827 F.3d 1052
United States Court of Appeals,
Federal Circuit.

AMGEN INC., Amgen Manufacturing Limited, Plaintiffs–Appellees
v.
APOTEX INC., Apotex Corp., Defendants–Appellants.

2016-1308
|
Decided: July 5, 2016

Synopsis

Background: Reference product sponsor (RPS) brought **patent** infringement action against biologics license applicant, which was seeking license, pursuant to Biologics Price Competition and Innovation Act (BPCIA), from the Food and Drug Administration (FDA), for its pegfilgrastim product based on such product's similarity to RPS's product. The United States District Court for the Southern District of Florida, No. 0:15-cv-61631-JIC, James I. Cohn, J., entered preliminary injunction, enjoining applicant from entering market unless it had given sponsor notice after receiving FDA license and then waited 180 days. Applicant appealed.

Holdings: The Court of Appeals, Taranto, Circuit Judge, held that:

[1] requirement that applicant for product could not market product for 180 days after providing RPS with notice was enforceable by injunction; and

[2] provision governing limitations on declaratory judgment actions brought under BPCIA did not make declaratory judgment action on **patent** the exclusive remedy for violations of BPCIA.

Affirmed.

West Headnotes (5)

[1] **Federal Courts** Preliminary injunction;temporary restraining order

The Court of Appeals reviews a district court's grant of a preliminary injunction for abuse of discretion, which may be established when a district court's decision is based on an error of law.

Cases that cite this headnote

[2] **Federal Courts** Preliminary injunction;temporary restraining order

When a district court's grant of a preliminary injunction rested on its interpretation of a statute, that is a question of law reviewed de novo by the Court of Appeals.

Cases that cite this headnote

[3] **Statutes** Mandatory or directory statutes

Use of the word "shall" in a statute generally indicates that a directive is mandatory.

1 Cases that cite this headnote

[4] **Health** Generic and orphan drugs;market exclusivity

Biologics Price Competition and Innovation Act (BPCIA) provision, requiring biologics license applicant to provide notice of commercial marketing to reference product sponsor (RPS) with 180 days' post-licensure notice was mandatory for applicant, and, thus, requirement that applicant for pegfilgrastim product could not market product for 180 days after providing RPS with notice was enforceable by injunction; provision contained no words that made applicability of notice rule turn on whether applicant provided notice that began information-exchange process, as required by BPCIA, between parties. Public Health Service Act, § 351(l)(8)(A), 42 U.S.C.A. § 262(l)(8)(A).

2 Cases that cite this headnote

[5] **Health** Generic and orphan drugs;market exclusivity

Biologics Price Competition and Innovation Act (BPCIA) provision governing limitations on declaratory judgment actions brought under BPCIA did not make declaratory judgment action on **patent** the exclusive remedy for violations of BPCIA provision requiring biologics license applicant to provide notice of commercial marketing to reference product sponsor (RPS) with 180 days' post-licensure notice, absent any language that excluded other remedies, or implied such exclusivity for seeking remedies. Public Health Service Act §§ 351, 352, 42 U.S.C.A. §§ 262(l)(8)(A), 262(l)(9)(C).

2 Cases that cite this headnote

***1053** Appeal from the United States District Court for the Southern District of Florida in No. 0:15-cv-61631-JIC, Judge James I. Cohn.

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Before Wallach, Bryson, and Taranto, Circuit Judges.

Opinion

Taranto, Circuit Judge.

This appeal involves an action brought by Amgen Inc. and Amgen Manufacturing Limited (collectively Amgen) against Apotex Inc. and Apotex Corp. (collectively Apotex) under the Biologics Price Competition and Innovation Act of 2009 (Biologics Act or BPCIA). Apotex has an application pending with the Food and Drug Administration, filed under the Biologics Act, that seeks permission to begin marketing a product allegedly "biosimilar" to Amgen's FDA-approved Neulasta®. For such an applicant, the Biologics Act lays out a step-by-step process for exchanging information and channeling litigation about **patents** relevant to the application. Apotex and Amgen proceeded several steps into that process, leading to the present suit in which Amgen alleges that Apotex's proposed marketing would infringe an Amgen **patent**.

This appeal, however, does not involve the merits of the infringement allegations. Rather, it involves Amgen's motion for a preliminary injunction concerning what will happen if and when the FDA licenses Apotex's proposed biosimilar product. Amgen sought a preliminary injunction to enforce a provision of the Biologics Act that requires a biosimilar-product applicant to give notice 180 days before commercially marketing its FDA-licensed product, 42 U.S.C. § 262(*l*)(8)(A). We held in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357–58 (Fed. Cir. 2015), among other things, that the 180-day period runs from *post*-licensure notice. Here, the district court, agreeing with Amgen, preliminarily enjoined Apotex from entering the market unless it has given Amgen notice after receiving the requested FDA license and then waited 180 days.

