No. 15-1039

In The
Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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

BRIEF FOR PETITIONER SANDOZ INC.

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QUESTIONS PRESENTED

In the Biologics Price Competition and Innovation Act of 2009 ("Biosimilars Act" or "BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products—*i.e.*, products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The Biosimilars Act's "Notice of commercial marketing" provision states that a biosimilar applicant shall provide notice to the incumbent seller of the biological product "not later than 180 days *before the date of the first commercial marketing* of the biological product licensed under" this abbreviated pathway. *Id.* § 262(*l*)(8)(A) (emphasis added).

The Federal Circuit concluded that a biosimilar applicant "may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). As the dissenting judge recognized, the Federal Circuit turned this mere notice provision into a grant of 180 days of additional exclusivity for all biological products beyond the exclusivity period Congress expressly provided—delaying the launch of all future biosimilars by six months. The Federal Circuit transformed the notice provision into a standalone requirement unconnected to the patent resolution provisions of the Biosimilars Act. It also disregarded the only remedy provided by Congress—the right to initiate patent litigation—and instead created its own extra-statutory injunctive remedy to bar the launch of FDA-approved biosimilars.

QUESTIONS PRESENTED—Continued

The questions presented are:

Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parties to the proceeding are listed in the caption.[1]

Pursuant to Rule 29.6, petitioner Sandoz Inc. states the following:

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

[1] Amgen Inc. and Amgen Manufacturing Limited are both respondents. This brief refers to those entities collectively as "Amgen."

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-55a) is reported at 794 F.3d 1347. The opinion of the district court (Pet. App. 56a-84a) is unreported but is available at 2015 WL 1264756.

JURISDICTION

The court of appeals entered judgment on July 21, 2015. Timely rehearing petitions were denied on October 16, 2015. Pet. App. 85a-86a. The Chief Justice extended the time for Sandoz to petition for a writ of certiorari to and including February 16, 2016, and Sandoz's petition was filed on that date. On March 21, 2016, Amgen filed a conditional cross-petition for a writ of certiorari. Both petitions were granted on January 13, 2017. This Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Biosimilars Act, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), and the relevant provisions of Titles 28, 35, and 42 of the United States Code amended by the Biosimilars Act are reprinted in an appendix to this brief. App., *infra*, 1a-83a.

1. Section 262(*l*)(2)(A) of Title 42 provides:

> **(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.

2. Section 262(*l*)(9)(C) of Title 42 provides:

(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.

3. Section 271(e) of Title 35 provides in part:

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

* * *

(C) * * *

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act [42 U.S.C. § 262(*l*)(2)(A)], 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 [42 U.S.C. § 262(*l*)(3)(A)(i)],

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) * * *

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

4. Section 262(*l*)(8)(A) of Title 42 provides:

(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).

5. Section 262(*l*)(9)(B) of Title 42 provides:

(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).

INTRODUCTION

Congress enacted the Biologics Price Competition and Innovation Act of 2009 ("Biosimilars Act" or "BPCIA") to promote competition in the market for biologics, critical medicines made within cells or organisms. At the time, spending on biologics comprised one-fifth of pharmaceutical expenditures and was increasing. But there was no mechanism for approving "generic" forms of biologics, as there long had been for chemically synthesized drugs. Congress therefore created a shorter route for approval of "biosimilars," which are biologics highly similar to medicines already approved as safe and effective. In exchange, Congress gave 12 years of exclusivity from biosimilar competition to holders of licenses of those already-approved biologics ("sponsors" or "reference product sponsors")—regardless of whether the sponsor has any valid patent claims that otherwise could keep the biosimilar off the market.

Congress also established processes for early resolution of patent disputes between sponsors and applicants seeking to introduce biosimilars. At each step, Congress expressly spelled out what actions must be taken to continue, while providing multiple points at which the parties may exit, with specified consequences for doing so. Regardless of the choices the parties make along the way, all routes lead to only one place: patent litigation.

But the Federal Circuit turned one of the statute's procedural steps into an enforceable right unto itself.

Under that ruling, introduction of every single biosimilar will be delayed six months more than Congress intended. The Federal Circuit reached this result by misconstruing the statute's "Notice of commercial marketing" provision. That provision calls for the biosimilar applicant to give "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)," that is, the abbreviated biosimilar pathway. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). This provision includes a single timing element: it is satisfied so long as notice is provided at least 180 days *before* commercial marketing. Nevertheless, the Federal Circuit interpreted it to include a second timing feature as well: the court thought notice could be given only *after* FDA approval of the biosimilar. Had Congress wanted that requirement, it would have said so directly, rather than by burying its intent in the single word "licensed," as the court of appeals concluded.

