Appeal No. 2015-1499

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

– v. –

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants-Appellees.

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

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

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April 3, 2015

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

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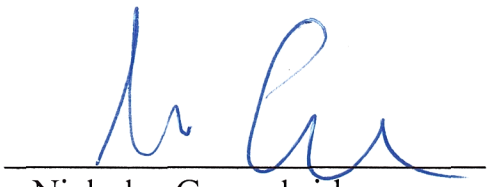

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CONFIDENTAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 28(d)(1)(B), Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") have prepared this public version of their brief in which they have redacted certain information designated confidential pursuant to the Protective Order, entered February 9, 2015. Specifically, the material omitted on pages 16 and 63 contains references to Defendants-Appellee Sandoz Inc. ("Sandoz")'s confidential information regarding Sandoz's pricing strategy and marketing and sales strategy, and was designated confidential by Sandoz during discovery under the terms of a Protective Order entered by the district court.

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, no other related cases are known to counsel for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") to be pending in this or any other court that will directly affect or be affected by this Court's decision on appeal.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331 and 1338(a).

The district court's March 19, 2015 Order: (1) denied Amgen's motion for a preliminary injunction, and (2) dismissed, with prejudice, Amgen's first and second causes of action and entered judgment in favor of Defendant-Appellee Sandoz Inc. ("Sandoz") on its first through fifth counterclaims. A0001-19.

Amgen timely appealed from the district court's denial of its preliminary injunction in the Order, A0024-26, over which this Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1) and (c)(1).

On March 25, 2015, the district court entered final judgment pursuant to Fed. R. Civ. P. 54(b) regarding the causes of action and counterclaims disposed of by the Order. A0020-23. Amgen timely appealed from that final judgment, A0024-26, over which this Court has jurisdiction pursuant to 28 U.S.C. § 1295(a).

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that, under the Biologics Price Competition and Innovation Act, Sandoz, a "subsection (k) applicant" (or, "Applicant") may elect not to comply with the requirement that it "shall provide" to Amgen, the reference product sponsor (or, "RPS"), a copy of its biologics license application ("BLA") and information describing "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).

2. Whether the district court erred in holding that Sandoz may comply with the requirement that the 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)" by giving notice before the biological product becomes "licensed." 42 U.S.C. § 262(*l*)(8)(A).

3. Whether the district court erred in holding that where Sandoz refused to provide its BLA and manufacturing information and provided untimely notice of commercial marketing, Amgen cannot compel Sandoz's compliance and its sole remedy is a declaratory judgment on patent issues under 42 U.S.C. § 262(*l*)(9).

4. Whether the district court erred in denying Amgen's motion for a preliminary injunction based on an erroneous interpretation of the BPCIA and an erroneous finding of no irreparable harm.

PRELIMINARY STATEMENT

This case presents issues of first impression regarding the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 119, 804 (2010). Before 2010, FDA approved biological products only under 42 U.S.C. § 262(a), which typically requires three phases of clinical trials to prove safety, and efficacy. A0047, 56-57 (A0045-83). The BPCIA created a new, abbreviated regulatory pathway, codified in 42 U.S.C. § 262(k), for approval of a biological product as "biosimilar to" a "reference product" that FDA had previously licensed under 42 U.S.C. § 262(a).

Congress enacted the BPCIA as part of the Affordable Care Act, because it was "the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804. Reflecting its breadth, the BPCIA amended the Public Health Service Act, the Patent Act, the Declaratory Judgment Act, and the Federal Food, Drug, and Cosmetic Act.

Prior to the BPCIA, innovators enjoyed permanent and exclusive rights to their clinical trial data and FDA license. In the BPCIA, Congress advanced the public's interest in price competition in part by diminishing these innovators' rights. After an innovator's product has been licensed for four years, the BPCIA permits a biosimilar applicant to "reference" the innovator's license, and thereby

apply for a license relying on the innovator's prior demonstration of safety and efficacy rather than generating its own clinical trial data. This abbreviated pathway permits FDA to approve the biosimilar product twelve years after the innovator's product was first licensed. Licensure through the biosimilar pathway saves the Applicant significant time, risk, and expense. A0001. It also lets the Applicant enter a market with established demand for the product. Congress also provided for approval of a biosimilar as "interchangeable" with the reference product, potentially allowing automatic substitution without prior authorization.

On the other side of the balance, Congress protected the public's interest in ensuring innovation and preserving the purpose of patents, by requiring the Applicant to provide the RPS with confidential information about the proposed biosimilar and its manufacture, requiring the parties to identify potentially relevant patents and to exchange detailed contentions about infringement, validity, and enforceability, and creating a new "Immediate patent infringement action" under 42 U.S.C. § 262(l)(6) that results from—and only from—the BPCIA-mandated exchange of information. This patent litigation, in turn, affects rights, obligations, and protections afforded to the RPS, the Applicant, and the public under the BPCIA. The BPCIA also protects the value of patents that may not become part of the subsection 262(l)(6) litigation, by preserving the status quo during a limited

statutory period occurring between FDA licensure of a biosimilar and its first commercial availability so that the RPS may seek injunctive relief on those patents.

Sandoz submitted a BLA under the abbreviated pathway for a biosimilar version of Amgen's NEUPOGEN® (filgrastim). A0005. This lawsuit arose because Sandoz pursued FDA approval and threatened to launch its product without respecting Amgen's rights under the BPCIA, refusing to comply with its disclosure and notice obligations. As the district court stated, "there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process." A0002. The district court erred in holding that the BPCIA lets an Applicant "elect[]" not to follow that process. A0009. This interpretation ignores the statute's plain language and its foundational interdependency between abbreviated approval and preservation of patent-protected innovation.

First, the district court erred in holding that Sandoz was not required to give Amgen a copy of its BLA and information about the processes for the manufacture of its biosimilar. The BPCIA says the Applicant "shall provide" that information within twenty days after notification that FDA has accepted its BLA for review, 42 U.S.C. § 262(*l*)(2)(A), and repeatedly refers to that information as "required" and to non-provision of it as "fail[ure]," *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). Refusing to provide the BLA and manufacturing information lets an Applicant avoid the "[i]mmediate patent

infringement action" under 42 U.S.C. § 262(*l*)(6) that is a cornerstone of the BPCIA. The district court nevertheless held that Sandoz was "within its rights" to "elect[]" not to provide Amgen with that information. A0002, 9.

Second, the district court erred in holding that Sandoz properly gave notice of commercial marketing before FDA had licensed its biosimilar, rather than after. The BPCIA requires the Applicant to provide notice 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) (emphasis added). Everywhere else section 262(*l*) refers to the product, it uses the phrase "the biological product that is the subject of" the BLA. *See* 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). That is because the Applicant may give 180 days' notice only after it has a "biological product licensed under subsection (k)"—*i.e.*, after FDA licensure. That provides time for the RPS to seek a preliminary injunction on patents that had not been listed for inclusion in the subsection 262(*l*)(6) lawsuit, as provided for in the very next statutory section, 42 U.S.C. § 262(*l*)(8)(B). Allowing an Applicant to give notice before FDA licensure is irreconcilable with the statute's text and purpose.

Third, the district court erred in holding that even if Amgen were correct that providing the BLA and manufacturing information under 42 U.S.C. § 262(*l*)(2)(A) is mandatory and notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A)

may not be given until after FDA licensure, there is no means—under the BPCIA, other federal laws, or state laws—by which an RPS can compel an Applicant to comply with those provisions. A0014 n.8, 18. The district court held that the RPS's exclusive remedy is a declaratory judgment for patent infringement under 42 U.S.C. § 262(*l*)(9), a provision that is neither remedial nor exclusive. A0018.

Fourth, from its erroneous reading of the BPCIA, the district court further erred in denying Amgen's motion for a preliminary injunction to compel Sandoz to comply with the terms of the BPCIA as properly construed.

Amgen respectfully requests that the Court reverse the district court's entry of final judgment in favor of Sandoz and its Order denying a preliminary injunction, and remand for further proceedings under the correct interpretation of the BPCIA.

STATEMENT OF THE CASE

This is an appeal from the district court's Order denying Amgen's motion for a preliminary injunction and final judgment under Rule 54(b).

Sandoz submitted a BLA to FDA under the BPCIA's abbreviated pathway, seeking approval of a biosimilar version of Amgen's biological product NEUPOGEN®. A0005. But Sandoz refused to follow the procedures of the BPCIA, namely providing its BLA and manufacturing information to Amgen and providing 180 days' advance notice after FDA licensure. A0002, 12.

Amgen sued Sandoz in the United States District Court for the Northern District of California, asserting that Sandoz's failure to comply with the BPCIA's procedures is a violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 et seq., and an act of conversion, and also asserting infringement of U.S. Patent No. 6,162,427 (the "'427 patent"). A0002. Sandoz counterclaimed for declaratory judgments adopting its interpretation of the BPCIA, and for noninfringement and invalidity of the '427 patent. *Id.*

The parties both moved for judgment, to resolve which party's construction of the BPCIA was correct. *Id.* Amgen also requested a preliminary injunction. A0016.

On March 19, 2015, the district court issued an Order that adopted Sandoz's positions on all issues, A0001-19, followed by entry of final judgment under Rule

54(b) on March 25, 2015. A0020-23. Amgen timely appealed the denial of its motion for a preliminary injunction and the final judgment. A0024-26. On March 27, 2015, this Court expedited Amgen's appeal.

STATEMENT OF THE FACTS

A. Amgen's NEUPOGEN® (filgrastim) Product

Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. A0048. One such product is NEUPOGEN® (filgrastim), a recombinantly produced biologic protein that stimulates the production of neutrophils, a type of white blood cells. A0058. It is used to counteract neutropenia, a neutrophil deficiency that makes a person highly susceptible to life-threatening infections and is a common side effect of chemotherapeutic drugs used to treat certain cancers. *Id.* Amgen has gained FDA approval for the use of NEUPOGEN® in the treatment of other conditions as well, including in connection with transplantation of certain cells in treating certain forms of blood cancer. *Id.*

In 1991, Amgen obtained regulatory approval for NEUPOGEN® under the traditional biologics regulatory pathway, 42 U.S.C. § 262(a). A0005. To obtain licensure, Amgen demonstrated to FDA that NEUPOGEN® "is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). FDA later approved additional therapeutic uses of NEUPOGEN®, each of which necessitated Amgen's further investment to conduct additional clinical testing and supplemental BLAs to prove safety and efficacy for the new uses. A0057.

The value of the biological license for NEUPOGEN® to Amgen, to would-be Applicants, and to society is the direct result of significant investments by Amgen. A0057-58. That is not unusual. The development of innovative pharmaceutical products requires the investment of enormous amounts of time, human resources, and money. A0057. The time to develop a drug is ten to fifteen years, and the average cost (including the cost of failures) was $1.2 billion or higher in the early 2000s. *Id.* (citing A0136-227).

As the BPCIA recognizes, Amgen—like other innovative biopharmaceutical companies—seeks to protect its investments through patenting its inventions. Amgen's patents on the molecule of filgrastim have expired, but Amgen's '427 patent covers use of filgrastim for particular approved uses. A0233-38. And it is undisputed that Amgen and its subsidiaries are the owners by assignment of more than 1,400 U.S. patents, many of which are directed to the manufacturing and purification of recombinant proteins. A0472. More than 400 of Amgen's patents fall within USPTO classifications that could apply to the recombinant production and purification of filgrastim. A0473.