We affirm. In *Amgen v. Sandoz*, we held that the commercial-marketing provision is mandatory, with the 180-day period beginning only upon post-licensure notice, and that an injunction was proper to enforce the provision against Sandoz, a biosimilar-product applicant that had entirely skipped the statutory process of information exchange and **patent**-litigation channeling. Apotex argues that a different result is required here—that the commercial-marketing provision is not mandatory and may not be enforced by an injunction—because it, unlike Sandoz, did launch the statutory process for exchanging **patent** information and channeling **patent** litigation. We reject ***1055** the asserted distinction. We hold that the commercial-marketing provision is mandatory and enforceable by injunction even for an applicant in Apotex's position.

BACKGROUND

Amgen markets FDA-approved Neulasta®, whose active ingredient is pegfilgrastim, a human-engineered protein that, in patients undergoing chemotherapy, can stimulate the production of neutrophils (a type of white blood cell) and thereby decrease the incidence of infection. Amgen received a biologics license from the FDA for Neulasta® in 2002 pursuant to 42 U.S.C. § 262(a). In 2014, Apotex filed an application for an FDA license to market a biosimilar version of Neulasta®,

invoking the "abbreviated pathway for regulatory approval of follow-on biological products that are 'highly similar' to a previously approved product ('reference product')," as described in *Amgen v. Sandoz*, 794 F.3d at 1351. Congress created that route to FDA licensure in the Biologics Act in 2010. 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.* Apotex's application is pending.

A

When Amgen obtained its license, it had to show that its biological product, Neulasta®, was "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). The Biologics Act authorizes enterprises like Apotex to gain approval, after a time, for a product sufficiently similar to the "reference product," without repeating all of the work of the pioneer, the "reference product sponsor" (defined at *id.* § 262(*l*)(1)(A)). Under § 262(k), an applicant may obtain a license by demonstrating, among other things, that its product is "biosimilar" to a reference product. In so doing, it may use publicly available information about the reference product's safety, purity, and potency to support its application. *Id.* § 262(k)(2)(A)(i), (iii). For the purpose of "balancing innovation and consumer interests," Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804, Congress prescribed that a biosimilar-product application under § 262(k) "may not be submitted" until four years after the reference product was first licensed under § 262(a) and that a biosimilar-product license "may not be made effective" until twelve years after the reference product was first licensed. 42 U.S.C. § 262(k)(7)(A), (B).

1

Of particular relevance here, the Biologics Act contains a detailed, multi-part subsection, § 262(*l*), that is focused in various ways on potential **patent** disputes between the reference product sponsor and biosimilar-product applicant. That subsection by its terms provides for two stages of litigation—one under paragraph (6), the other under paragraph (8). In this opinion, we will often refer to paragraphs and subparagraphs within that subsection without repeating the "§ 262(*l*)"; unless otherwise made clear, any such shorthand references are to that subsection. We also will usually call the § 262(k) applicant simply the "applicant."

The § 262(*l*) provisions of principal present significance are as follows. Under (2)(A), within 20 days after the FDA notifies the applicant that its application has been accepted for review, the applicant is to give notice to the reference product sponsor by providing the application as well as information describing the manufacturing process. § 262(*l*)(2)(A). Under (3)(A), within 60 days of receiving that notice, the reference product sponsor is to provide a list of **patents** that could reasonably be asserted against the applicant and ***1056** specify which it would be prepared to license to the applicant. § 262(*l*)(3)(A). Under (3)(B), within 60 days after receiving that list, the applicant is to respond with a detailed statement identifying why each **patent** on the reference product sponsor's list is invalid, unenforceable, or not infringed, or declaring that it does not intend to commercially market the biosimilar product before a particular **patent** expires, and also addressing the reference product sponsor's statement of readiness to license. § 262(*l*)(3)(B)(ii), (iii). The applicant, in its response, *may* also provide its own list of **patents** that it believes could reasonably be asserted against it. § 262(*l*)(3)(B)(i). Under (3)(C), then, within 60 days of receiving the applicant's (3)(B) response, the reference product sponsor is to provide a detailed reply regarding those **patents** on its (3)(A) list as to which the applicant has asserted non-infringement, invalidity, or unenforceability. § 262(*l*)(3)(C).

While the reference product sponsor may later supplement its (3)(A) list under paragraph (7), it is the original lists under (3) that form the basis of the next steps in the process leading to immediate litigation under paragraph (6). Those steps begin with paragraph (4), which requires that the reference product sponsor and the applicant enter into good-faith negotiations over which of the **patents** listed under (3) will be the subject of an immediate **patent**-infringement action. § 262(*l*)(4)(A). If the parties reach agreement, (6)(A) provides that the reference product sponsor must bring an action

for infringement on all such **patents** within 30 days. § 262(*l*)(6)(A); *see* 35 U.S.C. § 271(e)(2)(C)(i). The applicant must then notify the FDA. § 262(*l*) (6)(C).

If the parties do not reach agreement within 15 days of starting their negotiation, (4)(B) directs the parties to paragraph (5) for the process that determines the scope of immediate litigation. § 262(*l*)(4)(B). That process gives the applicant a scope-limiting ability, based on an exchange of lists of **patents** to be litigated. The applicant tells the reference product sponsor how many **patents** will be on the applicant's list; that number caps how many **patents** the reference product sponsor may list, except that if the applicant lists none, the reference product sponsor may list one; and the two sides exchange lists. § 262(*l*)(5). Within 30 days, under (6)(B), the reference product sponsor must sue for infringement on precisely those **patents** that appear on the combined lists. § 262(*l*)(6)(B). And the applicant must notify the FDA. § 262(*l*) (6)(C). Notably, the immediate litigation is limited to a single **patent** if the applicant lists no **patents**, no matter how many **patents** the reference product sponsor designated in (3)(A) as reasonably assertable against the making, selling, etc., of the proposed biosimilar product. § 262(*l*) (5)(B)(ii)(II).