The Federal Circuit then compounded its error in two independent ways. The Biosimilars Act specifies consequences for not following its procedural steps. Yet the Federal Circuit erroneously added its own remedy: a mandatory, 180-day injunction against commercial marketing of the biosimilar, even *after* it is licensed by the FDA. In addition, rather than reading the statutory provisions in context and as part of a coherent design, the Federal Circuit erroneously read the notice provision as a freestanding requirement, divorced from

the role it plays in the statute's patent resolution regime.

The upshot of all these errors is a windfall for sponsors at the expense of competition and patients. The Federal Circuit held that notice may not be given until after FDA approval of a biosimilar, triggering a six-month waiting period for every biosimilar, enforceable by a mandatory injunction against commercial marketing. That means that sponsors receive 12 and one-half years of exclusivity from biosimilar competition, rather than the 12 years Congress intended. This will be true for every single biosimilar, even where the sponsor lacks any patent protection at all for its biologic or the parties already have resolved all their patent disputes.

The portion of the Federal Circuit's judgment on the notice of commercial marketing provision should be reversed, and the balance struck by Congress in the Biosimilars Act restored.

STATEMENT

A. Need For Biosimilar Approval Pathway

Biologics are medicines distinct from traditional, chemically synthesized pharmaceuticals (often referred to as "small-molecule" drugs). Biologics are either naturally occurring or engineered "from a variety of natural sources—human, animal, or microorganism." FDA, *What Are "Biologics" Questions and*

Answers (last updated Aug. 5, 2015) ("*What are 'Biologics'?*");[2] *see* 42 U.S.C. § 262(i)(1).

Biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." *What Are "Biologics"?* Biologics are thus "among the most important pharmaceutical products available in the United States," but they also "generally are very expensive." Federal Trade Commission ("FTC"), *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, 78 Fed. Reg. 68,840, 68,841 (Nov. 15, 2013).

When Congress passed the Biosimilars Act in 2010, purchases of biologics represented 21% of the $307 billion spent annually on medicines, and spending on biologics was increasing materially. CA JA A389-A391. Many individual biologics were extraordinarily costly. For example, the annual cost of Cerezyme, used to treat Gaucher's disease, was $200,000, and the annual cost of Humira, used to treat (among other things) Crohn's disease, was $51,000. Judith A. Johnson, Cong. Research Serv., RL34045, *FDA Regulation of Follow-On Biologics* 1 (2010) ("CRS Report").

At that time, there was no pathway for expedited approval for most "biosimilars," *i.e.*, biologics that are "highly similar" to already-approved biologics,

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[2] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm.

42 U.S.C. § 262(i)(2). By contrast, there had long been an abbreviated licensing process for generic small-molecule drugs under the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j). Competition from generic drugs made available through that process resulted in more than $1 trillion in savings to the U.S. healthcare system between 1999 and 2010. *See* Letter from John E. Dicken, Health Care Dir., Government Accountability Office ("GAO"), to Hon. Orrin G. Hatch, Ranking Member, Senate Comm. on Fin. 4, 10 (Jan. 31, 2012). The record before Congress showed that an abbreviated licensing process for biosimilars would create more competition and save government and private payors billions of dollars. CRS Report at 1, 4.

B. Statutory Background

To promote such competition and achieve those savings, Congress enacted the Biosimilars Act. Congress struck a careful balance in the statute between facilitating prompt access to cost-saving biosimilars and promoting innovation in biological products. Biosimilars Act § 7001(b), 124 Stat. at 804 (reproduced at App., *infra*, 45a).

The Biosimilars Act created an abbreviated pathway for approval of biosimilars. 42 U.S.C. § 262(k). To expedite market entry, the statute allows a biosimilar application to rely on the evidence of safety and efficacy for an already-approved reference product. *Ibid.*

In exchange, the Biosimilars Act gives holders of biologic licenses issued through the traditional approval pathway a lengthy period without any competition from biosimilars, regardless of whether sponsors have any valid patent claims. *Id.* § 262(k)(7).

