat a plaintiff's motion. *Id.* Regardless of what facts or affirmative defenses may be raised by an answer, however, a plaintiff's motion may not be granted absent a showing that he or she "is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1550 (9th Cir. 1989).

Rule 56(a) of the Federal Rules of Civil Procedure provides that a "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The party who seeks summary judgment bears the initial responsibility of identifying the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party satisfies this initial

burden, it shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324. "Only disputes over facts that might affect the outcome of the suit under governing law" are material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine issue exists if the non-moving party presents evidence from which a reasonable factfinder, viewing the evidence in the light most favorable to that party, could resolve the material issue in his or her favor. *Id.* at 248–49.

IV. DISCUSSION

As noted above, this dispute hinges on the interpretation of two portions of subsection 42 U.S.C. § 262(*l*) of the BCPIA. According to Amgen, Sandoz acted unlawfully because it (1) failed to comply with subsection (*l*)'s disclosure and negotiation procedures; and (2) intends to market its biosimilar immediately upon receiving FDA approval, rather than waiting until at least 180 days thereafter. These actions, Amgen avers, constitute the predicate wrongful behavior to sustain its claims under the UCL. Sandoz also committed conversion, avers Amgen, by making use of Amgen's FDA license for Neupogen in its biosimilarity BLA.[4]

Sandoz contends its actions have comported with the letter and spirit of the BPCIA, necessitating, therefore, the denial of Amgen's motion and dismissal of its UCL and conversion claims. As the analysis below demonstrates, Sandoz's reading of the statute is the more coherent of the two, and merits granting, in part, Sandoz's motion.

The interpretation of a statute is a question of law whose answer begins with an examination of the plain meaning of the statute. *United States v. Gomez–Osorio*, 957 F.2d 636, 639 (9th Cir. 1992). Words not otherwise defined take on their ordinary, common meaning. The court must, however, read a statute's language in context and with regard to its role in the overall

[4] While Amgen contended at oral argument that the BPCIA enables a private right of action from which its suit against Sandoz could, alternatively, have arisen, this set of motions does not properly raise that issue and it, accordingly, will not be addressed. Amgen is left with the untenable argument that Congress intended not a self-contained statutory scheme under the BPCIA, but rather contemplated a hunt by reference product sponsors through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation.

statutory framework, looking to legislative history as appropriate. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Morton*, 467 U.S. 822, 828 (1984). If the statutory language is unambiguous, and the statutory scheme is coherent and consistent, that should mark the end of a court's interpretative inquiry. *Miranda v. Anchondo*, 684 F.3d 844, 849 (9th Cir. 2012).

A. BPCIA: Disclosure and Negotiation Procedures

As noted above, Sandoz elected not to supply Amgen with a copy of its BLA and manufacturing process description within twenty days from notice that the FDA had accepted its application for review,[5] and to engage in subsection (*l*)'s subsequent series of disclosures and negotiations regarding potential patent disputes. These acts, Amgen avers, amount to unlawful transgressions of mandatory requirements for subsection (k) applicants set forth in 42 U.S.C. § 262(*l*)(2)-(8). Indeed, these paragraphs repeatedly use the word "shall" to describe the parties' obligations under its prescribed procedures. Subparagraph (*l*)(9)(B) moreover characterizes lack of compliance as a "fail[ure] to provide the application and information required."

While such phrasing lends support to Amgen's reading, Sandoz's overall interpretation of the statute's plain language is more persuasive. While Amgen correctly notes that subsection (*l*) uses the word "may" in certain paragraphs, thereby suggesting that the use of "shall" in others implies an action is required, several countervailing factors reflect otherwise. First, that an action "shall" be taken does not imply it is mandatory in all contexts. It is fair to read subsection (*l*) to demand that, if both parties wish to take advantage of its disclosure procedures, then they "shall" follow the prescribed procedures; in other words, these procedures are "required" where the parties elect to take advantage of their benefits, and may be taken away when parties "fail."

That compliance allows an applicant to enjoy a temporary safe harbor from litigation and, potentially, to resolve or narrow patent disputes outside court proceedings, bolsters this reading.

[5] Whether Amgen effectively declined access to Sandoz's BLA within these twenty days pursuant to Sandoz's July 2014 letters is a factual matter disputed by the parties, and is not at issue here.

Subparagraphs (*l*) (9)(B) and (C) contemplate the scenario in which an applicant does not comply at all with disclosure procedures, or fails to follow through after having begun the process. They allow the reference product sponsor to commence patent litigation immediately in either instance—removing (or precluding) availability to the applicant of a litigation safe harbor. Congress took the additional step in the BPCIA to amend 35 U.S.C. § 271(e) to add that an applicant's failure to disclose information regarding a potentially infringed patent under subsection (*l*)'s requirements is immediately actionable, making it clear that such a dispute is ripe for adjudication.

Such an interpretation would not be wholly without precedent; other district courts faced with a similar question have found that failure to comply with a provision containing "shall" was not unlawful, where the statute contemplated and provided for such a scenario. See *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082, 1087 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014) (finding a statute stating that "[e]very conveyance of real estate shall be recorded" and that "every such conveyance not so recorded shall be void" was not mandatory because the statutory language "specifically contemplate[d] that not all conveyances will be recorded and outlines the consequence of failing to do so.")

Further, while Amgen contends persuasively that use of subsection (*l*)'s procedures can serve important public interests, including potential reduction of patent litigation and protection for innovators, nowhere does the statute evidence Congressional intent to enhance innovators' substantive rights. In contrast to numerous other federal civil statutes which offer a claim for relief and specify remedies, here Congress did more than remain silent—it expressly directed reference product sponsors to commence patent infringement litigation in the event of an applicant's non-compliance. Even in subsection (*l*) itself, subparagraph (*l*)(8)(B) is clear in providing the remedy of a preliminary injunction for failure to give the 180-day notice required in (*l*)(8)(A). It is therefore evident that Congress intended merely to encourage use of the statute's dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit. The statute contains no stick to

force compliance in all instances, and Amgen does not identify any basis to impute one.

Indeed Sandoz's decision not to comply with subsection (*l*) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords an applicant many benefits: it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product launch to protect the investment it made in developing its biosimilar.

On the other hand, subsection (*l*) lays out a process that could take up to 230 days—just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged with an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

Perhaps confident in its limited exposure to liability and eager to resolve patent disputes so as not to face delays to market entry, Sandoz opted to invite a suit from Amgen soon after filing its BLA with the FDA.[6] Had the parties followed subsection (*l*)'s disclosure and negotiation

[6] While Amgen contends that the path chosen by Sandoz enables biosimilar producers to evade liability for patent infringement because biosimilar producers may keep reference product sponsors in the dark about their biosimilarity BLAs and plans to take their products to market, the 180-day notice requirement addressed below mitigates such concerns. With six months' advance notice of a biosimilar producer's intent to commence sales, a reference product sponsor who believes it may have an infringement claim can file suit to access the biosimilarity BLA, manufacturing process, and other relevant information via discovery—as in any other typical instance of potential infringement. While Amgen may have preferred that Sandoz share this information voluntarily, the BPCIA rendered it Sandoz's choice to make.

procedures, it is unlikely the present infringement action—filed in October 2014—would have even commenced until mid-March 2015, given the 230-day timeline over which subsection (*l*)'s procedures are designed to unfold. Sandoz therefore traded in the chance to narrow the scope of potential litigation with Amgen through subsection (*l*)'s steps, in exchange for the expediency of an immediate lawsuit. The BPCIA's plain language and overall statutory scheme support a reading that renders this decision entirely permissible.

B. BPCIA: One Hundred Eighty Days' Notice Prior to First Commercial Marketing

The most reasonable interpretation of paragraph (*l*)(8) of 42 U.S.C. § 262 also favors Sandoz. As noted above, this provision dictates that an 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). Upon receiving such notice, the reference product sponsor may seek a court order enjoining such market entry until a court can decide issues of patent validity or infringement. 42 U.S.C. § 262(*l*)(8)(B). It may also initiate a declaratory judgment action. 42 U.S.C. § 262(*l*)(9)(B).

Amgen makes too much of the phrase quoted above from subparagraph (*l*)(8)(A). It argues that the word "licensed," a past tense verb, means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry. Amgen draws support for this reading from Congress's use in other paragraphs of the statute of the phrase "subject of an application under subsection (k)" to refer to biosimilars. *See, e.g.*, 42 U.S.C. § 262(i)(2). Congress employs the distinction between the two phrasings, asserts Amgen, to signal whether it intends a particular provision to refer to a biosimilar before or after it has received FDA approval. Amgen contends that the only logical conclusion, therefore, is that because (*l*)(8)(A) refers not to the "subject of an application," but rather a "licensed" product, FDA approval must be a condition precedent to valid notice.

Amgen's attempt to bolster this interpretation by referencing a prior decision of this district, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12,

2013), has little effect. In that case, Sandoz sued to obtain a declaratory judgment that two patents were invalid, unenforceable and would not be infringed if Sandoz used, offered to sell, sold, or imported a drug product "biosimilar" to Amgen's etanercept product Enbrel. Finding for Amgen on Article III standing grounds, the court stated merely in passing that, in addition, Sandoz could not obtain a declaratory judgment prior to filing an FDA biosimilarity application according to the procedures set forth in 42 U.S.C. § 262(*l*). While Sandoz contended that its suit complied with section 262(*l*), which permits actions for declaratory judgment once a manufacturer of a licensed biosimilar has provided notice of commercial marketing, the district court—looking only to the language of the statute itself—wrote that "as a matter of law, [Sandoz] cannot have provided a [such notice] because . . . its [biosimilar] product is not 'licensed under subsection (k).'" *Id.* The Federal Circuit affirmed the district court's ruling on standing grounds, but expressly declined to address its BPCIA interpretation, which had not been briefed for the district court and was not dispositive in its ruling. This prior case, therefore, has little persuasive authority over the present dispute.

Indeed the more persuasive interpretation accounts for the fact that FDA approval must precede market entry. It would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its "first commercial marketing" a biosimilar must, in all instances, be a "licensed" product. "Before" modifies "first commercial marketing"; "licensed" refers only to "biological product"—not the appropriate time for notice.

