Nos. 15-1039, 15-1195

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OPENING AND RESPONSE BRIEF FOR AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act created a streamlined pathway for the licensure of biological products that are "biosimilar" to or "interchangeable" with a previously approved biological product, known as a reference product. 42 U.S.C. §262(k). Congress enacted a detailed procedure for the resolution of patent disputes between §262(k) applicants and reference product manufacturers, known as sponsors. *Id.* §262(*l*). The petitions present two questions concerning whether the §262(*l*) framework is mandatory or optional for applicants:

1. Is an applicant required to provide the sponsor with 180 days' notice after licensure and before it begins marketing its biosimilar product, and may a court enforce that duty by ordering the applicant not to market its product until 180 days after a post-licensure notice?

2. Is an applicant required to provide the sponsor with a copy of its biologics license application and related manufacturing information, and may a court issue an order enforcing that duty?

PARTIES TO THE PROCEEDING

The parties to the proceeding are listed in the caption. This brief refers to the respondents collectively as "Amgen."

CORPORATE DISCLOSURE STATEMENT

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation, and no publicly held corporation owns 10 percent or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with 10 percent or greater ownership in Amgen Manufacturing Limited.

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INTRODUCTION

The Biologics Price Competition and Innovation Act (BPCIA) creates a streamlined pathway for FDA licensure of biosimilars. Under that pathway, follow-on applicants can rely on data developed by biologic pioneers establishing the safety and efficacy of the approved biologic. When an applicant chooses to take advantage of the streamlined pathway, 42 U.S.C. §262(k), the statute mandates a comprehensive, two-phase procedure to ensure the fair and efficient resolution of patent disputes between the applicant and the pioneer, *id.* §262(*l*). If enforced as written, the orderly and predictable process set forth in the BPCIA achieves Congress's goal of balancing innovation and consumer interests. This case arises from Sandoz's attempt to undermine that balance by enjoying the benefits of streamlined FDA approval without following the pathway's associated patent-dispute rules.

The consolidated petitions present the Court with a fundamental dispute: Are applicants required to follow the framework Congress created, or may they choose to ignore it? Sandoz urges the latter, arguing that §262(*l*) presents not a series of commands but a series of choices. For example, where the statute says an applicant invoking the streamlined pathway "shall" provide its application and manufacturing information, 42 U.S.C. §262(*l*)(2)(A), Sandoz believes Congress simply created a choice. The same is true, in Sandoz's view, of the rest of the provisions in §262(*l*): the pioneer's duty to provide a list of relevant patents and state its intention with respect to granting a patent license; the applicant's duty to respond to that list with any noninfringement, invalidity, or unenforceability contentions or a statement that it will wait for patents to expire; the parties' duty to negotiate which patents to lit-

igate immediately; the applicant's duty to provide notice of commercial marketing; and so on. *Id.* §262(*l*)(3)-(8). Sandoz's flowchart (at 12) encapsulates its perspective. Over and over again, Congress stated that the applicant or sponsor "shall" do something. Yet over and over again, Sandoz suggests, Congress was really presenting the parties with a choice about whether or not to do what the statute says. In Sandoz's view, no court may require an applicant to take the steps that Congress provided it "shall" take.

Sandoz's construction of the BPCIA is fundamentally wrong. It rewrites the text, ignores the structure, and defies the purposes of the statute. That is particularly true with respect to the two provisions at issue here: the requirement that an applicant "shall provide to the reference product sponsor a copy of [its] application" and "information that describes the process or processes used to manufacture" its biosimilar product, 42 U.S.C. §262(*l*)(2)(A), and the requirement that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)," *id.* §262(*l*)(8)(A).

Those requirements facilitate the orderly dispute-resolution process Congress intended. By providing its application and manufacturing information, the applicant enables the sponsor to determine which of its patents may be infringed by the manufacture, import, sale, and use of the biosimilar, averting needless litigation. The parties negotiate over which listed patents to litigate immediately and which should be deferred to a second phase of litigation—for example, because the applicant may volunteer to wait for one or more patents to expire, the parties may agree to a patent license, or the applicant may avoid infringement by changing a

manufacturing parameter or seeking approval for only certain uses. The provision of a post-licensure marketing notice then creates a 180-day window for orderly proceedings on phase-two patents—those not singled out for immediate litigation, or those acquired after the sponsor initially identifies relevant patents—before the biosimilar enters the market. In the 180-day notice window, the sponsor can assess its phase-two patents with full information about the scope and terms of the biosimilar license, commence litigation, and (if appropriate) seek a preliminary injunction with adequate time for briefing, discovery, argument, and decision before the market is flooded with infringing biosimilars.

Sandoz's interpretation would replace that orderly process with chaos. Were Sandoz correct that an applicant can choose not to provide the initial disclosures or a marketing notice, a sponsor might not learn of the application for a potentially infringing biosimilar until the FDA licensed it. Even when the applicant chooses to notify the sponsor of the submission of its application, as Sandoz did, failure to disclose the application and manufacturing information will leave the sponsor without a clear understanding of which of its patents would be infringed. And if an applicant can provide a marketing notice at any time before licensure, as Sandoz argues, then the two phases of patent litigation could merge, become inverted, or splinter into a proliferation of patent suits.

In any of these scenarios, the applicant's concealment of information—both about the nature of its product and manufacturing processes, and about the anticipated timing of launch—would make it difficult for sponsors to seek injunctive relief and for courts to adjudicate such requests. The sponsor would thus be left sprinting to the courthouse with incomplete infor-

mation to seek an emergency injunction or temporary restraining order upon learning of an imminent or in-progress launch. Such emergency proceedings are burdensome for courts under any circumstances, and they are particularly burdensome and error-prone in complex patent cases. And even where sponsors manage to obtain emergency relief, it may come too late to protect them, since generic manufacturers often flood the market as soon as the FDA issues its approval. The resulting uncertainty would profoundly undermine the traditional incentives for innovation and investment that patents provide.

This Court often faces the unenviable task of choosing between a straightforward interpretation of a statute's text and structure and an alternative interpretation that better serves Congress's purpose. This case presents no such conundrum. Congress enacted a detailed framework for the orderly resolution of patent disputes involving biosimilars. The statute uses mandatory language, and Sandoz suggests no reason why compliance with the mandates is impossible or unworkable. Yet, rather than simply following the steps Congress laid out, Sandoz asks the Court to deem them all optional, obliterating Congress's goals of order and efficiency. The Court should instead enforce the statute Congress wrote.

OPINIONS BELOW

The court of appeals' opinion (Pet. App. 1a-55a) is reported at 794 F.3d 1347. The court of appeals' order denying rehearing (Pet. App. 85a-86a) is unreported. The district court's opinion (Pet. App. 56a-84a) is unreported but is available at 2015 WL 1264756.

JURISDICTION

The court of appeals entered judgment on July 21, 2015, and denied timely petitions for rehearing on October 16, 2015. In No. 15-1039, the Chief Justice extended the time to file a petition for certiorari to and including February 16, 2016, and Sandoz filed its petition on that date. Amgen timely filed its conditional cross-petition, No. 15-1195, on March 21, 2016. The Court granted both petitions on January 13, 2017. The Court's jurisdiction rests on 28 U.S.C. §1254(1).

The injunction that Sandoz challenges expired on September 2, 2015. Sandoz contends (at 26 n.5) that "the dispute between the parties remains live because it is capable of repetition yet evading review." Amgen is not privy to Sandoz's business plans or whether it intends to provide notice or disclosures to Amgen with respect to any future biosimilar applications.[1] Accordingly, Amgen cannot advise whether Sandoz's statement is properly understood as a representation that there is "a reasonable expectation or a demonstrated probability that the same controversy will recur involving the same complaining party." *FEC* v. *Wisconsin Right to Life, Inc.*, 551 U.S. 449, 463 (2007) (internal quotation marks omitted).

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[1] Amgen and Sandoz are currently litigating two other patent-infringement cases arising from biosimilar applications. In one—*Immunex Corp.* v. *Sandoz Inc.*, No. 16-cv-1118 (D.N.J.)—the FDA approved Sandoz's application in 2016 but Sandoz stipulated to a preliminary injunction against launch. In the other—*Amgen Inc.* v. *Sandoz Inc.*, No. 16-cv-2581 (N.D. Cal.)—the FDA responded without approving Sandoz's application in 2016; Amgen does not know the current status of that application.

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of 21 U.S.C. §355, 28 U.S.C. §2201, 35 U.S.C. §271, and 42 U.S.C. §262 are reprinted in the appendix.

STATEMENT

A. The Biologics Industry

Biologics are groundbreaking medicines used to treat a range of complex and debilitating illnesses. Unlike traditional "small-molecule" drugs that are chemically synthesized, biologics are manufactured using living organisms. Congressional Research Service, *P.L. 111-148: Intellectual Property Provisions for Follow-On Biologics* (2010 CRS Report) 1 (2010). The resulting molecules are typically complex, and "'small differences between manufacturing processes can cause significant differences in the[ir] clinical properties.'" Congressional Research Service, *Follow-On Biologics: The Law and Intellectual Property Issues* 15 (2014).

Until 2010, a company seeking to market a therapeutic biologic could obtain FDA approval only by submitting a biologics license application under 42 U.S.C. §262(a). Under §262(a), the applicant must demonstrate that its biologic is "safe, pure, and potent." *Id.* §262(a)(2)(C)(i). This requires extensive laboratory data on the biologic's composition and properties, and information about its manufacturing processes and process parameters, as well as the results of typically three phases of human clinical trials. CAJA56; *see* 21 C.F.R. pt. 601. Developing a biologic and obtaining §262(a) approval requires an enormous investment. The process is highly risky, takes 10-15 years, CAJA57, and costs on average $1.2 billion, Pet. App. 41a n.1. As a result of the risk, costs, and sophisticated manufac-

turing techniques, biologics are generally more expensive than traditional drugs. 2010 CRS Report 1.

B. Statutory History

Seeking to "balanc[e] innovation and consumer interests," Congress enacted the BPCIA in 2010. Pub. L. No. 111-148, §7001(b), 124 Stat. 804, 804. Before the BPCIA, no streamlined approval pathway existed for "generic" biologics, as it did for generic small-molecule drugs under the Hatch-Waxman Act. The BPCIA created a streamlined pathway, drawing on certain features of the Hatch-Waxman Act but departing significantly with respect to others, due to the substantial differences between biologics and small-molecule drugs—including, most fundamentally, the inability to establish that one biologic is *identical* to another.

1. Enacted in 1984, the Hatch-Waxman Act created an expedited pathway allowing generic drugs to be approved on a showing that they are "bioequivalent" to an approved drug, without the need for clinical trials of safety or efficacy. 21 U.S.C. §355(j)(2)(A)(i), (iv).

The Act created several exclusivity periods during which the FDA cannot approve a generic version of the pioneer drug. A pioneer drug with a new active ingredient receives five years of exclusivity, 21 U.S.C. §355(j)(5)(F)(ii), and the pioneer can receive additional three-year exclusivity periods if it conducts clinical studies that support new conditions of approval or changes to the drug, *id.* §355(j)(5)(F)(iii)-(iv).

Separate from these periods of non-patent exclusivity, the Hatch-Waxman Act created procedures for the orderly resolution of patent disputes. The Act made the submission of an abbreviated new drug application an artificial act of infringement, and it created a mech-

anism for identifying relevant patents and resolving any claims before a generic's launch. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676-678 (1990).

Under the Hatch-Waxman Act's streamlined process, if an applicant disputes whether a patent is valid or infringed, the pioneering company has 45 days to file an infringement suit. If it does so, the statute automatically stays FDA approval of the generic drug for up to 30 months—thus imposing a mandatory waiting period that facilitates the resolution of patent disputes before the generic's launch. 21 U.S.C. §355(j)(5)(B)(iii).

2. By the early 2000s, the biologics industry had grown significantly.[2] Members of Congress became increasingly interested in adapting the Hatch-Waxman model to the biologics context, to promote competition while "preserving incentives for brand-name companies to develop new and innovative therapies." *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. 2 (2007) (statement of Rep. Pallone); *see Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary* (2009 Hearing), 111th Cong. 2 (2009) (explaining the need to "incentivize[] the extraordinary investment required to develop new biologics" while "not discourag[ing] biosimilar introduction" (statement of Rep. Johnson)).

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[2] 2010 CRS Report 1 (20% of available pharmaceuticals are biologics and some experts estimate nearly half of all newly approved pharmaceuticals will be biologics).

Congress recognized that biologics are significantly more complex than small-molecule drugs and are subject to the vagaries of manufacture in living organisms. Even a biologic that is *similar* to a pioneering product will necessarily be manufactured under different conditions, using different organisms and different manufacturing processes. As a result, a follow-on product cannot be shown to be *identical* to the pioneering product (as chemically synthesized generic drugs can). That difference has significant implications for patent disputes. For example, the patents a pioneering company can assert against one competing manufacturer may be quite different from the patents it can assert against another. And potentially applicable patents include not only composition and method-of-use patents, but also, importantly, process patents claiming techniques for producing, purifying, and testing the biologic. *See* 2009 Hearing 43, 97 (statement of Biotechnology Industry Organization (BIO)). These issues significantly influenced the framework Congress developed for identifying relevant patents and resolving disputes.