Given the deadlines set in § 262(*l*), and the time commonly taken for FDA review, we may assume that the early litigation under paragraph (6) will be initiated before the FDA licenses the applicant's biosimilar product. But the Biologics Act —having provided for a narrowing of the scope of the paragraph (6) litigation, including by allowing the applicant to exclude potentially meritorious **patents** from that litigation—provides, in paragraph (8), for a second stage of **patent** litigation.

Paragraph (8) does so by first requiring, in (8)(A), that the applicant give the reference product sponsor notice at least 180 days before commercially marketing its "licensed" product. § 262(*l*)(8)(A). We held in *Amgen v. Sandoz* that the notice starting the 180-day clock must follow, not precede, the licensure. 794 F.3d at 1357–58. (8)(B) then declares that, after receiving the (8)(A) post-licensure notice but before the ***1057** applicant's commercial marketing begins, the reference product sponsor may seek a preliminary injunction based on any **patent** within either of two classes. The first class, expressly described in (8)(B), consists of the **patents** that appeared on any of the original paragraph (3) lists, minus **patents** that were the subject of paragraph (6) litigation (by agreement under (4) or by the narrowing process under (5)). § 262(*l*) (8)(B). The second class consists of certain **patents** that were issued to or exclusively licensed by the reference product sponsor after it gave the applicant its (3)(A) list. As to those **patents**, paragraph (7) prescribes an information exchange and states that they "shall be subject to paragraph (8)," § 262(*l*)(7)—which evidently means that **patents** within (7) are to be treated as falling under (8)(B). For this second-stage litigation, (8)(C) requires that the parties reasonably cooperate to expedite new discovery needed in connection with the preliminary-injunction motion. § 262(*l*)(8)(C).

Paragraph (9) of § 262(*l*) reinforces the just-described channeling of litigation and provides incentives for the applicant to proceed in those channels. It does so by addressing when declaratory-judgment actions are or are not available in certain circumstances—in (9)(C), as to applicants that simply bypass the process of information exchange that begins with (2)(A); and in (9)(A) and (B), as to applicants that begin but do not complete the process.

(9)(C) addresses an applicant that does not even provide the first-step notice under (2)(A). For such an applicant, the reference product sponsor, but not the applicant, may bring an action under 28 U.S.C. § 2201 for a declaratory judgment of "infringement, validity, or enforceability of any **patent** that claims the biological product or a use of the biological product." § 262(*l*) (9)(C). The subject of such action is not limited by reference to any **patent** lists.

(9)(A) and (B) together address an applicant that does provide the (2)(A) notice. (9)(A) protects the two-stage litigation scheme under paragraphs (6) and (8): it declares that neither side may bring a declaratory-judgment action relating to any **patent** described in (8)(B) for the second-stage litigation until after the (post-licensure) 180-day notice of commercial marketing under (8)(A) is received. § 262(*l*)(9)(A). [1] Then, (9)(B) reinforces the applicant's incentives to complete the orderly process: it specifies that the (9)(A) bar on declaratory-judgment actions is lifted for the reference product sponsor, but not for the applicant, if an applicant that has given the (2)(A) notice "fails to complete an action required" of the

applicant at specified steps past the (2)(A) step. The specified applicant duties are those prescribed by paragraph (3)(B)(ii) (responding to the reference product sponsor's (3)(A) list); by paragraph (5) (furnishing lists defining the first-stage litigation in the absence of agreement); by paragraph (6)(C)(i) (notifying the FDA of the first-stage litigation); by paragraph (7) (responding to the reference product sponsor's update of its (3)(A) list); and by paragraph (8)(A) (providing a 180-day notice before commercial marketing of the licensed product). A failure of the applicant at any of those stages lifts the (9)(A) bar on the reference product sponsor, allowing it to bring a declaratory-judgment action ***1058** on any **patent** on its (3)(A) list as supplemented under (7). § 262(*l*)(9)(B).

2

Besides setting out the foregoing regime, the Biologics Act amended the infringement provision of the **Patent** Act, 35 U.S.C. § 271, in a way that is tied to that regime. *See* Pub. L. No. 111-148, § 7002(c)(1), 124 Stat. at 815–16. As amended, 35 U.S.C. § 271(e)(2) provides that, in two circumstances, it is "an act of infringement" for a person "to submit" "an application seeking approval of a biological product" if the purpose 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)(C)(i), (ii). The two circumstances involve, respectively, an applicant that has launched the Biologics Act information-exchange process we have described and an applicant that has not.