Even more problematic with Amgen's reading is the impact it would have on the overall statutory scheme. Because the FDA cannot license a biosimilar until twelve years after approval of a reference product, Amgen's reading would tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A).[7] Had Congress intended to make the exclusivity period twelve and one-half years, it

[7] Amgen contends that because the FDA approval process may entail modifications to a biosimilar's properties or manufacturing process, allowing applicants to give 180-day notice prior to FDA approval would burden sponsors with the unfair task of having to aim infringement claims at a moving target. While this statutory construction may indeed disadvantage sponsors in some

could not have chosen a more convoluted method of doing so. Moreover, Congress presumably could have been far more explicit had it intended for infringement suits to commence only once a biosimilar receives FDA approval. It was, therefore, not wrongful for Sandoz to give Amgen its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) in July 2014, in advance of receiving FDA approval.[8]

C. Amgen's State-Law Claims for Unlawful Business Practices and Conversion

Because Sandoz's actions did not violate the BPCIA, it has committed no unlawful or wrongful predicate act to sustain Amgen's claims under the UCL and for conversion. A plaintiff may proceed under the UCL on three possible theories. First, "unlawful" conduct that violates another law is independently actionable under § 17200. *Cel–Tech Commc'ns, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999). Alternatively, a plaintiff may plead that defendants' conduct is "unfair" within the meaning of the several standards developed by the courts. *Id.* at 186–87, 83 (finding of unfairness must be "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition"); *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (requiring, in consumer cases, "unfairness be tied to a 'legislatively declared' policy" or that the harm to consumers outweighs the utility of the challenged conduct). Finally, a plaintiff may challenge "fraudulent" conduct by showing that "members of the public are likely to be deceived" by the challenged business acts or practices. *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009); *Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 838 (2006) (elements of violation of UCL for "fraudulent" business practices are distinct from common law fraud). Amgen tethers its UCL claim to only the first theory, averring that Sandoz behaved unlawfully by violating both subsection (*l*)'s disclosure and negotiation procedures and paragraph (*l*)(8)(A)'s 180-day notice requirement. As shown above,

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respects, such policy considerations are for Congress, not the courts, to address.

[8] In addition, had Sandoz failed to do so, it would be subject only to the consequences prescribed in 42 U.S.C. § 262(*l*)(9)(B)—an action for declaratory judgment regarding patent infringement, viability, or enforceability.

however, Sandoz's actions are within its rights and subject only to the consequences contemplated in the BPCIA. Because Amgen has not shown that Sandoz violated any provision of law, its UCL claim fails.

Amgen further alleges that Sandoz's reliance on Amgen's FDA license for Neupogen in its subsection (k) application constitutes conversion. To sustain a claim for conversion, a plaintiff must demonstrate (1) the plaintiff's ownership or right to possession of the property; (2) the defendant's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen*, 68 Cal. App. 4th 1062 (1998).

Sandoz's "wrongful act," alleges Amgen, was making use of Amgen's FDA license for Neupogen without complying with subsection (*l*)'s disclosure and negotiation procedures. Yet the BPCIA expressly contemplates that a subsection (k) applicant will rely on the reference product's license and other publicly available safety and efficacy information about the reference product. Indeed, as Sandoz's decision to forego the benefits of subsection (*l*)'s disclosure and negotiation procedures and instead open itself up to immediate suit for patent infringement was entirely permissible under 42 U.S.C. § 262, Sandoz has committed no wrongful act. The effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in addition to exacting the consequences written expressly into the legislation itself—is unworkable. Amgen therefore cannot maintain a claim for either unlawful business practices or conversion, and both claims are dismissed with prejudice pursuant to Sandoz's motion.

D. Sandoz's Counterclaims for Patent Noninfringement and Invalidity

Amgen contends that 42 U.S.C. § 262(*l*)(9)(C) bars the counterclaims for declaratory judgment of noninfringement and invalidity Sandoz alleges in response to Amgen's averment that Sandoz infringed its '427 patent. Subparagraph (*l*)(9)(C) states that where, as here, an applicant has not provided its BLA and manufacturing process information to the reference product sponsor, "the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or

enforceability of any patent that claims the biological product or a use of the biological product." According to Amgen, this provision prohibits Sandoz, a subsection (k) applicant who has not provided its BLA and manufacturing process information to its sponsor, from raising its counterclaims for declaratory judgment regarding the '427 patent.

Asserting a counterclaim is not the equivalent of commencing a lawsuit. *See Alexander v. Hillman*, 296 U.S. 222, 241 (1935). The BPCIA addresses only an applicant's ability to "bring an action," not to assert a counterclaim if placed in a position to defend against an infringement suit. Furthermore, as Sandoz's counterclaims arise from the same transaction or occurrence that is the subject of Amgen's claim—the validity and relevance of Amgen's '427 patent—they are compulsory, and would be waived if not asserted. Barring such claims in particular raises "real due process concerns." *See U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 505 F. Supp. 2d 20, 26 (D.D.C. 2007). Sandoz's sixth and seventh counterclaims regarding Amgen's '427 patent are, therefore, not barred by the BPCIA.

E. Amgen's Motion for Preliminary Injunction

Amgen has claimed it is entitled to both preliminary relief in advance of a decision on the merits, and, in the event of a decision in its favor, an injunctive remedy placing the parties where they would have stood had Sandoz fully complied with the BPCIA as Amgen interprets it. To obtain a preliminary injunction, a plaintiff must establish a likelihood of success on the merits; that he or she is likely to suffer irreparable harm in the absence of preliminary relief; that the balance of equities tips in his or her favor; and that an injunction would serve the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Federal Circuit applies this standard in reviewing the grant or denial of an injunction where the issues at play are unique to patent law. Where they are not, it applies the law of the regional circuit (here, the Ninth Circuit). *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). The Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after

the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm. *Id.* at 1135.

The parties disagree as to which standard is appropriate here. Yet because it cannot demonstrate serious questions as to the merits, let alone a likelihood of success, Amgen is foreclosed from injunctive relief under either formulation of the test for injunctive relief.

Indeed, the analysis above resolves in Sandoz's favor the merits as to the issues raised in the parties' cross-motions. Neither Sandoz's failure to supply its BLA and manufacturing process information within twenty days of learning the FDA had accepted its application for approval and subsequent decision to forego subsection (*l*)'s disclosure and negotiation procedures,[9] nor its intention to proceed to market by giving 180-day in advance of FDA approval, constitutes wrongful or unlawful behavior. As Amgen has failed to show otherwise, neither Amgen's UCL claim nor its conversion claim is, therefore, viable; and it has yet to proceed on its remaining claim for patent infringement.

Amgen furthermore does not carry its burden to demonstrate that irreparable harm will result in the absence of injunctive relief. Amgen argues market entry of Sandoz's biosimilar filgrastim product will cause it irreparable harm in several respects, specifically by: (1) delaying or precluding Amgen (through its sales of biosimilar filgrastim and diversion of revenue from Amgen) from undertaking research and development for new drugs and potentially causing Amgen to lose staff and scientists; (2) diverting Amgen sales representatives' energy from selling new products to competing with Sandoz for filgrastim market share; (3) causing Amgen to drop

[9] Even were the BPCIA to render unlawful an applicant's failure to supply its BLA and manufacturing process information to the reference product sponsor within twenty days, whether Sandoz made such information available to Amgen in a timely manner is a factual dispute between the parties that need not be reached here.

the price of Neupogen to remain competitive; and (4) damaging Amgen's customer relationships and goodwill in the event that the Court compels Sandoz to remove its product from the market, thereby prompting Amgen to enforce the order or raise its prices to where they were prior to Sandoz's market entry.

Not only are such harms at best highly speculative; they are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen. While Amgen has averred infringement of its '427 patent and argues that Sandoz's biosimilar filgrastim has the potential to infringe some four hundred more, *see* Declaration of Stuart Watt, it has not raised these contentions for a disposition at this juncture. It must, therefore, be assumed that no such infringement has occurred. As the twelve-year exclusivity period for Neupogen long ago expired, there exists no substantive bar to market entry for Sandoz's biosimilar filgrastim—and, consequently, no basis on which Amgen is entitled to injunctive relief or other remedies for disadvantages it may suffer due to market competition from Sandoz.

V. CONCLUSION

For the all of the aforementioned reasons, Amgen's motions for partial judgment on the pleadings or partial summary judgment in the alternative, and for preliminary injunction, are denied. Its claims under the UCL and for conversion are, furthermore, dismissed with prejudice.

Insofar as the above interpretation of the BPCIA is consistent with Sandoz's first through fifth counterclaims, judgment is hereby entered in Sandoz's favor. The BPCIA renders permissible a subsection (k) applicant's decision not to provide its BLA and/or manufacturing information to the reference product sponsor, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C). Such a decision alone does not offer a basis for the sponsor to obtain injunctive relief, restitution, or damages against the applicant; indeed, 42 U.S.C. § 262(*l*)(9) sets out the exclusive consequences for an applicant who elects not to provide its BLA and/or manufacturing information, or participate in any aspect of subsection (*l*)'s disclosure and negotiation process. As the BPCIA contemplates that a subsection (k) applicant will use the reference product sponsor's FDA license, and does not declare it unlawful for the applicant to do

so without participating in subsection (*l*)'s disclosure and negotiation process, there exists no predicate wrongful act on which to base Amgen's conversion claim.[10] In addition, the BPCIA poses no bar to Sandoz's sixth and seventh counterclaims for patent noninfringement and invalidity as to Amgen's '427 patent.

IT IS SO ORDERED.

Dated: March 19, 2015

RICHARD SEEBORG
United States District Judge

United States District Court
Northern District of California

[10] Whether a sponsor otherwise maintains some exclusive property rights over an FDA license obtained for a biologic product is beyond the scope of this disposition.

EXHIBIT 3

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **~~[PROPOSED]~~ FINAL JUDGMENT UNDER RULE 54(B) AND ORDER ESTABLISHING SCHEDULE FOR RULE 62(C) PROCEEDINGS AND STAYING ALL OTHER PROCEEDINGS** The Honorable Richard Seeborg

On March 19, 2015, the Court issued its Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction. (ECF No. 105.) The Court's Order dismissed with prejudice the first and second causes of action brought by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") and entered judgment in favor of Defendant Sandoz Inc. ("Sandoz") on Sandoz's first, second, third, fourth, and fifth counterclaims insofar as those counterclaims are consistent with the Court's interpretation of the Biologics Price Competition and Innovation Act ("BPCIA"). The Order also denied Amgen's motion for a preliminary injunction, as well as Amgen's motion for judgment on the pleadings (or alternatively for partial summary judgment) on Sandoz's sixth and seventh counterclaims, allowing those counterclaims to proceed.

Following the Court's March 19, 2015, Order, the only claims remaining before the Court relate to Amgen's '427 patent: Amgen's claim of infringement, and Sandoz's counterclaims of noninfringement and invalidity. These remaining patent claims are distinct and separable from the two claims and five counterclaims that were adjudicated in the March 19, 2015, Order.

Pursuant to the parties' agreement that, should either party appeal the decision of this Court, the parties would jointly seek expedited review in the Federal Circuit, the parties have jointly moved for entry of final judgment under Rule 54(b) of the Federal Rules of Civil Procedure so as to facilitate an immediate appeal of the BPCIA-related claims, all of which were resolved by the Court's March 19, 2015, Order.

Rule 54(b) certification is not available as of right. Rather, it requires that the judgment to be entered be final as to the claims it addresses, and that there be no just reason for delay. *See e.g., W.L. Gore & Associates, Inc. v. International Medical Prosthetics Research Associates, Inc.*, 975 F.2d 858, 862 (Fed. Cir. 1991). A judgment is final for Rule 54(b) purposes where it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action." *Id.* at 861-62 (emphasis omitted) (citing *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 436 (1956)). In determining whether there is just reason for delay, the Court considers "such factors as whether the claims under review [are] separable from the others remaining to be adjudicated and whether the nature of the claims already determined [are] such that no appellate court would have to decide the same issue more than once even if there were subsequent appeals." *Id.* at 862 (quoting *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 8 (1980)).

