No. 2015-1499

United States Court of Appeals for the Federal Circuit

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

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

NON-CONFIDENTIAL BRIEF FOR DEFENDANT-APPELLEE SANDOZ INC.

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APRIL 21, 2015

CERTIFICATE OF INTEREST

Counsel for defendant-appellee Sandoz Inc. certifies the following:

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

Sandoz Inc.

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

N/A

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

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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

Morrison & Foerster LLP: Rachel Krevans, Deanne E. Maynard, Grant J. Esposito, Joseph R. Palmore, Erik J. Olson, David C. Doyle, Marc A. Hearron, Anders T. Aannestad, Eric C. Pai, Stephen D. Keane, Julie Y. Park. Kirkland & Ellis LLP: James F. Hurst, Michael D. Shumsky, John K. Crisham, Reid P. Huefner.

Dated: April 21, 2015 /s/ Deanne E. Maynard

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CONFIDENTIAL MATERIAL

Materials that were made confidential pursuant to the protective order have been highlighted in the confidential version of the brief and redacted from the non-confidential version of the brief. These materials include confidential business information from internal documents, deposition transcripts, and other exhibits filed in the district court.

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STATEMENT OF RELATED CASES

Counsel for defendant-appellee Sandoz Inc. are aware of one pending case that may be affected directly by this Court's decision: *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, No. 15-cv-10698 (D. Mass. filed Mar. 6, 2015). Counsel are unaware of any other pending case in this or any other court that directly will affect or be affected by this Court's decision.

JURISDICTIONAL STATEMENT

Sandoz agrees with the statement by plaintiffs-appellants Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen"), except that Amgen's appeal from the preliminary injunction denial is moot. *Infra*, Part IV.A.

STATEMENT OF THE ISSUES

1. Whether, as the district court concluded, a biosimilar applicant acts lawfully under the Biologics Price Competition and Innovation Act ("BPCIA") when, as the BPCIA expressly contemplates, it declines to provide its biologics application to the reference product sponsor under 42 U.S.C. § 262(*l*)(2)(A) and allows the sponsor to commence an immediate suit for patent infringement, 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C).

2. Whether, as the district court concluded, a biosimilar applicant acts lawfully under the BPCIA when it provides "[n]otice of commercial marketing," 42 U.S.C. § 262(*l*)(8)(A), to the sponsor at least 180 days before commercially marketing its biosimilar product, regardless of whether the product is licensed by the FDA at the time of the notice.

3. Whether, as the district court concluded, a sponsor is limited to the sole recourse expressly provided in the BPCIA – the patent infringement suit Amgen already has filed.

4. Whether (a) Amgen's preliminary injunction appeal is moot, and (b) even if not moot, the preliminary injunction denial should be affirmed because it is based on factual findings that are not clearly erroneous.

INTRODUCTION

To prevail on appeal, Amgen must demonstrate *both* that Sandoz acted "unlawfully" when it took procedural paths expressly provided by the Biologics Price Competition and Innovation Act *and* that Amgen is entitled to have courts provide relief foreclosed by the BPCIA. Amgen can make neither showing. Sandoz's actions fully complied with the BPCIA, and the statute itself provides Amgen's sole recourse: litigation to assert any patent rights.

At the time Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act, purchases of biological pharmaceuticals represented 21% of the $307 billion spent annually on medicines, and those expenditures were increasing materially. A389-A391. The record before Congress showed that introducing more competition into this market could save government and private payors tens of billions of dollars.[1] Congress thus enacted the BPCIA to promote competition in the biologics market and reduce prices.

The BPCIA created a new, abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products – i.e., biological products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The BPCIA allows a biosimilar applicant to rely in part on the

[1] *See, e.g.*, Judith A. Johnson, Cong. Research Serv., RL34045, FDA Regulation of Follow-On Biologics 3 (2009).

sponsor's license for the approved reference product. *Id.* § 262(k). In return, sponsors of approved biological products receive a full 12 years of market exclusivity – regardless of whether they have any valid patent claims. *Id.* § 262(k)(7)(A).

The BPCIA also created a carefully reticulated patent-resolution regime. Those patent-resolution provisions go well beyond the patent-exchange process in Section 262(*l*) on which Amgen focuses. The BPCIA made interlocking amendments to Titles 28, 35, and 42 of the U.S. Code. A423-A440 (BPCIA, Pub. L. No. 111-148, 124 Stat. 804 (2010) (codified at 28 U.S.C. § 2201(b); 35 U.S.C. § 271(e)(2)(C), (4)(D), (6); 42 U.S.C. § 262(k)-(m))). These patent-resolution provisions are intended to resolve any patent disputes as early as possible, preferably before FDA approval of the biosimilar.

Specifically, the BPCIA creates a new "artificial" act of infringement that allows litigation of disputes before any actual infringement occurs. 35 U.S.C. § 271(e)(2)(C). In addition, the BPCIA specifies the circumstances governing which party (the applicant and/or the sponsor) may commence a pre-approval suit based on this artificial infringement, when such a suit can be brought, which patents can be included, and what the patent remedies can be. *Id.* § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*). The particular contours of any

such suit depend on the actions taken or not taken by the applicant and the sponsor at each step of the process.

As just one component of this comprehensive patent-resolution scheme, the BPCIA sets out a back-and-forth, multi-step process of information exchange between the applicant and the sponsor regarding the sponsor's possible patent claims. 42 U.S.C. § 262(*l*)(2)-(6). At each of those steps, Congress carefully spelled out both the action the party "shall" take to continue with the process and, if the party declines, what follows. Each step has benefits and burdens for both the sponsor and the applicant. Critically, none of those steps is an end unto itself. Instead, each is simply a procedural means to a substantive goal: resolving patent disputes so that non-infringing biosimilars can be available to patients as expeditiously as possible.

The first issue in this appeal involves one of those sequenced "shall" provisions. Section 262(*l*)(2)(A) provides that, within 20 days of the FDA's acceptance of a biosimilar application, the applicant "shall provide" a copy of the application to the reference product sponsor as the first step in the patent-exchange process. *Id.* § 262(*l*)(2)(A). The BPCIA then expressly lays out a separate path for resolving any patent disputes in the event the applicant does not take that step: patent infringement litigation, with the scope and timing at the sole discretion of the sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

Amgen plucks one word – "shall" – out of Section 262(*l*)(2)(A); observes that "shall" is "generally, mandatory"; and contends that an applicant therefore must be acting "unlawfully" if the applicant does not provide its application to the sponsor within 20 days. But when subsection (*l*)(2) is viewed in context (as it must be), Amgen cannot be right. Like subsection (*l*)(2), subsection (*l*)(6) provides that the sponsor "*shall* bring an action for patent infringement" within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). It cannot seriously be contended that this "shall" mandates that the sponsor *must* sue the applicant *in all circumstances*, or else it has violated the BPCIA. To the contrary, Congress expressly contemplated that the applicant or the sponsor might *not* take the "shall" actions in subsections (*l*)(2) and (*l*)(6), and provided the consequences for not doing so. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(6)(A)-(B).

Taking a procedural path that the BPCIA expressly laid out cannot be unlawful conduct. Rather, as the district court correctly concluded, each "shall" in subsection (*l*) simply establishes a mandatory condition precedent that *must* be taken for the patent-exchange process to continue. A9-A11. That interpretation gives full and ordinary meaning to the word "shall."

Amgen argues that the BPCIA's procedural provisions must be enforced because, without Sandoz's application, Amgen purportedly could not determine whether it had any patent claim to assert. Congress obviously believed otherwise,

expressly providing that the failure to provide the application gave the sponsor the immediate right to commence a suit for artificial infringement. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). Indeed, this very suit belies Amgen's argument: Amgen was able to file the patent suit Congress contemplated, and having filed it, contends it has learned through discovery about additional patent claims it could assert.

Amgen's second argument is that Sandoz "violated" the BPCIA by providing its notice of commercial marketing too early. That argument is equally unavailing. As the district court correctly concluded, the plain language provides for "[n]otice of commercial marketing" at least 180 days before commercial marketing. Sandoz satisfied this provision by notifying Amgen in July 2014 that it would begin selling filgrastim upon FDA approval, which Sandoz accurately predicted would come in the first half of 2015. That was more than ample notice for Amgen to seek injunctive relief before Sandoz marketed its biosimilar – if Amgen has any valid patent claims.

Amgen's contrary view again seizes on a single word out of context: "licensed." But there is no support in the statute for Amgen's view that the notice of commercial marketing cannot be given before FDA licensure. That would transform the "[n]otice" provision into a 180-day bar against marketing, essentially an automatic, bondless injunction during which the FDA-licensed biosimilar would

not be available to patients who need it. This would be so even where the sponsor has no patents to assert. And it effectively would extend the sponsor's market exclusivity to 12.5 years with respect to every first-approved biosimilar.

Finally, even if Amgen's interpretation of the BPCIA were correct, it would still not be entitled to an injunction against commercial marketing. Any such injunction could be based only on a claim of patent infringement. Congress expressly provided that the BPCIA's patent remedies are the "*only remedies* which may be granted by a court" for an applicant's submission of a biosimilar application without providing its application to the sponsor. 35 U.S.C. § 271(e)(4) (emphasis added). That provision, by itself, forecloses both the implied federal right of action and state-law remedies that Amgen seeks to engraft onto the BPCIA in response to Sandoz's withholding of its application. Moreover, the BPCIA's comprehensive set of recourse provisions – including authorization of a patent infringement suit by the sponsor if the application or notice of commercial marketing is not provided – forecloses the fashioning of additional remedies to "enforce" the statute's terms.

If Amgen has any valid patent claims, it should litigate them. Instead, it has pursued this appeal, which involves *no* claim of patent infringement. It has not sought an injunction based on alleged infringement of the one patent it did assert. That Amgen would rather press procedural arguments than patent claims in an

attempt to delay Sandoz's competing biosimilar is not surprising: since 2014, Amgen has stated that its material U.S. patents for filgrastim expired in 2013 and that Amgen expected to face competition in the United States. But Amgen's lack of viable patent claims is no reason for this Court to rewrite the BPCIA. Congress did not make it "unlawful" for either party to fail to take any step in the patent-exchange process, and it provided no means to compel those steps.