Specifically, one circumstance is when the **patent** "is identified in the list of **patents** described in" paragraph (3), "including as provided under" paragraph (7), of the Biologics Act's **patent** provisions described above. 35 U.S.C. § 271(e)(2)(C)(i). Filing the biosimilar application is an act of infringement of **patents** that the reference product sponsor has listed through the Biologics Act's prescribed processes, which occurs only when the applicant has provided the (2)(A) notice. The other circumstance involves an applicant that "fails to provide the application and information required" under (2)(A). In that case, filing the biosimilar application is an act of infringement as to a **patent** that "could be identified pursuant to" (3)(A), *i.e.*, a **patent** that the reference product sponsor could identify as one it believes "could reasonably be asserted" with respect to the biosimilar product at issue. 35 U.S.C. § 271(e)(2)(C)(ii).

35 U.S.C. § 271(e)(4) addresses remedies for such infringements. Subparagraphs (B) and (C) authorize injunctions and damages, and subparagraph (D) states that "the court shall order a permanent injunction" against infringement of a **patent** in certain cases decided in the Biologics Act's first-stage (paragraph (6)) litigation. 35 U.S.C. § 271(e)(4)(D). Section 271(e)(4) adds that those remedies "are the only remedies which may be granted by a court for an act of infringement described in paragraph (2)," except for attorney's fees. 35 U.S.C. § 271(e)(4).

35 U.S.C. § 271(e)(6), however, then limits the just-described remedies in two ways evidently designed to reinforce the reference product sponsor's incentives to follow the distinctive Biologics Act's **patent** process where the applicant has launched that process. *First*: If the reference product sponsor is late in bringing the first-stage infringement action under § 262(*l*)'s paragraph (6), *i.e.*, does so more than 30 days after the scope of that litigation has been determined under (4) or (5), the only remedy the reference product sponsor can get in that action is a reasonable royalty. 35 U.S.C. § 271(e)(6)(A), (B). [2] *Second*: If a **patent** that the reference product sponsor should have included on its (3)(A) list or its (7) supplement "was not timely included," then the owner of that **patent** may not sue for infringement under 35 U.S.C. § 271 with respect to the biological product at issue. 35 U.S.C. § 271(e)(6)(C).

***1059** B

In October 2014, Apotex filed a biologics license application with the FDA under 42 U.S.C. § 262(k), listing Amgen's Neulasta® as the reference product, and the FDA accepted Apotex's application for review on December 15, 2014. On December 31, 2014, Apotex provided Amgen a copy of the application and information detailing Apotex's pegfilgrastim

manufacturing process, complying with § 262(*l*)'s paragraph (2)(A). Amgen provided Apotex its (3)(A) list on February 27, 2015, identifying three **patents**, and Apotex provided its (3)(B) **patent**-specific response on April 17, 2015. In that response, Apotex certified that it did not intend to begin commercial marketing before two of the **patents** had expired and, as to the remaining **patent**, described bases for asserting non-infringement and invalidity. The same day, Apotex sent a letter to Amgen stating that it was thereby providing notice of future commercial marketing pursuant to (8)(A), though Apotex lacked (as it still lacks) an FDA license. On June 16, 2015, Amgen furnished Apotex its (3)(C) reply regarding validity and infringement. The parties then negotiated under (4) and agreed to an immediate action under (6)(A) for infringement of the two then-extant **patents**; Amgen filed that action on August 6, 2015; and when one of the **patents** expired in October 2015, that action became about only one **patent**, U.S. **Patent** No. 8,952,138.

C

Just before that action was filed, this court decided *Amgen v. Sandoz*. The court held first that a biosimilar-product applicant cannot be compelled to provide notice of FDA review under (2)(A) and that an infringement suit under 35 U.S.C. § 271(e)(2) is the reference product sponsor's remedy if the applicant does not provide such notice. The court stressed that 35 U.S.C. § 271(e)(2)(c)(ii) declares precisely that conduct—filing an application and failing to give the (2)(A) notice—to constitute an infringement (of a **patent** that could have been listed under (3)(A)) and that § 271(e)(4) declares the monetary and injunctive remedies in a suit for that infringement to be the exclusive remedies for that conduct. 794 F.3d at 1354–57.

The court next addressed the (8)(A) requirement of a 180-day notice of commercial marketing. The court held that the (8)(A) notice must be a notice given after FDA licensure of the biosimilar product, not before, and that pre-licensure notices are of no legal effect for purposes of (8)(A). *Id.* at 1358. It explained that the statutory 180-day period runs from licensure, "at which time the product, its therapeutic uses, and its manufacturing processes are fixed" by licensure. *Id.* The purpose, the court explained, is to "provide[ ] 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," the alternative being a rush in decision-making about requesting or issuing a preliminary injunction. *Id.*; *see id.* at 1360 ("The purpose of [(8)(A)] is clear: requiring notice of commercial marketing be given to allow the [reference product sponsor] a period of time to assess and act upon its **patent** rights.").

The court then concluded that (8)(A) is "mandatory": "A question exists ... concerning whether the 'shall' provision in [(8)(A)] is mandatory. We conclude that it is." *Id.* at 1359. The court added that (8)(A) is "a standalone notice provision," not dependent on the earlier information-exchange provisions. *Id.* at 1359–60. And for the case before it, involving an applicant (Sandoz) that did not provide notice of FDA review under (2)(A), and hence did not come under (9)(B), there could be no basis for finding the declaratory-judgment ***1060** action referred to in (9)(B) to be the exclusive remedy for an (8)(A) violation. *Id.* On that basis, the court held it appropriate to enjoin commercial marketing until 180 days after the post-licensure notice. *Id.* at 1362.