Having considered the standard for entry of judgment under Rule 54(b), the Court finds that it is appropriate to enter judgment under Rule 54(b) as to Amgen's first and second causes of action and as to Sandoz's first through fifth counterclaims. There is no just reason to delay entry of final judgment on these adjudicated claims and counterclaims. They all relate to the correct interpretation of the BPCIA and do not address the sole subject of the remaining claims and counterclaims (Amgen's third cause of action and Sandoz's sixth and seventh counterclaims), which relate to enforceability, infringement, and validity of the '427 patent. Moreover, the claims and counterclaims decided by the Court's March 19, 2015, Order raise important legal issues that

are time-sensitive not only to the emerging biosimilar industry but also to the parties here: the Food and Drug Administration has now approved Sandoz's application for its biosimilar product (the first biosimilar that the FDA has approved), implicating concerns about prejudice to the parties that could result from a delayed appeal on the BPCIA-related claims and counterclaims. Finally, entry of a Rule 54(b) judgment is especially appropriate here, where Amgen intends to appeal now the denial of the preliminary injunction under 28 U.S.C. § 1292(a), because entry of such judgment will allow the entire March 19, 2015, Order to be appealed together.

The parties have also jointly requested entry of a scheduling order for Amgen's contemplated motion for an injunction under Rule 62(c). Additionally, the parties jointly have requested entry of an order staying all remaining proceedings in this Court (apart from those on the contemplated Rule 62(c) motion) until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b) judgment and this Court's March 19, 2015, Order.

Accordingly, it is ORDERED and ADJUDGED:

1. FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Sandoz and against Amgen on Amgen's first and second causes of action, as well as on Sandoz's first, second, third, fourth, and fifth counterclaims in accordance with the Court's March 19, 2015, Order.

2. Amgen will make any motion for an injunction under Rule 62(c) no later than Tuesday, March 24, 2015. Sandoz will file its response to any such motion by March 31, 2015. Amgen will file its optional reply by April 2, 2015.

3. All other proceedings in this Court related to this matter, except for the entry of the jointly requested Rule 54(b) judgment and Amgen's contemplated Rule 62(c) motion, are STAYED until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b) judgment and this Court's March 19, 2015, Order. During the period of the stay imposed by this paragraph, Amgen may continue efforts to effect service on Sandoz International GmbH and Sandoz GmbH, provided, however, that the time to move, answer, or otherwise respond to the complaint for either entity so served is tolled until twenty days after the expiration of the stay imposed by this paragraph.

Dated: 3/25, 2015

THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

EXHIBIT 4

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **AMGEN PLAINTIFFS' NOTICE OF APPEAL**

NOTICE OF APPEAL

NOTICE IS HEREBY GIVEN that Amgen Inc., and Amgen Manufacturing, Limited, ("Amgen"), Plaintiffs in the above named case, hereby appeal to the United States Court of Appeals for the Federal Circuit from:

1. The district court's denial of Amgen's motion for a preliminary injunction in the March 19, 2015 Order (Dkt. No. 105). Attached as Exhibit A is a true and correct copy of the denial of Amgen's motion for a preliminary injunction.
2. The district court's judgment under Fed. R. Cir. P. 54(b) dismissing Amgen's first and second causes of action with prejudice and entering judgment in favor of Sandoz on Sandoz's first, second, third, fourth, and fifty counterclaims, dated March 25, 2015, (Dkt. No. 111) and all rulings, proceedings, orders, findings, and decisions (whether oral or written) interlocutory thereto or underlying the judgment. Attached as Exhibit B is a true and correct copy of the Rule 54(b) judgment.

Date: March 25, 2015

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EXHIBIT 5

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER DENYING MOTION FOR INJUNCTION PENDING APPEAL

On March 25, 2015, this Court entered final judgment under Rule 54(b) of the Federal Rules of Civil Procedure as to its March 19 order on the parties' cross motions for judgment on the pleadings, dismissing with prejudice Plaintiffs Amgen, Inc. and Amgen Manufacturing, Limited's (collectively "Amgen") first and second claims for relief; granting judgment in favor of defendant Sandoz, Inc. et al.'s first through fifth counterclaims; and denying Amgen's motion for a preliminary injunction. On March 27, 2015, Amgen filed an appeal of this order with the United States Court of Appeals for the Federal Circuit. Amgen furthermore moves this Court for an injunction secured by bond that would restrain Sandoz from launching its biosimilar product pending the outcome of its appeal, pursuant to Rule 62(c), or, in the event this Court denied an injunction pending appeal, an injunction lasting until the Federal Circuit can rule on the appeal of such an order. The parties have stipulated that, upon this Court's denial of Amgen's application,

Amgen will appeal it to the Federal Circuit within two days.[1]

Rule 62(c) affords a district court from which an interlocutory order or final judgment that grants, dissolves, or denies an injunction is on appeal, the discretion to "suspend, modify, restore, or grant an injunction" while the appeal is pending "on terms for bond or other terms that secure the opposing party's rights" on a finding that such relief is warranted. Courts evaluate motions for preliminary injunction and motions for injunction pending appeal using similar standards. *See Alaska Conservation Council v. U.S. Army Corps of Engineers*, 472 F.3d 1097, 1100 (9th Cir. 2006). In *Winter v. Natural Resources Defense Council*, the Supreme Court declared that in order to obtain an injunction, a plaintiff must establish that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of injunctive relief, (3) the balance of the equities tips in its favor, and (4) an injunction is in the public interest. 555 U.S. 7, 20 (2008). *See also Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (setting forth substantially the same factors in deciding whether to grant a Rule 62(c) motion).

As noted in the prior order on the parties' cross motions for judgment on the pleadings and denying Amgen's motion for a preliminary injunction, the Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm." *Id.* at 1135; *see also Conservation Congress v. U.S. Forest Service*, 803 F. Supp. 2d 1126, 1129-30 (E.D. Cal.

[1] Sandoz has agreed to refrain from launching its filgrastim biosimilar product, Zarxio, until the earlier of May 11, 2015, or a decision by the Federal Circuit on Amgen's application for an injunction pending appeal. The Federal Circuit has already granted Amgen's unopposed motion to expedite briefing, ensuring its completion by April 30; and the parties have requested that the Federal Circuit hear this matter in its June calendar.

2011) (applying *Cottrell*'s "serious questions" version of the sliding scale test on a Rule 62(c) motion).[2]

While Amgen raises significant and novel legal questions as to the merits of its case, as noted in the Court's prior order, its tenuous and highly contingent showing of irreparable harm forecloses injunctive relief. Indeed, Amgen repeats, to no avail, its previously considered grounds for contending it will suffer irreparable harm. Even taking into account the additional evidentiary material filed subsequent to the hearing on the parties' motions, Amgen's showing of potential price erosion, harm to Amgen's customer relations and goodwill, and diversion of Amgen's sales representatives' energy, is speculative. Moreover, even if these ramifications were certain to occur, according to this Court's interpretation of the BPCIA, any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent. Amgen having made no showing as to this latter point, the likelihood of it wrongfully suffering irreparable harm appears slim and does not merit injunctive relief. Amgen's contention that Sandoz overstates the prejudice it would suffer in the face of an injunction pending appeal does not, therefore, tip the balance of equities in Amgen's favor.

Accordingly, Amgen's motion for an injunction pending appeal to the Federal Circuit of this Court's order on the parties' cross motions for judgment on the pleadings and Amgen's motion for preliminary injunction or, in the alternative, pending appeal of this order, is denied.

IT IS SO ORDERED.

Dated: April 15, 2015

RICHARD SEEBORG
United States District Judge

[2] The parties clash on which standard should apply here. In matters not unique to patent law, the Federal Circuit typically defers to the law of the regional circuit from which the case arises. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). In any case, the issue of which standard should apply to Amgen's motion need not be decided here, as Amgen fails to clear the hurdles set forth under either standard.

EXHIBIT 6

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

ON MOTION

PER CURIAM.

O R D E R

Amgen Inc. et al. move for an injunction "preventing Sandoz [Inc.] from marketing, selling, offering for sale, or importing into the United States its FDA-approved ZARXIO® biosimilar product until this Court resolves the appeal." Sandoz opposes.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion is granted, effective immediately.

(2) The parties are directed to respond concerning what amount of a bond, if any, should be posted for each day that the injunction is in place. Sandoz shall file, within seven days of this order, a document not to exceed 10 pages explaining what amount of bond should be posted. Amgen shall file, within seven days of Sandoz's filing, a response not to exceed 10 pages. The bond amount will be determined by subsequent order of the court.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

EXHIBIT 7

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 07/21/2015

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

Each side shall bear its own costs.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

15-1499 - Amgen Inc. v. Sandoz Inc.
United States District Court for the Northern District of California, Case No. 3:14-cv-04741-RS

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

Decided: July 21, 2015

NICHOLAS P. GROOMBRIDGE, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, NY, argued for plaintiffs-appellants. Also represented by ERIC ALAN STONE, JENNIFER H. WU, JENNIFER GORDON, PETER SANDEL, MICHAEL T. WU, ARIELLE K. LINSEY; WENDY A. WHITEFORD, LOIS M. KWASIGROCH, KIMBERLIN L. MORLEY, Amgen Inc., Thousand Oaks, CA; VERNON M. WINTERS, ALEXANDER DAVID BAXTER, Sidley Austin LLP, San Francisco, CA.

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for defendant-appellee. Also represented by JOSEPH R. PALMORE, MARC A. HEARRON; RACHEL KREVANS, San Francisco, CA; JULIE PARK, San Diego, CA.

MICHAEL A. MORIN, Latham & Watkins LLP, Washington, DC, for amicus curiae AbbVie Inc. Also represented by DAVID PENN FRAZIER, GREGORY G. GARRE, MELISSA ARBUS SHERRY, CASEY L. DWYER, ROBERT J. GAJARSA.

GREGORY DISKANT, Patterson Belknap Webb & Tyler LLP, New York, NY, for amicus curiae Janssen Biotech, Inc. Also represented by IRENA ROYZMAN; DIANNE B. ELDERKIN, BARBARA MULLIN, Akin Gump, Strauss, Hauer & Feld, LLP, Philadelphia, PA.

LISA BARONS PENSABENE, O'Melveny & Myers LLP, New York, NY, for amicus curiae Biotechnology Industry Organization. Also represented by FILKO PRUGO.

CARLOS T. ANGULO, Zuckerman Spaeder LLP, Washington, DC, for amicus curiae Generic Pharmaceutical Association.

CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, for amici curiae Hospira, Inc., Celltrion Healthcare Co., Ltd., Celltrion, Inc. Also represented by ANDREW C. NICHOLS; SAMUEL S. PARK, Chicago, IL; PETER E. PERKOWSKI, Los Angeles, CA.

