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

PETITION FOR REHEARING EN BANC BY DEFENDANT-APPELLEE SANDOZ INC.

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AUGUST 20, 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: August 20, 2015 /s/ Deanne E. Maynard

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Based on my professional judgment, I believe the panel decision is contrary to *Alexander v. Sandoval*, 532 U.S. 275 (2001), and *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). It also presents the following precedent-setting question of exceptional importance:

The "Notice of commercial marketing" provision of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") provides:

> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C. § 262(*l*)(8)(A). The majority held that this notice must be given 180 days *before* commercial marketing but cannot be given until *after* licensure by the Food and Drug Administration ("FDA"). The majority thus effectively granted 180 days of exclusivity for all biological products beyond what Congress expressly provided in the BPCIA. In doing so, the majority ignored the only remedy provided by Congress in the BPCIA – the right to initiate patent litigation – and instead created a new automatic injunction remedy. Did the panel correctly interpret and apply Section 262(*l*)(8)(A)?

/s/ Deanne E. Maynard
Attorney of Record for Sandoz Inc.

INTRODUCTION

Congress enacted the BPCIA as part of the Patient Protection and Affordable

Care Act to promote competition in the biologics market and reduce prices. The record before Congress showed that more competition could save government and private payors tens of billions of dollars. *E.g.*, J.A. Johnson, CRS, RL34045, FDA Regulation of Follow-On Biologics 3 (2009). Congress balanced this need for competition with promotion of innovation, providing a twelve-year exclusivity period that a sponsor will enjoy in return for its investment in innovation, regardless of patent protection. And Congress provided for early resolution of patent disputes, before FDA approval, by creating new artificial-infringement actions. But Congress did not link FDA licensure to the outcome or pendency of any such suit. Rather, it provided that the FDA could license a biosimilar immediately upon expiration of the statutorily-determined exclusivity period.

In a fragmented decision, a panel of this Court issued a ruling that disrupts the balance struck by Congress. If left unreviewed, the ruling will delay access by patients to all biosimilars for six months longer than Congress intended. The panel reached that result by erroneously reading the BPCIA's *pre-marketing* notice provision as a *post-approval* notice provision. That reading is inconsistent with the text, structure, and purpose of the BPCIA.

By its terms, the notice provision simply calls for 180 days' notice *before* an expected product launch. It does not require that the notice be *after* FDA approval. Indeed, special notice at that point would be superfluous, as FDA licensure is a

public act. By precluding notice before approval, the panel ignored the broader role that the notice plays in facilitating early resolution of patent disputes. Contrary to Congress's intent, the ruling will necessarily delay resolution of patent disputes until after FDA approval. The majority reached that erroneous conclusion by focusing on the word "licensed" in subsection (*l*)(8)(A). But that simply refers to the product that will be marketed, which will of course be licensed.

The majority compounded its error by ignoring the remedy provided by Congress and instead creating a new remedy not contemplated by the BPCIA: "a 180-day injunction beyond the express twelve-year statutory exclusivity period." Chen, J., dissent 2. As evidenced by the Hatch-Waxman Act, Congress knew how to stay FDA approval for 180 days; it also knew how to authorize injunctions to enforce subsection (*l*)(8)(A). It did neither. Instead, it provided sponsors with a powerful remedy: an artificial-infringement suit. 42 U.S.C. § 262(*l*)(9)(B), (C); 35 U.S.C. § 271(e)(2)(C). Although Amgen brought such a claim, it made no attempt to justify an injunction based on any alleged patent infringement by Sandoz.

Without any such patent showing, the BPCIA allowed Sandoz to make its biosimilar filgrastim product Zarxio® available to cancer patients upon FDA approval on March 6, 2015: (1) Sandoz had provided notice of its intent to market more than six months before that, on July 8, 2014, giving Amgen time to bring suit (which it did), and (2) any exclusivity period had expired, as Amgen already has

enjoyed 24 years of exclusivity. *See* slip op. 6-7. Instead, due to the panel's interpretation of the BPCIA's notice provision, cancer patients are still waiting.