STATEMENT OF THE CASE

A. The BPCIA

1. Abbreviated approval in exchange for exclusivity period

Congress struck a careful balance in the BPCIA between facilitating prompt access to cost-saving biosimilars and promoting innovation in biological products. BPCIA § 7001(b), 124 Stat. at 804; A423. The statute allows an applicant to rely in part on the sponsor's license for the approved reference product in order to speed biosimilar market entry. 42 U.S.C. § 262(k). In exchange, the BPCIA gives biologics sponsors a total of 12 years without biosimilar competition: a 4-year period of data exclusivity as well as an additional 8-year period of *market* exclusivity. *Id.* § 262(k)(7).

This lengthy period of market exclusivity for sponsors is one example of how the BPCIA differs significantly from the Hatch-Waxman Act. That Act, which applies to small-molecule drugs, gives holders of an approved New Drug

Application only 5 years of *data* exclusivity, 21 U.S.C. § 355(c)(3)(E)(ii), and links FDA approval of generic drugs to the outcome of patent litigation, *id.* § 355(j)(5)(B)(iii). In contrast, the BPCIA provides sponsors a longer period of *market* exclusivity, but does not link FDA approval of biosimilars to the outcome of patent litigation. 42 U.S.C. § 262(k)(7)(A).

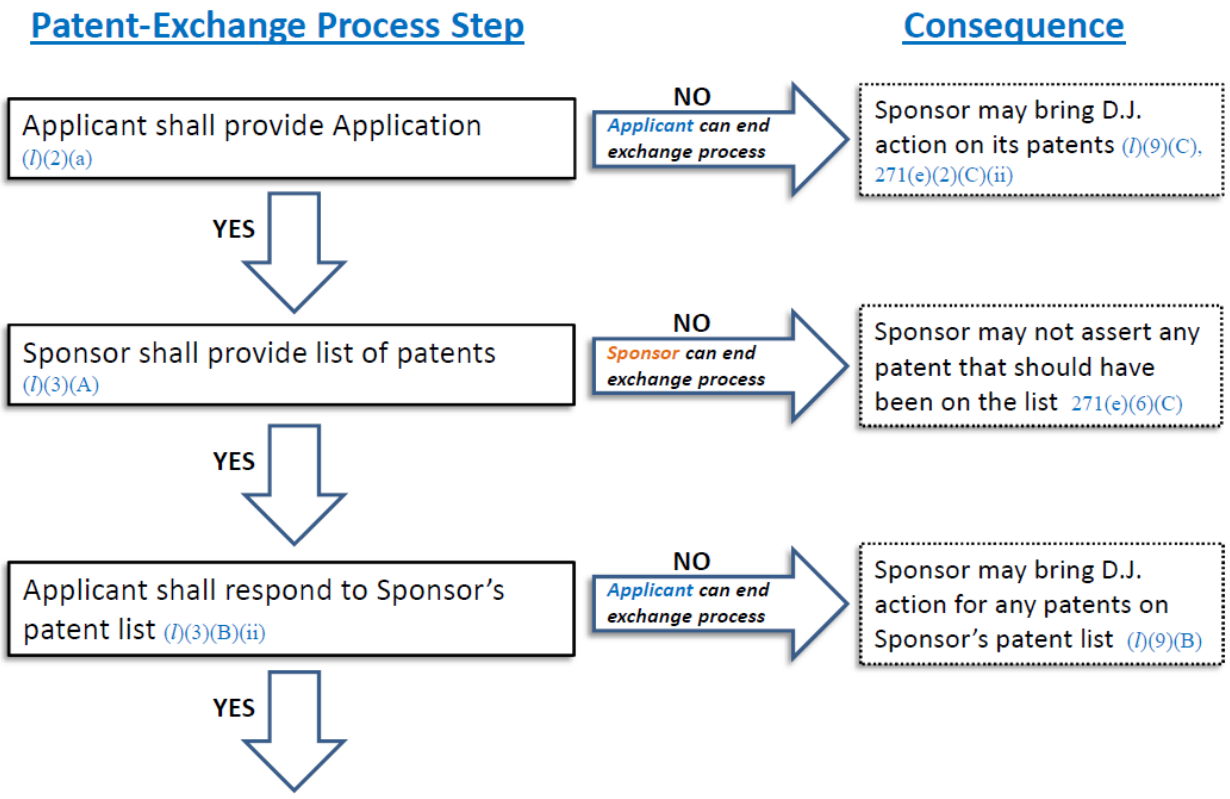
2. Multiple avenues to resolve patent disputes

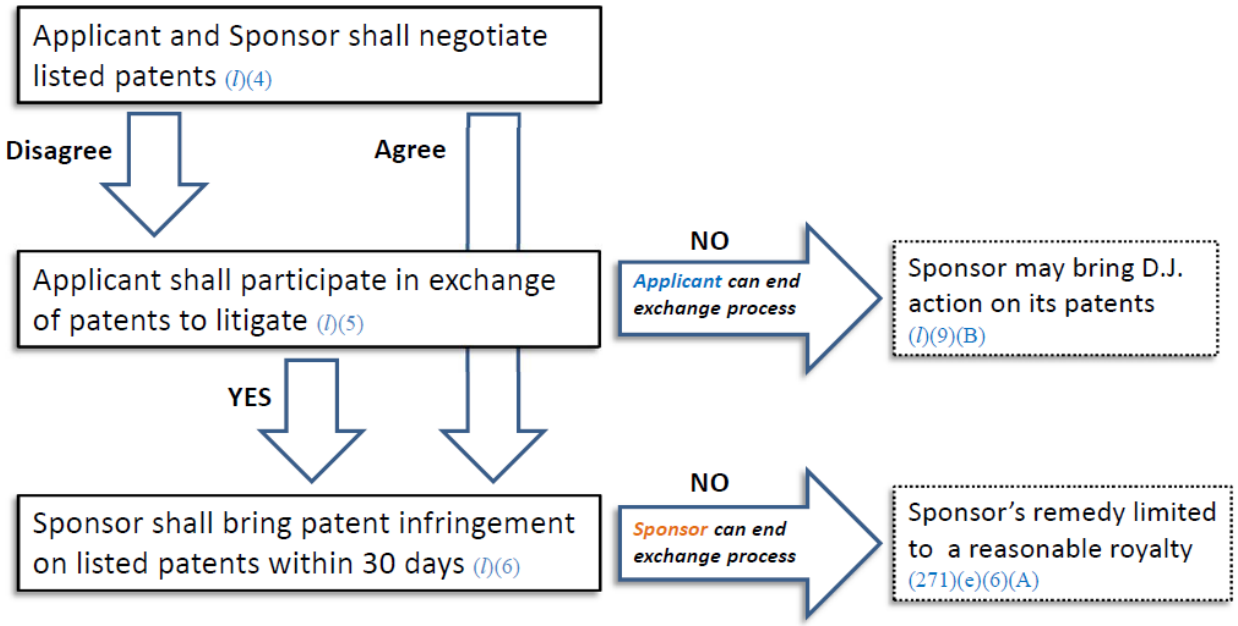
Aside from the exclusivity provisions in subsection (k), the BPCIA created a carefully reticulated regime to facilitate resolution of patent disputes as quickly as possible. At the center of this regime are the BPCIA's amendments to the Patent Act permitting litigation of patent claims well before any actual infringement from the commercial launch of a biosimilar. In particular, the BPCIA makes it an artificial "act of infringement to submit" a biosimilar application to the FDA under certain circumstances. 35 U.S.C. § 271(e)(2)(C). Under ordinary principles, this act of artificial infringement would allow either the sponsor or the applicant to invoke the Declaratory Judgment Act, 28 U.S.C. § 2201(a), to bring suit to determine whether the proposed biologic would infringe the sponsor's patent claims. *See Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344, 1351 (Fed. Cir. 2004). But the BPCIA elsewhere limits who can bring this suit, whether and when it can be brought, which patents can be included, and what the remedies can be – depending on the actions and inactions of the applicant and/or the sponsor. 35

U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*). Regardless of the parties' actions or inactions, the end result is a possible pre-approval infringement suit. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B).

One way of reaching that pre-approval patent litigation is to complete the BPCIA's patent-exchange process from beginning to end. If the applicant and the sponsor were to complete that entire process, the following would occur. As a condition precedent to starting the process, the applicant "shall provide to the reference product sponsor a copy of the application submitted" within 20 days of FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). The sponsor then lists patents for which it believes it could reasonably assert an infringement claim and identifies which patents it might license. *Id.* § 262(*l*)(3)(A). The applicant provides its non-infringement, invalidity, and unenforceability opinions and responds to the sponsor's identification of patents for a potential license. *Id.* § 262(*l*)(3)(B). The sponsor and applicant then negotiate over which patents should be litigated before launch. *Id.* § 262(*l*)(4)(A). If they fail to agree, they exchange lists of patents each believes should be litigated. *Id.* § 262(*l*)(4)(B), (5). At the end of the exchange, the sponsor "shall bring" an infringement suit within 30 days on the patents agreed to by the parties or included in the exchanged lists. *Id.* § 262(*l*)(6)(A)-(B).

Although each of these steps begins with "shall," the BPCIA expressly contemplates that either the applicant or sponsor may not follow them, thus ending the patent-exchange process at a number of points. As summarized in this chart, the applicant's or sponsor's decision to continue the process (or not) at every step has a defined, patent-litigation consequence:





A2050-A2051.

Each decision point presents benefits and burdens to both parties. For example, if the applicant timely provides its application under Section 262(*l*)(2)(A) and thus initiates the patent-exchange process, the applicant benefits in several ways. Doing so forestalls immediate patent litigation under the artificial-infringement provision. 42 U.S.C. § 262(*l*)(9)(A). If the process continues, the applicant can limit the number of patents that are litigated during the process. *Id.* § 262(*l*)(4)-(5). To obtain those benefits of the patent-exchange process, however, the applicant must disclose its highly confidential application and manufacturing information to the sponsor without the benefit of a court protective order and may have to wait up to eight months before any patent litigation may begin. *Id.* § 262(*l*)(1)-(6), (9)(A).