D

In the present case, Amgen filed a motion in October 2015 asking the district court to issue a preliminary injunction that would require Apotex to provide an (8)(A) notice if and when it receives a license and to delay any commercial marketing for 180 days from that notice. The parties stipulated that Amgen will be irreparably harmed if Apotex enters the market without giving the requested 180 days' notice, the balance of the hardships favors Amgen, and the public interest favors the issuance of an injunction. The decision whether to grant the preliminary-injunction motion, therefore, turned on Amgen's likelihood of success on the legal question presented: whether the (8)(A) notice requirement is a mandatory one enforceable by injunction as to an applicant (such as Apotex) that, unlike Sandoz in *Amgen v. Sandoz*, gave the (2)(A)

notice to launch the information-exchange process leading to the paragraph (6) infringement suit. Notably, there is no dispute that Apotex's pre-licensure April 2015 notice is of no effect under (8)(A) as construed in *Amgen v. Sandoz*.

The district court agreed with Amgen and granted a preliminary injunction. The court noted that "[t]he [BPCIA] is intended to provide an orderly process for evaluating **patent** claims in the context of biosimilar products." J.A. 6. In particular, the (8)(A) notice-of-commercial-marketing requirement " '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.' " *Id.* (quoting *Amgen v. Sandoz*, 794 F.3d at 1358). The court concluded: "That defined statutory window exists for all biosimilar products that obtain FDA licenses, regardless of whether the subsection (k) applicant complies with § 262(*l*)(2)." *Id.* The court disagreed with Apotex's contention that this conclusion should be rejected in order to avoid adding 180 days to § 262(k)(7)'s 12-year exclusivity period for reference product sponsors. J.A. 7. The court also disagreed with Apotex's contention that paragraph (9) establishes that the exclusive remedy for failure to provide the (8)(A) notice of commercial marketing is a declaratory judgment on the **patent**-law merits of the **patents** at issue, no matter how rushed the litigation of those issues might be without the 180 days' notice. *Id.*

Apotex appeals the district court's grant of a preliminary injunction. We have jurisdiction under 28 U.S.C. § 1292(a)(1) and (c)(1).

DISCUSSION

[1] **[2]** We review a district court's grant of a preliminary injunction for abuse of discretion, which may be established when a district court's decision is based on an error of law. *Endo Pharm. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1373–74 (Fed. Cir. 2014); *U.S. Commodity Futures Trading Comm'n v. Hunter Wise Commodities, LLC*, 749 F.3d 967, 973 (11th Cir. 2014). Here, the district court's grant of an injunction rested on its interpretation of a statute, a question of law we review de novo. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). We agree with the district court: that Apotex gave a (2)(A) notice provides only a factual distinction, not a legally material distinction, between its situation and that of Sandoz in *Amgen v. Sandoz*. The (8)(A) requirement of 180 days' post- ***1061** licensure notice before commercial marketing, we conclude, is a mandatory one enforceable by injunction whether or not a (2)(A) notice was given.

[3] Paragraph (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)." § 262(*l*)(8)(A) (emphasis added). The word "shall" generally indicates that the directive is mandatory. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 661–62, 127 S.Ct. 2518, 168 L.Ed.2d 467 (2007); *Lopez v. Davis*, 531 U.S. 230, 241, 121 S.Ct. 714, 148 L.Ed.2d 635 (2001); *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998). We ruled in *Amgen v. Sandoz* that this language is, indeed, "mandatory," and we did not say that it was mandatory only in no-(2)(A)-notice circumstances. 794 F.3d at 1359.

[4] The language of (8)(A) is categorical in the sense relevant here. It contains no words that make the applicability of its notice rule turn on whether the applicant took the earlier step of giving the (2)(A) notice that begins the § 262(*l*) information-exchange process. And in *Amgen v. Sandoz* we stated that (8)(A) was "a standalone notice provision" not dependent on the information-exchange processes that begin with (2)(A). *Id.* at 1359–60.

There also is no other statutory language that effectively compels a treatment of (8)(A) as non-mandatory, contrary to the usual meaning of its "shall" terms. In this respect, (8)(A) differs materially from (2)(A). For (2)(A), as this court explained in *Amgen v. Sandoz*, the language of 35 U.S.C. § 271(e)(2) & (4) forces (2)(A)'s "shall" not to be a term of enforceable compulsory obligation. Section 271(e)(2)(C)(ii) declares to be an act of infringement the filing of a biosimilar-product application coupled to a failure to give the (2)(A) notice, and § 271(e)(4) declares that the **patent**-merits infringement

suit, with specified damages and injunctive relief, is the exclusive remedy for that combination. Compelling the applicant to provide the (2)(A) notice would go beyond that remedy, thus contradicting the congressional command that the infringement remedies of § 271(e)(4) are " 'the *only* remedies which may be granted by a court for an act of infringement described in [§ 271(e)(2)].' " *Amgen v. Sandoz*, 794 F.3d at 1356 (quoting § 271(e)(4); emphasis added by *Amgen v. Sandoz*). For (8)(A), in contrast, as *Amgen v. Sandoz* necessarily recognized in finding it "mandatory," there is no comparable textual source of a contradiction that would be created by following the usual mandatory-character interpretation.