B. Sandoz's BLA for Biosimilar Filgrastim

Sandoz filed a BLA under the BPCIA's abbreviated pathway of 42 U.S.C. § 262(k) for approval of its biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. FDA notified Sandoz that it had accepted

its BLA for review on July 7, 2014. A0005. FDA approved Sandoz's BLA on March 6, 2015. A1773-818. Sandoz will market its filgrastim product under the name ZARXIO®, *id.*, in direct competition with NEUPOGEN®.

ZARXIO® is the first biosimilar that FDA has approved. A0065. Under the abbreviated pathway, Sandoz received FDA approval for ZARXIO® for all of NEUPOGEN®'s approved uses. A1773-818.

C. Sandoz's Refusal to Comply with the BPCIA

As part of the BPCIA, Congress enacted procedures that commence at the same time FDA begins review of the BLA and serve to protect the RPS's innovation. They are codified in 42 U.S.C. § 262(*l*), "Patents," and in amendments to the Patent Act in 35 U.S.C. § 271(e).

Subsection 262(*l*)(2)(A) provides that within 20 days of FDA's acceptance of the BLA for review, the 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." It is undisputed that Sandoz did not provide Amgen with its BLA and manufacturing information within twenty days of FDA's notification of acceptance of that BLA. A0005-6, 9. It is also undisputed that Sandoz continued to pursue FDA approval of its product under the BPCIA.

Had Sandoz provided Amgen with its BLA and manufacturing information as required, Amgen would have been able to identify those patents for which Amgen believes a claim of patent infringement could reasonably be asserted. A0071-72. Amgen would have identified those patents to Sandoz under subsection 262(*l*)(3)(A), and the parties would have been able to conduct the detailed exchange of patents and claim-by-claim infringement, validity, and enforceability contentions that the statute requires, *see* 42 U.S.C. § 262(*l*)(3)-(5). *Id.* That exchange would have led to a negotiated resolution of the patent disputes or an informed patent-infringement lawsuit under subsection 262(*l*)(6), with the attendant legal implications under the other provisions of the BPCIA, including remedies available under 35 U.S.C. § 271(e)(4). A0066-68.

Sandoz's refusal to provide its BLA and manufacturing information materially prejudiced Amgen. A0071-73. While Sandoz was moving its application through the abbreviated pathway, it denied Amgen that time and information needed to detect Sandoz's patent infringement and commence an action under the BPCIA before FDA licensure. *Id.* The processes by which a biological product is made, including production and purification, are secret. That is why the BPCIA requires that the Applicant produce information about manufacturing processes to the RPS, with confidentiality procedures set forth in 42 U.S.C. § 262(*l*)(1). Indeed, Amgen just recently received Sandoz's BLA during

discovery in this case, and was able to identify two manufacturing patents that it believes would be infringed by Sandoz's manufacture of its filgrastim product. A1353.

Another of the provisions of the "Patents" section of the BPCIA is a requirement that, after FDA licenses the biosimilar product, the Applicant must give the RPS at least 180 days' notice before the first commercial marketing of the licensed product: "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)." 42 U.S.C. § 262(*l*)(8)(A). On Amgen's reading of the BPCIA, Sandoz refused to comply with this provision too. On July 8, 2014, the day after FDA accepted its BLA for review, Sandoz wrote to Amgen that, "[i]t is Sandoz's reasoned belief that the application will be approved by the FDA in or around Q1/2 of 2015, and Sandoz intends to launch the biosimilar filgrastim product in the U.S. immediately upon FDA approval." A1472 (A1471-79). Sandoz later clarified that it viewed this sentence as starting the notification period under subsection 262(*l*)(8), A0071; A1774, even though FDA had only just accepted the BLA for review and was months or perhaps years away, if ever, from "licens[ing]" the Sandoz product.

Had Sandoz given notice after the date FDA licensed its product—rather than when FDA first accepted its BLA for review—Amgen could have had notice

of the product that had actually been licensed and thus used the notice period as intended, to commence an orderly preliminary injunction process.

D. The District Court Proceedings

After Amgen sued Sandoz for violating the UCL, for conversion, and for infringement of the '427 patent, Sandoz counterclaimed for a declaratory judgment in favor of its interpretation of the BPCIA, its first through fifth counterclaims. A0002, 7. (Sandoz's sixth and seventh counterclaims, for declaratory judgments of noninfringement and invalidity of the '427 patent, are not at issue on this appeal, nor is Amgen's third cause of action, for infringement of that patent.)

1. The Parties' Motions

Both parties moved for partial judgment on the pleadings on the BPCIA issues. A0002. Amgen argued that 42 U.S.C. § 262(*l*)(2)(A) required Sandoz to provide Amgen with a copy of its BLA and manufacturing information within 20 days of notification by FDA of acceptance of Sandoz's BLA, and that 42 U.S.C. § 262(*l*)(8)(A) required Sandoz, after FDA licensure, to provide Amgen with at least 180 days' notice before first commercial marketing of its licensed product. *Id.*; A0005-08 Sandoz argued that it did not need to provide its BLA and manufacturing information, that its notice of commercial marketing was timely, and that Amgen's sole remedy was to commence a declaratory judgment action on a patent pursuant to 42 U.S.C. § 262(*l*)(9). *Id.*

Following a recommendation from FDA's Oncologic Drug Advisory Committee to approve Sandoz's BLA, A1464-70 ¶ 9, Amgen sought a preliminary injunction preventing Sandoz from commercially marketing ZARXIO®. A0016.

With respect to likelihood of success, Amgen made the same arguments as it had in its motion for judgment on the pleadings. A0017.

With respect to irreparable harm, Amgen submitted evidence that it would suffer irreparable price erosion, as a pharmaceutical company experiences when it faces unlawful generic competition. A0017-18. [redacted] This would ensure price erosion in the market for filgrastim. Amgen further argued that it would be irreparably harmed through "patent uncertainty" if the district court condoned Sandoz's disregard of the mandatory, patent-protecting provisions of the BPCIA, degrading the value of patents as a whole, including Amgen's and all innovators' patent portfolios, and rendering innovation of biological products less attractive for investors. A0460-62; A1916-18. Amgen also argued that the decrease in revenue from NEUPOGEN® caused by ZARXIO®'s premature market entry would directly harm Amgen's investment in research and development. A0017. Finally, Amgen argued that premature competition with ZARXIO® would divert Amgen's

salesforce away from three innovative medicines that are at a critical stage in their introduction to the market, permanently harming their uptake. *Id.*

With respect to the equities, Amgen argued that it would suffer more harm from the commercial launch of Sandoz's biosimilar product than Sandoz would suffer from an injunction. A0452. Amgen also asserted that the public interest is served by requiring Sandoz to comply with the law as Congress wrote it. A0451-52.

2. The District Court's March 19, 2015 Order and March 25, 2015 Final Judgment

In a March 19, 2015 Order (A0001-19), the district court ruled in favor of Sandoz on all issues raised in the parties' motions.

The district court held that Sandoz was "within its rights" under the BPCIA to "elect[]" not to provide Amgen with its BLA and manufacturing information, "subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C)." A0002, 9, 18. The district court further held that even if Sandoz violated the BPCIA by refusing to provide its BLA and manufacturing information, Amgen's exclusive remedy was a declaratory judgment action on a patent under 42 U.S.C. § 262(*l*)(9)(C), and that Amgen had no means by which to obtain injunctive relief, restitution, or damages. A00018.

The district court also adopted Sandoz's reading of 42 U.S.C. § 262(*l*)(8), holding that notice of commercial marketing may be provided prior to FDA

approval, rather than only after FDA approval when there is a licensed biological product. A0012-14. The district court further held that even if Sandoz provided untimely notice under subsection 262(*l*)(8), Amgen's exclusive remedy was a declaratory judgment action under 42 U.S.C. § 262(*l*)(9)(B). A0014 n.8.

Having determined that "Sandoz's actions did not violate the BPCIA," the district court held that Sandoz "has committed no unlawful or wrongful predicate act to sustain" Amgen's state-law claims. A0014.

The district court also entered judgment in favor of Sandoz on its counterclaims seeking declaratory judgments of the correctness of its reading of the BPCIA. A0018.

Finally, the district court denied Amgen's motion for a preliminary injunction, finding that Amgen could not demonstrate serious questions as to the merits or a likelihood of success. A0017. The court dismissed Amgen's evidence of irreparable harm as "at best highly speculative" and as "based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen." A0018.

On March 25, 2015, the district court entered final judgment under Rule 54(b) as to the causes of action and counterclaims that relate to the BPCIA issues. A0020-23. The district court reasoned that there is no reason to delay entry on the claims and counterclaims adjudicated in the Order that "all relate to the correct

interpretation of the BPCIA and do not address the sole subject of the remaining ['427 patent] claims and counterclaims." A0021.

Amgen timely appealed both the judgment and the district court's denial of Amgen's motion for a preliminary injunction. A0024-26.

SUMMARY OF THE ARGUMENT

The issues of first impression presented here as to the interpretation of the BPCIA are of importance not only to these parties—with Sandoz poised to begin commercial marketing of the first FDA approved biosimilar—but to the biopharmaceutical industry. Indeed, FDA itself is monitoring the resolution of this case; it recently denied a related Citizen's Petition by Amgen "[i]n light of the ongoing litigation regarding interpretation of" the BPCIA.[1] The district court's decision, if affirmed, would not just upend the statutory scheme as between Amgen and Sandoz, but permit every Applicant to gain the benefit of referencing the innovator's license while sidestepping the provisions of the BPCIA that protect innovation.

Congress enacted the BPCIA to establish "a biosimilars pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804. In enacting the BPCIA, Congress borrowed from "the Hatch-Waxman Act's process for use of an Abbreviated New Drug Application (ANDA), rather than a full New Drug Application, to obtain approval of generic versions of previously approved drugs. *E.g.*, 21 U.S.C. § 355(j)." *Sandoz, Inc. v. Amgen, Inc.*,

[1] FDA Citizen Petition Response, Docket No. FDA-2014-P-1771-004 (March 25, 2015), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2014-P-1771-0004.

773 F.3d 1274, 1276 (Fed. Cir. 2014). Just as in the BPCIA, in the Hatch-Waxman Act[2] "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Dey Pharma, LP v. Sunovion Pharms. Inc.,* 677 F.3d 1158, 1159 (Fed. Cir. 2012) (quoting *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

The district court made two fundamental errors in analyzing the BPCIA: it found that the patent-exchange and notice procedures of the statute are optional, although they are phrased in mandatory language and described as "required;" and it held that even if those provisions are mandatory, an RPS cannot compel an unwilling Applicant to comply with them—an action for a declaration of patent rights is all that is available. Those errors caused the district court wrongly to enter judgment in favor of Sandoz, and wrongly to deny Amgen the preliminary injunction that would have compelled Sandoz to comply with the law it chose to violate. Amgen respectfully requests that this Court hold that if an Applicant chooses to avail itself of the subsection 262(k) pathway, the patent-exchange provisions of the BPCIA are mandatory, as their plain terms and context make

[2] The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)

clear, and that where an Applicant fails to comply with those terms, district courts have broad power, under state and federal laws, to fashion appropriate remedies, including to compel compliance.

First, the district court erred in holding that Sandoz may elect not to comply with the requirement that the Applicant "shall provide to the reference product sponsor a copy of" its BLA "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). This determination is inconsistent with the plain, mandatory language of the statute. It is also inconsistent with the integrated statutory scheme that starts with the RPS receiving information about the biosimilar product prior to commencing litigation pursuant to subsection 262(*l*)(6). The Applicant's disclosure of its BLA and manufacturing information is how the RPS assesses whether any patents are infringed, prior to commencing the exchange of patent lists and contentions that lead up to the identification of patents for litigation under subsection 262(*l*)(6).