On the other hand, an applicant's decision not to provide its application under subsection (*l*)(2)(A) carries costs for the applicant and confers benefits on the sponsor. In particular, the applicant subjects itself to the risk of an immediate, pre-launch suit based on its act of artificial infringement and is disabled from commencing its own suit. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Such an immediate suit (like Amgen's patent claim in this case) has many benefits for the sponsor. The sponsor can obtain the biosimilar application in discovery (as Amgen did here). The applicant has no control over which patents, or how many, the sponsor can assert. 42 U.S.C. § 262(*l*)(9)(C). The sponsor decides whether and when to sue and can delay suit until after FDA approval, effectively forcing the applicant to launch at risk.

Despite these consequences from not providing an application, this path may nonetheless be preferable for an applicant that seeks a quick resolution, believes that no unexpired patents covering the sponsor's product will remain after the exclusivity period expires, and/or has concerns about turning over its application without a protective order – especially where, as here, the sponsor is not just a direct competitor with respect to the biological product but is a significant competitor in the biosimilar market.

3. Notice of commercial marketing

The BPCIA also contains a "[n]otice of commercial marketing" provision. *Id.* § 262(*l*)(8)(A). That provision states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." *Id.*

Consistent with the goal of resolving possible patent disputes before approval, this provision provides notice to the sponsor that a biosimilar is at least six months from coming to market. This allows the sponsor to seek a preliminary injunction to enforce any patent claims it has not yet been able to enforce in the exchange process. If the applicant initiated the patent-exchange process and continued it until the infringement suit contemplated by Section 262(*l*)(6), the applicant enjoyed a stay of litigation with respect to the other patents that the parties identified in their initial lists. *Id.* § 262(*l*)(9)(A)-(B). Providing the notice of commercial marketing lifts that stay and allows the sponsor to seek a preliminary injunction based on those unresolved patents. *Id.* § 262(*l*)(8)(B), (9)(A).[2]

[2] Section 262(*l*)(8)(B) applies where the sponsor provided its initial list of patents to the applicant. If, however, no list was provided because the application was not timely provided, the sponsor already could have sued. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C).

The BPCIA also specifies the consequence for not providing the notice of commercial marketing: "the reference product sponsor, but not the subsection (k) applicant, may bring an action" for a declaration of infringement, validity, or enforceability of any patent on the sponsor's initial patent list. *Id.* § 262(*l*)(9)(B).

B. Factual Background

1. Amgen's filgrastim product, Neupogen®

For 24 years, Amgen has marketed the biological product filgrastim under the brand name Neupogen®. A5. Amgen's market exclusivity already has lasted twice as long as the 12-year period Congress deemed sufficient to encourage innovation in biologics. 42 U.S.C. § 262(k)(7)(A).

Since February 2014, Amgen's annual and quarterly reports have stated: "Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States . . . ." A915; A960.

2. Sandoz's biosimilar application

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. A5. The next day, Sandoz notified Amgen of its application, that it expected FDA approval in the first half of 2015, and that it "intend[ed] to launch the biosimilar filgrastim product in the U.S. immediately upon FDA approval." A1472-A1473.

In the same letter, Sandoz offered to provide Amgen its application subject to confidentiality terms that were more protective than the BPCIA's default terms. A1472-A1479. The BPCIA expressly contemplates that parties may agree to such terms. A1473 n.1 (citing 42 U.S.C. § 262(*l*)(1)(A)). Amgen declined Sandoz's offer. A1481-A1482.

Concerned about sharing its application with a competitor, and in light of Amgen's statements that it has no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the most expeditious path to resolution of any patent claims. A1495-A1497. On July 25, 2014, Sandoz informed Amgen that "Amgen [was] entitled to start a declaratory judgment action under 42 U.S.C. § 262(*l*)(9)(C)," A1496, and that Amgen could "obtain access to the biosimilar application" in that suit under court-ordered confidentiality protections. A1495. Sandoz again offered to provide Amgen its application under industry-standard confidentiality protections. A1495-A1503. Amgen rejected that offer. A1505-A1507.

Thus, as early as July 28, 2014, Amgen could have sued Sandoz for patent infringement. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). It did not.

C. Proceedings Below

1. Amgen sues on two state-law claims and one patent claim

Months later, on October 24, 2014, Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, alleging that Sandoz's purported "violations of the BPCIA satisfy the 'unlawful' prong of § 17200." A45-A83 at A74. Amgen also brought a state-law claim for conversion, alleging that Sandoz wrongfully used Amgen's license. A77.

Additionally, explicitly invoking the recourse in Section 262(*l*)(9)(C), Amgen brought a claim for artificial infringement under 35 U.S.C. § 271(e)(2)(C)(ii). Although Amgen now contends (at 44) it could not know which patents to assert unless Sandoz provided its application pursuant to Section 262(*l*)(2)(A), Amgen knew enough to allege infringement of U.S. Patent No. 6,162,427 ("'427 patent"). A79-A80.

When it filed its complaint, Amgen did not seek a preliminary injunction.

2. Sandoz answers and counterclaims

Sandoz answered and counterclaimed. A256-A288. Sandoz's first through fifth counterclaims sought declaratory judgments concerning the correct interpretation of the BPCIA. A282-A285. Sandoz's sixth and seventh counterclaims sought declaratory judgments of non-infringement and invalidity of the '427 patent. A286-A287.

3. Amgen and Sandoz cross-move for judgment on the pleadings

On January 6, 2015, Amgen moved for partial judgment on the pleadings. Amgen's motion was limited to the "unlawful" element of its California UCL claim, seeking a ruling that Sandoz's "failure" to provide its application timely and its "premature" notice of commercial marketing were "violations" of the BPCIA. A305.[3]

Sandoz cross-moved for judgment on the pleadings on Amgen's state-law claims and Sandoz's first through fifth counterclaims. A351-A379; A633-A650.

4. Amgen moves for a preliminary injunction on state-law claims

On January 7, 2015, FDA's Oncologic Drugs Advisory Committee unanimously recommended Sandoz's filgrastim for approval. A1464-A1470; A1575-A1576. Amgen still did not move for a preliminary injunction.

On February 5, 2015, Amgen finally moved for a preliminary injunction. Based solely on its state-law claims, not on alleged patent infringement, Amgen sought to enjoin Sandoz from launching until it performed all the BPCIA's procedural steps. A469; *see* A668-A699.

[3] Amgen requests (at 66) this Court to enter "judgment in Amgen's favor on its claims." But such a judgment, which would go beyond what Amgen requested in district court, could not be entered for Amgen until outstanding legal and factual issues are addressed, A374-378; A645-A649. *See Fountain v. Filson*, 336 U.S. 681, 682-83 (1949) (per curiam).

On February 9, 2015, after the court issued Sandoz's proposed protective order, Amgen finally accepted Sandoz's application. A734; A1353. Although Amgen suggests (at 14) it now has "identif[ied] two manufacturing patents that it believes would be infringed by Sandoz's manufacture of its filgrastim product," it has not formally asserted them.

5. FDA approves Sandoz's application

On March 6, 2015, the FDA approved Sandoz's biosimilar filgrastim product Zarxio®, the first biosimilar product approved under the BPCIA. A1774-A1818. To allow time for the district court to rule, Sandoz agreed not to launch its product until the earlier of April 10, 2015, or a partial judgment in its favor, and to give Amgen five days' notice before launching. A2 n.3. After the district court's ruling, Sandoz further agreed not to launch until the earlier of this Court's ruling on Amgen's motion for an injunction pending appeal, or May 11, 2015. A1946.

6. The district court's ruling

On March 19, 2015, the district court denied Amgen's motions and granted Sandoz's motion for judgment on Amgen's state-law claims and Sandoz's first through fifth counterclaims. A1-A19.

Withholding application not unlawful. The district court held that it was lawful for Sandoz not to provide Amgen its application within 20 days of acceptance by FDA. A9-A12. The court explained that the BPCIA "reflect[s] an

integrated scheme that provides consequences for the choice either party makes at each step" of the process. A4-A5. "Subparagraphs (*l*)(9)(B) and (C) contemplate the scenario in which an applicant does not comply at all with disclosure procedures." A10. Rather than allowing the sponsor to compel use of the patent-exchange process, they "allow the reference product sponsor to commence patent litigation immediately." A10.

In light of this, the district court concluded that the provision "that an action 'shall' be taken does not imply it is mandatory in all contexts." A9. Rather, the BPCIA "demand[s] 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.'" A9. The court reasoned that the statute offers an applicant the "carrot" of a litigation safe harbor if it pursues the patent-exchange process but "contains no stick to force compliance in all instances." A10-A11.

The district court explained that "Sandoz's decision not to comply with subsection (*l*) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes." A11. An applicant, such as Sandoz, that has "good reason to believe that no unexpired relevant patents relate to its biosimilar" may forgo the process and subject itself to an infringement suit

immediately. A11. "The BPCIA's plain language and overall statutory scheme support a reading that renders this decision entirely permissible." A12.

Notice of commercial marketing in advance of FDA licensure not unlawful. The district court also held it was "not wrongful for Sandoz to give Amgen its 180 days' notice" of commercial marketing before FDA licensure. A14. "[L]icensed" in Section 262(*l*)(8)(A) refers only to the fact that the product must be licensed before marketing; "licensed" does not refer to "the appropriate time for notice." A13.

The district court further explained that "[e]ven more problematic with Amgen's reading" of the "[n]otice" provision is that it 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)." A13. "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." A13-A14.

No state-law claims. The district court concluded that "[b]ecause 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." A14.

Denial of preliminary injunction. The district court denied Amgen's preliminary injunction motion. The court held Amgen could not show success on the merits. It also found as fact that Amgen did not "carry its burden to

demonstrate that irreparable harm will result." A17. The court rejected each of Amgen's asserted irreparable harms for two distinct reasons, finding as fact that "[n]ot 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." A18.