Amgen v. Sandoz likewise disposes of Apotex's argument that giving (8)(A) its plain meaning would effectively extend, by six months, the 12-year exclusivity period given to a reference product sponsor by § 262(k)(7). *See* 794 F.3d at 1358. Notably, § 262(k)(7) by its terms establishes the 12-year date only as an earliest date, not a latest date, on which a biosimilar license can take effect. Even when entry is delayed under (8)(A) to what amounts to 12 years plus 180 days after the reference product sponsor's licensure, the result is consistent with § 262(k)(7).

Moreover, it is implicit in the Biologics Act that any such delay beyond 12 years should occur less and less as time goes by. Doubtless, there will be some exclusivity periods beyond 12 years in the early years of the Biologics Act, as biosimilars are introduced for reference products licensed well before the Act was adopted in 2010. But as time passes, more and more of the ***1062** reference products will be newer, and a biosimilar-product applicant, entitled to file an application a mere four years after licensure of the reference product, § 262(k)(7)(B), can seek approval long before the 12-year exclusivity period is up. *See Amgen v. Sandoz*, 794 F.3d at 1358 (the "extra 180 days will not likely be the usual case, as [biosimilar-product applications] will often be filed during the 12-year exclusivity period"). In such circumstances, we have been pointed to no reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date—a possibility suggested by § 262(k)(7)(A)'s language about when the FDA approval may "be made effective." And we read (8)(A) as allowing the 180-day notice of commercial marketing to be sent as soon as the license issues, even if it is not yet effective, because it is at the time of the license that "the product, its therapeutic uses, and its manufacturing processes are fixed." *Id.* at 1358.

In any event, the established and evident purpose of (8)(A) covers applicants that file (2)(A) notices as well as those that do not. As this court explained in *Amgen v. Sandoz*, the purpose is to ensure that, starting from when the applicant's product, uses, and processes are fixed by the license, the necessary decision-making regarding further **patent** litigation is not conducted under time pressure that will impair its fairness and accuracy. *Id.* at 1358, 1360. At the least, the reference product sponsor needs time to make a decision about seeking relief based on yet-to-be litigated **patents**, and a district court needs time for litigants to prepare their cases, in a complicated area, to provide a reliable basis for judgment. While that may not be true in every single case, Congress clearly made a categorical fixed-period judgment in (8)(A)—as it did elsewhere in the Biologics Act—and we have explained that the "statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case." *Id.* at 1358.

That litigation-focused purpose extends to applicants that launch and pursue the information-exchange process of § 262(*l*). For those applicants as for others, the final biosimilar product cannot be known with certainty until the FDA license issues. Moreover, as we have described, § 262(*l*) affirmatively contemplates two stages of litigation (under paragraphs (6) and (8)), and it contemplates that the first stage of litigation may omit **patents** the reference product sponsor has good grounds to assert, whether **patents** already in the hands of the reference product sponsor or **patents** newly in its hands under paragraph (7). It gives the applicant substantial authority to force such a limitation on the scope of the first-stage litigation. [3] And it provides for the reference ***1063** product sponsor to "seek a preliminary injunction" after the licensure and (8)(A) notice. *See* § 262(*l*)(8)(B). The 180-day period gives the reference product sponsor time to assess its infringement position for the final FDA-approved product as to yet-to-be-litigated **patents**. And if there is such litigation, it gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury.

This is evident on the face of § 262(*l*). And the Biologics Act's legislative history confirms the aim to avoid the uncertainties and deficiencies associated with a process in which requests for temporary restraining orders and preliminary injunctions are presented and adjudicated on short notice. *See*, *e.g.*, *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 201–02 (2009) (statement of Teresa Stanek Rea, President of the American Intellectual Property Law Ass'n) (without a pre-launch **patent**-dispute mechanism, "**patent** disputes in this area would strain the federal judiciary by requiring—in preliminary injunction proceedings—resolution of the complex legal and scientific questions involved with each biosimilar product launch ... in a pressurized context and without the benefit of a complete evidentiary record"); *id.* at 80 (statement of Jeffrey Kushan, on behalf of the Biotechnology Industry Organization) ("forcing **patent** disputes to commence only after a biosimilar has been placed on the market ... will raise the prospect that a court will not enforce the exclusive rights of the **patent** by issuing an injunction preventing the continued marketing of the biosimilar"); *id.* at 9 (statement of Rep. Anna Eshoo) ("[A] simple, streamlined **patent** resolution process ... will help 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."); *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 17–18 (2009) (statement of Rep. Marsha Blackburn); *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 85 (2007) (statement of Dr. David Schenkein, Vice President, Clinical Hematology/Oncology, Genentech, Inc.); *see also An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. at 798–800.