The House and Senate considered a range of alternative schemes that would provide notice of potentially applicable patents and a means for resolving disputes. Some bills proposed *optional* information-exchange and dispute-resolution procedures. *See* H.R. 1427, 111th Cong. §3(a)(2) (2009) (proposed §262(k)(18)(F)); S. 623, 110th Cong. §3(a)(2) (2007) (proposed §262(k)(17)(E)); H.R. 6257, 109th Cong. §3(a)(2) (2006) (proposed §262(k)(16)(E)). Under those proposals, a competing applicant could request information from the pioneering company about patents relevant to the original biologic. The applicant could then decide whether to provide a "notice" with a "detailed statement" explaining its position that particular patents were "invalid,

[were] unenforceable, or [would] not be infringed." H.R. 1427 §3(a)(2) (proposed §262(k)(18)(B)). The bills then envisioned two phases of litigation. The pioneering company could immediately sue the applicant on any patent for which the applicant had chosen to provide a notice. But it could not sue on any other patents until after the applicant had launched the product. *See, e.g.*, *id.* (proposed §262(k)(18)(D)).

At the final congressional hearing on a streamlined biologics pathway, Congress heard testimony about the importance of a *mandatory* information-exchange procedure that would allow the pioneering manufacturer to "conduct [an] informed analysis" of whether any of its patents were implicated by an application for a similar product. 2009 Hearing 204 (statement of American Intellectual Property Law Association (AIPLA)). Witnesses also testified about the importance of resolving patent disputes before commercial marketing of a newly approved product. They explained that permitting a company to launch a competing product in the face of pending patent litigation would lead to "a longer period of uncertainty." *Id.* at 77 (BIO); *see also id.* at 201 (AIPLA).

Congress ultimately rejected the optional procedures contemplated by the bills discussed above. In 2009, the House passed a competing bill, which stated that the applicant "shall provide" its application and certain other information to the pioneering company. H.R. 1548, 111th Cong. §101(a)(2) (2009) (proposed §262(*l*)(4)(A)(i)); *see* Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 778 (2010). The Senate passed an amendment that likewise stated the applicant "shall provide" the required information to the pioneering company, and set forth a com-

prehensive two-stage framework for resolving patent disputes. *See* Carver 777. That amendment was modeled on S. 1695, 110th Cong. (2007), a compromise bill negotiated by the Senate Health, Education, Labor and Pensions Committee in 2007. Carver 776-777. As enacted, the BPCIA "largely tracks" the provisions of S. 1695. *Id.* at 746; *see also id.* at 806.

C. The Biologics Price Competition And Innovation Act

Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The BPCIA establishes a streamlined approval pathway for biologics shown to be highly similar to approved products, 42 U.S.C. §262(k), accompanied by a series of steps to ensure the orderly resolution of patent disputes and the sponsor's opportunity to seek a preliminary injunction before launch of a follow-on product, *id.* §262(*l*).

Under the BPCIA's streamlined pathway, an applicant can submit an abbreviated biologics license application that "reference[s]" another company's previously approved biologic (the reference product). 42 U.S.C. §262(i)(4). If it does so, the applicant need not conduct a full complement of clinical trials, nor does the FDA require it to test the biosimilar for each of the reference product's licensed medical conditions. Instead, the FDA evaluates the application against the reference product and approves it if the applicant's product is "biosimilar to [the] reference product," meaning that it is "highly similar to the reference product" and there are "no clinically meaningful differences" between the two products with respect to "safety, purity, and potency." *Id.* §262(i)(2)(A), (B), (k)(2)(A)(i)(I). Biologics

for which streamlined approval is sought are known as biosimilars. 2009 Hearing 1.

The FDA may further designate a biosimilar as "interchangeable" with the reference product if the applicant meets additional safety criteria. An interchangeable biosimilar "may be substituted for the reference product without the intervention of the health care provider." 42 U.S.C. §262(i)(3). The first interchangeable product is guaranteed an exclusivity period during which the FDA cannot approve another biosimilar as interchangeable for the same reference product.

By design, the streamlined pathway means that companies can launch competing biologics without undertaking the same investment as pioneering companies. To help ensure that pioneering companies will continue investing in the development and approval of new biologics, the BPCIA carved out a period of time for each product during which applicants cannot take advantage of the streamlined pathway. Applicants cannot file biosimilar applications until four years after the FDA first licenses the reference product. 42 U.S.C. §262(k)(7)(B). And the FDA cannot make approval of a biosimilar effective until 12 years after first licensure of the reference product. *Id.* §262(k)(7)(A).

In effect, whereas a sponsor had previously enjoyed unlimited control over whether another company could rely on its product and clinical data to gain approval for a competing drug, the BPCIA limited that right to a 12-year data exclusivity period. As before, moreover, the sponsor is not guaranteed freedom from competition during the 12-year period: Other manufacturers are free to seek approval for competing products under §262(a)'s traditional pathway. One company, in

fact, obtained §262(a) approval for a filgrastim product—the same biologic at issue in this case.

Congress also protected the well-recognized incentives for invention by providing an orderly process for resolution of patent disputes between the applicant and the sponsor. Following the Hatch-Waxman model, the BPCIA created limits on declaratory-judgment actions concerning drug patents, 42 U.S.C. §262(*l*)(9), and amended the Patent Act to create an artificial act of infringement so as to facilitate adjudication of certain patent disputes during the streamlined approval process, 35 U.S.C. §271(e)(2)(C). The BPCIA then set forth an intricate series of steps—starting shortly after the FDA begins review of the biosimilar application—for parties to identify which patents are infringed and resolve disputes over the validity, enforceability, and infringement of those patents.

Unlike some earlier biosimilars bills, the BPCIA specified those steps in mandatory rather than discretionary terms. The process begins when the applicant chooses to submit an application under the streamlined pathway. The applicant "*shall* provide" the sponsor's counsel with "confidential access to the information *required* to be produced pursuant to paragraph (2)." 42 U.S.C. §262(*l*)(1)(B)(i) (emphases added). Within 20 days after the FDA accepts the application for review, the applicant "*shall* provide to the reference product sponsor a copy of [its] application … and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." *Id.* §262(*l*)(2)(A) (emphasis added). It "*may* provide" additional information upon request. *Id.* §262(*l*)(2)(B) (emphasis added). The sponsor uses that information to determine which, if any, of

its patents might be infringed by the manufacture, use, import, or sale of the biosimilar. *Id.* §262(*l*)(1)(D).

The parties then conduct a series of exchanges about the relevant patents with the goal of narrowing and resolving potential disputes—whether through a license, an agreement to defer commercial marketing until a patent expires, or (if necessary) an infringement suit. Within 60 days after receiving the application and manufacturing information under §262(*l*)(2)(A), the sponsor "shall provide" to the applicant a list of patents that it could reasonably assert, identifying any that it would be willing to license. 42 U.S.C. §262(*l*)(3)(A). Within 60 days after receiving that list, the applicant "may provide" a list of additional patents that the sponsor could reasonably assert and "shall provide" a response with respect to each patent on the sponsor's list. *Id.* §262(*l*)(3)(B)(i), (iii). That response can consist of either a statement that the patent is invalid, unenforceable, or will not be infringed, or a commitment not to begin commercial marketing until the patent expires. *Id.* §262(*l*)(3)(B)(ii). Within 60 days after receiving the applicant's response, the sponsor "shall provide" its own statement with respect to the validity, enforceability, and infringement of each patent. *Id.* §262(*l*)(3)(C).

The sponsor and the applicant then determine which, if any, patents on their lists are appropriate subjects of an immediate infringement action. The parties first attempt to agree on the patents to be immediately litigated. 42 U.S.C. §262(*l*)(4)(A). If they fail to agree within 15 days, the applicant "shall notify" the sponsor of the number of patents it will designate for immediate litigation. *Id.* §262(*l*)(4)(B), (*l*)(5)(A). That number limits the number of patents the sponsor can list, unless the applicant designates no patents, in which case the sponsor can designate one. *Id.* §262(*l*)(5)(B)(ii). The

applicant and the sponsor then "simultaneously exchange" the lists of patents that each believes should be the subject of immediate litigation. *Id.* §262(*l*)(5)(B)(i). The sponsor "shall bring an action for patent infringement" of each patent identified on the parties' lists—the so-called phase-one patents—within 30 days after either the parties' agreement or the exchange of their separate lists. *Id.* §262(*l*)(6)(A)-(B).

Consistent with Congress's intent to facilitate efficient resolution of patent disputes, these provisions require the parties to identify patent claims that can meaningfully be adjudicated or otherwise resolved before the FDA determines what, precisely, will be licensed—including what active ingredient, what formulation, what uses, what delivery system, and what manufacturing processes. The sponsor and applicant may, for example, agree to litigate an obviously relevant composition patent, while deferring litigation on method-of-use and process patents that are only potentially relevant—either because the original application may be amended or supplemented during review or because there may be uncertainty about the uses for which the FDA will approve the biosimilar and about whether it will require the applicant to alter its manufacturing process.

The statute provides for a second, deferred phase of litigation concerning two sets of potentially applicable patents: (1) those identified in the exchanges but not chosen for immediate litigation in phase one; and (2) those issued to or exclusively licensed by the sponsor after the sponsor provides its original list, 42 U.S.C. §262(*l*)(7). Section 262(*l*)(7)'s provision for newly obtained patents accounts for the fact that pioneering companies continue to innovate long after the initial invention of the biologic itself—including by developing

new cell lines, therapeutic uses, formulations, and manufacturing processes. Companies often prosecute those patents over several years.

The trigger for the second phase of litigation is a notice that the applicant must provide to the 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). Two consequences follow from that notice. First, before the applicant begins commercial marketing of the biosimilar, the sponsor can seek a preliminary injunction against its manufacture or sale until a court resolves disputes over the validity, enforceability, and infringement of the relevant patents. *Id.* §262(*l*)(8)(B). If the sponsor seeks a preliminary injunction, the sponsor and applicant "shall reasonably cooperate to expedite [any] further discovery" needed to resolve the motion. *Id.* §262(*l*)(8)(C). Second, the applicant or sponsor may bring a declaratory-judgment action as to the phase-two patents. *Id.* §262(*l*)(9)(A).

The statute restricts the availability of declaratory-judgment actions *before* the marketing notice. 42 U.S.C. §262(*l*)(9)(A). If an applicant "fails to provide the application and information required under paragraph (2)(A)," the applicant may not bring a declaratory-judgment action. *Id.* §262(*l*)(9)(C). Similarly, the applicant may not bring a declaratory-judgment action if it complies with §262(*l*)(2)(A) but fails to comply with certain subsequent obligations under §262(*l*). *Id.* §262(*l*)(9)(B). In other words, the applicant can bring a declaratory-judgment action only if it fully complies with § 262(*l*) and provides the marketing notice. The sponsor, by contrast, is not barred from bringing a declaratory-judgment action *unless* the applicant fulfills all of the specified obligations, in which case the spon-

sor must wait until it receives the marketing notice to bring such an action on phase-two patents. *Id.* §262(*l*)(9)(A).

D. Facts Of This Case

Amgen created and developed filgrastim, a biopharmaceutical version of a human protein known as granulocyte colony stimulating factor. Filgrastim stimulates the production of neutrophils, a type of white blood cell that fights infection.

In 1991, the FDA approved Amgen's §262(a) application to market filgrastim under the brand name Neupogen. Pet. App. 62a. The FDA initially approved Neupogen for the treatment of neutropenia, a white blood cell deficiency, in cancer patients undergoing chemotherapy. Through continued research and development, Amgen has since obtained FDA approval for additional therapeutic uses, including the promotion of faster engraftment for bone marrow transplant patients. *Id.* 63a. Amgen's patent on filgrastim itself has expired, but as of 2014 Amgen held an unexpired patent on a therapeutic use for filgrastim and on production and purification processes that could apply to the manufacture of filgrastim. CAJA472-473.

In May 2014, Sandoz filed an application under §262(k) for a biosimilar version of Neupogen, to be marketed as Zarxio. Pet. App. 8a. The FDA accepted Sandoz's application for review on July 7, 2014, *id.* 63a, triggering Sandoz's obligation under §262(*l*)(2)(A) to provide a copy of its application and manufacturing information within 20 days. Sandoz notified Amgen the following day that it had filed an application referencing Neupogen, but it refused to provide the information

required by §262(*l*)(2)(A). *Id.* 8a.[3] Instead, it stated that Amgen could file a declaratory-judgment action as permitted by §262(*l*)(9)(C). CAJA1496. Sandoz also informed Amgen that it intended to launch Zarxio immediately upon receiving FDA approval. CAJA1472.

E. District Court Proceedings

In October 2014, Amgen sued Sandoz in the Northern District of California. First, Amgen alleged that Sandoz had violated California's Unfair Competition Law (UCL)—which prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code §17200—by failing to comply with its duties under §262(*l*)(2)(A) and §262(*l*)(8)(A). CAJA73-75. Second, Amgen alleged that Sandoz's actions had unlawfully converted Amgen's Neupogen license for Sandoz's benefit by making use of the license under §262(k) without complying with §262(*l*). CAJA76-79. Finally, Amgen asserted infringement of U.S. Patent No. 6,162,427, which claims a method for using filgrastim to promote stem cell mobilization in stem cell transplant patients. CAJA79-80.

Sandoz counterclaimed for a declaration that applicants may choose not to provide their applications and

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[3] Sandoz offered to provide confidential access to its application—but not its manufacturing information—if Amgen agreed to terms different from those in the BPCIA. Among other things, the terms would have allowed Sandoz to redact any information Sandoz deemed irrelevant and would have restricted outside counsel's access. CAJA1465-1466, 1474-1478, 1498-1502. Given the discrepancies between Sandoz's proposed terms and the BPCIA's provisions, the district court correctly noted "there is no dispute that Sandoz did not engage in 42 U.S.C. §262's disclosure and dispute resolution process." Pet. App. 58a.

manufacturing information under §262(*l*)(2)(A), subject only to the declaratory-judgment consequences set forth in §262(*l*)(9). CAJA282-285. Amgen eventually obtained a copy of Sandoz's application, through discovery, on February 9, 2015—seven months after the FDA accepted Sandoz's application for review and six months after §262(*l*)(2)(A) required Sandoz to produce it. Pet. App. 63a.