Before NEWMAN, LOURIE, and CHEN, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion concurring in part, dissenting in part filed by *Circuit Judge* NEWMAN.

Opinion dissenting in part filed by *Circuit Judge* CHEN.

LOURIE, *Circuit Judge*.

This appeal presents issues of first impression relating to the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010). Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen") appeal from the decision of the United States District Court for the Northern District of California (1) dismissing Amgen's state law claims of unfair competition and conversion with prejudice because Sandoz Inc. ("Sandoz") did not violate the information-disclosure and notice-of-commercial-marketing provisions of the BPCIA, respectively codified at 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(8)(A); (2) granting judgment on the pleadings to Sandoz on its counterclaims seeking a declaratory judgment that it correctly interpreted the BPCIA; and (3) denying Amgen's motion for a preliminary injunction based on its state law claims. *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015) ("*Opinion*").

For the reasons stated below, we affirm the dismissal of Amgen's state law claims of unfair competition and conversion, vacate the judgment on Sandoz's counterclaims and direct the district court to enter judgment consistent with our interpretation of the BPCIA, and remand for further proceedings consistent with this opinion.

A. BACKGROUND

I.

In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA,[1] which

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[1] Winston Churchill once described Russia as "a riddle wrapped in a mystery inside an enigma." Winston Churchill, *The Russian Enigma* (BBC radio broadcast

established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product ("reference product"). Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.). Congress established such "a biosimilar pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

The BPCIA has certain similarities in its goals and procedures to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984), but it has several obvious differences. We note this as a matter of historical interest, but otherwise do not comment on those similarities and differences.

Traditionally, the Food and Drug Administration ("FDA") approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a). An applicant filing a biologics license application ("BLA") typically provides clinical data to demonstrate the safety and efficacy of its product. In contrast, under the abbreviated pathway created by the BPCIA, codified at 42 U.S.C. § 262(k), an applicant filing an abbreviated biologics license application ("aBLA" or "subsection (k) application") instead submits information to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." 42 U.S.C.

Oct. 1, 1939), *available at* http://www.churchill-society-london.org.uk/RusnEnig.html. That is this statute. In these opinions, we do our best to unravel the riddle, solve the mystery, and comprehend the enigma.

§ 262(k)(2)–(5); *see also id.* § 262(i). The BPCIA thus permits a biosimilar applicant to rely in part on the approved license of a reference product.

To balance innovation and price competition, Congress enacted the BPCIA to provide a four-year and a twelve-year exclusivity period to a reference product, both beginning on the date of first licensure of the reference product. Specifically, a subsection (k) application "may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(B), and approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(A). Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to twelve years of exclusivity against follow-on products, regardless of patent protection.

Moreover, the BPCIA established a patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code. The BPCIA amended the Patent Act to create an artificial "act of infringement" and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6). The BPCIA also established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes. *See* 42 U.S.C. § 262(*l*).

Under that process, codified at 42 U.S.C. § 262(*l*), the biosimilar applicant grants the RPS confidential access to its aBLA and the manufacturing information regarding the biosimilar product no later than 20 days after the FDA accepts its application for review. *Id.* § 262(*l*)(1)–(2). The parties then exchange lists of patents for which they

believe a claim of patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange, which could take up to six months, the parties negotiate to formulate a list of patents ("listed patents") that would be the subject of an immediate infringement action, *id.* § 262(*l*)(4)–(5), and the RPS then sues the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). That information exchange and negotiation thus contemplates an immediate infringement action brought by the RPS based only on listed patents.

Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the RPS at least 180 days prior to commercial marketing of its product licensed under subsection (k), which then allows the RPS a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents (collectively, "non-listed patents"). *Id.* § 262(*l*)(7)–(8).

Subsection 262(*l*) additionally provides, in paragraph (*l*)(9)(A), that if the applicant discloses the information "required under paragraph (2)(A)," then neither the RPS nor the applicant may bring a declaratory judgment action based on the non-listed patents prior to the date on which the RPS receives the notice of commercial marketing under paragraph (*l*)(8)(A). *Id.* § 262(*l*)(9)(A). Paragraphs (*l*)(9)(B) and (*l*)(9)(C), however, permit the RPS, but not the applicant, to seek declaratory relief in the event that the applicant fails to comply with certain provisions of subsection (*l*). *Id.* § 262(*l*)(9)(B)–(C).

II.

Amgen has marketed filgrastim under the brand name Neupogen® ("Neupogen") since 1991. In May 2014,

Sandoz filed an aBLA, seeking FDA approval of a biosimilar filgrastim product, for which Neupogen is the reference product. On July 7, 2014, Sandoz received notification from the FDA that it had accepted Sandoz's application for review.

On July 8, 2014, Sandoz notified Amgen that it had filed a biosimilar application referencing Neupogen; that it believed that the application would be approved in "Q1/2 of 2015"; and that it intended to launch its biosimilar product immediately upon FDA approval. J.A. 1472. Later in July, in response to Amgen's inquiry, Sandoz confirmed that the FDA had accepted its application for review, but Sandoz informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that Amgen was entitled to sue Sandoz under § 262(*l*)(9)(C). J.A. 1495–96. Sandoz thus did not disclose its aBLA or its product's manufacturing information to Amgen according to § 262(*l*)(2)(A).

Subsequently, on March 6, 2015, the FDA approved Sandoz's aBLA for all approved uses of Amgen's Neupogen. Although Sandoz has maintained that it gave an operative notice of commercial marketing in July 2014, it nevertheless gave a "further notice of commercial marketing" to Amgen on the date of FDA approval. J.A. 1774. Sandoz intended to launch its filgrastim product under the trade name Zarxio.

III.

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of (1) unfair competition for unlawful business practices under California Business & Professions Code § 17200 et seq. ("UCL"), based on two alleged violations of the BPCIA; (2) conversion for allegedly wrongful use of Amgen's approved license on Neupogen; and (3) infringement of Amgen's U.S. Patent 6,162,427 (the "'427 patent"), which claims a

method of using filgrastim. Amgen alleged that Sandoz violated the BPCIA by failing to disclose the required information under § 262(*l*)(2)(A) and by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval of its biosimilar product. Sandoz counterclaimed for a declaratory judgment that it correctly interpreted the BPCIA as permitting its actions, and that the '427 patent was invalid and not infringed.

In January 2015, the parties filed cross-motions for judgment on the pleadings on Amgen's state law claims and Sandoz's counterclaims interpreting the BPCIA. In February 2015, Amgen also filed a motion for a preliminary injunction based solely on its state law claims to enjoin Sandoz from launching Zarxio after FDA approval. Also in February 2015, through discovery, Amgen obtained access to Sandoz's biosimilar application.

On March 19, 2015, the district court granted partial judgment on the pleadings to Sandoz on its BPCIA counterclaims to the extent that Sandoz's interpretation of the statute is consistent with the court's interpretation. Specifically, the district court concluded that: (1) the BPCIA renders permissible a subsection (k) applicant's decision not to disclose its aBLA and the manufacturing information to the RPS, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) such a decision alone does not offer a basis for the RPS to obtain injunctive relief, restitution, or damages against the applicant; and (3) the applicant may give notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval. *Opinion*, 2015 WL 1264756, at *8, *11.

Based on its interpretation of the BPCIA, the district court then dismissed Amgen's unfair competition and conversion claims with prejudice because it concluded that Sandoz did not violate the BPCIA or act unlawfully. *Id.* at *8–9. The court also denied Amgen's motion for a

preliminary injunction based on its state law claims, noting that Amgen "has yet to proceed on its remaining claim for patent infringement." *Id.* at *10.

On the parties' joint motion, the district court entered final judgment as to Amgen's unfair competition and conversion claims and as to Sandoz's BPCIA counterclaims under Rule 54(b) of the Federal Rules of Civil Procedure. The parties' claims and counterclaims relating to infringement, validity, and enforceability of the '427 patent remain pending at the district court.

Amgen timely appealed from the final judgment and from the denial of a preliminary injunction; we have jurisdiction under 28 U.S.C. § 1295(a)(1) and § 1292(a)(1) and (c)(1).

B. DISCUSSION

We apply the procedural law of the regional circuit, here the Ninth Circuit, when reviewing a district court's grant of a motion for judgment on the pleadings. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007). The Ninth Circuit reviews the grant of judgment on the pleadings *de novo*, *Peterson v. California*, 604 F.3d 1166, 1169 (9th Cir. 2010), and "accept[s] all material allegations in the complaint as true and construe[s] them in the light most favorable to [the non-moving party]," *Turner v. Cook*, 362 F.3d 1219, 1225 (9th Cir. 2004) (third alteration in original). Issues of statutory interpretation are also reviewed *de novo*. *Qantas Airways Ltd. v. United States*, 62 F.3d 385, 387 (Fed. Cir. 1995).

Because Amgen's state law claims of unfair competition and conversion are premised on the proper interpretation of the BPCIA, we first interpret the relevant provisions of the BPCIA and then consider Amgen's state law claims in light of that interpretation.

I.

We first consider whether the district court erred in concluding that a subsection (k) applicant may elect not to disclose its aBLA and the manufacturing information under 42 U.S.C. § 262(*l*)(2)(A), subject only to the consequences set forth in § 262(*l*)(9)(C). Paragraph (*l*)(2)(A) provides that:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant *shall provide* to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application . . . .

42 U.S.C. § 262(*l*)(2)(A) (emphasis added). Paragraph (*l*)(9)(C) provides that:

> If a subsection (k) applicant *fails to provide the application and information required under paragraph (2)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of *infringement, validity, or enforceability of any patent* that claims the biological product or a use of the biological product.

Id. § 262(*l*)(9)(C) (emphases added). Additionally, 35 U.S.C. § 271(e)(2)(C)(ii), as amended by the BPCIA, provides that:

> It shall be an act of infringement to submit . . . if the applicant for the application *fails to provide the application and information required* under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a pa-

> tent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act . . . .

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added).[2]

Amgen argues that the language "shall provide" in paragraph (*l*)(2)(A) suggests that the information disclosure is mandatory, not merely permissible. Amgen contends that other provisions of the BPCIA refer to the information as "required" under paragraph (*l*)(2)(A) and also refer to non-disclosure as a failure to comply with the Act. Amgen argues that, by refusing to provide the required information, a subsection (k) applicant unlawfully evades the detection of process patent infringement and avoids an immediate infringement action under § 262(*l*)(6). Amgen also argues that paragraph (*l*)(9)(C) is merely a limitation on declaratory judgment action, not a remedy, let alone the exclusive remedy, for noncompliance with paragraph (*l*)(2)(A).