If the pre-marketing notice contemplated by Congress cannot be given until after licensure, many more patients will have to wait six months longer than Congress intended for every biosimilar. Each panel member had a different interpretation of this important statute, and the fragmented interpretation will bind industry, district courts, and subsequent panels of this Court. The full Court should weigh in so that the interpretation of subsection (*l*)(8)(A) is correct from the outset.

BACKGROUND

The BPCIA created a pathway for the FDA to license "biosimilar" products that are "highly similar" to approved biological products by allowing a biosimilar applicant to rely in part on the approval of the sponsor's product. 42 U.S.C. § 262(i)(2), (k). "To balance innovation and price competition," Congress provided sponsors "up to twelve years of exclusivity against follow-on products, regardless of patent protection." Slip op. 5 (citing 42 U.S.C. § 262(k)(7)(A)).

The BPCIA also facilitates early resolution of potential patent disputes. It amended the Patent Act to make submitting a biosimilar application to the FDA an artificial act of infringement under certain circumstances. 35 U.S.C. § 271(e)(2)(C). That enables a declaratory judgment action before any actual infringement is imminent. Who can bring such an action, when, and for what relief

depends on the actions or inactions at each step of a multi-step information exchange process between the applicant and the sponsor regarding the sponsor's possible patent claims. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9). Congress spelled out both the action the applicant or sponsor "shall" take to continue the process, and if that party declines, what follows. The end result is a possible pre-approval artificial-infringement suit. *Id.*

Properly considering the statute as a whole, the panel correctly concluded that the BPCIA "explicitly contemplates" that an applicant might not take the first step in this process: disclosing its application to the sponsor under subsection (*l*)(2)(A). Slip op. 12. As the panel concluded, the BPCIA "specifically sets forth the consequence for such failure: the [sponsor] may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." *Id.* at 12-13. Both of those provisions "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." *Id.* at 14.

But the majority failed to use that properly holistic, statutory-based approach in interpreting the "Notice of commercial marketing" provision. It read that provision as precluding notice before approval, defeating the notice's purpose in artificial-infringement suits. And it created an exclusivity not contemplated by Congress, looking outside the statute in creating an automatic injunctive remedy.

ARGUMENT

I. THE PANEL'S INTEPRETATION OF THE PRE-MARKETING NOTICE PROVISION DISTORTS THE STATUTORY SCHEME

A. The Majority Disrupts The Careful Balance Struck By Congress

Congress sought to facilitate prompt access to cost-saving biosimilars while promoting innovation in biologics. BPCIA § 7001(b), 124 Stat. at 804; A423. As Judge Chen explained, the majority's reading of the notice-of-marketing provision gives the sponsor an "extra-statutory exclusivity windfall" – "a 180-day injunction beyond the express twelve-year statutory exclusivity period." Chen, J., dissent 2. "If Congress intended to create a 180-day automatic stay it understood how to do so." *Id.* at 9. For example, Congress expressly extended the exclusivity period to "12 years and 6 months rather than 12 years" for sponsors that successfully complete pediatric studies. 42 U.S.C. § 262(m)(2)(A). Congress also "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is given. Chen, J., dissent 9. Such a provision would have been "analogous to the thirty-month stay of the Hatch-Waxman Act, which provides for an automatic stay during which the FDA cannot approve the ANDA." *Id.* Congress did neither.

B. The Panel Undermines The BPCIA's Patent-Resolution Regime

While adding six months of exclusivity found nowhere in the statute, the panel also rendered actual statutory provisions irrelevant. According to the panel,

giving notice "allows the [sponsor] a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents." Slip op. 6. But that purpose is better served by *pre-marketing* notice; it does not require waiting until *post-approval,* as Sandoz's pre-approval notice showed here. Amgen sued well before approval.