Rule 54(b) judgment. On March 25, 2015, the district court entered final judgment under Federal Rule of Civil Procedure 54(b) on the non-patent claims and counterclaims. A20-A23. The court granted the parties' joint request to stay all other proceedings, including Amgen's patent-infringement claim. A22.[4]

SUMMARY OF ARGUMENT

I. Read in the context of the BPCIA as a whole, the "shall" provision in Section 262(*l*)(2)(A) is a mandatory condition precedent to engaging in the patent-exchange process, not a mandatory requirement in all circumstances. To take advantage of the patent-exchange procedures, the applicant must provide the sponsor its application within 20 days of being notified that the FDA has accepted it for review. This interpretation is consistent with uses of "shall" in other provisions in subsection (*l*), as well as with uses of "shall" in other statutory schemes. It also gives full effect to both "shall" and "may" in subsection (*l*)(2)(A).

[4] On April 15, 2015, the district court denied Amgen's motion for an injunction pending appeal. A2078-A2080.

Moreover, Congress determined that if the application is not provided within 20 days, an immediate infringement action is the proper recourse. The sponsor may then obtain the application in discovery. Congress carefully balanced the interests between sponsors and applicants, determined what the consequences should be at each step of the process for not completing it, and allowed the parties to weigh the benefits of proceeding against the consequences of not. Sandoz did not act unlawfully in taking a path expressly laid out by Congress.

II. The plain terms of the "[n]otice of commercial marketing" provision are satisfied when an applicant provides notice at least 180 days before it commercially markets its product. 42 U.S.C. § 262(*l*)(8)(A). The word "licensed" in subsection (*l*)(8)(A) reflects the fact that, at the time of commercial marketing, the product must be licensed. After all, subsection (*l*)(8)(A) refers to an "applicant" (not the "holder" of a license) as the provider of the notice. Sandoz thus did not act unlawfully by providing notice before its biosimilar was licensed.

If, as Amgen argues, a biosimilar must be licensed before notice may be given, that would transform this mere "[n]otice" provision into an automatic, six-month bar against marketing of every licensed biosimilar product. Had that been Congress's intent, it would have said so.

III. Sandoz did nothing "unlawful" under the BPCIA. Even assuming it had, the BPCIA itself would provide Amgen's only recourse: initiation of

immediate patent litigation. Amgen now contends on appeal that it should additionally have an implied right of action under the BPCIA to enjoin the commercial launch of Sandoz's biosimilar until Sandoz complies with the subsection (*l*) procedures. But Amgen pleaded no such claim in its complaint and, in any event, it is meritless. Far from authorizing the injunction sought by Amgen, the statute expressly provides that the patent remedies it provides for an applicant's failure to provide an application are exclusive. This unavailability of non-statutory remedies is confirmed by the BPCIA's overall structure.

Nor may Amgen seek a remedy under California law. A California UCL action is unavailable where, as here, the underlying statute that has allegedly been violated expressly provides that its remedies are exclusive. Amgen's state-law claim for conversion fails because, among other reasons, Amgen has not alleged conversion of an intangible property right. Finally, even if Amgen could surmount these hurdles, any state-law injunction against commercial marketing designed to "enforce" the BPCIA's procedural steps would be preempted.

IV. Amgen's preliminary injunction appeal is moot now that the district court has entered judgment on Amgen's state-law claims. In any event, the denial should be affirmed because it is based on factual findings that Amgen has not shown to be clearly erroneous.

STANDARD OF REVIEW

A judgment on the pleadings is reviewed under the standard of the regional circuit, which here is de novo. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1380 (Fed. Cir. 2011). The interpretation of statutory provisions specific to patent law, such as the BPCIA, are governed by Federal Circuit law. *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 182 F.3d 1356, 1359 (Fed. Cir. 1999).

Denial of a preliminary injunction is reviewed for abuse of discretion. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Underlying factual findings, including the lack of irreparable harm, are reviewed only for clear error. *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009).

ARGUMENT

Amgen acknowledges that its state-law claims fail unless it can prove that Sandoz acted unlawfully. Amgen Br. 59-61. The district court correctly concluded that Sandoz did not. A14. Sandoz's actions were consistent with the text, structure, and purpose of the BPCIA. It is Amgen's reading that would upend the federal scheme.

I. THE DISTRICT COURT CORRECTLY HELD THAT IT WAS NOT UNLAWFUL FOR SANDOZ NOT TO PROVIDE ITS APPLICATION UNDER SECTION 262(*l*)(2)(A)

A. The BPCIA Does Not Mandate That The Patent-Exchange Process Be Followed In All Circumstances

"It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). A court "should not confine itself to examining a particular statutory provision in isolation." *Id.* at 132. Applying these principles, the district court correctly concluded that when the applicant or the sponsor does not take one of the procedural steps in subsection (*l*), it has not acted unlawfully. A9-A12.

1. Section (l)(2)(A) is a condition precedent to engaging in the exchange process

As explained above, the BPCIA creates an integrated patent-resolution regime. *See supra* pp. 9-13. It amends the Patent Act to make submission of an application to the FDA an artificial act of infringement under certain circumstances. 35 U.S.C. § 271(e)(2)(C). It also establishes a framework in Section 262(*l*) of Title 42 that determines who can bring such a suit, when it can be brought, and for what relief. 42 U.S.C. § 262(*l*)(2)-(9); *see* 35 U.S.C. § 271(e)(4), (6). Subsection (*l*) provides a patent-exchange process by which the parties can identify patent claims, negotiate a possible license, or ultimately litigate

validity and infringement. At the same time, the BPCIA specifically contemplates that the applicant or sponsor might not pursue the patent-exchange process to completion and expressly provides the consequences for not doing so. 35 U.S.C. § 271(e)(2)(C)(ii), (6); 42 U.S.C. § 262(*l*)(9)(B)-(C).

In the context of this integrated patent-resolution regime, the district court correctly concluded that the "shall" in Section (*l*)(2)(A) denotes a mandatory requirement to engaging in the patent-exchange process, not a mandatory requirement in all circumstances. A9-A11. *If* an applicant wishes to engage in the patent-exchange process, it "shall" timely provide its application to the sponsor. 42 U.S.C. § 262(*l*)(2)(A). But the applicant is not required to initiate the patent-exchange process. "*If* a subsection (k) applicant fails to provide [its] application," then the sponsor can immediately commence litigation under the BPCIA's amendments to the Patent Act for artificial infringement. *Id.* § 262(*l*)(9)(C) (emphasis added); 35 U.S.C. § 271(e)(2)(C)(ii).

Amgen's myopic focus (at 26-38) on the "generally, mandatory" nature of the word "shall" is therefore beside the point. Under the district court's interpretation of the statute, the "shall" in Section 262(*l*)(2) is mandatory: it specifies an action that an applicant *must* take in order to proceed to the next step of the patent-exchange process. When the applicant does not satisfy that condition precedent, the statute shifts the parties onto a different track to resolve patent

disputes: immediate, pre-launch patent litigation. As the district court correctly concluded (A9-A12), it cannot "violate" the BPCIA to choose this alternative track established by the BPCIA itself.

2. Other "shall" provisions of subsection (l) confirm they are not mandatory in all circumstances

Other provisions confirm that the word "shall" as used in subsection (*l*) does not denote a mandatory requirement in all circumstances. For example, subsection (*l*)(6) provides that at the end of the patent-exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6)(A)-(B) (emphasis added).

Amgen tellingly does not quote this "shall" in its litany of quotations. Amgen Br. 28-31. But the BPCIA uses the same "shall" in subsection (*l*)(6) that Amgen highlights in subsections (*l*)(2), (3), and (4). *Id.* "[I]dentical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007).

Thus, if Amgen were correct that "shall" in subsection (*l*) means mandatory in all circumstances, then a sponsor who fails to file a timely suit for artificial infringement is "violating" subsection (*l*)(6). That would be true no matter the reason, including a simple decision to avoid litigation expense until learning whether the biosimilar will be approved. But it is not rational to believe that Congress mandated that private parties sue other private parties. Rather, just as

with the "shall" provision in subsection (*l*)(2), the requirement that a sponsor "shall" sue within a specified time frame is a condition precedent to other statutory benefits, namely, the availability of the full patent-law remedies provided in Section 271(e), including injunctive relief. 35 U.S.C. § 271(e)(4), (6)(B). And, just as in subsection (*l*)(2), the BPCIA expressly contemplates that a sponsor might not perform the "shall" act in subsection (*l*)(6). It provides that if the sponsor brings an action for artificial infringement "after the expiration of the 30-day period," then "the sole and exclusive remedy that may be granted by a court . . . shall be a reasonable royalty." 35 U.S.C. § 271(e)(6)(A)(ii)(I), (B).

This same structure is present throughout Section 262(*l*). Despite many instances of "shall," the sponsor or the applicant may exit the process at multiple points, and at each of those points, the BPCIA delineates the effect of that choice on the scope and timing of any patent lawsuit. *See supra* pp. 11-12; A2050-A2051. As the district court correctly concluded, the BPCIA "reflect[s] 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." A4-A5. None of those choices could be described as "unlawful."

3. The district court gave full and ordinary meanings to the terms "shall," "may," "required," and "fails"

Contrary to Amgen's contention (at 37-38), the district court's interpretation gives full effect to the distinction between "shall" and "may" in Section 262(*l*)(2). Providing the application within 20 days is *required* for an applicant to participate in the patent-exchange process. 42 U.S.C. § 262(*l*)(2)(A). If an applicant provides its application, it also "*may* provide to the reference product sponsor additional information." *Id.* § 262(*l*)(2)(B) (emphasis added). But providing such additional information is not a condition precedent to participating in the process.

Contrary to Amgen's suggestion (at 38), the statute's use of "required" and "fails" (*e.g.*, 42 U.S.C. § 262(*l*)(9)(C)) is consistent with the district court's interpretation. The "required" information must be provided to continue in the process, and if the applicant "fails" to satisfy that condition precedent, statutory consequences follow. *Id.* Neither term demonstrates that withholding the application is a "violation" of the BPCIA.