In addition, the district court erred in holding that Sandoz may satisfy the BPCIA requirement that it "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)" by giving notice prior to FDA licensure. 42 U.S.C. § 262(*l*)(8)(A). Had Congress wished to permit notice of

commercial marketing prior to FDA licensure, it would not have used the word "licensed" in this provision; it would have chosen instead to refer to the biological product that is the "subject of the application," as Congress did in every other instance in subsection 262(*l*). The district court's determination that the 180-days' notice may be given when the BLA is filed eviscerates the value of the notice provision, which is to give the RPS notice in the context of an FDA-issued license and the opportunity in that context, to seek a preliminary injunction based on patents that were identified in the patent exchange process of the BPCIA but not listed by the parties for the litigation under § 262(*l*)(6). 42 U.S.C. § 262(*l*)(8)(B).

Second, the district court erred by holding that there is no way for an RPS to compel compliance with the BPCIA. Instead, the district court determined that the sole remedy available to the RPS for injury resulting from an Applicant's violation of either (or both) of these provisions is to bring an action for a declaration of the RPS's patent rights under subsections (*l*)(9)(B) and (C). That is not a remedy. If the Applicant fails to provide the required notice and proceeds instead to market its commercial product immediately upon approval (as Sandoz said it would do here), the RPS will bring an infringement action under 35 U.S.C. § 271, likely seeking emergency relief. Bringing a declaratory judgment action would be meaningless. Further, any type of patent lawsuit might be impossible at that point, because without the required detail in the disclosures of § 262(*l*)(2)(A) the RPS often will

be unable to tell what patents are infringed, especially with respect to patents on methods of manufacturing, and thus will be unable to assert the rights that the disclosure process is designed to protect.

The district court's interpretations of the BPCIA cannot stand because they would convert a statute designed to balance the interests of the Applicant and the RPS into one that benefits only the Applicant. That was not what Congress intended. Applicants receive enormous benefits under the BPCIA, such as time and cost savings from an abbreviated approval pathway. The RPS, too, is supposed to benefit from the BPCIA, including by access to the Applicant's BLA and manufacturing information contemporaneous with FDA review and by advance notice of marketing after licensure. The courts, too, benefit from this balance, because patent disputes are presented in a well-managed process.

The district court's decision upends this balance. The one-sidedness of the approach is clear: the entire discussion of the policy considerations of the statute, A0011, addresses the benefits and risks to the Applicant, with no discussion of the concomitant rights intended to be afforded to the RPS.

Accordingly, Amgen respectfully submits that this Court should reverse the district court's construction of the BPCIA as incorrect. From that basis, Amgen respectfully requests that the Court (i) reverse the district court's entry of judgment in favor of Sandoz on Amgen's UCL and conversion claims; (ii) reverse the district

court's entry of judgment on Sandoz's counterclaims; (iii) reverse the district court's denial of Amgen's motion for preliminary injunction; and (iv) remand for further proceedings based on the correct interpretation of the BPCIA, including entry of judgment in Amgen's favor on its claims and Sandoz's counterclaims and entry of an appropriate injunction.

ARGUMENT

This Court reviews the district court's judgment on the parties' cross-motions for judgment on the pleadings de novo, following Ninth Circuit law, accepting the material allegations in the complaint as true. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1380 (Fed. Cir. 2011).

The Court reviews the district court's denial of Amgen's application for a preliminary injunction under an abuse-of-discretion standard, and can reverse the district court's conclusion if "'the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'" *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1352 (Fed. Cir. 2012) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)).

I. The BPCIA Provides a Carefully Crafted Regulatory Scheme of Mandatory Disclosure and Up to Two Phases of Dispute Resolution

The BPCIA created an abbreviated pathway for FDA licensure of biological products, 42 U.S.C. § 262(k), upon a determination that the biological product is "biosimilar" to a "reference product" previously licensed under the full approval pathway, 42 U.S.C. § 262(a). *See* 42 U.S.C. § 262(i)(4). In creating the biosimilar pathway Congress sought to "balanc[e] innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

On the one hand, the BPCIA's abbreviated pathway lets the Applicant save "years of research and millions in costs" compared to the traditional approval pathway under § 262(a), A0001, and effectively limits the innovator's rights as previously enjoyed. On the other hand, the BPCIA compels the Applicant to provide confidential information to the RPS so that the RPS can identify and protect its patent rights while FDA review is ongoing, and compels the Applicant to provide notice after FDA licensure and before commercial marketing so the RPS can act to prevent irreparable harm that may result. The BPCIA achieves this balance through a detailed and elaborate procedure for patent-dispute resolution set forth in subsection 262(*l*) and integrated into other provisions of the BPCIA.

The patent-dispute resolution procedure contemplates two phases distinguished by the patents each phase addresses. These phases may result in overlapping litigation, depending on when the BLA is filed and how quickly an FDA license is granted. The first phase commences within twenty days of FDA's notification of acceptance of the BLA and involves the RPS and the Applicant identifying a first set of patents and exchanging claim-by-claim infringement, validity, and enforceability contentions. It culminates in an immediate patent infringement lawsuit under 42 U.S.C. § 262(*l*)(6), if necessary, which includes specified patents identified in this first phase. The subsection 262(*l*)(6) lawsuit itself is then used throughout the BPCIA—in subsection 262(*l*), but also in the

subsection 262(k) approval pathway and in the Patent Act—to establish various rights and obligations of both the Applicant and the RPS, and to affect third parties' rights.

The second phase can involve patents initially identified by the parties pursuant to subsection 262(*l*)(3) but not listed for inclusion in the subsection 262(*l*)(6) litigation, as well as patents issued or in-licensed after the subsection 262(*l*)(3) list was generated. After notice of commercial marketing is provided (*i.e.*, at or after FDA licensure of the biosimilar product), the RPS may seek a preliminary injunction on those patents under subsection 262(*l*)(8)(B) before commercial marketing begins, and the limitation on declaratory judgment actions on those patents in subsection 262(*l*)(9)(A) expires. If the RPS seeks such a preliminary injunction, the statute compels the RPS and Applicant to "cooperate to expedite such further discovery as needed in connection with the preliminary injunction motion." 42 U.S.C. § 262(*l*)(8)(C).

A. Phase One: The Patent List, Exchanges of Contentions, and Immediate Infringement Action

The first phase of dispute resolution is described in 42 U.S.C. § 262(*l*)(2) through (*l*)(6). It begins with the Applicant providing its BLA and manufacturing information to the RPS within 20 days of FDA providing notice of accepting the BLA. 42 U.S.C. § 262(*l*)(2)(A). Sandoz did not comply with this requirement,

and Amgen was therefore denied the value of first identifying patent infringement at the outset of FDA's review of Sandoz's BLA.

Thereafter, the parties spend up to 180 days identifying an initial list of potentially applicable patents and stating their positions regarding licensing, entry relative to patent expiry, and infringement, validity, and enforceability.

- First, within 60 days after receiving the BLA and manufacturing information, the RPS "shall provide" the Applicant a list of all patents for which the RPS believes a claim of infringement could reasonably be asserted, and identify those patents the RPS would be prepared to license to the Applicant. 42 U.S.C. § 262(*l*)(3)(A).

- Within 60 days thereafter, the Applicant "may provide" its own list of additional patents that could be infringed, and "shall provide" for each listed patent either a statement that it will remain off the market until the patent expires or, on a claim-by-claim basis, a detailed statement of its factual and legal basis for believing that the patent is invalid, unenforceable, or not infringed, as well as a response to the RPS's identification of patents it would be prepared to license. 42 U.S.C. § 262(*l*)(3)(B).

- Then, within 60 days thereafter, the RPS "shall provide," for the disputed patents, a reciprocal detailed statement with its position that each patent will be infringed and is valid and enforceable. 42 U.S.C. § 262(*l*)(3)(C).

The exchanges in subsection 262(*l*)(3) benefit both the RPS and the Applicant. Having received the BLA and manufacturing information, the RPS can identify which patents in its portfolio read on the product, the processes by which it is made, or its therapeutic use. When the RPS identifies those patents, the

Applicant learns what patent disputes there are prior to launch. Both parties learn whether any such patents can be licensed, and for which patents the Applicant will await expiry before launching, in either case avoiding litigation. And for those patents that are in dispute, each party learns the other's detailed contentions regarding infringement, validity, and enforceability, and can make judgments about the litigation risks associated with each patent.

The next step in Phase One is for the parties to attempt to agree, under subsection 262(*l*)(4), on which of the patents listed pursuant to subsection 262(*l*)(3), if any, should be included in an immediate patent-infringement action and, failing agreement, to follow an enforced dispute-resolution procedure under subsection 262(*l*)(5) to identify those patents:

- Under subsection 262(*l*)(4), the parties "shall engage" in good-faith negotiations to agree on "which, if any, patents" listed by either party in the subsection 262(*l*)(3) exchanges "shall be the subject of an action for patent infringement" under § 262(*l*)(6). 42 U.S.C. § 262(*l*)(4)(A).

- If the parties cannot agree within 15 days on which patent should be listed for inclusion in the lawsuit, subsection 262(*l*)(5) requires the Applicant to state the number of patents it will list for inclusion in that lawsuit, and each of the Applicant and RPS may then identify that number of patents. If the applicant lists no patents, the RPS may nevertheless list one patent. 42 U.S.C. § 262(*l*)(4)(B), (5).

Once the parties have arrived at the list of patents on which suit will be brought, the RPS is then directed to bring an "Immediate patent infringement

action" on each of the listed patents within 30 days. 42 U.S.C. § 262(*l*)(6). The Applicant must provide the complaint to FDA, which must publish it in the Federal Register. *Id.*

B. Phase Two: Later-Issued Patents, Patents Not Previously Listed, Declaratory Judgment, and Preliminary Injunction

The second phase of the dispute-resolution process includes a distinct set of patents: those that were initially included in the parties' lists under subsection 262(*l*)(3) but were not listed for inclusion in the subsection 262(*l*)(6) lawsuit, as well as "[n]ewly issued or licensed patents" that become part of the RPS's subsection 262(*l*)(3)(A) list by virtue of subsection 262(*l*)(7).

As described below, litigation over these Phase Two patents may begin when FDA licenses the biosimilar product and the Applicant gives the notice provided for by subsection 262(*l*)(8)(A). That provision then triggers preliminary injunction practice for the Phase Two patents under subsection 262(*l*)(8)(B), and declaratory judgment actions under subsection 262(*l*)(9)(A). Thus, subsection 262(*l*)(8), entitled "Notice of commercial marketing and preliminary injunction," provides:

> (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).

42 U.S.C. § 262(*l*)(8)(A), (B). Subsection 262(*l*)(7) provides that "[n]ewly issued or licensed patents" are also "subject to paragraph (8)."

The interplay between subsections 262(*l*)(8)(A) and (*l*)(8)(B) is clear: once FDA has approved the Applicant's BLA, the Applicant must give at least 180 days' notice before commercially marketing the product. The RPS may use that notice period to seek a preliminary injunction on the Phase Two patents.

C. Limitations on Declaratory Judgments

The BPCIA borrows from the Hatch-Waxman Act and prohibits gaming the system by placing limits on actions for declaratory judgments on the patents not

listed for inclusion in the subsection 262(*l*)(6) lawsuit. That prohibition ends after FDA licenses the biosimilar and when the Applicant gives at least 180 days' advance notice of first commercial marketing. Thus, subsection 262(*l*)(9), entitled "Limitation on declaratory judgment action," provides:

> (9) Limitation on declaratory judgment action
>
> (A) Subsection (k) application provided—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

The patents covered by this bar to declaratory judgment actions are those in Phase Two: patents that were listed in subsection 262(*l*)(3) but not listed for inclusion in the subsection 262(*l*)(6) lawsuit under either subsection 262(*l*)(4) or (*l*)(5), plus later-issued or licensed patents under subsection 262(*l*)(7).