The panel's holding also overlooks and disrupts the larger role that the notice plays in the BPCIA's patent resolution scheme. To be sure, when the applicant does not provide its application under subsection (*l*)(2), the sponsor can bring an immediate artificial-infringement suit on *any* patents, regardless of notice. *See* Chen, J., dissent 8-9. But when the applicant and the sponsor are engaging (or have engaged) in the patent-exchange process, the notice is the key to allowing the sponsor to litigate any patents that have not been selected for litigation as of the time of the notice: the notice lifts the stay on artificial-infringement declaratory judgment suits. 42 U.S.C. § 262(*l*)(9)(A) (lifting stay on patents described in § 262(*l*)(8)(B)(i) and (ii)). Provision of the notice also allows the sponsor (if and when it chooses) to ask for preliminary injunctive relief. *Id*. § 262(*l*)(8)(B).

But if, as the panel held, notice cannot be given until after FDA approval, it will mean that, in *every* situation where the parties participate in the patent-exchange process, any not-yet-litigated patent disputes cannot even *begin* until

after FDA approval. That will frustrate Congress's goal of having patent disputes resolved early so that biosimilars can be available to patients as soon as possible.

Moreover, by defining the patents to which the stay applies as the intersection of the patents described in subsection (*l*)(8)(B)(i) and (ii) (42 U.S.C. § 262(*l*)(9)(A)), Congress contemplated multiple possible situations, including where the sponsor and applicant ultimately engage in a subsection (*l*)(6) suit (*see* slip op. 6) but also where approval might be expected before the patent-exchange process can be completed. The latter situation may often be the case in the initial years of the BPCIA's implementation, as the FDA has committed to approve applications within 10 months. A65 & n.1. But under the majority's ruling, this elaborate scheme regarding the effect of the notice is rendered largely unnecessary.

The panel thought that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Slip op. 17. But the entire premise of the BPCIA's artificial-infringement actions is that disputes can be resolved based on the filed application. 42 U.S.C. § 262(*l*)(2)(A). It is the *application* that "circumscribes and dominates the assessment of potential infringement." *Cf. Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014). Once the biosimilar is licensed, there is no need for the very pre-approval artificial-infringement suits the notice allows. The sponsor or applicant can file suit and

seek a preliminary injunction under 35 U.S.C. § 271(a) and/or (g). *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997).

Finally, providing notice after FDA approval would be superfluous. FDA licensure of a biosimilar is a public act. There is no need for special "notice" of it.

C. The Text Calls For Notice Before Marketing, Not After Licensure

The disruption of the statutory scheme caused by the majority's reading of subsection (*l*)(8)(A) is unsupported by the provision itself. It is entitled "Notice of commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). It requires only that notice be provided "180 days before the date of the first commercial marketing." *Id.* Nothing requires that an applicant wait until after approval, then provide notice, then wait six months more. Congress knew how to require that something be both "after" one event and "before" another; it did that in subsection (*l*)(8)(B), not in (*l*)(8)(A). *Id.* § 262(*l*)(8)(B) ("*After* receiving the notice under subparagraph (A) *and before* such date of the first commercial marketing . . . .") (emphasis added). Indeed, subsection (*l*)(8)(A) expressly authorizes a "subsection (k) *applicant*" to provide notice, not the "holder" of a license. *See* 42 U.S.C. § 262(m)(3).

The panel's holding that an effective notice cannot be given until after FDA approval rests entirely on the phrase "the biological product licensed under subsection (k)." But as the district court explained (A13), the word "licensed" simply reflects that a product cannot legally be commercially marketed *unless* it is

"licensed under subsection (k)." *See* 42 U.S.C. § 262(a)(1)(A). The panel pointed to other provisions of subsection (*l*) that refer to "the biological product that is the subject of" the application. Slip op. 16-17. But none of those provisions refers to the future status of the product once it is "licensed."

D. The Majority's Injunction Conflicts With Governing Authority

The majority's flawed reading of the notice provision caused it to distort the BPCIA's patent-oriented remedial scheme. If it had properly read the provision as allowing notice before approval, the notice still would have provided the sponsor with "a period of time to assess and act upon its patent rights," but without the need for the majority to create an automatic injunction against marketing an already-approved product. *Cf.* slip op. 21. But because it read the *pre-marketing* notice as a *post-approval* notice, the majority believed that the provision contained an unstated 180-day bar to marketing. And because the majority ignored the only remedy provided in the BPCIA and instead concluded that the BPCIA provided no consequence "if Sandoz attempts to launch in disregard of the requirement of paragraph (*l*)(8)(A), as we have interpreted it," *id.* at 19, it created its own remedy: a private right of action for an automatic, bondless injunction barring Sandoz from "marketing, selling, offering for sale, or importing into the United States" its biosimilar product until 180 days after its post-approval notice. Dkt. 105; slip op. 25. That ruling conflicts with the BPCIA and with generally applicable

principles enunciated by the Supreme Court and other courts of appeals.