Amgen moved for a preliminary injunction preventing Sandoz from marketing Zarxio, relying on its likelihood of success on its state-law claims. Dist. Ct. Dkt. 56 at 12-15. Sandoz moved to dismiss Amgen's state-law claims and moved for judgment on the pleadings on its counterclaims.

On March 6, 2015, while the motions were pending, the FDA approved Sandoz's application for Zarxio. Pet. App. 8a-9a. The approval letter noted that Sandoz had submitted over two dozen amendments to its application over the course of the FDA's consideration, but it did not disclose the substance of those amendments. CAJA1775. The approval letter authorized the use of Zarxio for the same indications as Neupogen and authorized Sandoz to manufacture Zarxio at facilities in Austria and Germany. CAJA1775-1776. Upon receiving the letter, Sandoz provided Amgen with "further notice" of its intention to begin commercial marketing. CAJA1774.

On March 19, 2015, the district court denied a preliminary injunction, dismissed Amgen's state-law claims, and entered judgment for Sandoz on its counterclaims relating to the interpretation of the BPCIA. Pet. App. 56a-58a. The court first held that an applicant may refuse to provide its application and manufacturing information, notwithstanding the mandatory

language in §262(*l*)(2)(A). *Id.* 68a-73a & n.6. If the applicant fails to provide that information, the court held, the sponsor can seek a declaratory judgment on the merits of its patent claims under §262(*l*)(9)(C). *Id.* 69a-70a. The court further held that Sandoz's initial notice of commercial marketing—provided the day the FDA accepted Sandoz's application—was legally effective because an applicant can give notice under §262(*l*)(8)(A) before obtaining FDA approval. *Id.* 73a-76a. Based on its conclusion that "Sandoz's actions did not violate the BPCIA," the court dismissed Amgen's state-law claims. *Id.* 77a. On March 25, 2015, the district court entered final judgment on the adjudicated claims to allow Amgen to file an appeal. CAJA20-23.

Sandoz agreed not to launch Zarxio until the earlier of May 11, 2015, or the Federal Circuit's decision on any request by Amgen for an injunction pending appeal. CAJA1946. The parties stipulated that further proceedings in the district court would be stayed until the issuance of the Federal Circuit's mandate. *Id.* Amgen agreed not to enforce its patents against Sandoz, and Sandoz agreed not to challenge the validity of those patents, during the period of any stay. *Id.*

F. Court Of Appeals Proceedings

On May 5, 2015, the Federal Circuit granted Amgen's motion under Federal Rule of Appellate Procedure 8(a) for an injunction prohibiting Sandoz from marketing or selling Zarxio during the appeal. C.A. Dkt. 105. After expedited briefing and argument, a divided panel of the Federal Circuit affirmed the district court's judgment in part and vacated it in part.

1. The panel unanimously held that an applicant's notice of commercial marketing under §262(*l*)(8)(A) is

effective only if given after the FDA licenses its product. Pet. App. 20a. The court relied on the statute's reference to commercial marketing of the "licensed" product, as well as the notice provision's purpose—namely, allowing the sponsor to assess the scope of the final license and "effectively determine whether, and on which patents, to seek a preliminary injunction from the court." *Id.* 20a-22a. The court rejected Sandoz's argument that requiring post-approval notice would improperly extend the 12-year period of exclusivity against biosimilar applications relying on the sponsor's data. *Id.* 22a.

A majority of the panel (Judge Lourie, joined by Judge Newman) held that it was appropriate to enjoin Sandoz from marketing Zarxio for 180 days after its post-licensure notice—until September 2, 2015. Pet. App. 31a. Judge Chen dissented from that holding. In his view, once an applicant refuses to provide its §262(*l*)(2)(A) disclosures, the remaining provisions of §262(*l*)—including the marketing-notice requirement—"cease to matter." *Id.* 43a.

2. A different majority (Judge Lourie, joined by Judge Chen) affirmed the district court's ruling that an applicant does not violate the BPCIA by refusing to provide its application and manufacturing information under §262(*l*)(2)(A). The majority agreed that the statutory text supports a mandatory construction of that provision. Pet. App 14a-15a. But it concluded that "'shall' in paragraph (*l*)(2)(A) does not mean 'must,'" on the theory that other provisions of the BPCIA "contemplate[]" the applicant's non-compliance. *Id.* 14a-16a. The majority held that a sponsor's only recourse in the event of the applicant's breach of §262(*l*)(2)(A) is to file a declaratory-judgment action on the merits of its patent claims under §262(*l*)(9)(C), or an infringement ac-

tion under 35 U.S.C. §271(e)(2)(C)(ii), or both. *Id.* 16a-18a.

Judge Newman dissented from that holding. Both the statute's plain text and its purposes of "avert[ing] and … expedit[ing] litigation," she urged, show that "shall" in §262(*l*)(2)(A) means "shall," not "may." Pet. App. 35a-40a.

3. The court of appeals affirmed the dismissal of Amgen's state-law claims. It reasoned that Amgen could not state a UCL claim based on §262(*l*)(2)(A) because Sandoz had not acted unlawfully by withholding the specified information, and that a claim based on Sandoz's failure to give effective notice of commercial marketing under §262(*l*)(8)(A) was moot in light of the extended injunction. Pet. App. 26a-28a.

4. Both parties sought rehearing en banc. Amgen moved for a temporary injunction against the launch of Zarxio until the rehearing petitions were resolved. C.A. Dkt. 124. The Federal Circuit denied that request, C.A. Dkt. 128, and Sandoz began marketing Zarxio on September 3, 2015.

The Federal Circuit then denied both rehearing petitions. After the mandate issued, the parties agreed to lift the stay on district court litigation of Amgen's patent claims and Sandoz's patent-related counterclaims. Amgen amended its complaint to include an additional claim of infringement—namely that Sandoz's manufacturing process for Zarxio infringes U.S. Patent No. 8,940,878, which covers a method of purifying proteins. That patent, which had been under consideration by the Patent Office for years, did not issue until January 27, 2015. Discovery is ongoing, with trial scheduled for December 2017.

5. Both parties petitioned for a writ of certiorari, and the Court sought the views of the United States. After receiving the views of the United States, the Court granted both petitions.

While the petitions were pending, a different panel of the Federal Circuit (Judge Taranto, joined by Judges Bryson and Wallach) held that an applicant must give post-licensure notice of commercial marketing regardless of whether it complies with §262(*l*)(2)(A). *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1066 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 591 (2016). Relying on the BPCIA's text, structure, and purpose—as well as this Court's precedents confirming the presumptive availability of injunctive relief—the Federal Circuit reaffirmed that a court may issue an injunction to enforce the applicant's duty to give post-licensure notice. *Id.* at 1063-1066.

SUMMARY OF ARGUMENT

1. Section 262(*l*)(8)(A) requires applicants to notify sponsors at least 180 days before "the first commercial marketing of the biological product licensed under subsection (k)." The statute's reference to a "licensed" product indicates that the notice must come after FDA licensure rather than before. Indeed, the reference to a "product licensed under" the streamlined pathway is unique in §262(*l*). Elsewhere, Congress referred to the biosimilar as a "product that is the subject of the [§262(k)] application." None of the provisions cited by Sandoz or the government overcomes this inference.

The structure of the BPCIA further supports reading §262(*l*)(8)(A) to require post-licensure notice. Section 262(*l*) divides patent litigation into two distinct phases—an immediate infringement action on patents

the parties deem appropriate for early resolution, and a subsequent action involving other patents. Allowing notice before licensure enables the applicant to collapse or even invert the two phases. The notice also authorizes the sponsor to seek a preliminary injunction against the launch of an approved biosimilar, preventing a change in the status quo during the adjudication of any remaining patent disputes. Congress did not mean to authorize preliminary injunction proceedings well before the sponsor is subject, as a result of the biosimilar's licensure, to the sort of concrete risk of harm that can justify an injunction.

Requiring applicants to provide post-licensure notice promotes §262(*l*)'s purpose of facilitating the orderly, pre-launch resolution of patent disputes. The biosimilar license granted by the FDA can differ significantly from both the reference product license and the license initially sought by the applicant. Modifications throughout the review process can easily affect the need for injunctive relief. Here, for example, Sandoz's application was amended 30 times. Sponsors need a post-licensure window to assess their patent rights, and determine whether to seek a preliminary injunction, once the scope of the applicant's permitted conduct is clearly defined by the biosimilar license.

Sandoz's interpretation would allow the applicant to provide notice at the time of submitting its application, often years before approval. A notice given in such circumstances is a notice in name only. In practice, it tells the sponsor nothing about when the biosimilar will be approved or, indeed, whether it is likely to be approved at all. A sponsor cannot seek injunctive relief against such a hazy risk of the biosimilar's launch; instead, it will have to rush to the courthouse to seek

emergency injunctive relief after learning of the biosimilar's licensure.

Because Sandoz claimed the right to launch its product fewer than 180 days after post-licensure notice, Amgen appropriately sought an injunction against that unlawful conduct under California's Unfair Competition Law. The Court need not address whether *federal* law independently authorizes an injunction requiring compliance with §262(*l*)(8)(A), because Amgen did not seek such relief. If it reaches that question, however, the Court should answer it in the affirmative. The BPCIA expressly authorizes sponsors to sue in federal court, and it does not limit the courts' inherent power to grant equitable relief for statutory violations in a properly filed suit. Whether the BPCIA creates a "private right of action" is the wrong question to ask—particularly given that, unlike in those cases that do address the availability of implied rights of action, the government does not enforce §262(*l*).

2. Section 262(*l*)(2)(A) states that an applicant "shall provide" the sponsor with a copy of its application and manufacturing information shortly after the FDA accepts its application for review. As the government recognizes, that is a command, not a choice. Nothing in the statute justifies departing from the ordinary, mandatory construction of the word "shall." To the contrary, neighboring provisions reinforce that construction by referring to the "information required" under §262(*l*)(2)(A) and by distinguishing it from information that the applicant "may" provide.

The BPCIA's purpose confirms what its text makes plain. Section 262(*l*)(2)(A) is an initial step in an intricate process for identifying and resolving patent disputes. By mandating early disclosure of the application

and manufacturing information, Congress ensured that the sponsor would have access to the facts necessary to identify patents it could reasonably assert against the applicant. Whether the parties engage in licensing negotiations, patent litigation, or both, the §262(*l*)(2)(A) disclosures enable the sponsor to narrow the dispute to patents that may actually be relevant. Sandoz's and the government's interpretation, by contrast, would force sponsors to sue on every potentially applicable patent and attempt to obtain the mandated information in discovery, or to add patents as discovery progresses. Such needlessly broad or evolving disputes are the opposite of what Congress had in mind. Indeed, Congress considered and rejected proposals that would have allowed the applicant to decide whether or not to participate in the dispute-resolution process.

Amgen appropriately sought an injunction under California's UCL to compel Sandoz to comply with §262(*l*)(2)(A). As with the marketing-notice provision, therefore, the Court need not decide whether federal law independently authorizes such an injunction. But if it reaches that question, the Court should answer it in the affirmative. Sandoz and the government principally argue that injunctive relief is inappropriate because two provisions allow a sponsor to file a declaratory-judgment or patent-infringement action if the applicant fails to provide the §262(*l*)(2)(A) information. But neither of those provisions purports to remedy the applicant's violation of §262(*l*)(2)(A), and neither provides a basis for concluding that §262(*l*)(2)(A) is unenforceable.

3. The error of Sandoz's interpretation is particularly clear in light of the *combined* effect of its positions on §262(*l*)(2)(A) and §262(*l*)(8)(A). Were Sandoz correct, the resolution of patent disputes relating to bio-

similars would diverge sharply from the orderly process Congress meant to create.

Under Sandoz's approach, a sponsor could be left totally in the dark about the existence of a pending application until the applicant launched its competing product upon receiving FDA approval. The sponsor would then have to rush to court to seek emergency injunctive relief on every potentially relevant patent, without having time to analyze the nature of the biosimilar and the scope of the FDA's approval, and without knowledge of the manufacturing process. The resulting proceedings would burden the courts by forcing them to decide complex disputes almost instantaneously. As experience with the Hatch-Waxman Act demonstrates, such compressed proceedings are arduous for the judiciary and unnecessarily prone to error.

The chaos caused by Sandoz's and the government's interpretation is reason enough to reject it. Amgen's interpretation of the statutory scheme is not merely more consistent with the statutory text and structure. It is also the only one that serves Congress's goal of promoting the orderly and efficient resolution of patent disputes.

ARGUMENT

I. APPLICANTS MUST PROVIDE 180-DAY MARKETING NOTICE AFTER LICENSURE

The Federal Circuit correctly (1) held that §262(*l*)(8)(A) requires applicants to provide a post-licensure notice at least 180 days before marketing, and (2) ordered Sandoz to comply with that mandatory obligation.

A. The Statutory Text Establishes That Notice Cannot Be Effective Until A Product Has Been Licensed

Section 262(*l*)(8)(A) states that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." (Emphasis added.) As the Federal Circuit observed, this reference to "'the biological product licensed under subsection (k)'" is unique within §262(*l*). Pet. App. 20a. Other provisions refer to "the biological product that is *the subject of*" the application. 42 U.S.C. §262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B) (emphasis added). That is a strong textual indication that §262(*l*)(8)(A), unlike the other provisions, refers to a product that has already been "licensed" by the FDA.