The bar to declaratory judgment actions benefits both the Applicant and the RPS by ensuring that the parties follow the procedures of subsections 262(*l*)(2) through (*l*)(6). The limitation on declaratory judgment actions persists with respect to the Applicant, but not the RPS, if the Applicant fails to complete a required act:

> (B) Subsequent failure to act by subsection (k) applicant—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).
>
> (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.

42 U.S.C. § 262(*l*)(9)(B), (C).

D. Amendments to the Patent Act

As with the Hatch-Waxman Act, the BPCIA makes the submission of an application an act of infringement. Where the Hatch-Waxman Act uses a public patent list[3] to define the set of patents implicated by this infringing act, the BPCIA uses the private disclosure process of subsections 262(*l*)(2)-(3) to generate a list, as supplemented by subsection 262(*l*)(7). 35 U.S.C. § 271(e)(2)(C)(i). And, if the Applicant fails to provide the information required under subsection 262(*l*)(2)(A)—its BLA and manufacturing information—then any patent that could

[3] The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

have been listed in the subsection 262(*l*)(3)(A)(i) exchange is implicated. 35 U.S.C. § 271(e)(2)(C)(ii).

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

The district court determined that the BPCIA enables a dispute-resolution procedure in which "applicants and sponsors may participate," and that "these procedures are 'required'" only "where the parties elect to take advantage of their benefits." A0001, 9 (emphases added). This is contrary to the plain language of the statute, which says Sandoz "shall provide" its BLA and manufacturing information to Amgen within 20 days of receiving FDA notification. 42 U.S.C. § 262(*l*)(2)(A). It is also inconsistent with the statute as a whole.

No other court has found that the BPCIA provisions are optional, and all have treated them as tied to FDA review. *See Hospira, Inc. v. Janssen Biotech, Inc.*, Civ. 14-7049 PAC, 2014 WL 6766263, at *1 (S.D.N.Y. Dec. 1, 2014) ("The BPCIA purposefully ties the dispute resolution process to events throughout the biosimilar approval process . . . ."); *accord Celltrion Healthcare Co. v. Kennedy Trust for Rheumatology Research,* Civ. 14-2256 PAC, 2014 WL 6765996, at *5 (S.D.N.Y. Dec. 1, 2014).

A. The Language of the BPCIA Confirms That Provision of the BLA and Manufacturing Information Is Mandatory

"[A]ll statutory construction cases . . . begin with the language of the statute." *Momenta*, 686 F.3d at 1353-54 (quoting *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002)). "The 'first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.'" *Id.* at 1354 (*quoting Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997)); *see also Intellectual Ventures II LLC v. JPMorgan Chase & Co.*, No. 14-1724, 2015 WL 1454828, at*3-4 (Fed. Cir. Apr. 1, 2015). "If the language of the statute is unambiguous, there is no second step: 'Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'" *Momenta,* 686 F.3d at 1354 (*quoting Robinson*, 519 U.S. at 340). "Whether the text of a statute is plain or ambiguous 'is determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole.'" *Id.* (*quoting Robinson*, 519 U.S. at 341).

Here, the meaning of subsection 262(*l*)(2) is unambiguous:

> (2) 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—
>
> (A) 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; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2) (emphases added). "Shall" is, generally, mandatory language. *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); *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998); Antonin Scalia & Bryan A. Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 114 (2012) ("[W]hen the word *shall* can reasonably read as mandatory, it ought to be so read.")

"Shall" is even more clearly mandatory where, as here, it is used in juxtaposition to the word "may." Under subsection 262(*l*)(2), the Applicant "shall" provide its BLA and manufacturing information, but only "may" provide anything else that the RPS requests. In *Jama v. Immigration & Customs Enforcement*, the Supreme Court considered a statute using both "may" and "shall" and relied on the distinction to construe the statute: "The word 'may' customarily connotes discretion. That connotation is particularly apt where, as here, 'may' is used in contraposition to the word 'shall'[.]" 543 U.S. 335, 346 (2005) (internal citation omitted); *see also Lopez*, 531 U.S. at 241. This Court has likewise distinguished

between "shall" and "may": "When, within the same statute, Congress uses both 'shall' and 'may,' it is differentiating between mandatory and discretionary tasks." *Huston v. United States*, 956 F.2d 259, 262 (Fed. Cir. 1992) (citing *Grav v. United States*, 886 F.2d 1305, 1307 (Fed. Cir. 1989)).

B. The Statute as a Whole Confirms that the Requirement is Mandatory

While the words of subsection 262(*l*)(2) are sufficient to prove that its terms are mandatory, other parts of the statute confirm that Sandoz is required to provide the BLA and manufacturing information to Amgen.

First, the BPCIA in four separate places refers to this information as "required." In two of those places, it further refers to non-provision of that information as "fail[ure]." Specifically, subsection 262(*l*)(1)(B)(i) refers to "the information required to be produced pursuant to paragraph (2);" subsections 262(*l*)(9)(A) and (*l*)(9)(C) each refer to the "information required under paragraph (2)(A);" and subsection 262(*l*)(9)(C) begins, "[i]f a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A)." (Emphases added). So do the BPCIA amendments to the Patent Act, which state: "if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act . . ." 35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added).

There is a very good reason that Congress chose to make disclosure of this information mandatory: without it, some of the most important information would remain secret. BLAs are themselves almost always confidential, as are the methods by which biologic products are made. *See, e.g.*, *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) (considering a process for producing transformable E. coli cells, and noting that the "claimed process was maintained as a secret.") An approval process based on biosimilarity heightens the risk of process-patent infringement. That is one example of why the BPCIA requires provision of manufacturing information, along with the BLA. 42 U.S.C. § 262(*l*)(2)(A). Without that disclosure, infringement of process patents would remain hidden, undermining the value of those innovations and the incentive to further innovate. Indeed, it is undisputed that Amgen has over 400 patents covering the recombinant creation and purification of proteins, some of which could cover filgrastim. A0473. Only through the disclosures of subsection 262(*l*)(2)(A) can the RPS identify and provide the list of patents called for in subsection 262(*l*)(3)(A).

Second, under the district court's construction of the BPCIA, an Applicant may elect not to provide the information required by subsection 262(*l*)(2)(A), and thus prevent the information-exchange and patent-listing processes of subsections 262(*l*)(3), (4), and (5) from occurring and ensure that there will be no subsection

262(*l*)(6) lawsuit. Because the subsection 262(*l*)(6) lawsuit is a lynchpin of the entire BPCIA, a construction that allows an Applicant to circumvent that lawsuit cannot be correct. For example:

- If the RPS prevails on a patent in a subsection 262(*l*)(6) lawsuit for infringement under 35 U.S.C. § 271(e)(2)(C) prior to the end of a period of exclusivity for the reference product prescribed by 42 U.S.C. § 262(k)(7), then under 35 U.S.C. § 271(e)(4)(D) the district court must order a permanent injunction against further infringement of that patent. But that provision—a significant right given to the RPS by the BPCIA—requires that the RPS prevail in a subsection 262(*l*)(6) lawsuit. If the Applicant prevents such a lawsuit by not providing its BLA and manufacturing information under subsection 262(*l*)(2)(A), and the RPS prevails on a patent in some other form of lawsuit, it must prove entitlement to an injunction under 35 U.S.C. § 271(e)(4)(B) or § 283; the Applicant has deprived the RPS of a mandatory injunction by preventing the subsection 262(*l*)(6) lawsuit.

- Applicants may gain additional exclusivity rights by seeking "interchangeability" status under 42 U.S.C. § 262(k)(6). That exclusivity lasts until the soonest to occur of five events. *See id.* § 262(k)(6)(A)-(C). Three of these require there to have been a subsection 262(*l*)(6) lawsuit against the biosimilar. *Id*. § 262(k)(6)(B)(i)-(ii), (C)(ii). By allowing Applicants to prevent

subsection 262(*l*)(6) lawsuits from being filed, the district court's construction of the BPCIA lets Applicants game this exclusivity process.

C. The District Court's Errors

Despite the statute's language and structure, the district court determined that "shall" in 42 U.S.C. § 262(*l*)(2)(A) is not mandatory and instead gives the Applicant the option to "elect[]" not to follow the prescribed procedures. A0009. According to the district court, the BPCIA "procedures are 'required' where the parties elect to take advantage of their benefits, and may be taken away when parties 'fail.'" *Id.* This is wrong as a matter of law. It cannot be the case that litigants can elect not to follow statutory procedures simply because they desire to do so. Otherwise, there would no reason for Congress to draft laws at all.

Indeed, where Congress wished to give Applicants the ability "to opt," it knew how to do that by using words of choice. For example, the confidentiality provisions in subsection 262(*l*)(1), in discussing the deletion of confidential information if no lawsuit is filed, contain the phrase, "if the reference product sponsor opts to destroy such information . . . ." 42 U.S.C. § 262(*l*)(1)(F). In order to give force to each of Congress's words in the statute, "shall" cannot be interpreted to allow parties to "opt out." Had Congress wanted to make the individual provisions mandatory only within a larger optional structure, it could have begun subsection 262(*l*) with words to the effect of, "if the subsection (k)

applicant and the reference product sponsor choose to follow the dispute-resolution procedures below, then within 20 days of FDA acceptance of the BLA, the applicant shall provide . . . ." It did not.

The district court relied on *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014), to support its holding that "shall" is not mandatory. That case, however, does not hold that "shall" is always optional; it simply confirms that "shall" is interpreted consistent with the statutory purpose. The Minnesota Recording Act requires that "[e]very conveyance of real estate shall be recorded" and "every such conveyance not so recorded shall be void as against any subsequent purchaser in good faith." *Id.* at 1086. The court held that this did not require that every conveyance be recorded; rather, the consequence of not recording a conveyance was that it was void. The decision noted that the purpose of the statute was to use "recording to resolve disputes between parties who have no contractual relationship, but who lay claim to the same title," and that the Minnesota Supreme Court held that the "Recording Act *creates no obligations*." *Id.* at 1089 (emphasis in original).

Under the Minnesota statute, a purchaser who does not record a conveyance of real estate does not get the protections of the statute, namely title to the property against a subsequent purchaser. Thus, the harm from non-compliance is visited on the non-compliant party, and not the subsequent purchaser. That is not the case

here. Unlike the Minnesota statute that "creates no obligations," the BPCIA does create obligations, to balance the interests of innovators and biosimilar applicants. "Shall" must be read as mandatory to give effect to the BPCIA's statutory text and purpose. Specifically, requiring the Applicant to provide the RPS with confidential information about the product and its manufacture provides substantive benefits to the RPS that permit it to commence patent infringement litigation concurrent with FDA's review of the BLA and to seek preliminary injunctive relief prior to commercial marketing of the licensed biosimilar. If the Applicant does not comply with this requirement, then it is the RPS who loses the protections of the statute—not the non-compliant Applicant. Thus, it would frustrate the purpose of the BPCIA to interpret "shall" to permit the Applicant to deprive the RPS of the protections of the statute.