The majority correctly recognized that the BPCIA has no provision "that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)." Slip op. 13. But it failed to recognize that the BPCIA also provides no right to compel compliance with the 180-day notice provision. The only provision in subsection (*l*) that Congress made enforceable by an injunction is the confidentiality provision. 42 U.S.C. § 262(*l*)(1)(H). But that is not to say that the BPCIA contemplates no remedy for noncompliance with subsection (*l*)(8)(A): it provides the right to seek a declaratory judgment for artificial infringement. *See* 42 U.S.C. § 262(*l*)(9)(B); 35 U.S.C. § 271(e)(2)(C).

The majority concluded that, "[w]hile it is true that paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." Slip op. 20. That is so, according to the majority, because subsection (*l*)(9)(B) permits an infringement suit on the patents included in the list created under subsection (*l*)(3)(A), but no such list is created if the applicant does not provide its application under subsection (*l*)(2)(A). *Id.*

But as Judge Chen explained, when there was no disclosure under subsection (*l*)(2)(A), a sponsor "does not need the remedy in (*l*)(9)(B) because

(*l*)(9)(C) and § 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action," as Amgen has done here. Chen, J., dissent 8. "[T]he absence of such a remedial provision in (*l*)(9)(B) *confirms* that Congress deemed any additional remedy to be unnecessary." *Id.* The sponsor already "possesses the statutory right to seek a preliminary injunction for any of its patents." *Id.*

Instead of adhering to this scheme expressly provided by the BPCIA, the majority fashioned its own remedy. But the Supreme Court has made clear that courts are not free to create their own remedies. *See Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001) (Unless a statute "displays an intent to create not just a private right but also a private remedy . . . . 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."). Where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989). As other Circuits have held, "to imply injunctive authority" in a statute that does not expressly provide it "would exceed what was contemplated by the executive and legislative branches in enacting" the statute and "arrogate to [courts] powers rightfully retained by those two branches of government." *Colorado v. Idarado Mining Co.*, 916 F.2d 1486, 1497-98 (10th Cir. 1990); *see United States v. EME*

Homer City Generation, L.P., 727 F.3d 274, 291-96 (3d Cir. 2013); *Wheeling-Pittsburgh Steel Corp. v. Mitsui & Co.*, 221 F.3d 924 (6th Cir. 2000).

Yet that is what the majority has done. Despite affirming dismissal of the only causes of action on appeal (two state-law claims), slip op. 24, it effectively recognized a private right of action for an automatic injunction to enforce anticipatorily its reading of subsection (*l*)(8)(A). But the BPCIA creates neither that right nor that remedy. And subsection (*l*)(8)(B) makes clear that, when Congress intended injunctive relief to be available, it said so expressly and conditioned it on a showing of valid patent rights. *See* 42 U.S.C. § 262(*l*)(8)(B) (allowing the sponsor to "*seek* a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product" (emphasis added)). The only mechanisms in the BPCIA for enjoining commercial marketing are patent-based remedies. *Id.* § 262(*l*)(8)(B), (9); 35 U.S.C. § 271(e)(2)(C). But the majority's ruling will provide a 180-day post-approval injunction to *every* sponsor, even where it has *no* patent claims.

The majority also erred by enjoining Sandoz without regard to traditional equitable factors, despite the district court's findings of no irreparable harm. *See* A18, A2080. That approach conflicts with *eBay Inc. v. MercExchange*, where the Supreme Court emphasized that it "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically

follows a determination" of a statutory violation. 547 U.S. 388, 392-93 (2006).