The length of that exclusivity period was hotly contested during the consideration of the bill and its predecessors. The FTC argued that no exclusivity period was necessary. FTC, *Emerging Health Care Issues: Follow-on Biologic Drug Competition* v, vii (June 2009) ("FTC Report").[3] By contrast, the biotechnology industry supported a 12-14 year exclusivity period. CRS Report at 3. The industry sought to justify that time period by arguing that patents did not adequately protect investment in biologics and this exclusivity period would substitute for patent protection. FTC Report at 25, 39-40. The President supported seven years. CRS Report at 3. As enacted, the Biosimilars Act provides that the FDA cannot "ma[k]e effective" approval of a biosimilar "until the date that is 12 years after the date on which the reference product was first licensed" by the FDA. 42 U.S.C. § 262(k)(7)(A).

To speed biologics to market once the 12-year exclusivity period expires, the Biosimilars Act also facilitates early resolution of potential patent disputes between sponsors and applicants. This process may begin when the biosimilar applicant files its

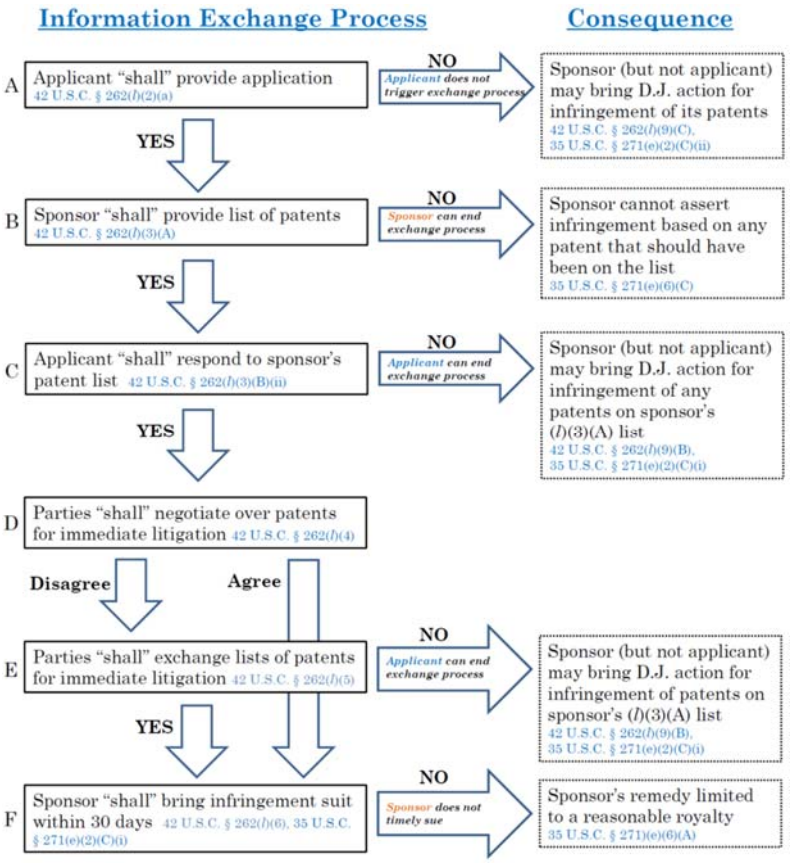
[3] https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competitionfederal-trade-commission-report/p083901biologicsreport.pdf.

application, which can happen as early as eight years before the sponsor's exclusivity period has expired. *See id.* § 262(k)(7)(B) (biosimilar applicant may submit its application to the FDA after the reference product has been licensed for at least four years). At that early time, a pre-marketing dispute over patent infringement and validity would not necessarily be of "sufficient immediacy and reality" to be litigated. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). To overcome that potential issue, the Biosimilars Act makes it an artificial "act of infringement to submit" a biosimilar application to the FDA under certain circumstances. 35 U.S.C. § 271(e)(2)(C); *cf. Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (discussing Congress's creation of an "artificial act of infringement" to "enable the judicial adjudication" of patent claims).

But the Biosimilars Act elsewhere limits who can obtain a declaratory judgment through those provisions, whether and when such actions can be brought, which patents can be included, and what other remedies are available—depending on the actions and inactions of the applicant, the sponsor, or both. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9). Regardless of the steps the parties do or do not take, however, the sole result is possible patent litigation. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (8)(B), (9)(A)-(C). Indeed, the statute specifies that patent-based remedies are "the *only* remedies which may be granted by a court" for the artificial

infringement created by the statute. 35 U.S.C. § 271(e)(4) (referring to *id.* § 271(e)(4)(A)-(D)) (emphasis added).