The district court also based its decision on its belief that permitting Sandoz "not to comply" with subsection 262(*l*) "operates to promote expedient resolution of patent disputes." A0011. That an Applicant could benefit from the expediency of an immediate lawsuit does not make the required provisions of the BPCIA any less mandatory. Congress crafted the BPCIA to accelerate price competition through an abbreviated regulatory pathway while protecting the innovator's ability to enforce its patent rights with the benefit of full information, not at the expense of those patent rights. The district court erred in not considering the RPS's

substantive interests when interpreting the BPCIA. *See* A0009-12. Indeed, what is most telling about the district court's balancing of factors is what is missing: the words of the statute, and the interests of the RPS. The BPCIA balances innovation and price competition. It does not exist to benefit only the Applicant.

The district court's explanation of how the process would work if the Applicant "elected" not to comply with these provisions confirms the district court's error. A0009. The district court explained that "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." A0011 n.6. That turns the statute on its head. Without the BLA and manufacturing information, an RPS may not have enough information to file suit, particularly with respect to its manufacturing patents. The BPCIA bolsters the value of manufacturing patents by requiring disclosures that make them more readily enforceable. The district court erred in holding that the BPCIA permits Sandoz to make a "choice" between providing the information required by the statute or "deci[ding] not to comply with subsection (*l*)." A0009, 11 & n.6.

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

Subsection 262(*l*)(8)(A) states that "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)." The parties disagree about two aspects of this provision: (i) whether notice is required at all, and (ii) whether notice may be provided prior to FDA licensure of the product.

The district court held that it was "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," and then stated in an accompanying footnote that "In addition, had Sandoz failed to do so [*i.e.*, had Sandoz not given notice at all], 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." A0014 & n.8.

Both holdings are errors of law. Notice may be given only after FDA has issued a license for the biological product, and notice must be given; it is not optional.

A. Notice of Commercial Marketing Requires FDA Licensure

1. Congress Deliberately Referred to a "Licensed" Product

The language of the statute controls. In every other place where section 262(*l*) refers to the biological product, it refers to "the biological product that is the subject of" the BLA. *See* 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). In only subsection 262(*l*)(8)(A), however, Congress referred to "the biological product licensed under subsection (k)." That distinction is significant: An Applicant may not give 180 days' notice before the product that was the subject of the application has become a "biological product licensed"—that is, until FDA licensure.

That is the logical reading of the words. "Licensed" means "[t]o whom or for which a licence has been granted; provided with a licence." 1 OXFORD ENGLISH DICTIONARY 245 (Oxford Univ. Press, Compact ed. 1971). It is also consistent with 42 U.S.C. § 262's other uses of the term "product licensed," which refer to a product that FDA has already licensed. *See*, *e.g.*, 42 U.S.C. § 262(d)(1), (i)(4), (k)(5). And it is precisely what another district court stated in another case between Amgen and Sandoz, where Sandoz purported to give its 180-day notice for a different product before it had even filed its BLA: "Sandoz cannot, as a matter of law, have provided a 'notice of commercial marketing' because, as discussed above, its etanercept product is not 'licensed under subsection (k).'"

Sandoz, Inc. v. Amgen, Inc., Civ. 13-2904 MMC, 2013 WL 6000069, at *2 (N.D. Cal. Nov 12, 2013), *aff'd on other grounds*, 773 F.3d 1274 (Fed. Cir. 2014).

2. Permitting Notice Only Upon Licensure Effectuates the Statutory Purpose

The only interpretation of subsection 262(*l*)(8)(A) that gives effect to the statutory scheme is one that requires notice to be given upon FDA licensure and not before it. Subsection 262(*l*)(8)(B), the next subsection, makes clear why notice must be given: to allow the RPS time to seek a preliminary injunction on patents not listed for the subsection 262(*l*)(6) patent-infringement lawsuit, including patents later issued or in-licensed. Recognizing that the time between the creation of the subsection 262(*l*)(3) lists and FDA approval may be lengthy, the statute provides a brief, 180-day period after licensure during which the RPS may bring a preliminary injunction application on these additional patents. For example, if an Applicant submits its BLA in 2014, triggering the subsection 262(*l*)(2) disclosure and 262(*l*)(3) exchanges, but does not receive FDA licensure until 2022 (due to exclusivity or lengthy FDA review), there may very well be patents that issue during that period or that were not designated for the subsection 262(*l*)(6) lawsuit but that the RPS wishes to assert upon FDA licensure many years later.

Given Congress's goal of striking a balance between innovation and consumer interests in the BPCIA, it makes sense that Congress intended the notice to follow licensure of the biosimilar product. That is the point at which the

product, its therapeutic uses, and its manufacturing processes are fixed. When the Applicant files its BLA, it does not know when (if ever) it will obtain FDA licensure. FDA can insist on changes to the product or its manufacture during review, so 180 days of notice given when the BLA is filed covers a time period qualitatively different than the 180 days following licensure. Prior to FDA licensure, any notice that could be given would be speculative as to the date of launch, the therapeutic uses, the formulation, the processes of manufacture, and many other details of the biological product that will be marketed. It is only during the period after FDA licensure—the one identified in the statute's text—that the RPS will know for certain what patents it can assert and can decide whether to seek preliminary injunctive relief on any of them.

The interchangeability exclusivity provisions of 42 U.S.C. § 262(k)(6) shed further light. As noted above, interchangeability exclusivity ends with the first to occur of five specified events. The first is one year after first commercial marketing of the first interchangeable biosimilar for a reference product. Another is eighteen months after FDA approval of that product, if there is no subsection 262(*l*)(6) lawsuit. *Compare id.* § 262(k)(6)(A), (C)(ii). The timeframes suggest that approval and commercial marketing will not occur simultaneously, as the district court's ruling would permit. Instead, the BPCIA recognizes that approval

and commercial marketing will be approximately 180 days apart, consistent with Amgen's interpretation of the notice period of subsection 262(*l*)(8)(A).

3. Allowing Notice To Be Given Prior to Licensure Frustrates the Purpose of the Statute

Subsection 262(*l*)(8)(B) states that after receiving the notice under subsection 262(*l*)(8)(A) and before the date of commercial marketing of the product, the RPS may bring a preliminary injunction on those patents that were not listed for the subsection 262(*l*)(6) lawsuit. But if the Applicant gives its notice when it files its BLA, that period may have long expired before the relevant patents have even been identified: the exchanges of subsections 262(*l*)(3) alone can cover 180 days, and the negotiations over the lists of patents for the subsection 262(*l*)(6) lawsuit in subsections 262(*l*)(4) and (5) can take up to twenty more days. The district court's construction thus allows an Applicant to provide 180 days' notice at a time when that notice period cannot be used for the very purpose for which it exists.

Likewise, the subsection 262(*l*)(9)(A) limitation on declaratory judgments would make no sense if the district court's interpretation were correct. That provision says that "[i]f a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A)" (emphasis added), bring a declaratory judgment action on the

patents described in subsection 262(*l*)(8)(B). The statute clearly contemplates that subsection 262(*l*)(8)(A) notice will be given only after the time for providing the BLA and manufacturing information under subsection 262(*l*)(2)(A), and only after the patents described in subsection 262(*l*)(8)(B) have been identified. Under the district court's reading, however, an Applicant could do exactly what Sandoz did here—give 180-day notice when it filed its BLA—thereby reducing the period in which neither party can file a declaratory judgment action to zero.

Indeed, the district court's construction makes the interplay between subsections 262(*l*)(9)(A), (B), and (C) untenable. If the Applicant may give notice when it files its BLA, and thus reduce to zero the period under subsection 262(*l*)(9)(A) in which declaratory judgment actions are barred, what happens if the Applicant brings such a declaratory judgment action and thereafter fails to complete one of the required steps listed in 262(*l*)(9)(B) or fails to provide the disclosure of subsection 262(*l*)(2)(A)? Is the pending declaratory judgment action then barred because of that failure? There is no way to reconcile these provisions if, as the district court held, notice may be given when the Applicant files its BLA.

Furthermore, the district court's interpretation renders the notice meaningless to the RPS. It adds no more useful information than does the filing of the BLA itself. Indeed, notice of an intent someday to commence commercial

marketing if and when FDA approval is granted on a product that may change and for one or more unidentified uses is no notice at all.

Only by construing the 180-day period as commencing upon licensure does the statutory scheme work as a whole and achieve Congress's goals.

B. The District Court's Errors

The district court rejected Amgen's proposed construction because it supposedly "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)." A0013. The court stated:

> Had Congress intended to make the exclusivity period twelve and one-half years, it 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.

A0013-14. Both sentences are wrong.

First, as in the Hatch-Waxman Act, "exclusivity" in the BPCIA means a period during which FDA may not approve another product for the same market. *Compare* 42 U.S.C. § 262(k)(7), *with* 21 U.S.C. § 355(j)(5)(B)(iv); *see also Sanofi-Aventis v. Apotex Inc.,* 659 F.3d 1171, 1175 (Fed. Cir. 2011) (Hatch-Waxman's 180-day period of exclusivity is one in "which the FDA would not approve other generic [ ] products . . . ."). The 180-period is not a period of "exclusivity" because it does not prevent the FDA from approving another product during that

period, and there could already be other biosimilars on the market. Rather than conferring exclusivity, the 180 days are simply a waiting period for the Applicant prior to commercial launch that gives the RPS notice so that it can act on the rights afforded under subsections 262(*l*)(8)(B) and (C).

Second, Amgen has never argued that "infringement suits" may commence only upon FDA approval. On the contrary, the statute is clear that the infringement lawsuit under subsection 262(*l*)(6) may commence—and often will commence—long before FDA approval.

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

In addition to holding that the information required under subsection 262(*l*)(2)(A) is not actually required and that notice under subsection 262(*l*)(8)(A) may be given before FDA approval or need not be given at all, the district court erred in holding that the sole remedy for the Applicant's non-compliance is a declaratory judgment action on patent issues under subsection 262(*l*)(9).

With respect to subsection 262(*l*)(2)(A), the district court held that, "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)." A0018 (emphasis added). The court was clear that in its view the declaratory judgment action is the

"exclusive consequence[]" of not providing the required information; an RPS cannot "obtain injunctive relief, restitution, or damages against the applicant." *Id.* Indeed, the district court entered judgment in favor of Sandoz on its counterclaims seeking a declaration that subsection 262(*l*)(9)(C) sets forth the exclusive consequence where an Applicant refuses to provide its BLA and manufacturing information, even if provision of that information "were 'mandatory' as Amgen contends." A0018; A0282-84. Likewise, with respect to subsection 262(*l*)(8)(A), the district court held that Sandoz's failure to provide timely notice, or even its complete failure to provide any notice, "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." A0014 n.8.

This is error. If the information-exchange and notice provisions of Section 262(*l*) are mandatory, then there must be some method of meaningfully remedying injury resulting from non-compliance, including simply compelling such compliance before competitive injury results from the violation. Giving an RPS the ability to bring a declaratory judgment action on patent issues is not an effective or substantive remedy, demonstrating that subsection 262(*l*)(9) is not, as Sandoz would have it, a remedial provision for non-compliance.

A. Subsection 262(*l*)(9) Is a Limitation on Declaratory Judgment Actions

As described above, 42 U.S.C. § 262(*l*)(9), entitled "Limitation on declaratory judgment action," prevents gun-jumping while the parties are following the BPCIA procedures. Subsection 262(*l*)(9)(A) provides that while the parties are following the procedures leading to the creation of patent lists for a subsection 262(*l*)(6) lawsuit, neither party may commence a declaratory judgment action on any other patents until the 180-day notice under subsection 262(*l*)(8)(A) has been given. Subsections 262(*l*)(9)(B) and (C) dispose of that restriction on the RPS's ability to seek a declaratory judgment sooner if the Applicant fails to comply with certain BPCIA provisions. For example, the restriction lifts, for only the RPS, when the Applicant either provides the information required under subsection 262(*l*)(2)(A) yet fails to complete some subsequent required act, or when the Applicant fails to provide the information required under subsection 262(*l*)(2)(A) altogether. 42 U.S.C. § 262(*l*)(9)(B), (C).