Sandoz responds that the "shall" provision in paragraph (*l*)(2)(A) is only a condition precedent to engaging in the information-exchange process of paragraphs (*l*)(3) through (*l*)(6), not a mandatory requirement in all circumstances. Sandoz contends that this interpretation is consistent with the use of "shall" in paragraph (*l*)(6), which provides that the RPS "shall" file an infringement suit. Sandoz notes that this use of "shall" cannot mean that the RPS violates the statute if it chooses not to file an infringement suit. Sandoz also responds that, under the BPCIA, if a subsection (k) applicant does not disclose the information under paragraph (*l*)(2)(A), then the sponsor may file an infringement suit under paragraph (*l*)(9)(C) and obtain the information in discovery, which Amgen has done. Sandoz also contends that it did not act

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[2] Section 351(*l*)(2)(A) of the Public Health Act corresponds to 42 U.S.C. § 262(*l*)(2)(A).

unlawfully by taking a path expressly contemplated by Congress and the BPCIA.

We conclude that, read in isolation, the "shall" provision in paragraph (*l*)(2)(A) appears to mean that a subsection (k) applicant is required to disclose its aBLA and manufacturing information to the RPS by the deadline specified in the statute. Indeed, the BPCIA refers to such information as "required" in other provisions. *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A), (*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Particularly, paragraph (*l*)(1)(B)(i) provides that "[w]hen" a subsection (k) applicant submits an aBLA to the FDA, "such applicant *shall* provide . . . confidential access to the information *required* to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate" (emphases added). Thus, under the plain language of paragraph (*l*)(1)(B)(i), *when* an applicant chooses the abbreviated pathway for regulatory approval of its biosimilar product, it is required to disclose its aBLA and manufacturing information to the RPS no later than 20 days after the FDA's notification of acceptance, but not when the "when" criterion is not met.

Such a reading of "shall" in paragraph (*l*)(2)(A) is supported by the use of "may" in paragraph (*l*)(2)(B), which provides that a subsection (k) applicant "may" provide additional information requested by the RPS by the statutory deadline. Paragraph (*l*)(2)'s use of "shall" in juxtaposition with "may" in the adjacent provision would appear to indicate that "shall" signals a requirement.

However, the "shall" provision in paragraph (*l*)(2)(A) cannot be read in isolation. In other provisions, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It specifically sets forth the consequence for such failure: the RPS may bring an

infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Those latter provisions indicate that "shall" in paragraph (*l*)(2)(A) does not mean "must." And the BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A).

Under 35 U.S.C. § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to disclose the required information under paragraph (*l*)(2)(A) is an artificial "act of infringement" of "a patent that could be identified" pursuant to paragraph (*l*)(3)(A)(i). 42 U.S.C. § 262(*l*)(9)(C) further provides that "[i]f a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A)," then the RPS, but not the subsection (k) applicant, may bring a declaratory judgment action on "any patent that claims the biological product or a use of the biological product."[3] As a direct consequence of failing to comply with paragraph (*l*)(2)(A), paragraph (*l*)(9)(C) bars the subsection (k) applicant from bringing a declara-

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[3] While it is true that 42 U.S.C. § 262(*l*)(9)(C) premises the declaration judgment action on "any patent that *claims the biological product or a use of the biological product*" (emphasis added), which does not appear to include process patents, 35 U.S.C. § 271(e)(2)(C)(ii) does contemplate an infringement action based on "a patent that *could be identified pursuant to [paragraph] (l)(3)(A)(i)*" (emphasis added), which does not exclude process patents. Section 271(e)(2)(C)(ii) allows the RPS to assert process patents, "if the [subsection (k)] applicant . . . fails to provide the application and information" and "the purpose of [the subsection (k)] submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2).

tory judgment action on patents that claim the biological product or its use.

Notably, both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A). Once the RPS brings an infringement suit under those two provisions, it can access the required information through discovery.[4]

Importantly, mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous. *Marx v. Gen. Revenue Corp.*, 568 U.S. __, 133 S. Ct. 1166, 1178 (2013) ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme."); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." (internal quotation marks omitted)).

Moreover, 35 U.S.C. § 271(e)(4) provides "the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2)" (emphasis added). Under § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required infor-

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[4] In addition, we note the existence of a rebuttable presumption in actions alleging infringement of a process patent under 35 U.S.C. § 271(g) relating to importation of products made abroad by a patented process. *See, e.g.*, *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1314 (Fed. Cir. 2011) (citing 35 U.S.C. § 295).

mation under paragraph (*l*)(2)(A) is such an act of infringement. Here, Amgen alleged that Sandoz violated the BPCIA, but the alleged violation is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the "only remedies."

We therefore conclude that, even though under paragraph (*l*)(2)(A), when read in isolation, a subsection (k) applicant would be required to disclose its aBLA and the manufacturing information to the RPS by the statutory deadline, we ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement. Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline.

II.

We next consider whether the district court erred in concluding that a subsection (k) applicant may satisfy its obligation to give notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) by doing so before the FDA licenses its product. Paragraph (*l*)(8)(A) provides that "[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." *Id.* § 262(*l*)(8)(A) (emphases added).

a.

Amgen argues that a subsection (k) applicant may give notice of commercial marketing only after it has a "biological product licensed under subsection (k)," meaning only after the FDA has licensed the biosimilar product. Amgen notes that elsewhere subsection (*l*) refers to the biosimilar product as "the biological product that is

the subject of" the application, which supports its interpretation of "licensed" in paragraph (*l*)(8)(A). Amgen explains that giving notice after FDA licensure provides time for the RPS to seek a preliminary injunction and to resolve patent disputes in a timely fashion. Amgen contends that allowing the applicant to give notice before FDA licensure is irreconcilable with the statute's text and purpose.

Sandoz responds that the plain terms of the notice provision are satisfied when an applicant provides notice at least 180 days before it commercially markets its product. According to Sandoz, the word "licensed" only means that, at the time of commercial marketing, the product must be licensed, but it does not limit the timing of the notice, which can be given before FDA licensure. Sandoz also argues that Amgen's construction of the notice provision would transform it into an automatic, additional, six-month bar against marketing of every licensed biosimilar product, which improperly extends the twelve-year exclusivity period under § 262(k)(7)(A).

We agree with Amgen that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The statutory language compels such an interpretation. It means that notice, to be effective under this statute, must be given only after the product is licensed by the FDA.

In subsection (*l*), only paragraph (*l*)(8)(A) refers to the product as "the biological product licensed under subsection (k)." In other provisions of subsection (*l*), the statute refers to the product as "the biological product that is the subject of" the application, even when discussing its commercial marketing. *E.g.*, 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), (*l*)(3)(C); *id.* § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(7)(B). If Congress intended paragraph (*l*)(8)(A) to

permit effective notice before the product is licensed, it would have used the "subject of" language.

While it is true that only a licensed product may be commercially marketed, it does not follow that whenever the future commercial marketing of a yet-to-be licensed product is discussed, it is the "licensed" product. It is not yet "the licensed product." Congress could have used the phrase "the biological product that is the subject of" the application in paragraph (*l*)(8)(A), as it did in other provisions, but it did not do so. *See, e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983).

We believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed. When a subsection (k) applicant files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses. Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court.

Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product. If a notice of commercial marketing could be given at any time before FDA licensure, the RPS would be left to guess the scope of the approved license and when commercial marketing would actually begin. Indeed, filing an aBLA only suggests that a subsection (k) applicant in-

tends to commercially market its product someday in the future.

Furthermore, requiring FDA licensure before notice of commercial marketing does not necessarily conflict with the twelve-year exclusivity period of § 262(k)(7)(A). It is true that in this case, as we decide *infra*, Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. Amgen had more than an "extra" 180 days, but that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products. A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case. Finally, it is counterintuitive to provide that notice of commercial marketing be given at a time before one knows when, or if, the product will be approved, or licensed.

We therefore conclude that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The district court thus erred in holding that a notice of commercial marketing under paragraph (*l*)(8)(A) may effectively be given before the biological product is licensed, and we therefore reverse its conclusion relating to its interpretation of § 262(*l*)(8)(A) and the date when Sandoz may market its product.

b.

We next consider the consequence in this case of our interpretation of paragraph (*l*)(8)(A). Paragraph (*l*)(8)(A) provides that the subsection (k) applicant "shall provide" notice of commercial marketing to the RPS no later than 180 days before commercial marketing of the licensed product. As we have concluded, an operative notice of

commercial marketing can only be given after FDA licensure. Here, Sandoz's notice in July 2014, the day after the FDA accepted its application for review, was premature and ineffective. However, the FDA approved Sandoz's aBLA on March 6, 2015, and Sandoz gave a "further" notice of commercial marketing on that day. J.A. 1774. These facts are uncontested. Oral Argument at 35:33–56, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. That notice in March 2015 thus serves as the operative and effective notice of commercial marketing in this case.

A question exists, however, concerning whether the "shall" provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is. Both paragraph (*l*)(2)(A) and (*l*)(8)(A) use the word "shall," which presumptively signals a statutory requirement. *See, e.g.*, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661–62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001). As we have noted with respect to paragraph (*l*)(2)(A), however, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to comply with the requirement of paragraph (*l*)(2)(A) and further specifies the consequence for such failure in 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Because of those explicit statutory provisions, and to avoid construing the statute so as to render them superfluous, we have interpreted the BPCIA as allowing noncompliance with paragraph (*l*)(2)(A), subject to the consequence specified in those other provisions.

In contrast, with respect to paragraph (*l*)(8)(A), we do not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A) here, which would be the case if Sandoz attempts to launch in disregard of the requirement of paragraph (*l*)(8)(A), as we have interpreted it. Sandoz argues that § 262(*l*)(9)(B) does specify the consequence for

noncompliance with paragraph (*l*)(8)(A). Paragraph (*l*)(9)(B), entitled "[s]ubsequent failure to act by subsection (k) applicant," provides that:

> If a subsection (k) applicant *fails to complete* an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or *paragraph (8)(A)*, the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of *any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).*

42 U.S.C. § 262(*l*)(9)(B) (emphases added).

While it is true that paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with. Indeed, the consequence specified in paragraph (*l*)(9)(B) is a declaratory judgment action brought by the RPS based on "any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)." 42 U.S.C. § 262(*l*)(9)(B). Here, however, because Sandoz did not provide the required information to Amgen under paragraph (*l*)(2)(A), Amgen was unable to compile a patent list as described in paragraph (*l*)(3)(A) or paragraph (*l*)(7).

Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*), and Sandoz concedes as much. Oral Argument at 39:30–52, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. Unlike the actions described in paragraphs (*l*)(3) through (*l*)(7), which all depend on, or are triggered by, the disclosure under paragraph (*l*)(2)(A), nothing in paragraph

(*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*). Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (*l*)(2)(A). The purpose of paragraph (*l*)(8)(A) is clear: requiring notice of commercial marketing be given to allow the RPS a period of time to assess and act upon its patent rights.

We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory. Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015.

III.

We next consider Amgen's unfair competition and conversion claims under California law. After finding that Sandoz did not violate the BPCIA, the district court dismissed Amgen's state law claims with prejudice. We affirm the dismissal based on our interpretation of the BPCIA.[5]

a.