That conclusion is reinforced by the statute's use of "biological product licensed" in other subsections to refer to approved products. Section 262(d)(1), for example, authorizes the recall of "a batch, lot, or other quantity of a product licensed under this section" if it "presents an imminent or substantial hazard to the public health." And §262(i)(4) defines "reference product" as "the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." Both references make sense only as applied to products that have received FDA approval.

Sandoz's textual counter-arguments are unpersuasive.

First, Sandoz argues (at 31-32) that, because notice is to be given by "[t]he subsection (k) applicant," Congress could not have meant for notice to be given exclu-

sively by the holder of an approved application. In the context of §262(*l*)(8)(A), however, "[t]he subsection (k) applicant" simply distinguishes the party that submitted the application from the reference product sponsor. The statute defines the phrase in that manner. It states that "a person that submits an application under subsection (k)," as distinct from "the sponsor of the application for the reference product," is "referred to in" §262(*l*) "as the 'subsection (k) applicant.'" 42 U.S.C. §262(*l*)(1)(A). An applicant remains the "person that submits an application under subsection (k)" even after the application is approved. And contrary to Sandoz's claim (at 32) that "Congress refers to parties with approved applications as 'holders'" elsewhere in the statute, §262 uses the term "holder" only in reference to "the holder of an approved application *under subsection (a)*"—*i.e.*, the traditional pathway. 42 U.S.C. §262(m)(3) (emphasis added). The term is never used to describe recipients of streamlined biosimilar approval.

Second, Sandoz argues (at 35) that §262(*l*)(8)(A) refers to the "product licensed under subsection (k)" only to distinguish it from products that employ the traditional pathway, §262(a). But the provision already refers to "[t]he subsection (k) applicant." No further clarification is necessary.

Third, Sandoz argues (at 33-34) that §262(*l*)(8)(A) refers to the "product licensed under subsection (k)" only because the product will necessarily be licensed at the time it is marketed (whether or not it is licensed when the marketing notice is given). But that argument cannot be squared with other provisions of §262(*l*) that refer to a product that will be licensed as the "subject of the application" under subsection (k), not the "product licensed under subsection (k)." One provision, for example, requires the applicant to explain its view

that the sponsor's patents are "invalid, unenforceable, or will not be infringed by the *commercial marketing* of the biological product that is the *subject of the subsection (k) application*." 42 U.S.C. §262(*l*)(3)(B)(ii)(I) (emphases added); *see also id.* §262(*l*)(3)(C) (similar, regarding the position of the reference product sponsor). Congress clearly expected the product described in the application to be licensed before it was "commercially market[ed]," as marketing without licensure would be illegal. Sandoz is therefore wrong to suggest that the "subject of the application" language is limited to contexts where Congress expected the product would not yet be licensed. Rather, what harmonizes the statute's varying usage of the two phrases is that Congress employed the "subject of the application" language where the *act required by the statute*—in §262(*l*)(3)(B)(ii)(I) and (*l*)(3)(C), for example, the explanations by the sponsor and applicant—must occur prior to approval. By contrast, Congress used the "product licensed" formulation where the required act must occur after approval. That is the case with the marketing notice required by §262(*l*)(8)(A).

Sandoz responds (at 34) by citing 42 U.S.C. §262(k)(5)(C), which states that the FDA's "authority … with respect to risk evaluation and mitigation strategies … shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a)." Sandoz points out that a separate provision, 21 U.S.C. §355-1(a)(1), allows the FDA to require drug applicants to submit "a proposed risk evaluation and mitigation strategy" as part of the application. But the existence of that separate provision explains why Congress could refer in §262(k)(5)(C) only to "products licensed under" the streamlined pathway, knowing that

§355-1(a)(1) would extend that authority (where relevant) to products awaiting approval. No parallel provision extends §262(*l*)(8)(A)'s reference to "licensed" products to include products awaiting approval.

B. The Statutory Structure Confirms That The Marketing Notice Must Follow Licensure

The structure of §262(*l*) confirms that the marketing notice required by §262(*l*)(8)(A) must be provided after licensure.

First, §262(*l*) creates two phases of patent litigation. *See supra* pp. 14-16. Phase one, an "[i]mmediate patent infringement action" brought under §262(*l*)(6), can include only a limited set of patents—those the parties agree are appropriate for early litigation, §262(*l*)(4), or those specified under §262(*l*)(5) when the parties cannot agree. Phase two covers all remaining patents on the parties' §262(*l*)(3) lists, as supplemented under §262(*l*)(7) with patents later acquired or licensed by the sponsor. The marketing notice triggers the start of the second phase by lifting the bar on declaratory-judgment actions brought by either party, 42 U.S.C. §262(*l*)(9)(A), and by authorizing the sponsor to seek a preliminary injunction, *id.* §262(*l*)(8)(B).

If Sandoz were correct that the marketing notice could be given at any time, the phase-two litigation could subsume the phase-one litigation or even begin before it. It makes no sense to suggest Congress went to the trouble of distinguishing two phases of litigation—labeling only the first an "[i]mmediate patent infringement action," 42 U.S.C. §262(*l*)(6)—if it meant to allow applicants to collapse or invert that distinction and thus render meaningless the statutory framework, *id.* §262(*l*)(3)-(5), that produces the distinction.

Second, Sandoz's interpretation would allow applicants to upend §262(*l*)'s detailed rules about which party can institute litigation and at what time. If both parties complete the steps required by §262(*l*), then neither party can bring a declaratory-judgment action on phase-two patents until the post-licensure marketing notice issues. If the applicant fails to comply with §262(*l*), then the sponsor—but not the applicant—may bring an early declaratory-judgment action. But Sandoz's interpretation would allow the applicant to (1) provide the §262(*l*)(2)(A) disclosures, (2) simultaneously give its marketing notice, and (3) immediately file a declaratory-judgment suit on *all* patents in the venue of its choice—all before it is clear whether the applicant will follow the subsequent steps of §262(*l*). The applicant could then prevent §262(*l*)(9)(B) from applying, and thus maintain its chosen venue, by going through the motions on the remainder of the information exchange. Alternatively, the applicant might argue that even if it later violates one or more of its §262(*l*) duties, §262(*l*)(9)(B) does not bar an action that has already been brought. Either way, allowing premature marketing notice could invert the intended order of proceedings.

Third, the marketing notice is not just the trigger for declaratory-judgment actions on phase-two patents. It also authorizes the sponsor to "seek a preliminary injunction prohibiting the … applicant from" manufacturing, importing, or selling its biosimilar product "until the court decides the issue of patent validity, enforcement, and infringement with respect to any" phase-two patent. 42 U.S.C. §262(*l*)(8)(B). Preliminary injunction proceedings by definition occur in exigent circumstances; no court can grant a preliminary injunction unless (among other things) the movant "is likely to suffer ir-

reparable harm in the absence of preliminary relief." *Winter* v. *NRDC, Inc.*, 555 U.S. 7, 20 (2008); *see also, e.g.*, *O'Shea* v. *Littleton*, 414 U.S. 488, 502 (1974) (among the "basic requisites of the issuance of equitable relief" is "the likelihood of substantial and immediate irreparable injury"). The fact that Congress made the marketing notice a trigger for preliminary injunction proceedings indicates that the notice must come after licensure, when the need for such relief is presented.

Fourth, because the marketing notice triggers the sponsor's right to seek an injunction, Congress must have expected that the notice would reflect the applicant's concrete expectation that marketing will occur. *See, e.g.*, *Winter*, 555 U.S. at 22 ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction."). Sandoz, by contrast, would allow an applicant to provide a "notice of commercial marketing" when it has nothing more than a *hope* that the FDA will approve its pending application. It is not clear how an applicant can provide "notice" of marketing when a condition precedent to marketing—namely, licensure—is wholly dependent on FDA action. And it is hard to imagine that Congress intended such a speculative "notice" to trigger injunction proceedings.

Fifth, the government posits (at 25) that "[a]n artificial-infringement claim cannot rest on a manufacturing-process patent alone." If that is correct, it is all the more critical that notice be provided after licensure, because the sponsor may be forced to bring any prelaunch claim for infringement of a process patent under the Declaratory Judgment Act, 28 U.S.C. §2201, seeking adjudication of a legal right based on 35 U.S.C. §271(a) or (g). In such circumstances, the sponsor will need to have notice at a time when it clearly signals

that a dispute is "'of sufficient immediacy and reality to warrant the issuance of a declaratory judgment,'" *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007). Otherwise, sponsors seeking to prevent actual infringement of manufacturing patents under 35 U.S.C. §271(a) might have no way of knowing when they could assert such claims before launch.

Sixth, Sandoz's argument is difficult to square with §262(*l*)(7). That provision states that when an applicable patent "is issued to, or exclusively licensed by, the reference product sponsor" after the initial exchange of lists, "such patent shall be subject to paragraph (8)"—*i.e.*, treated as a phase-two patent. *See, e.g.*, *Apotex*, 827 F.3d at 1057. So long as the phase-two litigation is deferred until the applicant provides a post-licensure marketing notice, that litigation can include all patents the sponsor may acquire between the initial exchange of lists and the date of notice. But if the applicant could provide an early marketing notice, triggering phase-two declaratory-judgment actions before licensure, the litigation of later-acquired patents could be completely disordered. There could, for example, be a proliferation of patent suits filed as new patents issue or are licensed by the sponsor. Congress presumably did not mean to leave such a gaping hole in §262(*l*)'s otherwise comprehensive framework.

Finally, Congress expected a gap of roughly 180 days between licensure and marketing of a biosimilar product. Section 262(k)(6) provides an exclusivity period for the first biosimilar to demonstrate "interchangeability" with the reference product. That period ends with the first of five events, one of which is "1 year after the first commercial marketing of the first interchangeable" product, and another of which is "18 months after approval of" that product. 42 U.S.C.

§262(k)(6)(A), (C)(ii). The juxtaposition of those timeframes implies Congress expected a gap of roughly six months between approval and marketing.

Sandoz notes (at 37) that 180 days is slightly shorter than six months. But to the extent that difference is meaningful, it simply shows Congress gave the applicant a few days' grace period before terminating the incentive for achieving the first interchangeable product, in case the applicant cannot give notice the day it receives approval or launch exactly 180 days after notice. Sandoz also argues (at 37-38) that the interchangeability provisions "have nothing to do with the notice of commercial marketing," or with "commercial marketing of a biosimilar as a *biosimilar*," because they apply only when more demanding interchangeability requirements are satisfied. But interchangeable products are a subset of biosimilars, and Sandoz does not (and could not) suggest that §262(*l*)(8)(A) applies differently to interchangeable biosimilars than to biosimilars in general. Although Congress did not want all biosimilars to enjoy the exclusivity afforded to the first interchangeable product, §262(k)(6)'s timing provisions shed light on the anticipated gap between approval and commercial marketing for all biosimilars.

C. A 180-Day Notice Period Serves Congress's Purpose Of Ensuring Orderly Proceedings

Amgen's construction of §262(*l*)(8)(A) also advances Congress's purpose of providing an orderly process for the resolution of patent disputes.

1. Sandoz claims (at 39) that the purpose of the §262(*l*)(8)(A) marketing notice is to inform the sponsor "that commercial marketing will commence in *at least* 180 days." (Emphasis added.) By that account, the no-

tice serves no purpose at all. An applicant could give the notice at the time of filing its application, and all the notice would convey is that the biosimilar might be marketed in six months, or perhaps eight years, or perhaps never.

The actual purpose of the notice is to create a 180-day, pre-launch window for the two types of proceedings triggered by the notice—a declaratory-judgment action with respect to the phase-two patents, 42 U.S.C. §262(*l*)(9)(A), and preliminary injunction proceedings to delay the biosimilar's launch until patent litigation has been resolved, *id.* §262(*l*)(8)(B). This period is not, as Sandoz suggests (at 30), "delay for delay's sake." Rather, as the Federal Circuit observed, "[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," and "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." Pet. App. 21a. The 180-day window is critical to both litigants and courts.

The window is critical for litigants because, before licensure, the sponsor may not know whether the manufacture and sale of the approved biosimilar would infringe its patents. Even if an applicant (unlike Sandoz) discloses its application and manufacturing information as required by §262(*l*)(2)(A), the applicant may amend its application during the review process (as Sandoz did 30 times, CAJA1775), and the FDA may license fewer than all of the products included in a single application,

21 C.F.R. §601.9(c).[4] And where (as here) the applicant has *not* provided the §262(*l*)(2)(A) disclosures, the sponsor will have even less basis to know whether its patents are at risk. For example, a biosimilar applicant may seek approval for a different formulation than the reference product, a different delivery device, a subset of the reference product's routes of administration and conditions of use, or different manufacturing techniques. FDA, *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, at 6-8 (2015).[5] All of those details can affect the infringement analysis.

Sandoz downplays (at 41) the need for a "'fully crystallized controversy'" as a "policy-based rationale," urging that Congress disagreed with that policy by authorizing "patent litigation well before … FDA approval." But that argument—like Sandoz's more general statement (at 40) that Congress intended "to facilitate early resolution of patent disputes"—ignores Congress's choice to create two phases of patent litigation over biosimilars, not just one. Congress recognized that some patents can and should be litigated or licensed early, and it provided a detailed procedure for the parties to identify, negotiate, and litigate those pa-

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[4] Coherus's amicus brief suggests (at 16-17) that "the reference sponsor can propound discovery requests" in phase-two litigation "to monitor amendments to the biosimilar application, and should such an amendment impact the infringement analysis, it can add or remove patents from the case as appropriate." It is difficult to imagine Congress intended this "shoot first, ask questions later" approach to be part of an orderly dispute-resolution process.