[5] Apotex's final argument is that paragraph (9) of § 262(*l*) makes a declaratory-judgment action, discussed in (9)(B), the exclusive remedy for violations of (8)(A). We reject that contention.

Apotex has not asserted that (8)(A) creates no privately enforceable right, even when asserted as part of an infringement action concerning **patent** rights whose fair and unhurried adjudication (8)(A) is designed ***1064** to protect. Nor has it identified any statutory commitment to a government agency of responsibility or authority to enforce or to seek to enforce the (8)(A) command. Instead, Apotex suggests that the only remedy for an applicant's unilateral denial to the reference product sponsor of the 180-day period for post-licensure litigation decision-making is a declaratory-judgment action on a **patent**—which (9)(B) permits if the applicant "fails to complete" any one of several steps, including the giving of the (8)(A) notice. § 262(*l*)(9)(B).

We cannot infer such an exclusive-remedy conclusion from paragraph (9). The Supreme Court long ago ruled that the federal courts' "equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command," whether "in so many words, or by a necessary and inescapable inference." *Porter v. Warner Holding Co.*, 328 U.S. 395, 398, 66 S.Ct. 1086, 90 L.Ed. 1332 (1946); *see Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960); *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001). Under that standard, or indeed under a straightforward understanding of paragraph (9) as it relates to (8)(A), we do not find that paragraph (9) establishes that a declaratory-judgment action is the sole remedy for violating (8)(A).

Apotex cannot point to any text providing for exclusivity. Nothing in paragraph (9) declares the exclusivity of the declaratory-judgment actions to which it refers—either in (9)(B) as it applies to an (8)(A) violation or more generally. (9)(A) bars certain declaratory-judgment actions, and (9)(B) & (C) state only that, in certain circumstances, the reference product sponsor "may bring" such an action. § 262(*l*)(9)(B), (C). There is no language that excludes other remedies for the conduct described.

Apotex's argument is therefore for an implied exclusivity of declaratory-judgment remedies. But it is clear that there is no such exclusivity implied by paragraph (9) generally. Most notably, when (9)(C) says that a declaratory-judgment action

may be brought under 28 U.S.C. § 2201 if an applicant does not give the (2)(A) notice, *see* § 262(*l*)(9)(C), it plainly does not imply exclusivity of that remedy: as *Amgen v. Sandoz* confirms, (9)(C) does not exclude the monetary and injunctive infringement remedies expressly authorized by 35 U.S.C. § 271(e)(4) for what is, after all, an infringement under § 271(e)(2). *See Amgen v. Sandoz*, 794 F.3d at 1357 ("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 remed*ies*") (emphases added); *id.* at 1359 (same). Nor has Apotex shown that (9)(B), when it applies, implicitly negates 35 U.S.C. § 271(e)(4)'s provision of damages and injunctive remedies (if otherwise appropriate and not curtailed by 35 U.S.C. § 271(e)(6)) for an application that is deemed by 35 U.S.C. § 271(e)(2)(C)(i) to be an infringement of a **patent** on a list under § 262(*l*) (3) (necessarily after a (2)(A) notice). [4] Against this generally *non*-exclusive character of the paragraph (9) declaratory-judgment remedy, it would be surprising ***1065** to infer exclusivity of that remedy specifically for an (8)(A) violation.

This court did not declare otherwise when it said in *Amgen v. Sandoz* "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)." 794 F.3d at 1359. We read that statement to mean only that, when there is noncompliance with (8)(A), the consequence *for the (9)(A) bar on declaratory judgments* is specified by (9)(B). That understanding reflects the express, limited language of (9)(B) and its evident connection to (9)(A). The court in *Amgen v. Sandoz* thus did not establish that the full remedial consequence of (8)(A) noncompliance is a declaratory-judgment action on the merits of the **patents**.

Such an exclusivity conclusion regarding (8)(A) would, in fact, make little sense. In the ordinary case, a declaratory-judgment action would not actually enforce the categorical "standalone," "mandatory" (8)(A) notice right, which would not be the subject of a declaratory-judgment **patent**-merits action. 794 F.3d at 1359–60. A declaratory-judgment action on the **patent** merits in the ordinary case would not serve (8)(A)'s essential purpose or, therefore, be a meaningful remedy *for the (8)(A) violation*.

In particular, relegating a reference product sponsor to a **patent**-merits declaratory-judgment action would introduce the very problem of rushed decision-making as to the **patent** merits that it is (8)(A)'s purpose to avoid. Noncompliance with (8)(A) means either entering the market without giving a post-licensure notice or giving a notice but then jumping the gun and entering the market before 180 days have passed. In either event, a reference product sponsor is likely not to know that the applicant will fail to provide the actual 180-day commercial-marketing notice required by (8)(A) until the applicant begins commercial marketing or, at least, declares that it may begin such marketing at any moment. The reference product sponsor will have to race to court for immediate relief to avoid irreparable harm from market entry, and the parties and the court, in dealing with a request for a temporary restraining order or a preliminary injunction, will engage in precisely the hurried motion practice that (8)(A) is designed to replace by ensuring a defined amount of time for pre-launch litigation. (9)(B) as a "remedy" is so gross a mismatch for the (8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as the exclusive remedy for (8)(A)'s violation.