Nothing in 42 U.S.C. § 262(*l*)(9) suggests that it is a remedial provision, let alone an exclusive remedy for non-compliance with the statute. Indeed, the BPCIA's limitation on declaratory judgment actions mirrors the related provisions of the Hatch-Waxman Act, which were designed to prevent gun-jumping declaratory judgment actions by ANDA filers. Under the "Civil action to obtain patent certainty" provision of the Hatch-Waxman Act, an ANDA filer who

provides a so-called Paragraph IV certification cannot file a declaratory judgment action until 45 days after providing that certification, in order to allow the innovator to instead file an infringement action during that period. *See* 21 U.S.C § 355(j)(5)(C)(i). Similarly, 42 U.S.C. § 262(*l*)(9) works together with the other provisions of the statute to create a mandatory procedure under which patent disputes are resolved.

B. Subsection 262(*l*)(9) Is Not a Remedial Provision

Subsection 262(*l*)(9)(B) and (C) are not remedies for the harm wrought by non-compliance with the BPCIA, and they provide no rights to the RPS that it did not already have under the Declaratory Judgment Act. Moreover, giving the RPS the ability to bring a declaratory judgment action provides no remedy at all for the harms at issue here: an Applicant's reference of the RPS's license to gain its own abbreviated approval while undermining the RPS's patent rights by refusing to provide the information required by subsection 262(*l*)(2)(A) and providing untimely notice or no notice under subsection 262(*l*)(8)(A).

Without the required disclosures of § 262(*l*)(2)(A), for example, the RPS often will be unable to tell what patents are infringed, and thus on which patents the RPS should commence litigation. Subsection 262(*l*)(9)(C) does not permit the RPS to get this information (through an injunction or otherwise) because it is directed to a "declaration of infringement, validity, or enforceability of any patent

that claims the biological product or a use of the biological product." Indeed, failing to provide manufacturing information can permit an Applicant to avoid litigation altogether. Without the manufacturing information, it is possible that the RPS will not have enough information to bring suit, whether for a declaratory judgment or otherwise. Having required the provision of manufacturing information to identify patent infringement, Congress could not have intended for Applicants to insulate themselves from suit by permitting non-compliance in favor of a declaration of rights on patents not directed to manufacturing processes.

Likewise, subsection 262(*l*)(9)(B) is not a remedy for a failure to give timely notice under subsection 262(*l*)(8)(A). It is true that subsection 262(*l*)(9)(B) lifts the bar to declaratory judgment actions of infringement by the RPS where the Applicant "fails to complete an action required of" it, and that one of those "required" actions is providing notice under "paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(B). But that does not mean that subsection 262(*l*)(9)(B) is a remedy for those failures. Consider, for example, the failure of the Applicant to provide FDA a copy of the complaint in a subsection 262(*l*)(6) lawsuit within 30 days of service, as required by subsection 262(*l*)(6)(C)(i). Failure to send the complaint also lifts the declaratory judgment bar for the RPS under subsection 262(*l*)(9)(B). But a patent declaratory judgment action brought by the RPS does not cure, or even have any direct relationship to, an Applicant's failure to send a complaint to FDA.

In the same way, a declaratory judgment action under subsection 262(*l*)(9)(B) would not remedy the harm resulting from failure to provide timely notice under subsection 262(*l*)(8)(A). If the Applicant begins commercial marketing without notice, the RPS will sue it for infringement under 35 U.S.C. § 271, seeking emergency relief. Filing a declaratory judgment action does not remedy the harm caused by commercial launch. And if part of the purpose of the 180-day notice provision in subsection 262(*l*)(8)(A) is to permit the orderly preliminary injunction process in subsection 262(*l*)(8)(B), a declaratory judgment action is no remedy for the failure to give that 180 days' notice.

C. Subsection 262(*l*)(9) Is Not An Exclusive Remedy

Subsection 262(*l*)(9) is not remedial. Neither is it the exclusive consequence of non-compliance with the BPCIA.

First, nothing in the BPCIA says the declaratory judgment actions under subsection 262(*l*)(9) are exclusive. The statute says that if the Applicant fails to take a required action, the RPS "may" bring a declaratory judgment action. It does not say "shall bring" a declaratory judgment action, nor does it say "may bring only" a declaratory judgment action, nor does it say anything about a declaratory judgment action being an exclusive remedy.

Congress knew how to specify when it intended BPCIA remedies to be exclusive, as it did in 35 U.S.C. § 271(e)(2). There, Congress wrote, "The

remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285." 35 U.S.C. § 271(e)(4). And in limiting the relief available where an RPS fails to commence a subsection 262(*l*)(6) lawsuit on a listed patent within the thirty-day period, Congress wrote, "the sole and exclusive remedy that may be granted" for that patent "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6)(B). There is no similar language in subsection 262(*l*)(9) stating that it is the sole and exclusive remedy for a violation of subsection 262(*l*)(2)(A).

D. District Courts Should Have Broad Power to Compel Compliance With the BPCIA

The district court erred in holding that there is no remedy, in federal or state law, to compel an Applicant to provide its BLA and manufacturing information or to provide timely notice of commercial marketing. A0018. Amgen submits that the BPCIA does not prohibit any cause of action that could remedy those harms.

Indeed, the district court's decision, which enters judgment on Sandoz's counterclaims that its interpretation of the BPCIA are correct, implies that Amgen could have brought an action under the BPCIA itself to enforce the exchange and notice provisions under its interpretation of the statute. If Sandoz's counterclaims that the statute is not mandatory are justiciable, then this Court or the district court

on remand can and should enter judgment on them in favor of Amgen, holding that the statute is mandatory.

Amgen chose to bring state-law claims rather than a cause of action under the BPCIA itself, and it was entirely appropriate for Amgen to do so. The state-law claims that Amgen pleaded represent part of an array of tools that should be available to an RPS and to the courts where an Applicant avails itself of the BPCIA abbreviated approval pathway but refuses to comply with other provisions of the BPCIA.

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

Amgen's principal place of business is in California. It sought relief for Sandoz's unlawful conduct under California law.

First, Amgen sued under California's UCL, which prohibits "any unlawful, unfair or fraudulent business act or practice[.]" Cal. Bus. & Prof. Code § 17200. The California Supreme Court has explained that the "unlawful" prong of the UCL "'borrows' violations of other laws and treats these violations, when committed pursuant to business activity, as unlawful practices independently actionable" under the UCL. *Farmers Ins. Exch. v. Superior Court*, 2 Cal. 4th 377, 383 (1992). Violations of federal statutes satisfy the "unlawful" prong of a UCL claim. *See, e.g., Citizens for a Better Env't-California v. Union Oil of California*, 996 F. Supp. 934, 938 (N.D. Cal. 1997) (UCL liability predicated on violation of Clean Water

Act); *Southwest Marine, Inc. v. Triple A Mach. Shop, Inc.*, 720 F. Supp. 805, 808 (N.D. Cal. 1989) (federal environmental laws); *Ballard v. Equifax Check Servs., Inc.*, 158 F. Supp. 2d 1163, 1176 (E.D. Cal. 2001) (federal Fair Debt Collection Practices Act). Here, Sandoz violated the UCL by seeking FDA approval of a biosimilar product under the BPCIA while it unlawfully refused to comply with the requirements of that statute that benefit Amgen, including by withholding its BLA and manufacturing information and by providing premature notice of commercial marketing.

Second, Amgen sued Sandoz for conversion, because Sandoz referenced Amgen's License for NEUPOGEN® and benefited from the work that Amgen did to obtain that license, without Amgen's consent and without providing to Amgen the benefits to which it is entitled under subsection 262(*l*). California conversion claims may be based on misuse of privileges and rights under federal law as well. *See*, *e.g, G.S. Rasmussen & Assocs., Inc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896, 903 (9th Cir. 1992). That case was about Federal Aviation Administration "Supplemental Type Certificates," which allow an airplane owner to get an airworthiness certificate for a design modification without the cost and delay of proving to the FAA that the modified plane will be safe. *Id.* at 899. Kalitta used Rasmussen's STC without Rasmussen's permission. *Id.* at 906-07. The Ninth Circuit held that Rasmussen stated a claim for conversion based on Kalitta's

improper conversion of Rasmussen's certificate to its own advantage. *Id.* at 908. So, too, here. Where Sandoz improperly uses Amgen's FDA license, Amgen has a valid claim for conversion.

2. The District Court's Errors

The district court held that there is no basis "for the sponsor to obtain injunctive relief, restitution, or damages" against an Applicant that fails to disclose the required BLA and manufacturing information, A0018, and asserted that it is "untenable" and "unworkable" for Congress to have intended an RPS to bring state law claims to enforce the BPCIA. A0008 n.4, 15. There is no requirement, however, that Congress have "intended" or "contemplated" state-law remedies. Those remedies exist under state law. They are rendered unavailable by federal law only under doctrines of preemption. The district court did not find preemption, nor did Sandoz argue that preemption applies. A0001-19; A1854-55, 76-77. There is no basis for a finding of preemption here, because no provision of the BPCIA conflicts with Amgen's state-law claims or states that Congress intended to displace state-law claims. *See, e.g., Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (preemption applies "either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively . . . or when state law is in actual conflict with federal law.").

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

A. The District Court's Likelihood-of-Success Decision Rests on Errors of Law

The district court denied Amgen's motion for a preliminary injunction, concluding that Amgen "cannot demonstrate serious questions as to the merits, let alone a likelihood of success[.]" A0017. As discussed above, the district court's reading of the BPCIA was erroneous. Thus, Amgen respectfully requests that this Court reverse the district court's denial of the preliminary injunction. *See, e.g.*, *Trebro Mfg., Inc. v. Firefly Equipment, LLC*, 748 F.3d 1159 (Fed Cir. 2014) (applying Ninth Circuit law to reverse denial of preliminary injunction).

B. The District Court Abused Its Discretion in Finding That Amgen Had Not Demonstrated Irreparable Harm

The district court abused its discretion in concluding that Amgen did not "carry its burden to demonstrate that irreparable harm will result in the absence of injunctive relief" and that that Amgen's harms are "highly speculative" and based on the as-yet unproven premise of patent infringement by Sandoz. A0017-18.

First, the harm to Amgen does not rest on the premise that Sandoz has infringed an Amgen patent. Amgen will suffer irreparable harm from ZARXIO® being on the market for the up-to-410 day period specified in the BPCIA procedure for patent-dispute resolution, with which Sandoz refused to comply.

Second, the harm wrought by price erosion is not "highly speculative." A0018. [redacted] Thus, to compete against ZARXIO®, Amgen will have to lower the price of NEUPOGEN®. A0477-79 (A0474-81); A0516-17. Once the price is lowered "it would be very difficult if not impossible for Amgen to simply raise its prices back to what they were before Zarxio competition." A0479. Accordingly, Amgen will face price erosion, just as any innovative pharmaceutical would suffer harm from unlawful generic competition. *See, e.g.*, *Abbott Labs. v. Sandoz Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (generic Biaxin®); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006) (generic Plavix®).

Third, the district court abused its discretion in ignoring one category of Amgen's irreparable harm showing, patent uncertainty. It is undisputed that Amgen has approximately 400 patents directed to methods of manufacturing recombinant proteins. A0473. By refusing to provide its BLA and manufacturing information as required by § 262(*l*)(2)(A), Sandoz made it impossible for Amgen to determine which of these patents read on the manufacture of Sandoz's biological product. Allowing an Applicant to market its product without complying with the BPCIA procedures that protect the RPS's patent rights undermines the value of

those patents irreparably. This is the unrebutted testimony of Amgen's economic expert. *See* A0518-19; A1749-50.