The majority's disregard for traditional equitable principles likewise led it to hold that Amgen need not post a bond. As the Seventh Circuit has emphasized, a bond of "zero—the upshot of an injunction without a bond—is bound to be too low." *Roche Diagnostics Corp. v. Med. Automation Sys.*, 646 F.3d 424, 428 (7th Cir. 2011). The Court should require one now.

Finally, at the very least, the injunction is overly broad. Its language is untethered from any provision in the BPCIA. Rather, it tracks the language of the Patent Act (Dkt. 105), going beyond marketing and, for example, restricting the ability of Sandoz to import product, even though Amgen has made no material attempt to enforce any of its patents.

II. THE FULL COURT'S REVIEW IS NEEDED NOW

Whether patients' access to biosimilars will be delayed is of critical importance to the pharmaceutical industry and purchasers, including taxpayers (through Medicare and Medicaid). In 2013, biologics accounted for $92 billion in spending in the United States. GPhA Amicus Br. 3 n.4. They are some of the most expensive drug products, costing on average $45 per patient per day. *Id.* at 3-4. Congress enacted the BPCIA to tackle these enormous costs. Its goals will be frustrated if the majority's interpretation of subsection (*l*)(8)(A) is not reversed.

The panel attempted to downplay the significance of its holding by

suggesting that the extra 180 days of exclusivity "will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period for other products." Slip op. 18. Even if the FDA could grant tentative approval under the BPCIA (which it cannot), the panel's conclusion hinges on the "licensed product" language in subsection (*l*)(8)(A). A tentatively approved product is not licensed. *See* FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014). As a result, were the majority decision to stand, *all* biosimilars will be delayed by 180 days.

Review is needed now. This issue will be a live controversy beyond September 2. Sandoz requests a bond from which it could collect if it ultimately prevails. Moreover, Sandoz will be a repeat biosimilar applicant and could not secure full appellate review in any future case within the 180-day period at stake. *See Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1173 (9th Cir. 2002) (a case is "capable of repetition, yet evading review" when it is likely to conclude before the appellate court can resolve it and "there is a reasonable expectation that the plaintiffs will be subjected to it again").

CONCLUSION

This petition should be granted, and Amgen should immediately be required to post a bond sufficient to cover the harm Sandoz has suffered since issuance of the injunction pending appeal.

Respectfully submitted,

/s/ Deanne E. Maynard

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Dated: August 20, 2015

ADDENDUM

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

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

Decided: July 21, 2015

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

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

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

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

LOURIE, *Circuit Judge*.

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

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

A. BACKGROUND

I.

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

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

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

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

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

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

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

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

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

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

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

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

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

II.

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

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

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

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

III.

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

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

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

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

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

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

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

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

B. DISCUSSION

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

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

I.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II.

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

a.

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

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

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

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

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

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

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

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

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

tends to commercially market its product someday in the future.

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

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

b.

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

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

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

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

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

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

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

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

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

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

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

III.

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

a.

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

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

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

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

b.

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

c.

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

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

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

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

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

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

IV.

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

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

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

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

V.

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

C. CONCLUSION

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

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

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

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

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

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

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

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

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

I

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

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

> **§262(*l*)(8)(A)** *Notice of commercial marketing*.-- The subsection (k) applicant **shall provide notice** to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product **licensed under subsection (k).**

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

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

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

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

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

II

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

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

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

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

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

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

(Emphases added).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

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

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

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

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

I

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

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

A

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

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

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

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

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

> **8) Notice of commercial marketing and preliminary injunction**
>
> **(A)** Notice of commercial marketing
>
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).
>
> **(B)** Preliminary injunction
>
> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
>
> **(i)** included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
>
> **(ii)** not included, as applicable, on—
>
> **(I)** the list of patents described in paragraph (4); or
>
> **(II)** the lists of patents described in paragraph (5)(B).

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

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

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

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

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

B

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

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

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

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

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

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

C

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

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

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

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

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

II

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

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

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

CERTIFICATE OF SERVICE

I hereby certify that 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 August 20, 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: August 20, 2015 /s/ Deanne E. Maynard

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