Under Cal. Bus. & Prof. Code § 17200, "unfair competition" includes "any unlawful, unfair or fraudulent business act or practice." Amgen's unfair competition claim is based solely on the "unlawful" prong, which requires a

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[5] In its cross-motion for judgment on the pleadings, Sandoz did not argue preemption as a defense to Amgen's state law claims, and thus the district court did not consider that issue. We therefore do not address preemption in this appeal.

showing that Sandoz acted unlawfully by violating another law, here, according to Amgen, the BPCIA. *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1168 (9th Cir. 2012); *see also Farmers Ins. Exch. v. Superior Court*, 826 P.2d 730, 734 (Cal. 1992). Under California law, UCL remedies are not available when the underlying law expressly provides that the remedies in that law are exclusive. *See* Cal. Bus. & Prof. Code § 17205; *Loeffler v. Target Corp.*, 324 P.3d 50, 76 (Cal. 2014).

As one basis of its unfair competition claim, Amgen alleges that Sandoz violated the BPCIA by failing to comply with § 262(*l*)(2)(A). As we have concluded, Sandoz did not violate the BPCIA by not disclosing its aBLA and the manufacturing information according to § 262(*l*)(2)(A). Sandoz took a path expressly contemplated by 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), and 35 U.S.C. § 271(e)(4) provides "the only remedies which may be granted by a court" for the alleged violation. We therefore affirm the dismissal of Amgen's unfair competition claim based on the alleged violation of § 262(*l*)(2)(A).

b.

As another basis of its unfair competition claim, Amgen also asserts that Sandoz violated the BPCIA by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) in July 2014, before FDA approval in March 2015. As indicated, under our interpretation of the BPCIA, the July 2014 notice is ineffective, and Sandoz gave the operative notice on March 6, 2015. Thus, as we have indicated, Sandoz may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015. And, as indicated below, we will extend the injunction pending appeal through September 2, 2015. Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot.

c.

We now turn to Amgen's conversion claim. To sustain a claim for conversion under California law, Amgen must demonstrate: (1) its ownership or right to possession of the property; (2) Sandoz's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen*, 80 Cal. Rptr. 2d 704, 706 (Cal. Ct. App. 1998). Amgen asserts that Sandoz wrongfully used Amgen's approved license on Neupogen by filing an aBLA referencing Neupogen but refusing to provide Amgen the benefits to which it is entitled under § 262(*l*). Sandoz responds that Amgen failed to show any "wrongful act" or to establish an exclusive ownership interest in the approved license on Neupogen to exclude Sandoz's aBLA.

We agree with Sandoz that Amgen failed to establish the requisite elements to sustain a claim of conversion under California law. As indicated, the BPCIA explicitly contemplates that a subsection (k) applicant might not disclose its aBLA and the manufacturing information by the statutory deadline, and provides that the RPS may sue for patent infringement, which Amgen has done. Amgen thus failed to show a "wrongful act."

Moreover, the BPCIA established the abbreviated pathway for FDA approval of follow-on biological products, allowing a subsection (k) applicant to use "publicly-available information" regarding the reference product in its application.[6] 42 U.S.C. § 262(k)(2). The BPCIA also

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[6] Amgen emphasizes in its briefs that Sandoz is wrongfully benefitting from Amgen's establishment of the safety and efficacy of filgrastim. Be that as it may, this is not the first time that Congress has allowed generic applicants to benefit from the early work of innovators. *See* Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984); s*ee also Ruckelshaus v. Monsanto Co.*, 467 U.S.

grants a 12-year exclusivity period to the RPS, during which approval of a subsection (k) application may not be made effective. *Id.* § 262(k)(7)(A). Neupogen's 12-year exclusivity period has long expired. Amgen therefore fails to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law.

We therefore affirm the dismissal of Amgen's unfair competition and conversion claims based on our interpretation of the relevant provisions of the BPCIA.

IV.

Amgen argues that the district court erred in denying its motion for a preliminary injunction based on an incorrect reading of the BPCIA and an erroneous finding that Amgen failed to show irreparable harm. Sandoz responds that Amgen's appeal is moot because it sought an injunction only until the district court decided the parties' cross-motions for judgment on the pleadings, which has already occurred. Sandoz also responds that, even if not moot, the district court did not abuse its discretion in denying the motion and did not clearly err in its factual findings.

We agree with Sandoz that Amgen's appeal from the denial of a preliminary injunction is moot. In its motion for a preliminary injunction, filed in the district court after it filed its motion for judgment on the pleadings, Amgen requested a preliminary injunction "until the Court decides the parties' motions for judgment on the pleadings," and "if the Court resolves those motions in Amgen's favor, until . . . the parties have been placed in the position they would be in had Sandoz complied with the BPCIA." *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. Feb. 5, 2015), ECF No. 56, at 25.

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986 (1984). That was a decision that Congress was entitled to make and it did so.

On March 19, 2015, the district court rendered its decision on the parties' cross-motions for judgment on the pleadings, deciding against Amgen on the merits and dismissing Amgen's state law claims with prejudice. In the same order, the court also denied Amgen's motion for a preliminary injunction, which was based solely on its state law claims. Because Amgen only requested a preliminary injunction until the district court decided the parties' motions for judgment on the pleadings, and the district court has resolved those motions against Amgen, Amgen's appeal from the denial of a preliminary injunction is moot. We therefore dismiss that aspect of Amgen's appeal.

V.

After the district court granted partial judgment on the pleadings in favor of Sandoz and denied Amgen's motion for a preliminary injunction, Amgen sought an injunction pending appeal, which the district court denied. Amgen then filed an emergency motion in this court for an injunction pending appeal. We granted the motion. In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015.

C. CONCLUSION

For the foregoing reasons, we affirm the dismissal of Amgen's unfair competition and conversion claims, vacate the district court's judgment on Sandoz's counterclaims interpreting the BPCIA, and direct the district court to enter judgment on those counterclaims consistent with this opinion. We also remand for the district court to consider the patent infringement claim and counterclaims relating to the '427 patent and any other patents properly brought into the district court action.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

NEWMAN, *Circuit Judge,* concurring in part, dissenting in part.

The immediate issue relates to the Biosimilar Price Competition and Innovation Act (BPCIA) and certain obligations of the innovator/patentee (called the "reference product sponsor," or "Sponsor") and the subsection (k) applicant. Subsection (k) authorizes a biosimilar applicant to use the Sponsor's clinical safety and efficacy data in order to obtain FDA license approval for commercial marketing of the biosimilar product. By acting under subsection (k) the applicant need not obtain its own clinical data for its biosimilar product, and can receive FDA licensure by showing that "the biological product is

biosimilar to a reference product," 42 U.S.C. §262(k), and has the same characteristics of safety, efficacy, and purity. *Id.*

To facilitate identification of and resolution of any patent issues, the BPCIA requires the subsection (k) applicant to notify the Sponsor at two critical stages of FDA review of the subsection (k) application. I agree with the court that notice of issuance of the FDA license is mandatory, and that this notice starts the 180-day stay of commercial marketing, in accordance with 42 U.S.C. §262(*l*)(8)(A). Thus I join Part A, Part (B)(II), and Part B(V) of the court's opinion.

However, notice of acceptance of the filing of the subsection (k) application is also mandatory, along with the accompanying documentary and information exchanges set in the BPCIA in accordance with 42 U.S.C. §262(*l*)(2)(A). I respectfully dissent from the court's holding that this activity is not required because the Sponsor might file an infringement suit in which it might learn this information though discovery.

Sandoz did not comply with either of these statutory requirements. These deliberate violations of the requirements of the BPCIA forfeit Sandoz' access to the benefits of the BPCIA.

I

Patent dispute resolution under the BPCIA has two phases. The "early phase" starts when the subsection (k) application is accepted by the FDA for review, and technical and patent information are then exchanged. The "later phase" starts when the FDA approves the biosimilar for commercial marketing. I comment only briefly on this later phase, for I agree, as the court holds, that 42 U.S.C. §262(*l*)(8) requires that this phase of inquiry and dispute resolution commences when the subsection (k) applicant notifies the Sponsor, after the FDA license is

granted. My concern is that my colleagues on this panel do not apply, to the earlier "shall provide" words, the same mandatory meaning as for subsection (*l*)(8)(A):

> **§262(*l*)(8)(A)** *Notice of commercial marketing*.-- The 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).**

(Emphases added). The BPCIA explicitly states that after licensure and before commercial marketing the Sponsor may seek a preliminary injunction while the patent aspects are resolved:

> **§262(*l*)(8)(B)** *Preliminary injunction*.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor **may seek a preliminary injunction** prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement [of any patent identified in the early stage or other defined proceedings.]

(Emphasis added). Sandoz proposed to circumvent this provision and launch its biosimilar product immediately upon its FDA licensure.

I share the court's interpretation of this statutory provision, which implements the purpose of the BPCIA "to ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee On*

Courts and Competition Policy of the House Committee On the Judiciary, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo) (emphasis added). The BPCIA requires the court to give effect to the intent of Congress. *See Ingersoll–Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990) ("To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute.")

II

The BPCIA provides for participants' recognition of potential patent issues at an early stage, and requires that as soon as the FDA accepts the biosimilar application for review, the subsection (k) applicant shall notify the Sponsor, and exchanges of patent-related information shall commence. Details are set forth in 42 U.S.C. §262(*l*)(2). My colleagues hold that compliance with these early notice and information provisions is not mandatory. I cannot agree, for: "The word 'shall' is ordinarily the language of command." *Alabama v. Bozeman*, 533 U.S. 146, 153 (2001).

The purpose of subsection 262(*l*) is to initiate patent-related activity, to exchange relevant information, to facilitate negotiations, and to expedite any litigation. Subsection (*l*)(2)(A) requires the subsection (k) applicant to notify the Sponsor within 20 days after the FDA accepts the subsection (k) application for review, and to describe the manufacturing process:

> **§262(*l*)(2)(A)** *Subsection (k) application information*.--Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant **shall provide** to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes **the process or processes used to manufacture**

> the biological product that is the subject of such application.

(Emphases added). Sandoz did not provide this information, although it is required, and the BPCIA provides for confidentiality:

> **§262(*l*)(1)(B)(i)** *Provision of confidential information*.--When a subsection (k) applicant submits an application under subsection (k), such applicant **shall provide** to the persons described in clause (ii), subject to the terms of this paragraph, **confidential access to the information required** to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines in its sole discretion to be appropriate.

(Emphases added).

This designated exchange of information is fundamental to the BPCIA purposes of efficient resolution of patent issues. However, my colleagues hold that compliance by the applicant is not mandatory, citing §262*(l)*(9)(C), which authorizes suit by the Sponsor if the applicant does not provide the paragraph (2)(A) information:

> **§262(*l*)(9)(C)** *Subsection (k) application not provided*.--If a **subsection (k) applicant fails to provide** the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims **the biological product or a use** of the biological product.

(Emphases added). This provision for declaratory action by the Sponsor is limited to "product" and "use" claims, and does not include manufacturing process patents, although the legislative record makes clear that for bio-

similars such patents may be highly material, and were so recognized during enactment. Amgen states that its patents here at issue relate primarily to manufacture.