Indeed, the BPCIA uses "fail[]" even when it is clear there is no mandatory obligation. Section 262(*l*)(4)(B), which is titled "Failure to reach agreement," discusses what happens if the parties "fail to agree on a final and complete list" of patents to litigate. *Id.* § 262(*l*)(4)(B). There is plainly no obligation for the parties to agree, yet the statute uses the word "fail" to describe when they do not.

4. Other statutory schemes use "shall" as a condition precedent

As the district court recognized, other statutory regimes similarly use "shall" to denote a condition precedent. A10. For example, the statute at issue in *County of Ramsey v. MERSCORP Holdings, Inc.*, provided: "Every conveyance of real estate *shall be recorded* in the office of the county recorder of the county where such real estate is situated; and *every such conveyance not so recorded* shall be void as against any subsequent purchaser . . . whose conveyance is first duly recorded." 962 F. Supp. 2d 1082, 1086 (D. Minn. 2013) (emphasis added), *aff'd*, 776 F.3d 947 (8th Cir. 2014). *Ramsey* concluded that "shall be recorded" was not mandatory in all circumstances because the statutory language "specifically contemplate[d] that not all conveyances will be recorded and outlines the consequence of failing to do so." *Id.* at 1087. So too here: while the BPCIA states that the application "shall" be provided, it expressly contemplates that not all applications will be provided and explicitly addresses what happens in that situation.

Similarly, and contrary to amicus AbbVie's contention (at 6), *National Federation of Independent Business v. Sebelius* ("*NFIB*"), supports the district court's conclusion here. 132 S. Ct. 2566 (2012). In arguing otherwise, AbbVie relies on a portion of Chief Justice Roberts' separate opinion that no other Justice joined, yet which AbbVie incorrectly states was "for a majority of the Court."

AbbVie Br. 6; *see* 132 S. Ct. at 2593 (passage cited by AbbVie, from Part III.B of opinion); *id.* at 2575.

The provisions at issue in *NFIB* provided that individuals "shall" maintain health coverage, 26 U.S.C. § 5000A(a), and imposed a "penalty" for the "failure" to meet that "requirement," *id.* § 5000A(b)(1). Examining the statute as a whole (and not just the word "shall" in isolation), a majority of the Court held that the failure to maintain health insurance was *not* "unlawful," but instead simply a condition precedent to avoiding a statutorily specified consequence under that law – "a payment to the IRS." *NFIB*, 132 S. Ct. at 2596-97.[5]

NFIB confirms that an applicant does not act unlawfully when it declines to provide its application under Section 262(*l*)(2)(A). As in *NFIB*, the statute here uses "shall" only as a condition precedent to avoiding a consequence specified by the statute itself. Indeed, this interpretation is even clearer here than in *NFIB* because nowhere does the BPCIA describe the consequence for not providing an application as a "penalty."

B. The BPCIA Reflects Congress's Careful Balancing Of Interests

The district court's conclusion correctly reflects that the BPCIA creates a balanced patent-resolution regime that confers benefits and burdens on both

[5] While the Chief Justice's separate opinion relied on the "constitutional avoidance canon" to support that conclusion, AbbVie Br. 6 n.2, the Court's majority did not, *NFIB*, 132 S. Ct. at 2594-2600.

sponsors and applicants. A4-A5. Specifically, with respect to provision of the application, Congress provided "the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit." A10. But "[t]he statute contains no stick to force compliance in all instances." A10-A11.

1. Congress determined sponsors do not need the application before suit to protect any patent rights

Amgen suggests (at 39) that Section 262(*l*)(2)(A) must be mandatory in all circumstances because, without the application, the sponsor will not be able to determine which of its patents the applicant will infringe. Congress concluded otherwise, and this case proves Congress correct.

After sitting on its rights for months, Amgen ultimately brought the claim for artificial infringement that Congress specifically provided for this precise situation. A79-A80. Such a suit is more than sufficient to protect any valid patent claims that a sponsor may have. Like all other patentee plaintiffs, a sponsor will have access to all the tools of discovery. The sponsor can obtain the biosimilar application under a protective order, just as Amgen did here. Indeed, in contrast to most patentees, sponsors can sue even before there is any actual infringement. 35 U.S.C. § 271(e)(2)(C)(ii).

Amgen's cries of unfairness at the lack of pre-suit informal discovery fall flat. Amgen Br. 39. Competitors rarely have access to each other's confidential manufacturing processes before filing suit. But they regularly file infringement

suits based on patents they reasonably believe are infringed after diligent investigation, such as pre-suit letters seeking information about manufacturing processes. If there is no response, the patentee can file suit without violating Rule 11. *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000). Then, after suing, patentees use discovery to learn detailed information and amend their complaints if necessary.

Here, Amgen is the source of any prejudice it suffers: Amgen could have received Sandoz's application long ago – any time from July 2014 on – either by accepting Sandoz's repeated offers to provide it or by filing this suit as soon as the BPCIA allowed.

2. The BPCIA provides benefits and imposes burdens for each of its procedural paths to resolving patent claims

Amgen also is wrong to suggest that if the applicant does not participate in the patent-exchange process, "it is the [sponsor] who loses the protections of the statute – not the non-compliant Applicant." Amgen Br. 43. The patent-resolution procedures (in both Section 262(*l*) and the Patent Act) have trade-offs for both sponsors and applicants.

There are benefits to the sponsor and costs to the applicant where, as here, the applicant does not participate in the process. If the applicant forgoes or terminates the patent-exchange process, the sponsor ends up with far more control over the scope and timing of the infringement suit. The sponsor can sue

immediately without having its patents limited by the process. Or the sponsor can wait to sue until the biosimilar is approved, leaving the applicant in the dark with respect to its patent exposure and forcing it to decide whether to launch at risk. 42 U.S.C. § 262(*l*)(9)(B)-(C); 35 U.S.C. § 271(e)(2)(C)(ii). The applicant forfeits the ability to bring certain actions that could otherwise be available under the Declaratory Judgment Act, *see supra* pp. 9-10, as well as the ability to receive pre-litigation information about potentially relevant patents. 42 U.S.C. § 262(*l*)(3)(A), (9)(C).

By contrast, participating in the patent-exchange process offers a variety of benefits to applicants. Not only does that path give the applicant a temporary safe harbor from litigation, *id.* § 262(*l*)(9)(A), it also allows the applicant to preview the patents that the sponsor believes are valid and infringed. *Id.* § 262(*l*)(3)(A). It allows the applicant, not the sponsor, to control how many patents are initially litigated. *Id.* § 262(*l*)(4), (5). And following the process increases the chance that the sponsor will bring certain patent-infringement actions within a specified timeframe, because otherwise the remedies in such a suit will be limited. *Id.* § 262(*l*)(6); 35 U.S.C. § 271(e)(6)(B). Amicus AbbVie (at 11) is thus simply wrong to suggest that applicants will never participate in the process.

But where, as here, an applicant "values expedience over risk mitigation," the statute allows it to subject itself to immediate suit rather than engage in the

process. A11. The patent-exchange process "could take up to 230 days" from the time the application is provided to the sponsor – "just to *commence* patent litigation." A11 (emphasis added). 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." A12. As the district court explained, "Sandoz's decision not to comply with subsection (*l*) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes." A11.

3. Contrary to Amgen's assertion, the Section 262(l)(6) lawsuit is not a "lynchpin of the entire BPCIA"

Finally, Amgen argues (at 40) that "[b]ecause 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." The premise of Amgen's argument is mistaken. A subsection (*l*)(6) lawsuit cannot be the lynchpin of the BPCIA, given that the BPCIA expressly contemplates the sponsor might not file one. 35 U.S.C. § 271(e)(6)(A)(ii)(I).

Moreover, a subsection (*l*)(6) lawsuit is only one of several statutory mechanisms for pre-launch infringement lawsuits. It is the prescribed mechanism if the parties carry through the patent-exchange process until the end, but if the applicant does not start the patent-exchange process, or ends it before completion, the sponsor can bring a suit under Section 262(*l*)(9)(B)-(C) and 35 U.S.C.

§ 271(e)(2)(C) immediately. Finally, a subsection (*l*)(6) lawsuit can hardly be the "lynchpin" of the statute's patent-adjudication process, when the applicant has the unilateral right to limit that suit to a single patent. 42 U.S.C. § 262(*l*)(4)(B), (5)(B)(ii)(II), (6)(B).

Nor would the exclusivity period for interchangeability be "game[d]" (Amgen Br. 40-41) under the district court's interpretation. Section 262(k)(6) provides for a period of biosimilar exclusivity for the first biosimilar approved as "interchangeable" with each reference product. 42 U.S.C. § 262(k)(6). The exclusivity period lasts until the earliest of several events, some of which involve Section 262(*l*)(6) suits. But Section 262(k)(6) expressly calculates the length of exclusivity for the first interchangeable biosimilar even without a Section 262(*l*)(6) suit. *Id.* § 262(k)(6)(A), (C)(ii). In other words, Congress again contemplated the absence of a Section 262(*l*)(6) suit.

* * *

In sum, the BPCIA contemplates that applicants will do exactly what Sandoz did here, and in those circumstances, it allows Amgen to file an immediate suit based on artificial infringement, which Amgen has done. Sandoz cannot have violated the BPCIA by following a path expressly provided in the BPCIA.

II. THE DISTRICT COURT CORRECTLY HELD THAT IT WAS NOT UNLAWFUL FOR SANDOZ TO PROVIDE NOTICE OF COMMERCIAL MARKETING BEFORE FDA LICENSURE

Sandoz likewise acted lawfully when it notified Amgen of its intent to market its filgrastim product. 42 U.S.C. § 262(*l*)(8)(A). As the district court correctly concluded, Amgen's argument that Sandoz's notice was *too early* conflicts with the text, structure, and purpose of the statute. A12-A14.

A. The Text Of Section 262(*l*)(8)(A) Provides For Notice Before Commercial Marketing, Not After FDA Licensure

Under its plain language, Sandoz satisfied Section 262(*l*)(8)(A). The "Notice of commercial marketing" provision states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Sandoz provided notice in July 2014, and 180 days passed without any commercial marketing of its filgrastim product. It therefore fully satisfied the notice provision.