Such litigation can occur at various stages of the Biosimilars Act's patent dispute resolution regime (entitled "Patents"), 42 U.S.C. § 262(*l*). The various potential paths to patent litigation are illustrated in the following flowchart and explained in the text that follows:



Provision or non-provision of application ("A" in flowchart). As a condition precedent to starting the information exchange process, the applicant "shall provide to the reference product sponsor a copy of the [biosimilar] application" (and associated manufacturing information) within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). The sponsor may use that information "for the sole and exclusive purpose of determining" whether it has a "reasonabl[e]" basis for a patent infringement claim. *Id.* § 262(*l*)(1)(D). If the applicant provides its application, neither it nor the sponsor may bring a declaratory judgment action on infringement, validity, or enforceability on certain patents until the applicant provides a notice of commercial marketing, *id.* § 262(*l*)(8)(A)-(B), or until another condition precedent is satisfied, *id.* § 262(*l*)(9)(B). *See id.* § 262(*l*)(9)(A).

If the applicant does *not* provide its application, the statute deems the submission of the biosimilar application to the FDA to be an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii). And the sponsor may sue on any patents, including process patents. *Id.* § 271(e)(2); 42 U.S.C. § 262(*l*)(9)(C); Pet. App. 16a & n.3. In such litigation, the sponsor may obtain the biosimilar application in discovery. *See* Pet. App. 17a. By contrast, the applicant is barred from bringing a declaratory judgment action of non-infringement or invalidity for "any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(*l*)(9)(C).

Provision or non-provision of patent list ("B" in flowchart). If the applicant provided its application, the sponsor has 60 days from receiving it to provide a list of patents for which it believes it could reasonably assert an infringement claim against the proposed biosimilar and to identify which patents it might license to the applicant. *Id.* § 262(*l*)(3)(A).

If the sponsor does not provide the list, it loses its ability to assert a patent infringement claim against the biosimilar based on any patent that should have been included on such list. 35 U.S.C. § 271(e)(6)(C).

Provision or non-provision of opinions ("C" in flowchart). If the sponsor provides a list, the applicant has 60 days to provide its non-infringement, invalidity, and unenforceability opinions on the sponsor's listed patents and also respond to the sponsor's identification of patents for a potential license. 42 U.S.C. § 262(*l*)(3)(B)(ii)-(iii). (The applicant may also provide its own list of the sponsor's patents for which the applicant "believes a claim of patent infringement could reasonably be asserted" by the sponsor. *Id.* § 262(*l*)(3)(B)(i).)

If the applicant does not provide its opinions, the sponsor (but not the applicant) may bring a declaratory judgment action for infringement of any patents on the sponsor's patent list. 35 U.S.C. § 271(e)(2)(C)(i); 42 U.S.C. § 262(*l*)(9)(B).

Narrowing of lists ("D" and "E" in flowchart). If the applicant provided its opinions, the sponsor "shall provide" within 60 days a "detailed statement"

providing "the factual and legal basis of the opinion of the reference product sponsor" that its identified patents "will be infringed" by the biosimilar and a "response to the [applicant's] statement[s] concerning validity and enforceability" of those patents. 42 U.S.C. § 262(*l*)(3)(C). The sponsor and applicant then "shall" negotiate in good faith over which patents should be litigated in an immediate suit. *Id.* § 262(*l*)(4)(A). If they "fail" to agree, they exchange lists of patents each believes should be litigated immediately. *Id.* § 262(*l*)(4)(B), (5). The "number of patents listed" by the sponsor cannot exceed the number listed by the applicant (unless the applicant lists no patents, in which case the sponsor may list only one). *Id.* § 262(*l*)(5)(B)(ii). The applicant thus can limit any immediate infringement suit to one patent.

If the applicant does not provide a list of patents in that exchange, the sponsor (but not the applicant) may bring a declaratory judgment action for any patents on the sponsor's original patent list. 35 U.S.C. § 271(e)(2)(C)(i); 42 U.S.C. § 262(*l*)(9)(B).

Litigation or not on listed patents ("F" in flowchart). If all prerequisite steps in the patent information exchange have been completed, the sponsor "shall bring" an infringement suit within 30 days on the patents agreed to by the parties or included in the exchanged lists. 42 U.S.C. § 262(*l*)(6)(A)-(B). (The Biosimilars Act also permits a second phase of litigation on any remaining or newly obtained patents. *See infra* p. 16.)