[5] *Available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf.

tents. 42 U.S.C. §262(*l*)(4)-(6). But the marketing notice triggers the second phase of litigation, regarding patents the parties did *not* think were appropriate for immediate litigation.

Sandoz's argument also ignores the key difference between the concreteness of the dispute required to support an artificial-infringement action and the concreteness of the dispute required to support a preliminary injunction. Under 35 U.S.C. §271(e)(2)(C), an artificial-infringement action rests on the submission of an application and tests whether infringement would occur if the applicant were to engage in the full scope of conduct for which it seeks licensure. *Cf. Sunovion Pharm., Inc.* v. *Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278-1279 (Fed. Cir. 2013) (Hatch-Waxman infringement judged against full scope of approval sought). The parties can thus litigate a phase-one action regarding the full scope of the license sought in the application, before it is clear what the applicant will actually be permitted to do, so long as the applicant's "*purpose* … is to obtain approval … to" sell, manufacture, or use a drug "claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. §271(e)(2) (emphasis added). If the sponsor prevails "in a final court decision" in such an action before the reference product exclusivity period has expired, the court must enjoin "any infringement of the patent." *Id.* §271(e)(4)(D). But if the phase-one litigation has not yet concluded by the time the FDA makes its approval effective—which is entirely possible—the sponsor cannot obtain a preliminary injunction against the manufacture, import, or sale of the licensed biosimilar without showing that the product, process, or use, *as licensed*, is likely to infringe its patents. A post-licensure marketing notice thus allows orderly injunctive proceedings not just with respect to phase-two

patents but with respect to phase-one patents still being litigated.

Whereas Amgen's interpretation of §262(*l*) would produce the order and efficiency Congress intended, Sandoz's would produce chaos. According to Sandoz, an applicant could give its marketing notice long before its product would ever be licensed, potentially as soon as it filed its application. But giving such an ill-defined time horizon for launch would make it exceedingly difficult for a sponsor to determine whether or when to seek an injunction. The sponsor could have trouble articulating why it was "likely to suffer irreparable harm in the absence of preliminary relief," why it was "likely to succeed on the merits," or why an injunction was "in the public interest," *Winter*, 555 U.S. at 20, without knowing the launch date of the biosimilar or the scope of FDA approval. *See, e.g.*, *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 111 (1983) (injunctive relief requires "a 'likelihood of substantial and immediate irreparable injury'").

The government recognizes as much. It agrees that a sponsor cannot seek preliminary injunctive relief "any significant amount of time before a biosimilar's commercial marketing," because "traditional equitable relief" is available only for those harms that "are sufficiently real and imminent." U.S. Br. 23-24; *see id.* at 31. Thus, the government frames the purpose of the §262(*l*)(8)(A) notice as "allow[ing] the sponsor to litigate its artificial-infringement claims on Round 2 patents in an action for declaratory relief and to seek injunctive relief *at an appropriate time in that action*." *Id.* at 31 (emphasis added). But the government fails to answer the key question: Without a post-licensure marketing notice, how will the sponsor know when is "an appropriate time" to seek a preliminary injunction?

Under Sandoz's view, sponsors may not know the biosimilar's launch is sufficiently imminent to seek injunctive relief until the launch has actually occurred. The sponsor *might* learn about the biosimilar's licensure through a public announcement. But under Sandoz's interpretation, nothing would prevent the applicant from launching its product immediately upon licensure, since the marketing notice could have been given more than 180 days earlier. Sponsors would therefore have to seek injunctive relief on an emergency basis.

Congress did not envision that result. Section 262(*l*)(8)(B) authorizes sponsors to "seek a preliminary injunction" against the "commercial manufacture or sale of" the approved biosimilar "[a]fter receiving the notice" of commercial marketing "and *before* … the first commercial marketing of" the biosimilar. (Emphasis added.) Congress saw no need for *post*-launch preliminary injunction proceedings, and its reference to preliminary injunctions rather than temporary restraining orders indicates that it expected there would be time for adversarial rather than ex parte proceedings. Post-launch proceedings would also impose an unfair burden on sponsors, who would have to explain why a preliminary injunction removing a product already on the market would serve "the public interest," *Winter*, 555 U.S. at 20.

2. Sandoz's construction would impose extraordinary burdens on district courts. The emergency proceedings that would be necessary under Sandoz's view would afford courts little time to examine potentially voluminous factual records and complex questions of patent law. Patents relating to biosimilars are among the most technical that a generalist judge is ever likely to encounter. For example, in Amgen's litigation

against Hospira over a biosimilar version of the biologic Epogen, one of the patents at issue "is directed to erythropoietin isoforms and erythropoietin compositions having specific numbers of attached sialic acid moieties, and methods for preparing the same." Complaint ¶71, Dkt. 1, *Amgen Inc.* v. *Hospira Inc.*, No. 15-cv-839 (D. Del. Sept. 18, 2015). Another "is directed to vertebrate cells which are capable of producing recombinant human erythropoietin, and processes for producing recombinant erythropoietin using such cells." *Id.* ¶75. It is difficult to imagine how a court conducting emergency proceedings, with no more than a few days or perhaps hours to issue a ruling, could sufficiently master the relevant issues to adjudicate patents like these.

Even when courts manage the burdens of emergency litigation, Sandoz's approach would hamper the efficacy of their remedial powers. Although there is little experience so far with biosimilars, manufacturers of traditional generic drugs have long positioned themselves to saturate the market with large quantities of generic drugs at the first opportunity. As an employee of AstraZeneca recently explained, "generic manufacturers commonly place six months or more worth of product into the market within days or hours of final approval." Decl. of Rod Wooten ¶19, Dkt. 22-2, *AstraZeneca Pharm. LP* v. *Burwell*, No. 16-cv-1336 (D.D.C. June 30, 2016).

Even a speedily issued preliminary injunction or temporary restraining order may not be quick enough to prevent large-scale market incursion by an infringing product. In 2008, for example, Teva obtained FDA approval to market its generic version of Pulmicort and launched immediately upon approval. By the time AstraZeneca secured a temporary restraining order

that same evening, Teva had flooded the market with approximately six months' worth of product. *Id.*; *see also* Dkt. 486 at 4, *Sanofi-Synthelabo* v. *Apotex Inc.*, No. 02-cv-2255 (S.D.N.Y. Oct. 19, 2010) (noting that Apotex shipped $884 million worth of a generic drug during the three weeks between launch and the issuance of a preliminary injunction). As the Federal Circuit has explained, "the [BPCIA'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." *Apotex*, 827 F.3d at 1063 (collecting numerous sources).

The Court should reject Sandoz's view that applicants may freely ignore the BPCIA's detailed dispute-resolution framework and substitute in its place the chaos Congress sought to avoid.

D. Courts May Order Applicants To Comply With The Notice Requirement

Section 262(*l*)(8)(A) is legally enforceable. Sandoz's contrary view would permit applicants to defy the 180-day notice requirement with impunity.

1. Injunctive relief is available under state law

The Court need not decide whether federal law authorizes an injunction to enforce §262(*l*)(8)(A), because Amgen sought an injunction not under federal law but under California's Unfair Competition Law (UCL). Amgen Opp. 28-29. The UCL provides that "[a]ny person who engages, has engaged, or proposes to engage in unfair competition may be enjoined in any court of competent jurisdiction." Cal. Bus. & Prof. Code §17203. Rather than "enforc[ing] the law on which a claim of

unlawful business practice is based"—here, the BPCIA—the UCL effectively "borrows violations of other laws and treats them as unlawful practices that [it] makes *independently* actionable" as a matter of state law. *Rose* v. *Bank of Am., N.A.*, 304 P.3d 181, 185 (Cal. 2013) (internal quotation marks omitted). Amgen relied on the UCL in seeking injunctive relief from the district court. CAJA73-75 (complaint); Dist. Ct. Dkt. 56 at 12-14 (preliminary injunction motion); *see* U.S. Br. 10.

"[R]espect for the States as 'independent sovereigns in our federal system' leads [courts] to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Wyeth* v. *Levine*, 555 U.S. 555, 565 n.3 (2009). As the party seeking dismissal of the state-law claims, Sandoz bears the heavy burden of overcoming the presumption against preemption. It has not even attempted to carry that burden, having affirmatively disavowed any preemption argument before the district court. *E.g.*, CAJA1854 ("We have not argued preemption of the state law claims.").

2. Injunctive relief is available under federal law

To the extent the Court addresses whether federal law authorizes an injunction requiring compliance with §262(*l*)(8)(A), it should reject Sandoz's position. That position would strip courts of traditional remedial authority and permit applicants to provide *no* notice of commercial marketing, or to violate their notice by entering the market before the 180-day period has run.

1. Sandoz primarily argues (at 43-45) that an injunction requiring compliance with the 180-day waiting period is unlawful because it would create a "private

right of action." But no one disputes that private litigants (including sponsors) have a right to sue under the BPCIA. The only question is whether, in the context of properly filed suits, courts may enforce the procedural framework enacted by Congress rather than allowing applicants to ignore it entirely.

That question does not implicate this Court's cases on private rights of action. Those cases address when private litigants—as opposed to the government—may sue to enforce a statute or regulation that does not expressly afford them that right. In *Alexander* v. *Sandoval*, for example, the question was "whether private individuals may sue to enforce disparate-impact regulations promulgated under Title VI of the Civil Rights Act of 1964." 532 U.S. 275, 278 (2001). The Court answered that question in the negative, explaining that, while "private individuals may sue to enforce … Title VI" itself, Congress intended that regulations promulgated "'to effectuate'" the statute would be enforceable by the government alone. *Id.* at 279, 288-291.

This case presents no similar issue. As Sandoz recognizes (at 55), the government plays no role in enforcing the BPCIA's patent-dispute framework.[6] And the

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[6] The FDA has stated that the patent-dispute provisions "do not involve FDA." Approval Pathway for Biosimilar and Interchangeable Biological Products, 75 Fed. Reg. 61,497, 61,498 (Oct. 5, 2010). The FDA also denied a citizen petition, filed by Amgen, asking the FDA to require that all §262(k) applicants certify that they have provided sponsors with the information required by §262(*l*)(2)(A). Letter from Janet Woodcock to Jeffrey Kushan 3-4 (Mar. 25, 2015), *available at* http://patentdocs.typepad.com/files/citizen_petition_denial_response.pdf.

The lack of governmental enforcement distinguishes the cases on which Mylan's amicus brief relies (at 13-14) for the proposition

BPCIA expressly contemplates suits brought by sponsors. It defines the submission of a §262(k) application as actionable infringement, 35 U.S.C. §271(e)(2)(C); directs the sponsor to file an infringement action on phase-one patents, 42 U.S.C. §262(*l*)(6); sets forth a framework for declaratory-judgment actions on phase-two patents, *id.* §262(*l*)(9); and provides for sponsors to seek preliminary injunctions against the launch of an approved biosimilar, *id.* §262(*l*)(8)(B).

2. The only question, then, is the scope of available relief: In a properly filed suit, may a federal court order the applicant to comply with §262(*l*)(8)(A) by not marketing its product earlier than 180 days after a post-licensure marketing notice? This 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.'" *Apotex*, 827 F.3d at 1064 (quoting *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 398 (1946)). There is no contrary command, either explicit or implicit, in this case. Earlier bills addressing biosimilars *would* have limited the courts' power to compel compliance with patent-dispute resolution procedures. *See* H.R. 1427 §3(a)(2) (proposed §262(k)(18)(F)) (providing that applicant "may not be compelled, by court order or otherwise, to initiate the procedures set forth" in the patent dispute-resolution provisions); S. 623 §3(a)(2) (proposed §262(k)(17)(E)); H.R. 6257 §3(a)(2) (proposed §262(k)(16)(E)). But the BPCIA as enacted contains no such language.

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that a private right of action is unavailable to enforce certain provisions of the Hatch-Waxman Act.

Sandoz argues (at 53) that *Apotex* is wrong to presume the power to grant equitable relief, on the theory that the correct presumption weighs *against* the recognition of a private right of action. But that again confuses the existence of a right of action with the existence of equitable power in a properly filed action. Because no one questions that sponsors may bring suit, only the latter question is relevant here.

Sandoz also takes issue (at 54-55) with the particular authorities *Apotex* relied on for the proposition that courts generally possess power to enjoin violations of the law. But authorities for that proposition are legion. *E.g.*, *Califano* v. *Yamasaki*, 442 U.S. 682, 705 (1979) ("Absent the clearest command to the contrary from Congress, federal courts retain their equitable power to issue injunctions in suits over which they have jurisdiction."); *United States* v. *Paradise*, 480 U.S. 149, 183-184 (1987) (plurality opinion) ("'Once a right and a violation have been shown, the scope of a district court's equitable powers to remedy past wrongs is broad, for breadth and flexibility are inherent in equitable remedies.'"). Sandoz cannot seriously contend that district courts presumptively *lack* the power to remedy violations of the law in cases properly before them.

3. The BPCIA does not preclude an injunction requiring notice

1. Sandoz argues (at 46-48) that the BPCIA precludes injunctions to enforce §262(*l*)(8)(A) by specifying a particular consequence for a breach of that provision—namely the opportunity for the sponsor to "bring an action … for a declaration of infringement, validity, or enforceability of any patent included in the list described in [§262(*l*)](3)(A), including as provided under

[§262(*l*)](7)." 42 U.S.C. §262(*l*)(9)(B). That argument fails for several reasons.