Amgen's contrary argument rests entirely on the phrase "biological product licensed" in Section 262(*l*)(8)(A). According to Amgen, an "[a]pplicant may not give 180 days' notice before the product that was the subject of the application has become a 'biological product licensed.'" Amgen Br. 46. For several reasons, the text of Section 262(*l*)(8)(A) forecloses that reading.

First, the "before" in Section 262(*l*)(8)(A) modifies "the date of the first commercial marketing." The phrase "biological product licensed under subsection (k)" simply identifies the product whose commercial marketing is relevant to measuring the 180-day period. A13. So long as notice is provided 180 days before *that* product is marketed, the provision has been satisfied. In cases like this one, where the sponsor's period of exclusivity has lapsed, first commercial marketing can occur the day FDA licenses the biosimilar.

Congress's pairing of "licensed" with "commercial marketing" simply reflects the fact that a product cannot legally be "commercial[ly] market[ed]" *unless* it is "licensed." 42 U.S.C. § 262(*l*)(8)(A); *see id.* § 262(a)(1)(A). Accordingly, at the time of "commercial marketing" (from which the 180 days is measured), the product must be "licensed under subsection (k)." *Id.* § 262(*l*)(8)(A). By contrast, none of the provisions that Amgen cites (at 46) that refer to "the biological product that is the subject of" the application refers to a future date when the product will be "licensed." 42 U.S.C. § 262(*l*)(8)(A).

Second, Section 262(*l*)(8)(A) expressly authorizes a "subsection (k) *applicant*" to provide the notice. *Id.* (emphasis added). The provision thus contemplates that the party providing the notice will do so when it has requested, but not yet received, FDA approval. After approval is granted, the party is no longer an "applicant." That interpretation is consistent with other parts of the

statute that distinguish between parties holding approved applications ("sponsors" or "holders") and those still seeking approval ("applicants"). *See, e.g.*, 42 U.S.C. § 262(*l*)(1)(A), (m)(3).[6]

Third, Section 262(*l*)(8)(A) is about "provid[ing] *notice* to the reference product sponsor." *Id.* § 262(*l*)(8)(A) (emphasis added). Indeed, its title is "*Notice* of commercial marketing." *Id.* (emphasis added). FDA licensure of a biosimilar is a public act. *See, e.g.*, FDA, *FDA Approves First Biosimilar Product Zarxio* (Mar. 6, 2015) (FDA press release announcing approval of Sandoz's application for filgrastim).[7] Special "notice" of a public licensure would be superfluous.

Amgen's interpretation would radically transform this mere "[n]otice" provision. Under Amgen's view, an applicant cannot provide notice until after FDA licensure, and then must wait 180 days before marketing. That would result in an automatic six-month bar – effectively a standardless, bondless injunction – against commercial marketing of already licensed biosimilars. And as Amgen told the district court, it would apply in *every* situation (A1888), regardless of whether

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[6] Amgen has suggested (A1913) that Section 262(k)(6) uses "applicant" to refer to a party with an FDA license. That section includes a series of time periods measured from events related to "an action instituted under subsection (*l*)(6) against the applicant that submitted the application." *E.g.*, 42 U.S.C. § 262(k)(6)(B)(i). But when a subsection (*l*)(6) action is first "instituted," FDA licensure typically would not have occurred.

[7] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.

the sponsor has any valid patent claims or whether it can demonstrate irreparable harm. Such an unthinking and automatic bar to market entry would conflict with Section 262(*l*)(8) itself. Section 262(*l*)(8)(B) requires the sponsor (upon receipt of the notice) to go to court to seek a preliminary injunction against commercial marketing by establishing the likelihood of success of proving infringement of a valid patent claim and irreparable harm in the absence of an injunction. 42 U.S.C. § 262(*l*)(8)(B).

Amgen's error is confirmed by the fact that its interpretation of the "notice" provision in subsection (*l*), which deals only with resolving patent disputes, would effectively amend the BPCIA's entirely separate exclusivity provisions. For each first-approved biosimilar, Amgen's reading of the notice provision 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)." A13. As the district court explained, "[h]ad Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." A13-A14.

The BPCIA exclusivity provision cited by the district court is entitled "Exclusivity for reference product" and provides that "[a]pproval of [a biosimilar] 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." 42 U.S.C. § 262(k)(7)(A) (emphasis added). Amgen's interpretation of the notice of commercial marketing provision would render the "made effective" provision illusory in cases like this one because, in Amgen's view, the approval of the biosimilar is *not* actually "effective" at that time, but instead only at a time 180 days later.[8]

B. Other Provisions Of The BPCIA Confirm That Notice Of Commercial Marketing May Be Provided Before FDA Licensure

The district court's straightforward reading of Section 262(*l*)(8)(A) is confirmed by other provisions of the BPCIA.

First, when Congress wanted to forbid an action before FDA licensure or extend the period of exclusivity, it made its intent express. Section 262(k)(7)(B) states that a biosimilar application "may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a)." 42 U.S.C. § 262(k)(7)(B). Had Congress intended the 180-

[8] Unlike Amgen, amicus Janssen Biotech states that the "better reading of the statute" would not necessarily lead to an extra 180 days of exclusivity in every case because "the statute allows for a license to be approved (although not made effective) while the marketing exclusivity is still in effect." Janssen Br. 26 & n.15; *see* Biotechnology Industry Organization Br. 19-20. But Janssen does not explain how a biologic with an ineffective approval could be considered "licensed," which would be required to trigger the notice provision under Amgen's view. Indeed, the FDA has described the 12-year exclusivity period as "the period of time" during which the "FDA is not permitted to *license*" a biosimilar. FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014) (emphasis added).

day period in Section 262(*l*)(8)(A) to begin running only at FDA licensure, it would have included a similar provision explicitly prohibiting notice until that time. Congress likewise made explicit its intent to extend exclusivity in Section 262(m), which provides incentives to conduct additional pediatric studies. If sponsors successfully complete such studies, their exclusivity period is extended to "12 years and 6 months rather than 12 years." *Id.* § 262(m)(2)(A).

Second, Amgen contends that the interchangeability exclusivity provisions of Section 262(k)(6) support its view. Amgen observes (at 48-49) that Section 262(k)(6)(A) ends interchangeability exclusivity "1 year after the first commercial marketing" of the first biosimilar, while Section 262(k)(6)(C)(ii) does so "18 months after approval" when there is no suit under Section 262(*l*)(6). Amgen posits (at 48-49) that this 6-month difference between the end dates supports its view of the notice provision. That is not so. Section 262(k)(6) envisions that these end dates will be *different*: it calls for the end of interchangeability exclusivity on "the earlier of" a series of dates, including the two highlighted by Amgen. 42 U.S.C. § 262(k)(6). Yet if there is a 180-day bar after approval before commercial marketing (as Amgen contends), then 1 year after commercial marketing would be the same as 18 months after approval whenever notice is given upon approval.

Finally, Amgen argues (at 45) that the district court erred in stating that, "had Sandoz failed to [provide a notice of commercial marketing], 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." A14 n.8. That statement was dictum because the court concluded Sandoz *did* provide notice of commercial marketing. In any event, it is correct: the BPCIA expressly provides that a declaratory judgment action by the sponsor is the (only) consequence for an applicant's failure to provide a notice of commercial marketing. 42 U.S.C. § 262(*l*)(9)(B).

C. Providing Notice Of Commercial Marketing Before FDA Licensure Is Consistent With The Statute's Purpose

The plain-text reading of Section 262(*l*)(8)(A) is consistent with the statutory purpose of providing for resolution of patent disputes before FDA approval.

Amgen posits a hypothetical in which an applicant submits its application in 2014 and engages in the subsection (*l*) exchange process at that time, "but does not receive FDA licensure until 2022." Amgen Br. 47. Under that scenario, Amgen says, "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 [sponsor] wishes to assert." *Id.* Nothing in the district court's interpretation would prevent the sponsor from initiating such a suit to seek a preliminary injunction under Section 262(*l*)(8). There is no harm in giving a sponsor *more* time to prepare for that eventuality.

Amgen suggests (at 48) that it would prefer to conduct patent litigation after FDA licensure because it speculates the FDA might require "changes to the product or its manufacture during review." Amgen cites nothing to support the notion that changes during the final 180 days of FDA review are likely to affect the patent analysis. In any event, the district court's interpretation would not prevent a sponsor from waiting until licensure to seek a preliminary injunction, if it so chose. The sponsor simply would not have the extraordinary benefit of the automatic and bondless injunction that Amgen tries to read into the "[n]otice" provision.

Moreover, Amgen's contention that, until FDA licensure, the sponsor will not "know for certain what patents it can assert," Amgen Br. 48, is contrary to the entire premise of the BPCIA's patent-exchange process and immediate artificial-infringement actions: parties can resolve patent disputes before FDA licensure.[9]

* * *

In short, Sandoz did not act unlawfully when it provided notice to Amgen.

[9] Amgen poses a series of hypothetical scenarios (at 49-50), all premised on speculation that an applicant would provide its application – thus triggering the process meant to narrow or avoid litigation – while at the same time providing its notice of commercial marketing – thus inviting immediate and open-ended litigation. Amgen fails to explain why any applicant would behave so irrationally, much less why Section 262(*l*)(8)(A)'s plain terms should be rewritten to guard against it.

III. EVEN IF AMGEN'S INTERPRETATION OF THE BPCIA WERE CORRECT, ITS RECOURSE WOULD BE LIMITED TO WHAT THE BPCIA ITSELF EXPRESSLY PROVIDES

As demonstrated above, Sandoz acted lawfully in not providing Amgen with its application within 20 days from FDA acceptance and by providing its notice of commercial marketing before FDA licensure. But even assuming Sandoz is incorrect on either or both points, Amgen still would have no claim. The BPCIA precisely details the consequences of a party's decision not to follow its procedural steps. An injunction barring commercial marketing without proof of patent infringement is not among them. Courts may not disregard that congressional choice and instead legislate their own remedies or "hunt . . . through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation." A8 n.4.