Finally, the district court abused its discretion in finding that harm to Amgen's customer relationships and goodwill was speculative. A0017-18. The unrebutted testimony of Amgen's witnesses is that Amgen would be forced to lower the net price of NEUPOGEN® if Sandoz priced its biosimilar filgrastim product lower than NEUPOGEN®. A0477-79; A0516-17. Any rapid attempt to rehabilitate NEUPOGEN®'s price would put customers underwater, fostering animosity toward Amgen. A0479-80.

C. The Balance of Equities and Public Interest Factors Favor the Grant of an Injunction

The balance of the equities and the public interest—neither of which the district court addressed—favor a preliminary injunction.

Without an injunction, Amgen faces diminution in the value of its patents, irreparable price erosion, and a loss of goodwill. A0493-95, 515-26. While Sandoz faces the possibility that another biosimilar filgrastim product could launch while Sandoz complied with the BPCIA, any such harm is of Sandoz's own making. Had Sandoz timely complied with the BPCIA, it would have been many months ahead of its closest competitor.

The public interest also favors an injunction. This Court has recognized that there is a strong public interest in encouraging investment in drug development and

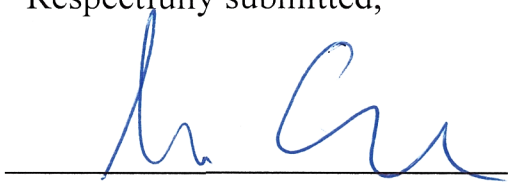
the fact that a generic may sell at a lower price does not override that important concern. *Sanofi-Synthelabo*, 470 F.3d at 1383-84. The same reasoning applies here because the BPCIA provisions are intended to foster innovation.

CONCLUSION

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

Dated: April 3, 2015

Respectfully submitted,



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ADDENDUM

INDEX TO ADDENDUM

§ 257a. Transferred

CODIFICATION

Section, Pub. L. 91–513, title I, § 4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which related to medical treatment of narcotics addiction, was transferred to section 290bb–2a of this title.

§ 258. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section, acts July 1, 1944, ch. 373, title III, § 342, 58 Stat. 699; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91–513, title I, § 2(a)(2)(A), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, related to employment, establishment of industries, plants, etc., sale of commodities, and disposition of proceeds.

§ 258a. Transferred

CODIFICATION

Section, act July 8, 1947, ch. 210, title II, § 201, 61 Stat. 269, which related to transfer of balances in working capital fund, narcotic hospitals, to surplus fund, was transferred and is set out as a note under section 290aa of this title.

§§ 259 to 261a. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section 259, acts July 1, 1944, ch. 373, title III, § 343, 58 Stat. 699; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–293, § 3, May 11, 1972, 86 Stat. 136; Pub. L. 98–473, title II, § 232(b), Oct. 12, 1984, 98 Stat. 2031, related to convict addicts or other persons with drug abuse or drug dependence problems.

Section 260, acts July 1, 1944, ch. 373, title III, § 344, 58 Stat. 701; June 25, 1948, ch. 654, § 5, 62 Stat. 1018; July 24, 1956, ch. 676, title III, § 302(b), 70 Stat. 622; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240, related to addicts and persons with drug abuse or drug dependence problems.

Section 260a, act July 1, 1944, ch. 373, title III, § 345, as added May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended July 24, 1956, ch. 676, title III, § 302(c), 70 Stat. 622; Pub. L. 91–358, title I, § 155(c)(32), July 29, 1970, 84 Stat. 572, related to admission of addicts committed from District of Columbia.

Section 261, acts July 1, 1944, ch. 373, title III, § 346, formerly § 345, 58 Stat. 701; renumbered § 346, May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended Pub. L. 91–513, title I, § 2(a)(2)(A), (5), Oct. 27, 1970, 84 Stat. 1240, related to penalties for introducing prohibited articles and substances into hospitals and escaping from, or aiding and abetting escape from hospitals.

Section 261a, act July 1, 1944, ch. 373, title III, § 347, as added May 8, 1954, ch. 195, § 4, 68 Stat. 80; amended Pub. L. 91–513, title I, § 2(a)(4), Oct. 27, 1970, 84 Stat. 1240, related to release of patients and determination by Surgeon General.

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c) of this section.

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(*o*), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(*o*), (p), 355–1].

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest ⅒ of 1 percent. For purposes of this paragraph, the term ''base quarter'', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et. seq.] if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) "Biological product" defined

In this section:

(1) The term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term ''biosimilar'' or ''biosimilarity'', in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term ''interchangeable'' or ''interchangeability'', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term ''reference product'' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(*o*), 505(p), and 505–1 of such Act [21 U.S.C. 355(*o*), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended

to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term ''final court decision'' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection 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).

(B) Filing period

An application under this subsection 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).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the ''subsection (k) applicant'') and the sponsor of the application for the reference product (referred to in this subsection as the ''reference product sponsor''), the provisions

of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(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 (referred to in this subsection as the ''confidential information'').

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the ''outside counsel''), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) 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—

(A) 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; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(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).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

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).

(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.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (*l*), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (i), (j), (k), (*l*), (p), (q)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3)[1] [21 U.S.C. 355a(d)(3)] is made later than 9 months prior to the expiration of such period.

(July 1, 1944, ch. 373, title III, § 351, 58 Stat. 702; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 85–881, § 2, Sept. 2, 1958, 72 Stat. 1704; Pub. L. 91–515, title II, § 291, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–660, title I, § 105(a), title III, § 315, Nov. 14, 1986, 100 Stat. 3751, 3783; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 104–134, title II, §§ 2102(d)(2), 2104, Apr. 26, 1996, 110 Stat. 1321–319, 1321–320; Pub. L. 105–115, title I, § 123(a)–(d), (g), Nov. 21, 1997, 111 Stat. 2323, 2324; Pub. L. 108–155, § 2(b)(3), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title IX, § 901(c), Sept. 27, 2007, 121 Stat. 939; Pub. L. 111–148, title VII, § 7002(a), (b), (g)(1), Mar. 23, 2010, 124 Stat. 804, 814, 819.)

REFERENCES IN TEXT

The effective date of this paragraph, referred to in subsec. (d)(2), is the effective date of section 315 of Pub. L. 99–660 which added subsec. (d)(2). See Effective Date of 1986 Amendment note set out below.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (g), (h), (j), and (k)(5)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Sections 526, 527(a), and 505A(d)(3), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which are classified to sections 360bb, 360cc(a), and 355a(d)(3), respectively, of Title 21, Food and Drugs.

AMENDMENTS

2010—Subsec. (a)(1)(A). Pub. L. 111–148, § 7002(a)(1), inserted ''under this subsection or subsection (k)'' after ''biologics license''.

Subsec. (i). Pub. L. 111–148, § 7002(b), substituted ''In this section:'' for ''In this section,'', designated remainder of existing provisions as par. (1), substituted ''The term'' for ''the term'', inserted ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,'', and added pars. (2) to (4).

Subsecs. (k), (*l*). Pub. L. 111–148, § 7002(a)(2), added subsecs. (k) and (*l*).

[1] See References in Text note below.

Subsec. (m). Pub. L. 111–148, §7002(g)(1), added subsec. (m).

2007—Subsec. (a)(2)(D). Pub. L. 110–85, §901(c)(1), added subpar. (D).

Subsec. (j). Pub. L. 110–85, §901(c)(2), inserted '', including the requirements under sections 505(*o*), 505(p), and 505–1 of such Act,'' after ''and Cosmetic Act''.

2003—Subsec. (a)(2)(B), (C). Pub. L. 108–155 added subpar. (B) and redesignated former subpar. (B) as (C).

1997—Subsec. (a). Pub. L. 105–115, §123(a)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to intrastate and interstate traffic in biological products and suspension or revocation of licenses as affecting prior sales.

Subsec. (b). Pub. L. 105–115, §123(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.''

Subsec. (c). Pub. L. 105–115, §123(c), substituted ''biological product.'' for ''virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession.''

Subsec. (d). Pub. L. 105–115, §123(a)(2), designated par. (2) as subsec. (d), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, in par. (2), substituted ''Any violation of paragraph (1)'' for ''Any violation of subparagraph (A)'' and substituted ''this paragraph'' for ''this subparagraph'' wherever appearing, and struck out former par. (1) which read as follows: ''Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.''

Subsec. (i). Pub. L. 105–115, §123(d), added subsec. (i).

Subsec. (j). Pub. L. 105–115, §123(g), added subsec. (j).

1996—Subsec. (h). Pub. L. 104–134, §2104, amended subsec. (h) generally, revising and restating former provisions, which also related to exportation of partially processed biological products.

Subsec. (h)(1)(A). Pub. L. 104–134, §2102(d)(2), substituted ''in a country listed under section 802(b)(1)'' for ''in a country listed under section 802(b)(A)'' and ''to a country listed under section 802(b)(1)'' for ''to a country listed under section 802(b)(4)''.

1992—Subsec. (c). Pub. L. 102–300, which directed substitution of ''Health and Human Services'' for ''Health, Education, and Welfare'', could not be executed because the words ''Health, Education, and Welfare'' did not appear in original statutory text. Previously, references to Department and Secretary of Health and Human Services were substituted for references to Federal Security Agency and its Administrator pursuant to provisions cited in Transfer of Functions note below.

1986—Subsec. (d). Pub. L. 99–660, §315, designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 99–660, §105(a), added subsec. (h).

1970—Subsecs. (a) to (c). Pub. L. 91–515 inserted ''vaccine, blood, blood component or derivative, allergenic product,'' after ''antitoxin'' wherever appearing.

1958—Subsec. (d). Pub. L. 85–881 struck out ''made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Secretary'' after ''regulations'' in first sentence.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1986 AMENDMENT

Section 105(b) of Pub. L. 99–660 provided that: ''Paragraph (1) of section 351(h) of the Public Health Service Act [former subsec. (h)(1) of this section] as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Nov. 14, 1986].''

Amendment by section 315 of Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

References to Secretary and Department of Health, Education, and Welfare substituted for references to Federal Security Administrator and Federal Security Agency, respectively, pursuant to Reorg. Plan No. 1 of 1953, §5, set out as a note under section 3501 of this title, which transferred all functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953. Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20.

PRODUCTS PREVIOUSLY APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Pub. L. 111–148, title VII, §7002(e), Mar. 23, 2010, 124 Stat. 817, provided that:

''(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

''(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

''(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act [Mar. 23, 2010]; and

''(B) such application—

''(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the 'Secretary') before the date of enactment of this Act; or

''(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

''(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act [42 U.S.C. 262] that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

''(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

''(5) DEFINITIONS.—For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).''

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Pub. L. 111–148, title VII, § 7002(f)(3)(B), (C), Mar. 23, 2010, 124 Stat. 818, 819, provided that:

''(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act [Mar. 23, 2010] and ending on October 1, 2010, the Secretary [of Health and Human Services] shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act) during such period.

''(C) AUDIT.—

''(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

''(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

''(II)(aa) such ratio determined under subclause (I); to

''(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act [42 U.S.C. 262(a)] (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

''(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) [42 U.S.C. 262(k)] to more appropriately account for the costs of reviewing such applications.

''(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.''

LICENSING OF ORPHAN PRODUCTS

Pub. L. 111–148, title VII, § 7002(h), Mar. 23, 2010, 124 Stat. 821, provided that: ''If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary [of Health and Human Services] only after the expiration for such reference product of the later of—

''(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

''(2) the 12-year period described in subsection (k)(7) of such section 351.''