The mention of (8)(A) in (9)(B) seems to play a limited role in the provision, whose primary purpose is to provide an incentive for an applicant to fulfill its obligations along § 262(*l*)'s litigation-channeling path once it starts on the path by giving a (2)(A) notice. (9)(A) bars specified declaratory-judgment actions until the (8)(A) notice is received, and without a further direction from Congress, that bar would by its terms last precisely until the (8)(A) notice is received. But Congress did go further in (9)(B), by identifying several earlier points in time at which the (9)(A) bar is lifted, for the reference product sponsor, if the applicant "fails to complete" any of the specified actions the applicant is obliged to take in the process designed to lead up to and end with the (8)(A) notice. With respect to the other actions listed in (9)(B)—namely, those required by (3)(B)(ii), (5), (6)(C)(i), and (7)—the bar is lifted earlier than otherwise would be implicit in (9)(A). With respect to a failure to complete an action required by (8)(A), it appears that (9)(B) also goes beyond what is implicit in (9)(A) by authorizing a declaratory judgment as ***1066** to an applicant that sends an (8)(A) notice (which upon receipt brings the (9)(A) bar to an end by (9)(A)'s terms) but then enters the market before 180 days have passed—which may be a "fail[ure] to complete" an action required by (8)(A). But even if (9)(B) does not have that application, it would still make sense for (8)(A) to be included in the (9)(B) list solely for completeness, to bring the chronological list of (9)

(A)-bar-lifting actions to its end point. It is hardly an unfamiliar role for a statutory provision to make explicit what otherwise would be implicit; such a provision is not superfluous. *See*, *e.g.*, *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 226, 128 S.Ct. 831, 169 L.Ed.2d 680 (2008); *Fort Stewart Sch. v. Fed. Labor Relations Auth.*, 495 U.S. 641, 646, 110 S.Ct. 2043, 109 L.Ed.2d 659 (1990).

Apotex would infer an outsize consequence from the mere modesty of the role played by (9)(B)'s mention of (8)(A). Apotex's proposed inference from (9)(B) would implicitly make (8)(A) neither mandatory nor standalone, despite (8)(A)'s language, and would reintroduce the very problems of rushed litigation—over **patents** the applicant is empowered to prevent being litigated earlier—that (8)(A) was enacted to avoid. The inference that Congress rendered unavailable direct injunctive enforcement of (8)(A)'s plain terms is unwarranted.

We conclude that an applicant must provide a reference product sponsor with 180 days' post-licensure notice before commercial marketing begins, regardless of whether the applicant provided the (2)(A) notice of FDA review. Because the parties here stipulated to the remaining preliminary-injunction factors, *see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394, 126 S.Ct. 1837, 164 L.Ed.2d 641 (2006), we affirm the district court's grant of a preliminary injunction without addressing those factors.

CONCLUSION

For the foregoing reasons, we affirm the district court's grant of a preliminary injunction.

AFFIRMED

All Citations

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Footnotes

1 The Declaratory Judgment Act, 28 U.S.C. § 2201(b), states: "For limitations on actions brought with respect to drug **patents** see" 21 U.S.C. §§ 355, 360b and 42 U.S.C. § 262. The Biologics Act added the § 262 reference. *See* Pub. L. No. 111-148, § 7002(c)(2), 124 Stat. at 816.

2 The same restriction applies if the reference product sponsor timely brought a paragraph (6) action that "was dismissed without prejudice or was not prosecuted to judgment in good faith." 35 U.S.C. § 271(e)(6)(A)(ii)(II).

3 Such applicant control is part of the design. *See Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 119 (2007) (statement of Bruce Downey, chairman of the Generic Pharmaceutical Ass'n and CEO of Barr Pharmaceuticals, Inc.) ("a biological **patent** system should provide a mechanism for litigating only those **patent** disputes that the generic company believes would delay its launch"); *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 209–10 (2009) (statement of Teresa Stanek Rea, President of the American Intellectual Property Law Ass'n) ("Under H.R. 1427, pre-launch litigation of any **patent** is entirely within the control of the follow-on applicant...."); Michael P. Dougherty, *The New Follow-on-Biologics Law: A Section by Section Analysis of the **Patent** Litigation Provisions in the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 231, 238 (2010) ("a significant feature of the Biologics Act" is that "it allows the applicant to limit litigation at this early stage of the application process to one **patent**"); Krista Hessler Carver, Jeffrey Elikan, & Erica Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 816 (2010) ("the BPCIA may operate to prevent patentees from asserting the relevant **patents** during the initial phase of litigation because the biosimilar applicant dictates how many **patents** can be asserted in the first instance").

4 We need not explore how the timing of actions for such Title 35 remedies is affected by § 262(*l*). We make the narrower point that (9)(B) does not make declaratory judgments exclusive and thereby wipe out the remedies expressly provided for in 35

U.S.C. § 271(e)(4). We need not say to what extent, if at all, a similar point applies to remedies provided for in, *e.g.*, 35 U.S.C. §§ 283, 284 for activities, such as actual or imminent market entry, that might be infringements under portions of 35 U.S.C. § 271 other than subsection (e)(2).

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