A. The BPCIA's Express Terms Provide The Sole Consequences For Not Providing An Application And/Or Notice Of Commercial Marketing

Section 262(*l*) and the amendments to the Patent Act establish a fully integrated procedural mechanism for addressing pre-launch patent disputes. They detail a series of procedural steps for both sponsors and applicants, and then provide for specific consequences depending on which steps are taken or not. Those consequences, and only those consequences, apply – even if Amgen were correct that the procedural steps are "mandatory" in all circumstances.

As particularly relevant here, the BPCIA expressly addresses the consequence if the "Subsection (k) application" is "not provided." 42 U.S.C. § 262(*l*)(9)(C). In that event, the applicant is deprived of the ability to bring a declaratory judgment action, and the sponsor is authorized to do so. *Id.* Amgen argues that this is not remedial, contending that it "provide[s] no rights to the [sponsor] that it did not already have under the Declaratory Judgment Act." Amgen Br. 55. That is not so: absent the BPCIA's amendments to the Patent Act, the sponsor would have no action simply based on an applicant's withholding of its application.

Amgen's argument overlooks two key points about the BPCIA: it creates an artificial act of infringement for the precise circumstances here – where an applicant submits a biosimilar application and then fails to provide the application to the sponsor – and the BPCIA expressly provides that the patent remedies it delineates are the *exclusive* remedies a court can award for that failure. Specifically, the BPCIA amended the Patent Act to provide that "if the applicant for the application fails to provide the application and information required under section [262](*l*)(2)(A)," the submission of the application to FDA constitutes an artificial act of infringement, thus ripening any patent dispute for immediate adjudication. 35 U.S.C. § 271(e)(2)(C)(ii). The BPCIA then specifies four patent-specific remedies. *Id.* § 271(e)(4)(A)-(D). Critically, the statute expressly

provides that "[t]he 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 by paragraph (2)." *Id.* § 271(e)(4) (emphasis added); *see id.* (exception only for attorneys' fees).

Amgen acknowledges (at 57-58) that this is an exclusive-remedies provision, citing it as evidence that "Congress knew how to specify when it intended BPCIA remedies to be exclusive." What Amgen fails to recognize is that the provision expressly prescribes the exclusive remedy for the very conduct about which Amgen complains – submitting a biologics application to the FDA while "fail[ing] to provide the application and information required under section [262](*l*)(2)(A)." 35 U.S.C. § 271(e)(2)(C)(ii), (4).

Congress likewise precisely specified the consequence when an applicant engages in the patent-exchange process but does not provide notice of commercial marketing. When that occurs, "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect only to certain specified patents identified during earlier steps in the patent-exchange process. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, inter alia, 42 U.S.C. § 262(*l*)(8)(A)).

B. Amgen's Request For Federal Remedies Not Provided By The BPCIA Is Waived And Meritless

Amgen agrees (at 27) that the BPCIA establishes "a detailed and elaborate procedure for patent-dispute resolution set forth in subsection 262(*l*) and integrated into other provisions of the BPCIA." At the same time, however, Amgen invites (at 52-61) the courts to ignore the remedies provided by Congress and to inject their own. Amgen contends (at 53) that the patent litigation made possible by the BPCIA is not a sufficiently "effective" response to an applicant's failure to provide its application or notice of commercial marketing. Based on this purported flaw in the statutory regime, Amgen argues (at 58-61) that courts should fashion federal remedies that Congress chose not to provide, such as a non-patent-based injunction against commercial marketing.

Because Amgen's complaint asserted only state-law claims (other than its patent-infringement claim), the district court correctly concluded that Amgen waived any claim to an implied private right of action to force compliance with the BPCIA's procedural mechanisms. A8 n.4; *Sow v. Fortville Police Dep't*, 636 F.3d 293, 301 (7th Cir. 2011); *accord* AbbVie Br. 27 n.7. Amgen asserted no such claim for good reason: it is wrong at every step.

As an initial matter, Amgen's premise that Congress provided ineffective consequences is incorrect. *See supra* pp. 9-15, 33-36. Indeed, as the district court explained, allowing a patent holder to sue is "a pretty powerful option." A1840.

In any event, Amgen's criticisms of the statutory consequences are entirely beside the point. Contrary to Amgen's contention (at 58), a federal court does not have "[b]road [p]ower" to invent a "cause of action" to provide a "remedy" for purported violations of federal statutes. "Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Accordingly, "[t]he judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy." *Id.*

In deciding what remedies are available, "[s]tatutory intent . . . is determinative." *Id.* "Without it, a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-87. Amgen thus gets the standard exactly backward when it contends (at 54, 57-58) that courts are free to fashion additional remedies because (according to Amgen) nothing in the statute expressly prohibits them from doing so. There is "no warrant to revise Congress's scheme simply because it did not 'affirmatively' preclude the availability of a judge-made action

at equity." *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1386 (2015).[10]

Amgen points to no evidence of affirmative congressional intent to permit injunctions against market entry to enforce the BPCIA's procedural steps. That failing, by itself, dooms Amgen's argument for an implied right of action for an injunction. *See Alexander*, 532 U.S. at 287.[11] In any event, the BPCIA demonstrates affirmative congressional intent to *foreclose* such a remedy: it expressly identifies the "only remedies" for the failure to provide the application. 35 U.S.C. § 271(e)(4).

Even without that express preclusion-of-remedies provision, however, the statute demonstrates an intent to preclude the creation of additional remedies.

First, "where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. National Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989). Here, as discussed above, the BPCIA

[10] Amicus Janssen cites (at 13-14) inapposite decisions addressing the available remedies where a party *has* a private right of action. *See, e.g., Barnes v. Gorman*, 536 U.S. 181, 185 (2002); *Franklin v. Gwinnett Cnty. Pub. Sch.*, 503 U.S. 60, 62-63 (1992). The question here is whether there is such an action in the first place.

[11] Nor is it relevant whether the provisions use "mandatory" language. Amgen Br. 53. In *In re Digimarc Corp. Derivative Litigation*, for example, the court found a substantive provision's "use [of] the hortatory 'shall' . . . irrelevant." 549 F.3d 1223, 1232 (9th Cir. 2008).

provides sponsors (but not applicants) the right to file a declaratory judgment action in the event the applicant does not provide its application or notice of commercial marketing, and immediately ripens the sponsor's claim so that it may seek traditional patent remedies. *See supra* pp. 13, 34-35. Congress's choice of those consequences precludes the judicial fashioning of additional ones.

Second, where Congress provides a particular *type* of remedy in one portion of a statute but not another, that choice must be given effect. *Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979). Here, Congress provided the opportunity to seek an injunction against commercial marketing of an applicant's product, and it did so based only on allegations of infringement of a valid patent claim. 35 U.S.C. § 271(e)(4)(B). Congress provided no injunction against commercial marketing based simply on a failure to provide an application or notice of commercial marketing.

Third, to claim the benefit of an implied right of action to enforce a federal statute, a party must demonstrate that it is a "member[] of the class for whose especial benefit [the statute] was enacted." *Northwest Airlines, Inc. v. Transport Workers Union of Am.*, 451 U.S. 77, 92 (1981). Amgen cannot make that showing here. Congress did not enact the BPCIA for the special benefit of sponsors. To the contrary, it enacted the law to establish a "biosimilars pathway *balancing*

innovation and consumer interests." BPCIA § 7001(b), 124 Stat. at 804 (emphasis added).

More generally, the provisions invoked by Amgen confer no substantive rights of the kind that might be enforceable through an implied right of action. *Cf. Alexander*, 532 U.S. at 288 (relying on absence of "rights-creating language" to reject implied right of action). Instead, they are purely procedural means to facilitate resolution of patent rights. All the substantive rights at issue derive from patent law and require a showing of a valid, infringed patent claim. It is therefore not surprising that no provision of the BPCIA authorizes an injunction to block entry of a biosimilar based on anything other than substantive patent rights. 42 U.S.C. § 262(*l*)(8)(B), (9)(B)-(C); 35 U.S.C. § 271(e)(2)(C), (4); *see Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-56 (Fed. Cir. 2003).

Amgen has itself (belatedly) followed that pathway by asserting a patent claim in this case. But it has not sought a preliminary injunction based on any patent – presumably because, as Amgen publicly has stated, it has no valid patent rights to enforce. *See supra* p. 15. As the district court correctly found, at this point, "[i]t must, therefore, be assumed that no such infringement has occurred."

A18. For this reason as well, the non-statutory remedy Amgen seeks is fundamentally inconsistent with the statutory design.[12]

C. Amgen Is Not Entitled To Any Remedy Under California Law

Until now, Amgen sought relief only under California law. The district court properly dismissed that strained effort. A14-A15.

1. California's unfair competition law does not apply

As an initial matter, Amgen's claim under the UCL requires as a necessary element a finding that Sandoz engaged in unlawful conduct. *Schnall v. Hertz Corp.*, 93 Cal. Rptr. 2d 439, 451 (Ct. App. 2000). Because Sandoz fully complied with the BPCIA (*see supra* Parts I-II), Amgen has no UCL claim. A14-A15.

Even putting aside that threshold defect, Amgen is not entitled to relief as a matter of California law for additional reasons.

California law provides that UCL remedies are not permitted when the underlying law "expressly provide[s]" that the remedies in that law are exclusive. Cal. Bus. & Prof. Code § 17205; *see Loeffler v. Target Corp.*, 324 P.3d 50, 76 (Cal. 2014). For example, when an underlying statute provides that "its remedies

[12] Amgen incorrectly suggests (at 58) that if Sandoz's declaratory-judgment counterclaims concerning the interpretation of the BPCIA are justiciable, that "implies that Amgen could have brought an action under the BPCIA itself." Sandoz's counterclaims are justiciable because they are defenses to Amgen's state-law claims. *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1300-01 (Fed. Cir. 2010).

'are the exclusive remedies available,'" additional remedies under the UCL are foreclosed. *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 950 P.2d 1086, 1099 (Cal. 1998) (quoting Cal. Civ. Code § 7104.)