First, §262(*l*)(9)(B) does not purport to *remedy* a marketing-notice violation. Rather, the purpose of §262(*l*)(9) as a whole, and §262(*l*)(9)(B) within it, is to ensure that applicants cannot short-circuit the dispute-resolution processes of §262(*l*) by seeking declaratory relief. Under §262(*l*)(9), the applicant may initiate a declaratory-judgment action on phase-two patents in only one circumstance—once it has fully complied with its obligations under §262(*l*) and given marketing notice. Because the sponsor has no obligation to file an infringement action on any remaining phase-two patents, allowing the applicant to file a declaratory-judgment action at that point ensures that the applicant can obtain patent certainty before launch.

Sections 262(*l*)(9)(B) and (C) serve the converse purpose of preserving the sponsor's background right to file a declaratory-judgment action in all circumstances except one—where the applicant is fully complying with its obligations under §262(*l*). If the applicant participates fully in the dispute-resolution process, then the sponsor (like the applicant) must await the marketing notice to seek declaratory relief on phase-two patents. But §262(*l*)(9)(B) ensures that the applicant cannot diminish the sponsor's rights simply by refusing to comply with the marketing-notice requirement and §262(*l*)'s other obligations. This preservation of existing rights does not provide a remedy for a marketing-notice violation—and certainly does not purport to provide an *exclusive* remedy.

Second, §262(*l*)(9)(B) would be a wholly ineffective remedy for a marketing-notice violation, further confirming that Congress did not intend it to serve that

purpose. As Judge Taranto explained in *Apotex*, "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 [§262(*l*)](8)(A)'s purpose to avoid." 827 F.3d at 1065. If the applicant launches its product without having given any marketing notice or without having waited the requisite 180 days after licensure, the sponsor is unlikely to learn of a breach of the notice requirement until launch has occurred. And when the sponsor does learn of the breach, it "will have to race to court for immediate relief" on a patent-infringement claim, forcing "the parties and the court … [to] engage in precisely the hurried motion practice that [§262(*l*)](8)(A) is designed to replace by ensuring a defined amount of time for pre-launch litigation." *Id.* Such a "'remedy' is so gross a mismatch for the [§262(*l*)](8)(A) right that it cannot fairly be treated, in the absence of any statutory language so stating, as … exclusive" of an injunction mandating compliance with the notice requirement. *Id.*

The Court should not interpret the BPCIA as creating a Catch-22 in which the exclusive remedy for a failure to give notice could be rendered meaningless by the failure to give notice. Courts should retain the authority to issue prospective injunctions *preventing* a breach of §262(*l*)(8)(A).

Third, §262(*l*)(9)(B) does not even apply in this case, given Sandoz's failure to provide the application and manufacturing information required by §262(*l*)(2)(A). As the structure of §262(*l*)(9) makes clear—and as both Sandoz (at 46) and the government (at 34-35) concede—§262(*l*)(9)(B) applies only where the applicant *complies* with §262(*l*)(2)(A) but "[s]ubsequent[ly]" fails to fulfill one of the other speci-

fied duties of §262(*l*). By contrast, §262(*l*)(9)(C) applies where the applicant fails to comply with §262(*l*)(2)(A). In cases like this one that are governed by subsection (C), not subsection (B), the statute simply does not specify a consequence for a breach of §262(*l*)(8)(A).

The government argues (at 35) that "specifically identifying" a declaratory-judgment "consequence for failing to give Section 262(*l*)(8)(A) notice is entirely unnecessary if the applicant failed at the outset to furnish the Section 262(*l*)(2)(A) information." "In those circumstances," the government says, "the BPCIA *already* provides that the sponsor may bring suit on any relevant patent." *Id.* That argument misses the point, however. Both Sandoz and the government lean heavily on the premise that §262(*l*) specifies a particular consequence for a breach of §262(*l*)(8)(A). But that premise is not correct where the applicant also breaches §262(*l*)(2)(A). Moreover, the provisions addressing a breach of §262(*l*)(2)(A) do not address the additional harm that occurs when an applicant also breaches §262(*l*)(8)(A) by launching without the required notice. *See supra* pp. 47-48.

Finally, as noted above (at 32), Sandoz's argument, that a marketing notice may be given at any time, would allow the applicant to circumvent §262(*l*)(9)'s framework for declaratory-judgment actions. Sandoz can hardly point to the sponsor's ability to file a declaratory-judgment suit under §262(*l*)(9)(B) as the exclusive consequence for a premature launch, when its interpretation could render that consequence toothless.

2. Alternatively, even if Sandoz were correct that the relevant question is whether §262(*l*)(8)(A) creates a right independently enforceable by a private litigant, that question should be answered in the affirmative.

As the Court explained in *Touche Ross & Co.* v. *Redington*, the task of determining whether the injured party may sue consists of "determining whether Congress intended to create the private right of action." 442 U.S. 560, 568 (1979); *see also, e.g.*, *Sandoval*, 532 U.S. at 286 ("The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy.").

For the reasons discussed above, it should be straightforward to conclude that Congress intended §262(*l*)(8)(A) to be enforceable by private litigants. The provision plays an essential role in the procedural framework Congress enacted, and the government does not enforce it. Denying courts the ability to enforce it by injunction, at the behest of private litigants, would render it a nullity. That would contravene this Court's "duty to give effect, if possible, to every clause and word of a statute," *Duncan* v. *Walker*, 533 U.S. 167, 174 (2001) (internal quotation marks omitted).

3. Sandoz argues (at 51-52) that Congress "expressly provide[d] an injunctive remedy" for a breach of §262(*l*)(1)'s confidentiality provisions, and that the Court should therefore infer it did not mean to provide such a remedy for a breach of §262(*l*)'s other provisions. But §262(*l*)(1)(H), which Sandoz characterizes as "provid[ing] an injunctive remedy," does nothing of the sort. Rather, it tells courts how to *apply* the traditional factors for equitable relief, by specifying that "[t]he disclosure of any confidential information … shall be deemed to cause the … applicant to suffer irreparable harm for which there is no adequate legal remedy," and that the court therefore "shall consider immediate injunctive relief to be an appropriate and necessary remedy for" such unlawful disclosures.

Section 262(*l*)(1)(H) thus supports Amgen's position on the availability of injunctive relief, not Sandoz's. It would make no sense for Congress to tell courts how to exercise their equitable power if Congress did not think the courts possessed such power.

4. The Federal Circuit did not reject the application of equitable factors

Contrary to Sandoz's argument (at 52), the Federal Circuit did not reject the proposition that an injunction against breach of §262(*l*)(8)(A) must be justified under the traditional factors for equitable relief. Although the Federal Circuit did not recite its application of the factors, there is no reason to think the court did not consider them. *See, e.g.*, *Hartman* v. *Nicholson*, 483 F.3d 1311, 1315 (Fed. Cir. 2007) ("That the court did not specifically mention the argument in its opinion forms no basis for an assumption that it did not consider it[.]" (internal quotation marks and brackets omitted)). To the contrary, since the parties briefed the application of the factors, both in the merits briefing and when Amgen sought an injunction pending appeal, the court presumably considered them. *E.g.*, Amgen C.A. Br. 62-65; Sandoz C.A. Br. 60-63.

Even if the Federal Circuit's failure to discuss the factors would otherwise be a basis to remand, there is no warrant for such factbound review here. The propriety of injunctive relief in this case is now moot; the injunction has expired, and Sandoz nowhere suggests this putative error is likely to recur in a case between the parties.

5. Post-licensure notice does not improperly extend the 12-year period of non-patent exclusivity

Sandoz argues (at 56-60) that courts cannot enforce the 180-day notice provision because doing so would effectively extend a 12-year period of exclusivity for reference products. That argument is unpersuasive for many reasons. Indeed, Sandoz itself proposed the dual system it now asks the Court to reject.

First, there is no conflict between the 180-day notice period and the text of §262(k)(7)(A), which states that the FDA's approval of a biosimilar application "may not be made effective … until the date that is 12 years after the date on which the reference product was first licensed." Contrary to Sandoz's argument (at 57), the enforcement of a 180-day notice period does not render the FDA's "'effective' approval *ineffective* for six months." The approval remains effective—but it is only a necessary condition, not a sufficient one, for the applicant to begin marketing its biosimilar. A 180-day post-licensure notice period is a distinct prerequisite.

Second, there is nothing unusual about delaying the market entry of a drug to facilitate orderly patent litigation. That is precisely the approach taken by the Hatch-Waxman Act, which provides a 30-month period for the resolution of patent disputes between pioneering and generic drug manufacturers. *See supra* p. 8. That period is achieved through an automatic stay of FDA approval and routinely delays market entry beyond the separate, non-patent exclusivity periods provided by the Act. Compared to the automatic 30-month stay, the BPCIA's 180-day window for allowing the sponsor to seek a preliminary injunction is quite modest.

Indeed, Sandoz and its corporate parent (Novartis) proposed precisely such a system during the legislative process. Specifically, they proposed having an exclusivity period of at least 12 years and a separate, post-licensure notice period during which market entry would be delayed to facilitate patent litigation. The proposal appeared in a submission to the House Energy and Commerce Committee on behalf of the Novartis group of companies, including its "Sandoz generics business." Letter from Paulo Costa, Novartis Corp., to Reps. Pallone & Deal (May 1, 2008). The submission noted that, "[g]iven the investments necessary in developing innovator biologics, a minimum of 12 years of exclusivity is essential and there may be sound arguments for more." *Id.* attachment 30. It further explained that, although the companies would prefer for the BPCIA not to include patent provisions, "[o]ne proposal that may be useful for all stakeholders as part of the new pathway is if, immediately *subsequent to the FDA issuing the license* for a follow-on biologic, the reference product holder is given notice of say 45 or 90 days in which to initiate suit if they believe they have patents infringed; *during this window, the follow-on sponsor will not launch their product.*" *Id.* at 27 (emphases added); *see also id.* at 29 ("The follow-on sponsor *would be precluded from launch* for a set period, 45 or 90 days has been suggested as appropriate, during which the reference product sponsor could choose to litigate." (emphasis added)).

A Sandoz employee made a similar point in testimony before the relevant Senate committee. The "process for follow-on biologics," he stated, "could include a 45-day notification of an issued approval, during which time the innovator would be alerted to an approval referencing its product, and the innovator could institute

litigation if it believed that its patent or other intellectual property rights have been violated." *Follow-On Biologics: Hearing Before the S. Comm. on Health, Labor, & Pensions*, 110th Cong. 36 (2007) (statement of Dr. Ajaz S. Hussain, Vice President and Global Head of Biopharmaceutical Development, Sandoz).

Although Sandoz's precise proposal was not accepted, these comments contradict Sandoz's current view that setting aside a post-approval period for orderly patent litigation is somehow inconsistent with the BPCIA's structure or would improperly extend the non-patent exclusivity period.

Third, it is incorrect to regard the 12-year period created by §262(k)(7)(A) as a period of *market* exclusivity—*i.e.*, monopoly rights. It is simply a period of *data* exclusivity, during which the sponsor's clinical and product data on file with the FDA are protected and cannot be a basis for licensure of a biosimilar under §262(k)'s streamlined process. During the data-exclusivity period, competing biologics may be approved through the conventional pathway, §262(a), which requires the applicant to generate its own safety and efficacy data rather than relying on the sponsor's. For example, Teva obtained conventional approval for a competing filgrastim product, known as Granix, in 2012. *See* FDA, *List of Licensed Biological Products* (Feb. 16, 2017).[7]

[7] *Available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM439049.pdf.

Fourth, Sandoz incorrectly suggests (at 10, 56) that the 12-year period was the sole fulcrum on which Congress balanced the interests of pioneering drug innovators and biosimilar applicants. Although the term of data exclusivity was a subject of considerable debate in Congress, so was the statute's dispute-resolution procedure. *See* Carver 721-723, 735-737, 745-746, 755-761, 771-773, 782-784, 798-802, 813-816. Sandoz is wrong to suggest that, because Congress limited sponsors' data-exclusivity period to 12 years, the BPCIA's dispute-resolution provisions should be given a one-sided interpretation. Before the BPCIA, an applicant could never use the sponsor's data without its permission.

More broadly, Sandoz is wrong to assume that the interests of reference product sponsors and biosimilar applicants are monolithically at odds. Amgen, for instance, manufactures both reference products and biosimilars. *See, e.g.*, FDA, *FDA Approves Amjevita, A Biosimilar to Humira* (Sept. 23, 2016).[8] Amgen's interest is in enforcing the orderly framework that Congress enacted to benefit applicants and sponsors alike—not in procuring what Sandoz calls "delay for delay's sake" (Br. 30), which would harm Amgen's own biosimilars business.

Fifth, because Amgen's reference product was first approved more than 12 years before Sandoz filed its application, this case does not present the question of how the FDA might handle a situation in which the biosimilar applicant sought approval well before the expiration of the 12-year period. In *Apotex*, the Federal

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[8] *Available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm522243.htm.

Circuit speculated that the FDA might be able to "issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date," allowing the applicant to give its marketing notice 180 days before the end of the 12-year period. 827 F.3d at 1062. If the FDA possesses such authority and determines to exercise it—premises that will have to await clarification in a future case—that would negate Sandoz's concern about extending the 12-year period.

Sixth, Sandoz's argument that the 180-day notice period will give sponsors a windfall even if there are no patents to assert rests on an unproven assumption and misunderstands the provision's purpose. Unless a sponsor is no longer engaged in developing its reference product or improving its biologic manufacturing processes, it will be rare that a sponsor has no patents to assert. Innovation does not stop with the discovery of a new therapeutic molecule or a single method of manufacturing and using it. Sponsors commonly invent new methods of using a molecule to treat patients, new formulations, new methods of manufacturing and purification, and so on. And just as innovation does not happen overnight, neither does patent prosecution; once an application makes it through the Patent Office's massive backlog, the process of reviewing and refining claims can take years. Patents are an important foundation of pioneering companies' willingness to make the substantial and uncertain investments needed to invent new products, processes, and uses.