SAVINGS GENERATED BY 2010 AMENDMENT

Pub. L. 111–148, title VII, § 7003, Mar. 23, 2010, 124 Stat. 821, provided that:

''(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title].

''(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.''

ENHANCED PENALTIES AND CONTROL OF BIOLOGICAL AGENTS

Pub. L. 104–132, title V, § 511, Apr. 24, 1996, 110 Stat. 1284, as amended by Pub. L. 107–188, title II, § 204, June 12, 2002, 116 Stat. 647, provided that:

''(a) FINDINGS.—The Congress finds that—

''(1) certain biological agents have the potential to pose a severe threat to public health and safety;

''(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

''(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

''(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

''(b) CRIMINAL ENFORCEMENT.—[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

''(c) TERRORISM.—[Amended section 2332a of Title 18.]''

§ 262a. Enhanced control of dangerous biological agents and toxins

(a) Regulatory control of certain biological agents and toxins

(1) List of biological agents and toxins

(A) In general

The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

(July 19, 1952, ch. 950, 66 Stat. 810; Pub. L. 103–465, title V, § 533(b)(3), Dec. 8, 1994, 108 Stat. 4989.)

HISTORICAL AND REVISION NOTES

This section states a condition in existing law not expressed in the existing statutes.

AMENDMENTS

1994—Pub. L. 103–465 substituted ''use, offer to sell, or sell'' for ''use or sell'' and inserted ''within the United States, or import the patented invention into the United States,'' after ''invention''.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

CHAPTER 27—GOVERNMENT INTERESTS IN PATENTS

AMENDMENTS

1965—Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261, struck out item 266 ''Issue of patents without fees to Government employees''.

[§ 266. Repealed. Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261]

Section, act July 19, 1952, ch. 950, § 1, 66 Stat. 811, provided for issuance of patents to government employees without fees.

EFFECTIVE DATE OF REPEAL

Repeal effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as an Effective Date of 1965 Amendment note under section 41 of this title.

§ 267. Time for taking action in Government applications

Notwithstanding the provisions of sections 133 and 151, the Director may extend the time for taking any action to three years, when an application has become the property of the United States and the head of the appropriate department or agency of the Government has certified to the Director that the invention disclosed therein is important to the armament or defense of the United States.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906; Pub. L. 112–29, § 20(j), Sept. 16, 2011, 125 Stat. 335.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 37 (R.S. 4894, amended (1) Mar. 3, 1897, ch. 391, § 4, 29 Stat. 692, 693, (2) July 6, 1916, ch. 225, § 1, 39 Stat. 345, 347–8, (3) Mar. 2, 1927, ch. 273, § 1, 44 Stat. 1335, (4) Aug. 7, 1939, ch. 568, 53 Stat. 1264).

This provision, which appears as the last two sentences of the corresponding section of the present statute (see note to section 133) is made a separate section and rewritten in simpler form.

AMENDMENTS

2011—Pub. L. 112–29 struck out ''of this title'' after ''151''.

2002—Pub. L. 107–273 made technical correction to directory language of Pub. L. 106–113. See 1999 Amendment note below.

1999—Pub. L. 106–113, as amended by Pub. L. 107–273, substituted ''Director'' for ''Commissioner'' in two places.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 20(j) of Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

CHAPTER 28—INFRINGEMENT OF PATENTS

AMENDMENTS

2011—Pub. L. 112–29, § 5(b), Sept. 16, 2011, 125 Stat. 299, amended item 273 generally, substituting ''Defense to infringement based on prior commercial use'' for ''Defense to infringement based on earlier inventor''.

1999—Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4302(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–557, added item 273.

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from

acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) 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 patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term ''whoever'' includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an ''offer for sale'' or an ''offer to sell'' by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 98–417, title II, § 202, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 98–622, title I, § 101(a), Nov. 8, 1984, 98 Stat. 3383; Pub. L. 100–418, title IX, § 9003, Aug. 23, 1988, 102 Stat. 1563; Pub. L. 100–670, title II, § 201(i), Nov. 16, 1988, 102 Stat. 3988; Pub. L. 100–703, title II, § 201, Nov. 19, 1988, 102 Stat. 4676; Pub. L. 102–560, § 2(a)(1), Oct. 28, 1992, 106 Stat. 4230; Pub. L. 103–465, title V, § 533(a), Dec. 8, 1994, 108 Stat. 4988; Pub. L. 108–173, title XI, § 1101(d), Dec. 8, 2003, 117 Stat. 2457; Pub. L. 111–148, title VII, § 7002(c)(1), Mar. 23, 2010, 124 Stat. 815.)

HISTORICAL AND REVISION NOTES

The first paragraph of this section is declaratory only, defining infringement.

Paragraphs (b) and (c) define and limit contributory infringement of a patent and paragraph (d) is ancillary to these paragraphs, see preliminary general description of bill. One who actively induces infringement as by aiding and abetting the same is liable as an infringer, and so is one who sells a component part of a patented invention or material or apparatus for use therein knowing the same to be especially made or especially adapted for use in the infringement of the patent except in the case of a staple article or commodity of commerce having other uses. A patentee is not deemed to have misused his patent solely by reason of doing anything authorized by the section.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(1), (2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. Sections 505 and 512 of the Act are classified to sections 355 and 360b, respectively, of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Act of March 4, 1913, referred to in subsec. (e)(1), (2), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are contained in the eighth paragraph under the heading ''Bureau of Animal Industry'' of act Mar. 4, 1913, at 37 Stat. 832, and are classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

Section 351 of the Public Health Service Act, referred to in subsec. (e)(2)(C), (4)(D), (6)(A), (C), is classified to section 262 of Title 42, The Public Health and Welfare.

AMENDMENTS

2010—Subsec. (e)(2). Pub. L. 111–148, § 7002(c)(1)(A)(iv), substituted '', veterinary biological product, or biological product'' for ''or veterinary biological product'' in concluding provisions.

Subsec. (e)(2)(C). Pub. L. 111–148, § 7002(c)(1)(A)(i)–(iii), added subpar. (C).

Subsec. (e)(4). Pub. L. 111–148, §7002(c)(1)(B)(iv), substituted ''(C), and (D)'' for ''and (C)'' in concluding provisions.

Subsec. (e)(4)(B). Pub. L. 111–148, §7002(c)(1)(B)(i), substituted '', veterinary biological product, or biological product'' for ''or veterinary biological product'' and struck out ''and'' at end.

Subsec. (e)(4)(C). Pub. L. 111–148, §7002(c)(1)(B)(ii), substituted '', veterinary biological product, or biological product'' for ''or veterinary biological product'' and '', and'' for period at end.

Subsec. (e)(4)(D). Pub. L. 111–148, §7002(c)(1)(B)(iii), added subpar. (D).

Subsec. (e)(6). Pub. L. 111–148, §7002(c)(1)(C), added par. (6).

2003—Subsec. (e)(5). Pub. L. 108–173 added par. (5).

1994—Subsec. (a). Pub. L. 103–465, §533(a)(1), inserted '', offers to sell,'' after ''uses'' and ''or imports into the United States any patented invention'' after ''the United States''.

Subsec. (c). Pub. L. 103–465, §533(a)(2), substituted ''offers to sell or sells within the United States or imports into the United States'' for ''sells''.

Subsec. (e)(1). Pub. L. 103–465, §533(a)(3)(A), substituted ''offer to sell, or sell within the United States or import into the United States'' for ''or sell''.

Subsec. (e)(3). Pub. L. 103–465, §533(a)(3)(B), substituted ''offering to sell, or selling within the United States or importing into the United States'' for ''or selling''.

Subsec. (e)(4)(B), (C). Pub. L. 103–465, §533(a)(3)(C), (D), substituted ''offer to sell, or sale within the United States or importation into the United States'' for ''or sale''.

Subsec. (g). Pub. L. 103–465, §533(a)(4), substituted ''offers to sell, sells,'' for ''sells'', ''importation, offer to sell, sale,'' for ''importation, sale,'', and ''other use, offer to sell, or'' for ''other use or''.

Subsec. (i). Pub. L. 103–465, §533(a)(5), added subsec. (i).

1992—Subsec. (h). Pub. L. 102–560 added subsec. (h).

1988—Subsec. (d). Pub. L. 100–703 added cls. (4) and (5).

Subsec. (e)(1). Pub. L. 100–670, §201(i)(1), inserted ''which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques'' after ''March 4, 1913)'' and ''or veterinary biological products'' after ''sale of drugs''.

Subsec. (e)(2). Pub. L. 100–670, §201(i)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.''

Subsec. (e)(4). Pub. L. 100–670, §201(i)(3), inserted ''or veterinary biological product'' after ''drug'' in subpars. (A) to (C).

Subsec. (g). Pub. L. 100–418 added subsec. (g).

1984—Subsec. (e). Pub. L. 98–417 added subsec. (e).

Subsec. (f). Pub. L. 98–622 added subsec. (f).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–560 effective with respect to violations that occur on or after Oct. 28, 1992, see section 4 of Pub. L. 102–560, set out as a note under section 2541 of Title 7, Agriculture.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–703, title II, §202, Nov. 19, 1988, 102 Stat. 4676, provided that: ''The amendment made by this title [amending this section] shall apply only to cases filed on or after the date of the enactment of this Act [Nov. 19, 1988].''

Pub. L. 100–418, title IX, §9006, Aug. 23, 1988, 102 Stat. 1566, provided that:

''(a) IN GENERAL.—The amendments made by this subtitle [subtitle A (§§9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending this section and sections 154 and 287 of this title] take effect 6 months after the date of enactment of this Act [Aug. 23, 1988] and, subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.

''(b) EXCEPTIONS.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This subsection shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

''(c) RETENTION OF OTHER REMEDIES.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930 [19 U.S.C. 1337], or under any other provision of law.''

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–622 applicable only to the supplying, or causing to be supplied, of any component or components of a patented invention after Nov. 8, 1984, see section 106(c) of Pub. L. 98–622, set out as a note under section 103 of this title.

REPORTS TO CONGRESS; EFFECT ON DOMESTIC INDUSTRIES OF PROCESS PATENT AMENDMENTS ACT OF 1988

Pub. L. 100–418, title IX, §9007, Aug. 23, 1988, 102 Stat. 1567, provided that the Secretary of Commerce was to make annual reports to Congress covering each of the successive five 1-year periods beginning 6 months after Aug. 23, 1988, on the effect of the amendments made by subtitle A (§§9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending sections 154, 271, and 287 of this title, on those domestic industries that submit complaints to the Department of Commerce alleging that their legitimate sources of supply have been adversely affected by the amendments.

§ 272. Temporary presence in the United States

The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 103–465, title V, §533(b)(4), Dec. 8, 1994, 108 Stat. 4989.)

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

[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.

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

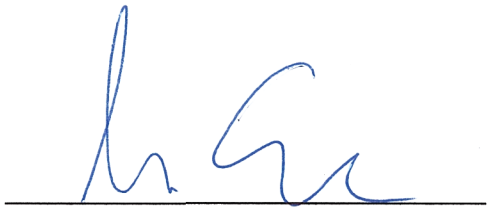
THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). The brief contains 13,949 words, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b). The word count includes the words counted by the Microsoft Word 2010 function.

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point font of Times New Roman.

Dated: April 3, 2015



Nicholas Groombridge

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd of April, 2015, I caused the foregoing Non-Confidential Opening Brief of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the foregoing Non-Confidential Opening Brief of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

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