I cannot agree that this provision excuses compliance by the subsection (k) applicant, even when such declaratory action is brought. Subsection (*l*)(9)(C) provides declaratory jurisdiction only for product or use claims. Absent adequate factual support in a complaint for manufacturing method claims, declaratory jurisdiction may be unsupported. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

The balance established in the BPCIA requires the statutorily identified disclosures at the threshold, in order both to avert and to expedite litigation. This purpose pervades the legislative record, as interested persons debated which provisions would be mandatory, and which permissive. *See, e.g.*, *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee on Courts and Competition Policy of the House Committee on the Judiciary*, 111th Cong. *passim* (2009) (debating the provisions of H.R. 1548, which provided for mandatory patent exchange, and H.R. 1427, which provided for discretionary patent exchange). *Compare also* S. 623, 110th Cong. § (3)(a)(2)(k)(17)(E) (2007) ("nothing in this paragraph requires an applicant or prospective applicant to invoke the [patent notification and exchange] procedures set forth in this paragraph") *with* S. 1695, 110th Cong. § (2)(a)(2)(*l*)(2)(A) (2007) (the subsection (k) applicant "shall provide" application and manufacturing information). *See Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) ("We ordinarily will not assume that Congress intended 'to enact language that it has earlier

discarded in favor of other language.'" (citations omitted)).

The BPCIA as enacted leaves no uncertainty as to which of its provisions are mandatory and which are permissive. For example, immediately after the "**shall**" provision of subsection *(l)*(2)(A), *ante*, subsection (*l*)(2)(B) states that a subsection (k) applicant

> **may** provide to the reference product sponsor **additional** information requested by or on behalf of the reference product sponsor.

(Emphases added). "[W]hen the same Rule uses both 'may' and 'shall', the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory." *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947).

In *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359–60 (1895), the Court stated that when Congress uses the "special contradistinction" of "shall" and "may," no "liberty can be taken with the plain words of the statute." As reiterated in *Sebelius v. Cloer*, 133 S. Ct. 1886, 1894 (2013), "[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." (alteration and internal quotation marks omitted). The BPCIA gestated during more than four years of study and debate. The record contains frequent reference to the experience of the Hatch-Waxman Act, as the BPCIA departed from that Act in seeking to "balance innovation and consumer interests" in the new and promising scientific era of biosimilars. BPCIA, Pub. L. No. 111-148, §7001(b), 124 Stat. 119, 804 (2010). Fidelity to that balance is the judicial obligation.

The details enacted and included in the BPCIA demonstrate the rigor of the statute and its compromises.

The BPCIA requires judicial implementation that conforms to "the design of the statute as a whole and to its object and policy." *Crandon v. United States,* 494 U.S. 152, 158 (1990). Subsection (k) and subsection (*l*) are components of an integrated framework; to enjoy the benefits of subsection (k), the biosimilar applicant is obligated to comply with subsection (*l*). Even on the district court's (and my colleagues') misplaced theory that subsection (*l*)(9)(C) excuses compliance with subsection (*l*)(2)(A), this would extend only to product and use claims, it does not excuse compliance as to manufacturing and process claims.

The BPCIA reflects an explicit balance of obligations and benefits. When a beneficiary of the statute withholds compliance with provisions enacted to benefit others, the withholder violates that balance. The consequences of the majority's ruling are significant, for the structure of the BPCIA requires that the subsection (k) applicant comply with the information exchange provisions, as a threshold to resolution of the Sponsor's patent rights.[1]

Subsection (*l*)(9) provides jurisdiction in the district court when a subsection (k) applicant fails to comply with subsection (*l*), but it does not ratify non-compliance. While "a party may waive any provision, either of a

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[1] The record recites the benefits of subsection (k) for biosimilar applicants. A study for the Congressional Research Service cites a Tufts report that found in 2006 the "average cost to develop a new biotechnology product is $1.2 billion." *Follow-On Biologics: The Law and Intellectual Property Issues, CRS Report for Congress*, Professor John Thomas, January 15, 1014, *passim*, n.32. The record explains that clinical safety and efficacy studies constitute the major portion of this development cost, and that subsection (k) authorizes the biosimilar applicant to rely on these data that the Sponsor provided to the FDA.

contract or of a statute, intended for his benefit," *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995), the party cannot waive or disregard a provision that benefits those in an adverse position. The provisions of 35 U.S.C. §262(*l*)(9) function as a continuing prohibition on a party who fails to comply with some aspect of the patent exchange provisions. That is, subsection (*l*)(9)(C) prevents a non-compliant party from obtaining relief through a declaratory judgment action, while that prohibition is lifted as to the aggrieved party. Subsection (*l*)(9)(C) states that a "reference product sponsor, but not the subsection (k) applicant, may bring" a declaratory judgment action "for a declaration of infringement, validity, or enforceability for any patent that claims the biological product or use of the biological product" when a subsection (k) applicant fails to provide the information required under subsection (*l*)(2)(A).

35 U.S.C. § 271(e)(2)(C)(ii) similarly states that it shall be an act of infringement if the applicant fails to provide the information required under paragraph (l)(2)(A). However, this does not diminish the obligation set by section (*l*)(1)(B)(i) that the subsection (k) applicant "shall provide … confidential access to the information required to be produced pursuant to paragraph (2)." Such obligation is mandatory.

Departure from the statutory obligation, to achieve purposes that the legislation intended to curtail, should not be judicially ratified. *See Cannon v. Univ. of Chicago*, 441 U.S. 677, 690 (1979) (disregard of a statute is a wrongful act). It is not denied that Sandoz obtained the benefit of the Amgen data in filing under subsection (k). Sandoz should be required to respect its obligations, in fidelity to the statute. I respectfully dissent from the majority's failure to require compliance with the obligations of the BPCIA.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

CHEN, *Circuit Judge*, dissenting-in-part.

I join the majority opinion except for Parts B.II.b and B.V. To properly interpret the BPCIA's patent litigation management process described in section 262(*l*), I agree that none of subsection (*l*)'s provisions may be read in isolation. In other words, to understand the meaning of any one provision in § 262(*l*), one must first recognize how it interrelates with the rest of subsection (*l*) and the rest of the BPCIA. Based on this understanding, I agree that a subsection (k) applicant's failure to supply the information described in (*l*)(2) to the reference product sponsor (RPS) is not a violation of the BPCIA, because the BPCIA itself, in (*l*)(9) and § 271(e)(2)(C)(ii), provides the RPS the

remedial course of action in such circumstances. Contrary to the majority, however, I view this context-based interpretation as applying with equal force to the interpretation of (*l*)(8). When reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)–(*l*)(7). Moreover, just as all the "shall" obligations set forth in (*l*)(3)–(*l*)(7) are contingent on the (k) applicant's performance of the first "shall" step in (*l*)(2), this is also true of the "shall" notice obligation in (*l*)(8). What this means is when, as here, the (k) applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)–(*l*)(8) cease to matter. In such a situation, as recognized by the majority opinion, the RPS's course of action is clearly defined in (*l*)(9) and § 271(e)(2)(C)(ii): the unfettered right to immediately pursue patent infringement litigation unconstrained by any of the timing controls or limits on the number of patents it may assert that would result from the (*l*)(2)–(*l*)(8) process. Based on this understanding, I do not view (*l*)(8)(A) as a "standalone provision" that provides, implicitly, the RPS a 180-day injunction beyond the express twelve-year statutory exclusivity period. Because the majority opinion interprets (*l*)(8) differently, giving Amgen, the RPS, an extra-statutory exclusivity windfall, I respectfully dissent.

I

"It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989). To that end, the Supreme Court has instructed that "statutory language cannot be construed in a vacuum." *Id.*; *see also Yates v. United States*, 135 S. Ct. 1074, 1081–82 (2015) (instructing courts to interpret statutory text by reference to "the specific context in which that language is used, and the broader context of

the statute as a whole." (quotation marks omitted)). In Part B.I, the majority properly recognizes that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." Majority Op. at 12. The majority carefully examines the larger statutory context—subsection (*l*) and § 271(e)(2)(C)(ii)—and correctly concludes that "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" Majority Op. at 13. As the majority recognizes, nothing in the BPCIA grants the RPS a procedural right to *compel* the (k) applicant's compliance with (*l*)(2)(A). In Part B.II, however, the majority holds that the word "shall" in (*l*)(8)(A) carries a different meaning than it does in (*l*)(2)(A). To reach that inconsistent result, the majority takes the view that (*l*)(8)(A) should be read in a vacuum, apart from the context and framework of subsection (*l*), including the language of (*l*)(8)(B). I respectfully disagree.

A

Entitled "Patents," § 262(*l*) of the BPCIA concerns one thing: patent litigation. Specifically, it specifies an elaborate information exchange process between the (k) applicant and the RPS that leads up to the expected patent infringement suit that comes during the pendency of a subsection (k) application. This process begins in (*l*)(2)(A) with the requirement that the (k) applicant disclose to the RPS its biosimilar application (aBLA) and manufacturing process information. Compliance with subsection (*l*)(2)(A) triggers a cascade of events contemplated by subsection (*l*), with each successive step reliant on the performance of one or more preceding steps. This intricate process includes: the exchange of patent lists that each party believes the RPS has reasonable grounds to assert against the (k) applicant, as well as the exchange of respective infringement, validity, and enforceability positions (§ 262(*l*)(3)); a process by which the parties may limit the patents in the infringement lawsuit (§ 262(*l*)(4)–(5)); a patent infringement lawsuit, filed by the RPS, limited to the patents listed in (*l*)(4) or (*l*)(5) (§ 262(*l*)(6)); a proce-

dure for updating the RPS's previously created (*l*)(3) patent list with newly issued or licensed patents (§ 262(*l*)(7)); a requirement that the (k) applicant provide a 180-day notice ahead of commercial marketing thereby giving the RPS time to seek a preliminary injunction on any (*l*)(3) listed patents not asserted in the limited (*l*)(6) patent infringement suit (§ 262(*l*)(8)); and authorization for the RPS to file an immediate declaratory judgment action for patent infringement if the (k) applicant fails to comply with its specified obligations recited in (*l*)(2), (*l*)(3), (*l*)(5), (*l*)(6), (*l*)(7), or (*l*)(8) (§ 262(*l*)(9)(B)–(C)). Importantly, subsection (*l*) does not relate to the FDA approval process (for that see subsection (k)). Nor is the approval process contingent on any events related to a possible patent dispute occurring in parallel with that approval process.

By enacting the provisions in subsection (*l*), Congress created a comprehensive, integrated litigation management system. These provisions also demonstrate that Congress anticipated the situation before us here, in which the (k) applicant refuses to engage in this litigation management process. Rather than forcing the (k) applicant, by court order or some other means, to engage in the subsection (*l*) process, or conditioning the (k) application's approval on the (k) applicant fulfilling the requirements set forth in subsection (*l*), Congress instead authorized the RPS in this situation to immediately file an infringement action. *See* § 262(*l*)(9) and 35 U.S.C. § 271(e)(2)(C)(ii).