Because sponsors continue to innovate and because patent prosecution takes time, multiple patents have been asserted in each of the actions brought under the BPCIA so far. Here, for example, Amgen owned no unexpired patents for the filgrastim molecule itself when it sued Sandoz for infringement in 2014, but it

still held an unexpired patent claiming a method of using filgrastim to treat patients.

Sandoz also ignores the possibility that a sponsor that does not initially have a patent to assert may obtain one. Section 262(*l*)(7)(A) provides that, when a new patent "is issued to, or exclusively licensed by, the reference product sponsor," after the sponsor's initial patent list under §262(*l*)(3)(A), the sponsor may add that patent to the list of those potentially infringed by the biosimilar. When that happens, "such patent shall be subject to paragraph (8)." 42 U.S.C. §262(*l*)(7). That means it is treated as a phase-two patent, which cannot be the basis of a declaratory-judgment action until the marketing notice. Here, for example, Amgen obtained a process patent on January 27, 2015, and later amended its complaint to allege infringement of that patent. Because the patent issued more than three months after Amgen's §262(*l*)(3)(A) initial patent list would have been due had Sandoz complied with §262(*l*), that patent would have come under §262(*l*)(7).

Sandoz also ignores the fact that, even if the sponsor ultimately determines that none of its patents would be infringed, it may need time to make that determination given the complexity of the issues. The potential for a sponsor to decide not to assert any patents during the 180-day notice period does not negate the need for the period, so that the sponsor can make a considered and informed decision.

In any event, the possibility of a case in which the sponsor owns no applicable patents is not a reason to construe §262(*l*)(8)(A) in a manner that would undermine its functionality in the vast majority of cases. Congress often adopts bright-line rules without vary-

ing them for improbable events like the one Sandoz posits.

II. Applicants Must Provide Sponsors With Their Applications And Manufacturing Information

The Federal Circuit erred in holding that applicants may refuse to comply with §262(*l*)(2)(A)'s requirement to disclose their applications and manufacturing information. In reaching that conclusion, the court unjustifiably read the phrase "shall provide" in §262(*l*)(2)(A) as discretionary rather than mandatory—a construction that conflicts not only with the court's interpretation of the same phrase in §262(*l*)(8)(A), but also with the statutory text and purpose.

A. The Statutory Text Establishes That Disclosure Is Mandatory

Section 262(*l*)(2)(A) provides that, no later than 20 days after the FDA notifies the applicant that its application has been accepted for review, the applicant "*shall* provide to the reference product sponsor a copy of [its] application" and "other information that describes the process or processes used to manufacture the biological product." (Emphasis added.) As this Court has repeatedly held, "'shall' is ordinarily 'the language of command.'" *Alabama* v. *Bozeman*, 533 U.S. 146, 153 (2001); *see also*, *e.g.*, *State Farm Fire & Cas. Co.* v. *United States ex rel. Rigsby*, 137 S. Ct. 436, 442 (2016) ("'[S]hall' … creates a mandatory rule the relator must follow.").

The text of §262(*l*)(2) provides no reason to deviate from the typical, mandatory meaning of the word "shall." To the contrary, the statute contrasts §262(*l*)(2)(A)'s directive that the applicant "*shall* provide" its application and manufacturing information

with §262(*l*)(2)(B)'s provision that the applicant "*may* provide … additional information requested by or on behalf of the reference product sponsor." (Emphases added.) "[W]hen the same [statute] 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); *see also*, *e.g.*, *United States ex rel. Siegel* v. *Thoman*, 156 U.S. 353, 360 (1895) (the use of "shall" and "may" "indicat[es] command in the one and permission in the other").

The separate provision governing the confidentiality of the dispute-resolution process further underscores this contrast. It distinguishes between "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." 42 U.S.C. §262(*l*)(1)(B)(i) (emphasis added).

Other provisions likewise reinforce that Congress viewed §262(*l*)(2)(A) as a command. Section 262(*l*)(9) twice refers to "the application and information *required*" under §262(*l*)(2)(A). (Emphasis added.) So does 35 U.S.C. §271(e)(2)(C)(ii). Those provisions further refer to an applicant's "*fail*[*ure*]" to provide the "required" information. If Congress understood §262(*l*)(2)(A) as permissive, it would instead have used language reflecting as much, as it did in other provisions. *E.g.*, 42 U.S.C. §262(*l*)(1)(F) (noting that the sponsor can "opt[]" to destroy confidential information instead of returning it).

The Federal Circuit nonetheless held that "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" Pet. App. 15a. The government notably does not defend that

holding. U.S. Br. 16 (agreeing that Federal Circuit "misconceived the relevant inquiry"). The Federal Circuit appeared to reason that §262(*l*)(2)(A) cannot impose a mandatory obligation because two other provisions "explicitly contemplate[]" the applicant's noncompliance by allowing a sponsor to bring a declaratory-judgment or patent-infringement action if the applicant fails to provide the §262(*l*)(2)(A) information. Pet. App. 15a (citing 42 U.S.C. §262(*l*)(9)(C); 35 U.S.C. §271(e)(2)(C)(ii)).

But neither of those provisions supports the inference that §262(*l*)(2)(A) is optional. Rather, they simply ensure that the sponsor is not denied access to the courts by the provisions of the BPCIA in the event of an applicant's non-compliance. And the fact that a statute "contemplates" possible noncompliance does not render compliance optional. For example, Federal Rule of Civil Procedure 37(c)(1) provides for various consequences if a party "fails to provide information or identify a witness as required by Rule 26(a)." Yet no one would characterize Rule 26(a)'s disclosure obligation as anything but mandatory. *See* Fed. R. Civ. P. 26(a)(1)(A) (party generally "*must*, without awaiting a discovery request, provide" certain information (emphasis added)).

B. The Statutory Purpose And Legislative History Confirm That Disclosure Is Mandatory

Construing §262(*l*)(2)(A) as mandatory advances an important congressional purpose—promoting the orderly resolution of patent disputes—in several ways.

First, §262(*l*)(2)(A) enables the sponsor to identify and narrow the list of patents implicated by the application. As Congress recognized, process patents—

those covering methods of purification or production—are particularly important in the biologics context. *Supra* p. 9. Without access to the applicant's manufacturing information, the sponsor cannot know whether the applicant's manufacturing process will practice its process patents. Furthermore, a biosimilar is only *similar* to the reference product; it need not have the same structure or formulation. *Id.* Without access to the biosimilar application, the sponsor may not know whether the biosimilar incorporates all the patented features of the reference product. Nor will it know whether the application is seeking approval for all existing indications or routes of administration or only a subset. The §262(*l*)(2)(A) disclosures give the sponsor the information necessary to determine which patents could be infringed.

The Federal Circuit downplayed the significance of §262(*l*)(2)(A) by suggesting that a sponsor can "access the required information through discovery" after filing suit. Pet. App. 17a. But the statute *entitles* the sponsor to this information, without delay or the burden of discovery disputes. Moreover, recent experience shows that accessing the information in discovery is uncertain and not an adequate substitute for timely, mandatory disclosure. In *Amgen Inc.* v. *Hospira, Inc.*, the applicant provided its application to the sponsor but refused to provide other manufacturing information. Appellant's Br. 8-10, Dkt. 28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). Unable to determine whether its manufacturing patents could reasonably be asserted, the sponsor sued on certain other patents and sought manufacturing information in discovery. *Id.* But the district court refused to compel production, deeming the requests irrelevant to the patent claims in suit. *Id.* at 12-13. If that erroneous understanding prevails in oth-

er courts, the only way for a sponsor that does not receive the §262(*l*)(2)(A) disclosures to protect its patent rights would be to throw professional caution to the wind and sue on *every* conceivably relevant patent—something sponsors will be reluctant to do. *Cf.* 2009 Hearing 208 (AIPLA) (noting that, without mandatory information-exchange provisions, a sponsor might lack a good-faith basis to assert certain patents).

Second, Sandoz ignores the role §262(*l*)(2)(A) plays within §262(*l*)'s broader dispute-resolution process. As described above, requiring the applicant to disclose its application and manufacturing information at the outset allows the sponsor to narrow the list of patents that could potentially be infringed by the biosimilar. The §262(*l*)(2)(A) disclosures also facilitate the next several steps in the process, which require the parties to exchange their respective positions on the validity, enforceability, and infringement of the patents the sponsor identifies—further narrowing the scope of the dispute. 42 U.S.C. §262(*l*)(3). Indeed, the disclosures may enable the parties to avert litigation by resolving their dispute through other means. The parties must, for example, exchange positions on their willingness to license specific patents. *Id.* §262(*l*)(3)(A)(ii), (B)(iii). And an applicant must decide whether to dispute each patent or simply agree to delay commercial marketing until the patent expires. *Id.* §262(*l*)(3)(B)(ii). These provisions, which depend on the applicant's §262(*l*)(2)(A) disclosures, reduce litigation and streamline it where it occurs.

Third, allowing an applicant to opt out of the information-exchange process would not only undermine the goal of informed and efficient dispute resolution; it would also unfairly limit the sponsor's remedies on patent-infringement claims. Section 271(e)(4)(D) enables a

sponsor to obtain a mandatory permanent injunction against infringement if (1) the reference product remains within the 12-year exclusivity period and (2) a court has adjudicated the dispute "in an action for infringement of the patent *under* [*§262*]*(l)(6)*." (Emphasis added.) An applicant that refuses to provide the information mandated by §262(*l*)(2)(A) can preclude the possibility of a §262(*l*)(6) action, unilaterally depriving the sponsor of the right to obtain a mandatory injunction.[9]

Finally, Congress considered and rejected a permissive rather than mandatory patent dispute-resolution scheme. An early proposal for a biosimilar pathway would have specified that "[t]he decision as to whether to invoke the [patent dispute-resolution] procedures … is left entirely to the discretion of the applicant." H.R. 6257 §3(a)(2) (proposed §262(k)(16)(E)). Two of the BPCIA's other predecessor bills—including one that remained under debate at the final House committee hearing—expressly provided that "[n]othing" in the statute "require[d] an applicant … to invoke" the patent dispute-resolution procedures. H.R. 1427 §3(a)(2) (proposed §262(k)(18)(F)); S. 623 §3(a)(2) (proposed §262(k)(17)(E)). Similarly, earlier discussion

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[9] The government argues (at 25-26) that the availability of a mandatory injunction "compensat[es]" the sponsor as a "counterbalance" for the applicant's control over the number of patents that can be litigated in a §262(*l*)(6) suit. But the government overstates the degree to which the applicant controls the scope of the phase-one litigation: The sponsor can always designate at least one patent for immediate litigation, and it can obtain a mandatory injunction if that patent is held infringed. Furthermore, a sponsor can also initiate litigation under §262(*l*)(6)—and thus obtain a mandatory injunction—if the parties *agree* on which patents to litigate. 42 U.S.C. §262(*l*)(4)(A), (*l*)(6)(A).

drafts of S. 1695—the bill on which the BPCIA was modeled, *see supra* p. 11—would have given the sponsor and the applicant "the option to notify each other regarding patents they deemed relevant." Carver 757.

In enacting the BPCIA, Congress abandoned such discretionary language and replaced it with a series of commands. This Court "ordinarily will not assume that Congress intended 'to enact statutory language that it has earlier discarded in favor of other language.'" *Chickasaw Nation* v. *United States*, 534 U.S. 84, 93 (2001). That would be the effect of adopting Sandoz's permissive construction of §262(*l*)(2)(A).

C. Courts May Order Applicants To Comply With The Disclosure Requirement

Sandoz and the government contend that, even if §262(*l*)(2)(A) mandates disclosure, a court may not order an applicant to comply.

As discussed above (at 42-43) in reference to §262(*l*)(8)(A), this Court need not decide whether federal law authorizes an injunction to enforce §262(*l*)(2)(A). Sandoz agrees that no party has sought such an injunction under the BPCIA. Sandoz Opp. 2. Amgen instead sought injunctive relief under California's UCL. And Sandoz has disavowed any claim that the UCL, or the scope of relief under it, are preempted. *Supra* p. 43.

In any event, federal law *does* authorize injunctions to enforce §262(*l*)(2)(A), for the same reasons it authorizes injunctions to enforce §262(*l*)(8)(A). *See supra* pp. 43-46. Whether or not the BPCIA confers a private right of action, it does not limit the courts' inherent power to grant equitable relief in a properly filed suit. *See supra* pp. 45-46. And even if the Court were to

reach the question whether the BPCIA confers a private right of action, it should have little difficulty concluding that Congress intended for the §262(*l*)(2)(A) duty to be enforceable, since the alternative would be to assume Congress enacted a functionally meaningless provision.

Sandoz and the government argue that Congress tied the courts' hands by specifying two consequences of a §262(*l*)(2)(A) violation, to the exclusion of others—namely, a declaratory-judgment action permitted by §262(*l*)(9)(C) and a patent-infringement suit under §271(e)(2)(C)(ii). Sandoz Opp. 26-27; U.S. Br. 17-19. Neither provision, however, purports to provide any remedy at all—let alone an exclusive remedy—for a §262(*l*)(2)(A) violation.