Here, as noted above, the BPCIA's amendments to the Patent Act expressly provide that the patent remedies it makes available "are the *only* remedies which may be granted by a court" for the failure to provide a biosimilar application. 35 U.S.C. § 271(e)(4) (emphasis added). Accordingly, additional remedies under the UCL are unavailable as a matter of California law.

Moreover, the authority to provide relief under the UCL is based on "a grant of broad equitable power." *Cortez v. Purolator Air Filtration Prods. Co.*, 999 P.2d 706, 717 (Cal. 2000). Accordingly, California law "does not mandate restitutionary or injunctive relief," even when a predicate for UCL liability has been shown. *Id.* Instead, "consideration of the equities between the parties is necessary to ensure an equitable result." *Id.* In a case like this one, however, Congress already balanced those equities. That legislative balance should control, and no additional remedy under California law should be afforded.

The mismatch between the UCL and the BPCIA is highlighted by the fact that any injunction Amgen could obtain would apply only in California. As this Court recently explained, "[n]either the California courts nor the California legislature are permitted to regulate commerce entirely outside of the state's

borders." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013), *petition for cert. filed*, 82 U.S.L.W. 3690 (U.S. May 15, 2014). Accordingly, the Court squarely held that injunctions issued under California law may apply only to "conduct occurring within California." *Id.* at 1360 (vacating nationwide injunction). Amgen's UCL cause of action is thus premised on the view that the balance of equities would support a California-only injunction for an applicant's failure to follow one of the BPCIA's procedural steps, while sales in the 49 other states would proceed. That arbitrary result should be rejected.

Even if Amgen could somehow surmount this problem, Amgen would then also have to establish that, under choice-of-law principles, California law should apply nationwide. *See Mazza v. American Honda Motor Co.*, 666 F.3d 581, 590 (9th Cir. 2012). Amgen could not do so. Amgen is a resident of California, but Sandoz has its principal place of business in New Jersey and is incorporated in Colorado, and the cancer patients to be treated reside throughout the United States. Amgen cites no other state statute that would permit the injunction Amgen seeks based on an alleged violation of federal law. Congress could not have intended that a federal statute designed to protect patients and payors across the country would be subject to such a patchwork enforcement scheme.

2. Amgen's conversion claim also fails

The district court also correctly dismissed (A15) Amgen's state-law claim for conversion, which was based on Amgen's allegation that "Sandoz referenced Amgen's License for NEUPOGEN® and benefitted 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*)." Amgen Br. 60. To state a claim for conversion, a party must allege, among other things, a "wrongful act." A15; *see In re Emery*, 317 F.3d 1064, 1069 (9th Cir. 2003). Here, however, there was none, as all of Sandoz's actions were permissible under the BPCIA. A15; *see supra* Parts I-II.

Moreover, Amgen has not properly pleaded conversion of an intangible property right. California law has a three-part test for identifying such a right. *Alderson v. United States*, 686 F.3d 791, 796 (9th Cir. 2012). Amgen cannot satisfy any of those elements. First, "the work that Amgen did to obtain [its] license" (Amgen Br. 60) is not a property "interest capable of precise definition." *Alderson*, 686 F.3d at 796. Moreover, the BPCIA expressly permits applicants to use sponsors' licenses to file their own applications. 42 U.S.C. § 262(k)(2)(A)(iii). Amgen thus cannot establish an exclusive ownership interest in its application, nor can it establish a "legitimate claim to exclusivity."

Further, California courts have consistently rejected theories that seek to expand conversion law where, as here, the proposed expansion would (a) interfere with the balance struck by a statute, such as the BPCIA, between the interests of the putative owner of intangible property rights and the interests of the public in the availability of important products and technologies; or (b) create an end-run around the requirements of patent law. *See Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 487-97 (Cal. 1990).

In short, California law does not provide remedies to Amgen that are unavailable to it under the BPCIA.

D. Amgen's State-Law Claims Are Preempted

Although Sandoz did not affirmatively argue preemption in its motion for judgment on the pleadings, amicus AbbVie contends that Amgen's state-law claims are not preempted. AbbVie Br. 24-27. There is no need to reach that question because, for the reasons given above, Amgen has no viable state-law claims to preempt. In any event, AbbVie is incorrect: any injunction against commercial marketing under California law to "enforce" the BPCIA's procedural steps would be preempted.

When a federal statute expressly provides that its remedies are exclusive, additional state remedies are preempted. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 144 (1990). Here, Congress's express intent to bar additional remedies

(federal or state) could hardly be clearer. 35 U.S.C. § 271(e)(4) (providing that Patent Act remedies "are the *only* remedies which may be granted by a court" for the failure to provide a biosimilar application (emphasis added)).

Even apart from that express exclusive-remedies provision, the state-law claims in this case would be preempted for the same reason such claims were preempted in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). That case involved state-law causes of action for allegedly false submissions to the FDA. *Id.* at 347. The Court observed that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied" and, for that reason, there was no presumption against preemption. *Id.* at 347-48 (internal quotation marks omitted). Even more so here: policing the BPCIA's patent-exchange process is not even remotely a field of traditional state regulation.

The Court in *Buckman* went on to find the state-law claims preempted because of the "comprehensive scheme" at issue and the FDA's statutorily conferred enforcement tools for policing such fraud. *Id.* at 348, 350. Here too, the federal scheme is comprehensive and intricate (as Amgen agrees, *see* Br. 27), and interjection of state-law injunctions would disrupt the balance struck by the statute's express provisions addressing the consequences when the BPCIA's procedural steps are not taken. A8 n.4.

IV. AMGEN'S APPEAL OF THE PRELIMINARY INJUNCTION DENIAL IS MOOT, AND WAS BASED ON FACTUAL FINDINGS THAT ARE NOT CLEARLY ERRONEOUS

A. This Aspect Of Amgen's Appeal Is Moot

The district court entered final judgment on the claims for which Amgen sought a preliminary injunction. A22. Indeed, Amgen sought a preliminary injunction only "until the [district] Court decides the parties' motions for judgment on the pleadings," which already occurred. A469. In such situations, this Court "decline[s] to decide whether the preliminary injunction should have been denied; the question is moot." *Fundicao Tupy S.A. v. United States*, 841 F.2d 1101, 1104 (Fed. Cir. 1988).

B. If Not Moot, The Preliminary Injunction Denial Should Be Affirmed

A preliminary injunction movant must establish a likelihood of success on the merits, irreparable harm without preliminary relief, and that the balance of equities and public interest favor an injunction. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Amgen cannot succeed on the merits. *See supra* Parts I-III. Nor did Amgen establish *any* of the other factors.

1. The district court's finding that Amgen's asserted harms are speculative is not clearly erroneous

The district court's finding that Amgen's claimed "harms are at best highly speculative" (A18) is not clearly erroneous.

First, Amgen seeks an injunction that tracks the language of the patent statute. A469. Yet Amgen asserts (at 62) it will be harmed not from infringement but from Sandoz's "being on the market for the up-to-410 day period specified in the BPCIA procedure for patent-dispute resolution." Nothing in the BPCIA suggests that those procedures alone were intended to allow a sponsor to keep a biosimilar off the market. Even if Sandoz had followed them, they ultimately would have led at most to Amgen's ability to file a patent-infringement suit. Showing infringement is the only way the BPCIA contemplates a bar against launching. Amgen has not tried to prove infringement, nor has it sought an injunction based on any patent claim.

Second, as the district court found, Amgen's price-erosion claim is speculative. A18. [redacted]

The documents Amgen cites (at 63) state only that Amgen "might" or "may" lower prices. A479; A516. Amgen's expert admitted Amgen's theory was "highly uncertain." A895-A896. And any price erosion could be remedied by patent-infringement damages. *Altana*, 566 F.3d at 1010-11.

Third, as the district court found, Amgen's claimed harm to goodwill is speculative. A18. Amgen's theory is contingent on Amgen's lowering Neupogen® prices, then forcing removal of Sandoz's product from the market, then rapidly rehabilitating prices. But as explained above, any price reduction by Amgen is speculative. Nor has Amgen established it has any patent rights to remove Sandoz's product from the market.

Fourth, Amgen argues (at 63) its 400-patent portfolio is somehow diminished because, without Sandoz's application, it was "impossible for Amgen to determine which of [its] patents read on the manufacture of Sandoz's biological product." But Sandoz's withholding of its application put Amgen in a *better* position to enforce its patent rights, permitting it to sue much earlier, in July 2014. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). Were Amgen diligent, it could have obtained Sandoz's application in discovery, evaluated it, added any patents to the litigation, and sought an injunction based on them. It did not.

Finally, Amgen's delays in suing and seeking a preliminary injunction negate its claimed irreparable harm. *Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

2. The equities and public interest weigh in Sandoz's favor

Through its considerable investment, Sandoz currently enjoys a head start over other filgrastim applicants expected to receive approval within a year.

A1063. Enjoining Sandoz's launch would cause Sandoz to lose that head start. A1060-A1068. Moreover, the BPCIA balances the interests of innovation *and* providing prompt access to biosimilars. BPCIA § 7001(b). The public interest in more affordable filgrastim would be harmed by an injunction. By contrast, Amgen already has been amply rewarded with 24 years of market exclusivity.

C. Amgen's Requested Injunction Was Unduly Broad

Any injunction would have been limited to California, *supra* pp. 55-56, and could have lasted only until April 11, 2015 – 60 days from when Sandoz produced its application. A734. Section 262(*l*)(3)(A) gave Amgen 60 days to identify its patents, which Amgen did not do. There is no basis for Amgen's requested 410-day injunction.

CONCLUSION

For the foregoing reasons, the Rule 54(b) judgment should be affirmed as soon as practicable, with opinion to follow as necessary. The appeal from the denial of the preliminary injunction motion should be dismissed as moot, or alternatively the denial should be affirmed.

Respectfully submitted,

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/s/ Deanne E. Maynard

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on April 21, 2015.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: April 21, 2015 /s/ Deanne E. Maynard

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

This brief complies with the type-volume limitation of Rule 32(a) of the Federal Rules of Appellate Procedure because it contains 13,824 words, including the words in the chart reproduced in the brief.

Dated: April 21, 2015 /s/ Deanne E. Maynard