If the sponsor does not timely bring an infringement suit under subsection (*l*)(6) (or does so but dismisses it without prejudice or fails to prosecute it in good faith), "the sole and exclusive remedy" it may secure for any finding of infringement "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6)(A)-(B).

Notice of commercial marketing. In addition, in subsection (*l*)(8)(A), the Biosimilars Act states that the applicant "shall provide notice" 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). When the parties have been engaging in the information exchange process, the notice of commercial marketing lifts the bar on declaratory judgment actions by either the applicant or the sponsor for listed patents (if any) that have not yet been litigated. *Id.* § 262(*l*)(9)(A). After receiving the notice, and before the date of "first commercial marketing" of the biosimilar, the sponsor may seek a preliminary injunction based on a showing of infringement of any not-yet-litigated patents. *Id.* § 262(*l*)(8)(B).

As with the above steps, however, the statute pairs the notice provision with an alternative procedural path. If the applicant does not provide the notice, the sponsor (but not the applicant) may bring a declaratory judgment action for any patents on the sponsor's original patent list (as well as any patents newly issued or licensed after the sponsor provided its original patent list). 35 U.S.C. § 271(e)(2)(C)(i); 42 U.S.C. § 262(*l*)(9)(B).

* * *

As this description shows, Congress linked steps in the information exchange process with consequences for not following them. Each consequence simply affects the scope and timing of patent litigation. For example, if the applicant does not take the first step (*i.e.*, provide its biosimilar application to the sponsor within 20 days of its acceptance by the FDA), *id.* § 262(*l*)(2)(A), the Biosimilars Act expressly lays out a specific path for resolving any patent disputes: patent infringement litigation, with the scope and timing at the sole discretion of the sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). In addition, where the applicant has initiated the information exchange process and the sponsor has provided its initial list of patents, the applicant's election not to provide the notice of commercial marketing means that "the reference product sponsor, but not the [biosimilar] applicant, may bring an action" for a declaration of infringement, validity, or enforceability of any patent on that list as well as any subsequently obtained patents. 42 U.S.C. § 262(*l*)(9)(B). Where the applicant has not triggered the information exchange process by providing its application, the sponsor already has a right to sue on any patent. *Id.* § 262(*l*)(9)(C).

In all cases—whether the information exchange process is never started, is started but not finished, or is followed to its end—the ultimate result is the same: patent litigation. *See* 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (8)(B), (9)(A)-(C).

C. Factual Background

1. Sandoz's biosimilar application

Since 1991, Amgen has marketed the biologic filgrastim under the brand name Neupogen®. Pet. App. 8a. Filgrastim is used to reduce the incidence of infection in certain cancer patients and to promote faster recovery in those who have undergone bone marrow transplants. Pet. App. 62a-63a.

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. Pet. App. 8a. At that point, Amgen had already marketed its filgrastim biologic without biosimilar competition for twice as long as the 12 years Congress deemed sufficient to encourage innovation in biologics. *Ibid.*; 42 U.S.C. § 262(k)(7)(A). The day after the FDA accepted Sandoz's application, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. Pet. App. 8a. Sandoz also provided notice that it intended to begin commercial marketing of its biosimilar filgrastim product in the United States immediately upon FDA approval. Pet. App. 8a; *see* 42 U.S.C. § 262(*l*)(8)(A) (notice of commercial marketing provision).

Amgen had publicly stated in filings with the Securities and Exchange Commission that it had no material, unexpired patents for filgrastim and that, as a result, it "now face[d] competition in the United States." CA JA A915, A960. Rather than engaging in the lengthy information exchange process to identify

patent claims Amgen had already said it did not have, Sandoz determined that lifting the bar on Amgen's ability to initiate immediate patent litigation was the best course. On July 25, 2014, Sandoz informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the Biosimilars Act thus permitted Amgen to bring a declaratory judgment action for patent infringement against Sandoz. CA JA A1495-A1497 (citing 42 U.S.C. § 262(*l*)(9)(C)).

2. Proceedings in district court

a. Several months later—in October 2014—Amgen sued Sandoz. Pet. App. 9a.

Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." Pet. App. 26a. Amgen alleged that Sandoz committed "unlawful" acts for purposes of the UCL by violating the Biosimilars Act. Pet. App. 9a. Specifically, Amgen alleged that Sandoz violated the Biosimilars Act (1) by not providing Amgen with Sandoz's biosimilar application within 20 days of FDA's acceptance of Sandoz's application and (2) by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval. *Ibid.*[4]

[4] Amgen also brought a state law claim for conversion, alleging that Sandoz wrongfully used Amgen's approved license for Neupogen®. Pet. App. 9a.

Expressly invoking the recourse provided by the Biosimilars Act, 35 U.S.C. § 271(e)(2)(C)(ii), Amgen also brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427, which claims a method of treating a patient using filgrastim. Pet. App. 9a; CA JA A79. But Amgen did not move for a preliminary injunction based on purported patent infringement (and still has not done so).

Sandoz counterclaimed, seeking declaratory judgments concerning, among other things, the correct interpretation of the Biosimilars Act. Pet. App. 9a.

b. On March 6, 2015, the FDA approved Sandoz's filgrastim product Zarxio®, the first biosimilar approved under the Biosimilars Act. Pet. App. 8a-9a. Although Sandoz "maintained that it gave an operative notice of commercial marketing in July 2014"—just after the FDA accepted its biosimilar application, *see supra* p. 18—Sandoz "nevertheless gave a 'further notice of commercial marketing' to Amgen on the date of FDA approval." Pet. App. 9a.

c. On March 19, 2015, the district court ruled for Sandoz on Amgen's state law claims and Sandoz's Biosimilars Act counterclaims. Pet. App. 56a-84a.

First, the district court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. Pet. App. 68a-73a. The court noted that Section 262(*l*)(2)(A) states that an applicant "shall provide" a copy of its application to the sponsor and that the information exchange provisions often "use the word 'shall' to

describe the parties' obligations under [subsection (*l*)'s] prescribed procedures." Pet. App. 69a. In context, however, the court explained that these provisions "demand that, if both parties wish to take advantage of [the Biosimilars Act's] disclosure procedures, then they 'shall' follow the prescribed procedures." *Ibid.* At the same time, the statute "contemplate[s] the scenario in which an applicant does not comply at all with disclosure procedures" by "allow[ing] the reference product sponsor to commence patent litigation immediately." Pet. App. 69a-70a.

Second, the district court concluded that it was lawful for Sandoz to provide its notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. Pet. App. 73a-76a. The court rejected Amgen's argument that the word "licensed" in the notice provision "means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry." Pet. App. 74a. The district court explained that "licensed" in the provision refers only to the fact that the product must be licensed before marketing and not to "the appropriate time for notice." Pet. App. 75a. The court further explained that "[e]ven more problematic with Amgen's reading" is that it would "tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A)." Pet. App. 75a-76a.

d. The district court entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's Biosimilars Act counterclaims. Pet. App. 11a.

3. Proceedings in the Federal Circuit

a. In May 2015, the Federal Circuit issued an injunction pending appeal, precluding Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. Pet. App. 31a; CAFC Dkt. No. 105.

b. On July 21, 2015, a fractured Federal Circuit panel affirmed the dismissal of Amgen's state law claims, vacated the judgment on Sandoz's counterclaims, and remanded. Pet. App. 1a-55a. The court also extended the injunction against commercial marketing of Sandoz's filgrastim through September 2, 2015—180 days from when the FDA approved the biosimilar and Sandoz provided its second notice of commercial marketing. Pet. App. 31a.

Disclosure of the application. A majority of the court of appeals panel (Judge Lourie joined by Judge Chen) agreed with Sandoz that the Biosimilars Act "explicitly contemplates" that an applicant might not take the first step in the information exchange process: disclosing its application to the sponsor under subsection (*l*)(2)(A). Pet. App. 15a. Accordingly, "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." *Ibid.* As the court explained, the Biosimilars Act "specifically sets forth the consequence" for not providing the application: "the [sponsor] may bring an

infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)," but the applicant remains barred from bringing its own declaratory judgment action. Pet. App. 15a-17a.

The court observed that the statute "has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)." Pet. App. 15a-16a. Further, both provisions triggered by an applicant's failure to disclose its application "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." Pet. App. 17a. "Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." Pet. App. 18a.

Judge Newman dissented from this part of the decision. Pet. App. 35a-42a (Newman, J., dissenting).