Focusing on (*l*)(8), Congress accounted for the possibility (perhaps strong likelihood) of a situation in which the (k) applicant has received FDA approval and is on the verge of commercially marketing its biosimilar product but the RPS was unable to assert all of its (*l*)(3) listed patents against the (k) applicant in the limited (*l*)(6) patent litigation. Entitled "Notice of commercial market-

ing and preliminary injunction," (*l*)(8), in relevant part, is set forth below:

> **8) Notice of commercial marketing and preliminary injunction**
>
> **(A)** Notice of commercial marketing
>
> The 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).
>
> **(B)** Preliminary injunction
>
> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
>
> **(i)** included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
>
> **(ii)** not included, as applicable, on—
>
> **(I)** the list of patents described in paragraph (4); or
>
> **(II)** the lists of patents described in paragraph (5)(B).

Subsection (*l*)(8)(A) requires the (k) applicant to give the RPS at least 180 days' notice of its intent to begin commercially marketing the biosimilar product. One of the key questions in this appeal is, "Why would Congress

insert a 180-day commercial marketing notice provision in a subsection devoted to organizing patent litigation?" Paragraph (*l*)(8)(B) provides the answer. As mentioned above, the process in (*l*)(4)–(5) can result in restricting the (*l*)(6) infringement action to a subset of the RPS's patents identified in (*l*)(3). Rather than permit the (k) applicant to launch its biosimilar product while the RPS is blocked from enforcing some of its patent rights, subsection (*l*)(8)(B) addresses that problem by authorizing the RPS to seek a preliminary injunction prohibiting commercial manufacture or sale based on the patents that were excluded from the (*l*)(6) action. Thus, the entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that an RPS will be able to assert all relevant patents before the (k) applicant launches its biosimilar product. Amgen confirmed this understanding of (*l*)(8)'s purpose at oral argument. Oral Argument at 20:10–20:05, *Amgen, Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

Given the purpose of (*l*)(8) and its express assumption that the parties have already performed the steps in (*l*)(3), and (*l*)(4)–(*l*)(5), the most logical conclusion when reading (*l*)(8) in context is that (*l*)(8)'s vitality is predicated on the performance of the preceding steps in subsection (*l*)'s litigation management process. Without first engaging in these procedures, (*l*)(8) lacks meaning. Similarly, for example, the statutory requirement in (*l*)(3) for the parties to exchange detailed positions on infringement and validity for the patents listed under (*l*)(3) no longer applies if the (k) applicant fails to comply with (*l*)(2). Paragraph (*l*)(8)'s interdependency on the preceding steps in subsection (*l*) is further reinforced by (*l*)(7)'s cross-reference to (*l*)(8). Paragraph (*l*)(7), which sets forth a process for the RPS to update its (*l*)(3) patent list with any newly issued or licensed patents, states that any such patents "shall be subject to paragraph (8)." 42 U.S.C.

§ 262(*l*)(7)(B). The interwoven structure of subsection (*l*) indicates that Congress viewed the procedures of (*l*)(8) as inseverable from the preceding steps in (*l*).

The majority, on the other hand, views (*l*)(8)(A) as a standalone notice provision that is not excused when the (k) applicant fails to comply with (*l*)(2).[1] Yet, no one disputes that the requirements of (*l*)(3) through (*l*)(7) are certainly excused in such a case. I recognize that (*l*)(8)(A), unlike (*l*)(3) through (*l*)(7), is not expressly conditioned on the earlier steps. I cannot, however, read (*l*)(8)(A) in complete isolation from (*l*)(8)(B), which *does* reference, and is predicated on the performance of, (*l*)(3) and (*l*)(4)–(*l*)(5). Thus, (*l*)(8) does not serve as a standalone provision; it is part and parcel to, and contingent upon, the preceding steps in the (*l*)(2)–(*l*)(8) litigation management regime. The most persuasive reading of subsection (*l*) as a whole is that Congress provided two paths to resolve patent disputes: (1) the intricate route expressed in (*l*)(2)–(*l*)(8); and (2) the immediate, more flexible route provided in (*l*)(9), should the (k) applicant falter on any of its obligations recited in (*l*)(2)–(*l*)(8).

B

The majority is also concerned with the absence of an express consequence for noncompliance with (*l*)(8)(A) in situations in which the (k) applicant does not comply with (*l*)(2). I agree with the majority that the remedy in

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[1] The majority states that Sandoz "concedes" that (*l*)(8)(A) is a standalone notice provision, citing to the oral argument. I understand Sandoz's position as accepting that (*l*)(8)(A) as a standalone provision is one possible interpretation. Oral Argument at 39:30–40:30, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all.

(*l*)(9)(B) does not provide relief in this scenario because the RPS's right to pursue additional patent litigation at this stage under (*l*)(9)(B) is contingent on using the patents that have been "included in the list described in paragraph (3)(A)." If a (k) applicant never carries out (*l*)(2), the RPS will never create an (*l*)(3) patent list. Such a failure to adhere to (*l*)(2) would defeat the RPS's opportunity to invoke (*l*)(9)(B) if the (k) applicant refuses to comply with (*l*)(8)(A)'s notice provision.

Contrary to the majority's conclusion, however, the absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary. Congress created the fallback provision of (*l*)(9)(C) for just these circumstances. An RPS does not need the remedy in (*l*)(9)(B) because (*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action when the (k) applicant fails to comply with (*l*)(2). At this point, the RPS possesses the statutory right to seek a preliminary injunction for any of its patents that "could be identified pursuant to section [262](*l*)(3)(A)(i)." 35 U.S.C. § 271(e)(2)(C)(ii). It therefore would have been superfluous for Congress to provide the RPS with authorization to initiate an additional, redundant infringement action under (*l*)(9)(B)[2] if the (k) applicant later does not comply

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[2] It is worth examining (*l*)(9)(B) closely for it shows how Congress understood the (*l*)(8) notice provision to be one part of the entire subsection (*l*) litigation management process. Under (*l*)(9)(B), if a (k) applicant fails to comply with any of its obligations recited in "paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), *or paragraph (8)(A)*," the RPS may immediately bring an infringement action on any patent the RPS listed in (l)(3). 42 U.S.C. § 262(*l*)(9)(B) (emphasis added). By grouping (*l*)(8)(A) with (*l*)(3), (*l*)(5), (*l*)(6), and (*l*)(7), all of

with (*l*)(8)(A). Not only is compliance with (*l*)(8)(A) unnecessary under such a circumstance, but no additional remedy is needed. Thus, after Sandoz failed to perform the (*l*)(2) requirement, the only relevant provision in subsection (*l*) became (*l*)(9)(C) and § 271(e)(2)(C)(ii).

C

The practical consequence of the majority's interpretation is that (*l*)(8)(A) provides an inherent right to an automatic 180-day injunction. The majority provides no basis in the statutory language to support this automatic injunction.[3] This relief is analogous to the thirty-month stay of the Hatch-Waxman Act, which provides for an automatic stay during which the FDA cannot approve the ANDA unless the patent infringement suit is resolved or the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If Congress intended to create a 180-day automatic stay it understood how to do so. It could have tied FDA approval to the notice provision. Yet, Congress declined to link FDA approval to a single provision in subsection (*l*). At bottom, the majority's view is in tension with the defined

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which are unquestionably part of the litigation management regime, and defining the scope of any infringement action by the patents listed in (*l*)(3), Congress evidenced that (*l*)(8)(A) is *not* a provision that stands apart from the others, but is instead part of an integrated regime with each part serving a common purpose.

[3] The majority believes that (*l*)(8)(A)'s notice provision plays a necessary role, when the (k) applicant fails to comply with (*l*)(2), to provide the RPS adequate notice of the aBLA and therefore a meaningful opportunity to assert its patent rights. In my view, the majority reads too much into (*l*)(8)(A) by empowering it with an injunction right in the limited circumstance when a (k) applicant fails to comply with (*l*)(2).

purpose of (*l*)(8) while providing the RPS with an atextual 180-day exclusivity windfall.

Notably, nothing in the majority opinion suggests that this automatic injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A). In fact, the majority's opinion creates an uncomfortable result in which the language of (*l*)(8)(A) is interpreted in two different ways, based on the (k) applicant's actions. In a situation like the present case, the (k) applicant cannot refuse to provide the 180-days' notice, because under the majority's reading, (*l*)(8)(A) authorizes an automatic entitlement to a 180 day injunction. But if a (k) applicant complies with all the requirements specified in (*l*)(2)–(*l*)(7), then the (k) applicant may still refuse to comply with the 180-day notice provision. In this scenario, there would be no automatic injunction because (*l*)(9)(B) provides the RPS with the authorization to immediately file suit on any patent it listed under (*l*)(3). Thus, in one scenario, (*l*)(8)(A) provides a 180-day injunction, but in the second scenario it does not. While the result in the latter scenario comes from the plain language of the statute, not so with the former. Nothing in the statute supports this peculiar outcome. As explained above, in my view, the better reading of (*l*)(8) is that it does not apply, just as (*l*)(3)–(*l*)(7) do not apply, when the (k) applicant fails to comply with (*l*)(2).

II

To be sure, (*l*)(8)(A) is an integral part of the procedures for managing patent litigation that arises as a result of a party filing an aBLA. Nevertheless, (*l*)(8)(A) is simply one piece of subsection (*l*)'s integrated patent dispute puzzle that ceases to matter, just like all the other pieces preceding (*l*)(8) cease to matter, once the (k) applicant fails to comply with (*l*)(2). I do not find support in

the statutory language to create an automatic 180-day injunction. Just as "shall" in (*l*)(2) does not mean "must," the same is true for the "shall" provision in (*l*)(8)(A), once it is read in context with the entirety of subsection (*l*).

As the majority opinion recognizes, this case requires us to "unravel the riddle, solve the mystery, and comprehend the enigma" that is the BPCIA. Majority Op. at 3 n.1. To fulfill our judicial obligation "to say what the law is," we must choose from a series of imperfect choices. In my view, the most coherent interpretation of (*l*)(8)(A) that is consistent with the rest of the BPCIA is the one I have described above. For these reasons, I respectfully dissent from the majority's holding that (*l*)(8) is a standalone provision with an inherent right to a 180-day injunction. Accordingly, I would dissolve the injunction pending appeal.

CERTIFICATE OF SERVICE

I hereby certify that on this 26th of August, 2015, I caused the foregoing Emergency Motion of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for an Injunction Pending En Banc Consideration and Review to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the Emergency Motion of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for an Injunction Pending En Banc Consideration and Review to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

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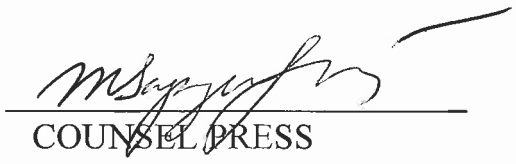

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