First, §262(*l*)(9)(C) simply allows the sponsor to go forward with a declaratory-judgment action (by lifting the bar imposed by §262(*l*)(9)(A)) if the applicant fails to make the disclosures required by §262(*l*)(2)(A). Ordinarily, §262(*l*)(9)(A) prevents both the sponsor and the applicant from seeking declaratory relief on phase-two patents before the applicant's provision of a marketing notice. But if the applicant refuses to initiate the information-exchange process that leads to a division among phase-one and phase-two patents, it makes no sense to force the sponsor to await the outcome of a process that cannot occur. The practical utility, if any, of the declaratory-judgment action depends on the sponsor's ability to identify an infringed patent without the required disclosures. But if the sponsor *can* identify certain patents as infringed, it should be able to bring an action with respect to those patents and seek an order compelling the applicant to comply with §262(*l*)(2)(A), so as not to delay the sponsor from litigating its patents prior to launch. Section 262(*l*)(9)(C)

thus accomplishes the limited and necessary purpose of eliminating a nonsensical obstacle to the sponsor's assertion of its patent rights. It does not purport to state the exclusive consequence of a §262(*l*)(2)(A) violation.

Second, the Federal Circuit relied on 35 U.S.C. §271(e)(4), which lists the "only remedies" a court may award for "*an act of infringement* described in" §271(e)(2). (Emphasis added.) Section 271(e)(2), in turn, makes it an "act of infringement to submit … an application seeking approval of a biologic[] … if the purpose of such submission is to obtain approval … to engage in the commercial manufacture, use, or sale" of a biologic in a manner that would infringe a patent covering the biologic or a method of using it. 35 U.S.C. §271(e)(2)(C). In general, the patents infringed by the submission are those identified by the parties under §262(*l*)(3) and (*l*)(7). *Id.* §271(e)(2)(C)(i). But if the applicant fails to provide the disclosures required by §262(*l*)(2)(A)—and, consequently, there is no comprehensive list of patents generated by §262(*l*)(3)—the submission infringes any patents that *could have been identified* under §262(*l*)(3). *Id.* §271(e)(2)(C)(ii). The Federal Circuit reasoned that the relevant "act of infringement" under §271(e)(2)(C) must be the submission of an application "coupled" with the failure to provide the required disclosures—and therefore that §271(e)(4) specifies the exclusive remedies for a breach of §262(*l*)(2)(A). *Apotex*, 827 F.3d at 1061; *see also* Pet. App. 18a.

But that reading of the statute is incorrect. As in the Hatch-Waxman context, the artificial act of infringement created by §271(e)(2)(C) is the *submission of the application*. *Cf. Eli Lilly*, 496 U.S. at 678 (noting that the "act of infringement" under the Hatch-Waxman Act "consists of submitting an abbreviated

new drug application"). The applicant's violation of §262(*l*)(2)(A) is not an act of infringement; it informs how the *scope* of the infringement is to be determined—that is, which patents are implicated by the submission. If the parties have engaged in the §262(*l*) process, §271(e)(2)(C)(i) deems infringed any patents identified under §262(*l*)(3). But where the applicant prevented the parties from reaching that stage by failing to comply with §262(*l*)(2)(A), all patents that *could* have been identified are deemed infringed. Because a breach of §262(*l*)(2)(A) is not an act of infringement, §271(e)(4) does not specify the exclusive remedies for it.

III. The Combined Effect Of Sandoz's Positions Illustrates Why Those Positions Are Incorrect

Sandoz's interpretations of §262(*l*)(2)(A) and §262(*l*)(8)(A) are incorrect even when those provisions are considered separately, as explained above. But the implausibility of Sandoz's view becomes even clearer in light of the combined effect of its positions.

1. In the most extreme case, Sandoz's interpretation would leave a sponsor unaware of the application until the day the FDA announces its approval. In Sandoz's view, an applicant could choose not to provide the disclosures required by §262(*l*)(2)(A), *and* refuse to provide at least 180 days' notice of commercial marketing. Sandoz Br. 60-62; U.S. Br. 32-33. The sponsor's only option to enforce its patent rights in that scenario would be to seek emergency injunctive relief after licensure, while the applicant seeks to rush onto the market.

Even after FDA approval, however, a sponsor would still lack information about the applicant's manufacturing process and might lack other pertinent infor-

mation, including about the biologic's structure. *See, e.g.*, 21 C.F.R. §601.51(f) (biologic's manufacturing information is "not available for public disclosure" even after approval). As a result, the sponsor might be unable to narrow the list of potentially relevant patents, leading to needlessly complex disputes on an emergency timeline. The government, like the Federal Circuit, dismisses this problem (at 25) by suggesting the sponsor can sue on some patents and obtain the §262(*l*)(2)(A) information through discovery. But that process is neither simple, nor certain, nor speedy. *See supra* pp. 61-62.[10]

Even if the sponsor obtains the application and manufacturing information in discovery, that would leave it virtually no time to analyze the technical detail, assess its patents, decide which patents to assert, and seek a temporary restraining order and preliminary injunction. Only then could the parties begin to litigate the claim construction, validity, enforceability, and infringement issues necessary to assess the sponsor's likelihood of success on the merits.

Such proceedings would impose crushing burdens on already busy courts and lead to rushed decisions on exceedingly complex disputes—exactly the opposite of the orderly process Congress intended. The Hatch-Waxman experience is again instructive. District courts forced to decide whether to grant emergency relief on compressed timetables have denied prelimi-

[10] The sponsor's inability to identify manufacturing-process patents that might be infringed would be exacerbated if, as the government contends (at 25), a sponsor can sue for artificial infringement only on patent claims covering compositions and uses of biosimilars.

nary injunctions and allowed generics to launch, only to have the patents subsequently be found valid and infringed.[11] The risk of similar errors is exacerbated if the sponsor must seek emergency relief on the day of launch without even knowing the relevant patents.

2. Sandoz contends (at 48-51) that sponsors will not be left in the dark. It points to a handful of ways a sponsor *might* learn about pending applications, including securities filings, an FDA clinical trial database, FDA advisory committee meetings, and voluntarily issued press releases. There is, of course, no indication that Congress intended for sponsors to have to scour these sources for information. On the contrary, Congress provided a simple way for sponsors to be notified about a pending application: It stated that applicants "shall provide" their applications to sponsors under §262(*l*)(2)(A).

Even if the statute placed the burden on sponsors to monitor available sources of public information, none of those sources would necessarily provide the sponsor with effective notice. An applicant might be a privately held company with few, if any, securities disclosure obligations, and even a publicly traded applicant might determine that filing the application is not sufficiently material to warrant disclosure. The clinical trial database will yield no information where, for example, the FDA exercises its discretion to deem a clinical trial unnecessary for a particular application,

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[11] Dkts. 151, 319, *Sanofi-Aventis Deutschland GmbH* v. *Glenmark Pharm. Inc., USA*, No. 07-cv-5855 (D.N.J. Jan. 14, 2011); Dkts. 249, 821, 1384, *Altana Pharma AG* v. *Teva Pharm. USA, Inc.*, No. 04-cv-2355 (D.N.J. Apr. 23, 2010); *see also* O'Malley et al., *Failure to Launch*, Intell. Prop. Mag. 30-32 (Apr. 2011).

42 U.S.C. §262(k)(2)(A)(ii), or where clinical trials were conducted abroad and therefore not included in the database. Nothing in §262(k) requires the FDA to hold an advisory committee meeting before approving every biologic. *Cf.* 21 U.S.C. §355(s)(2) (FDA need "not refer the drug to advisory committee prior to approval" if it provides "a summary of the reasons … in the action letter on the application"). And an applicant can always decide not to issue a press release.

Moreover, even if sponsors might learn about the *existence* of an application through other channels, that is not enough. A sponsor will not know the application's particulars or the relevant manufacturing information, without which the sponsor may have difficulty determining which patents are potentially infringed. *See supra* pp. 60-61. And without the §262(*l*)(8)(A) notice, the sponsor will not know when commercial marketing will begin—and thus when to seek a preliminary injunction against the biosimilar's launch.

Sandoz and the government suggest that upon learning of the existence of an application—which could be years before the commercial marketing of a biosimilar—the sponsor should seek declaratory relief on any patent *potentially* infringed by the manufacture, sale, import, or use of the biologic. Without the disclosure mandated by §262(*l*)(2)(A), the result could be a needlessly broad action asserting dozens or hundreds of patents. And as the government seems to recognize (at 23-24, 31), a request for a preliminary injunction is appropriately adjudicated only when the biosimilar's launch is imminent. Neither Sandoz nor the government explains how a sponsor that does not receive marketing notice is supposed to determine when that point has arrived, without waiting until the biosimilar is licensed.

3. Sandoz's response to these grave implications is the unsubstantiated assertion (at 51) that "no rational applicant" would "'surprise' a sponsor by commercially marketing without notice … in the face of potentially viable patents." That assumption is dubious. It is not uncommon for generic drug makers to "launch at risk"—that is, launch their products while patent claims remain pending. *E.g.*, O'Malley et al., *Failure to Launch*, Intell. Prop. Mag. 30, 30-32 (Apr. 2011) (noting several "at-risk" launches by generic companies between 2007 and 2011); *see also AstraZeneca AB* v. *Apotex Corp.*, 782 F.3d 1324, 1330, 1340-1341 (Fed. Cir. 2015) (setting forth damages rules that apply where pharmaceutical companies "launch their products … knowing that they [are] at risk of later being held to infringe").

Even applicants that would not want to launch in the face of viable patents can easily miscalculate the risks, underestimating the strength of some of the sponsor's patents or failing to identify others. This case provides a good example. Sandoz claims (at 18) to have relied on a statement in Amgen's securities disclosures that its "material U.S. patents for filgrastim … [had] expired." CAJA915, 960. But that was misguided. As Amgen had explained the previous year, only a composition-of-matter patent and a principal method-of-use patent for filgrastim were being referenced.[12] The disclosure did not purport to list every Amgen patent that could apply to the manufacture, use, or sale of biosimilar filgrastim products. Sandoz's speculative assump-

[12] Amgen Inc., Annual Report (Form 10-K) at 4-5 (Feb. 27, 2013), *available at* https://www.sec.gov/Archives/edgar/data/318154/000144530513000364/amgn-12312012x10k.htm.

tions should therefore give the Court no confidence that construing §262(*l*) as optional will avoid chaos.

* * *

This Court sometimes must choose between an interpretation that most naturally reflects a statute's text and structure and one that better promotes the statute's purpose. Here, these indicia of statutory meaning point in the same direction. Congress enacted a detailed framework for the orderly resolution of patent disputes between biosimilar applicants and reference product sponsors. It repeatedly stated that applicants and sponsors "shall" carry out the steps in that framework. The structure of the statute, in which each step builds on its predecessors, depends on the parties' compliance. And when the parties comply, the result is an efficient resolution of patent disputes.

Instead of just following the framework Congress enacted, Sandoz asks the Court to hold that the entire framework is optional—the result of which would be a process so hopelessly disordered that Congress cannot have envisioned it. There is no reason for the Court to adopt that approach.

CONCLUSION

The Federal Circuit's judgment should be affirmed in part and reversed in part.

Respectfully submitted.

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APPENDIX

21 U.S.C. §355. New drugs

* * *

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in

consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

> (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
>
> * * *
>
> (iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);
>
> * * *
>
> (vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect

to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * *

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

* * *

[5](B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

* * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certifi-

cation and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

* * *

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

* * *

[F](ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the ex-

piration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports

of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

* * *

28 U.S.C. §2201. Creation of a remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

35 U.S.C. §271. Infringement of patent

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

* * *

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

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

* * *

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

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

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

* * *

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

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

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

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

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

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be grant-

ed by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * *

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

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

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

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

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

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

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

action under this section for infringement of the patent with respect to the biological product.

* * *

42 U.S.C. §262. Regulation of biological products

* * *

(i) "Biological product" defined

In this section:

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

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

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

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

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product

may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

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

* * *

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

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

(2) Content

(A) In general

(i) Required information

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

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

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

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

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

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

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

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

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biolog-

ical product continues to be safe, pure, and potent.

(ii) Determination by Secretary

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

(iii) Additional information

An application submitted under this subsection—

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

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

(B) Interchangeability

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

* * *

(5) General rules

* * *

(C) Risk evaluation and mitigation strategies

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

(6) Exclusivity for first interchangeable biological product

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

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

(B) 18 months after—

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

(ii) the dismissal with or without prejudice of an action instituted under subsec-

tion (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

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

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

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

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the

reference product was first licensed under subsection (a).

(C) First licensure

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

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

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

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

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

* * *

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the

application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

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

(II) In-house counsel

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

(iii) Patent owner access

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

(C) Limitation on disclosure

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

(D) Use of confidential information

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

(E) Ownership of confidential information

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

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any

publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

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

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

(H) Effect of violation

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

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application

has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

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

(3) List and description of patents

(A) List by reference product sponsor

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

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

(ii) an identification of the patents on such list that the reference product sponsor

would be prepared to license to the subsection (k) applicant.

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

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

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

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

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

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

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

(C) Description by reference product sponsor

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

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall

be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

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

(5) Patent resolution if no agreement

(A) Number of patents

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

(B) Exchange of patent lists

(i) In general

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

(I) the list of patents that the subsection (k) applicant believes should be

the subject of an action for patent infringement under paragraph (6); and

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

(ii) Number of patents listed by reference product sponsor

(I) In general

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

(II) Exception

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

(6) Immediate patent infringement action

(A) Action if agreement on patent list

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

(B) Action if no agreement on patent list

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

(C) Notification and publication of complaint

(i) Notification to Secretary

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

(ii) Publication by Secretary

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

(7) Newly issued or licensed patents

In the case of a patent that—

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

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference prod-

uct sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

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

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

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

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of pa-

tent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

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

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

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

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

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

(C) Subsection (k) application not provided

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

(m) Pediatric studies

* * *

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder

agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

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

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

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