Notice of commercial marketing. The Federal Circuit interpreted the Biosimilars Act's notice of commercial marketing provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). The Federal Circuit read the phrase "licensed under subsection (k)" to require that notice "be given only after the product is licensed by the FDA," rather than as simply referring to the fact that the biosimilar will be licensed before marketing. *Ibid.* Based on this reading of the statute, the court

concluded that Sandoz's July 2014 notice of commercial marketing was "premature and ineffective" and that Sandoz's March 2015 notice "serves as the operative and effective notice of commercial marketing in this case." Pet. App. 23a.

Injunction. As noted above, a panel majority had concluded that the Biosimilars Act provides the exclusive consequence for not disclosing a biosimilar application under subsection (*l*)(2)(A). Pet. App. 15a. In contrast, however, a second majority (Judge Lourie joined by Judge Newman) did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with" the notice of commercial marketing provision in a case, like this one, where the information exchange process did not take place. Pet. App. 24a-25a. The majority acknowledged that subsection (*l*)(9)(B) expressly provides that if a biosimilar applicant does not provide its notice of commercial marketing, "'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 prepared by the sponsor earlier in the information exchange process and any newly obtained patents. *Ibid.* (quoting 42 U.S.C. § 262(*l*)(9)(B)) (emphasis omitted).

The majority observed, however, that this consequence "does not apply" where, as here, the biosimilar applicant did not initiate the information exchange process because the referenced "list" of patents that could be the basis of a declaratory judgment action

does not exist. Pet. App. 25a. The majority further concluded that the notice provision is a "mandatory," "standalone" provision with which an applicant must comply, regardless of whether the applicant has disclosed its application under subsection (*l*)(2)(A) and initiated the information exchange process. Pet. App. 25a-26a.

The court then ruled (without specifying any source of its remedial authority to do so) that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015." Pet. App. 26a. And the majority fashioned its own injunctive remedy: "In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015"—that is, 180 days from Sandoz's post-approval notice of commercial marketing. Pet. App. 31a.

Judge Chen dissented from this portion of the decision. Pet. App. 42a-55a. He criticized the majority's reading of the notice provision as giving the reference product sponsor "an extra-statutory exclusivity windfall." Pet. App. 44a. Judge Chen did not "view (*l*)(8)(A) as a 'standalone provision' that provides, implicitly, the [reference product sponsor] a 180-day injunction beyond the express twelve-year statutory exclusivity period." Pet. App. 43a-44a. He noted that Congress knew how to "create a 180-day automatic stay" if it wished to do so. Pet. App. 52a-53a. For example, Congress "could have tied FDA approval to the notice provision" by

providing that FDA approval cannot be effective until 180 days after notice is given. Pet. App. 53a.

Judge Chen explained that, "[w]hen reading (*l*)(8) in the context of subsection (*l*) as a whole, it becomes clear that (*l*)(8) is simply part and parcel of the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)." Pet. App. 43a. He would have held that, "when, as here, the [biosimilar] applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Ibid.* Moreover, recognizing that subsection (*l*) "concerns one thing: patent litigation," Pet. App. 45a, Judge Chen would have held that the Biosimilars Act provides the exclusive consequence for failure to provide 180 days' notice: the sponsor may sue for patent infringement. Pet. App. 51a-52a.

c. Sandoz launched its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015—upon expiration of the Federal Circuit's injunction.[5]

SUMMARY OF ARGUMENT

The Federal Circuit erred by transforming a mere notice provision into a six-month bar on marketing FDA-approved biosimilars—enforceable by a judicially invented injunction and imposed even where no patent rights are at issue.

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[5] Despite the launch of Sandoz's biosimilar, the dispute between the parties remains live because it is capable of repetition yet evading review. *See* Pet. 36-37; U.S. Cert. Br. 22-24.

I. Under the plain text of Section 262(*l*)(8)(A), notice of commercial marketing can be given before FDA approval of a biosimilar. The provision includes one and only one timing constraint: the applicant is to give notice at least "180 days before the date of the first commercial marketing" of its biosimilar. There is no corresponding constraint stating that notice must come *after* FDA approval. And Congress knew how to require that an action be both "after" one event and "before" another—it used that express formulation in the provision immediately following subsection (*l*)(8)(A).

The Federal Circuit reached its contrary conclusion by overreading the word "licensed" in subsection (*l*)(8)(A). That word merely refers to the applicant's proposed biosimilar product, which will be "licensed" by the time of marketing. Nothing in the text provides that an applicant must wait until the FDA publicly approves its biosimilar, then provide "notice" of its self-evident intent to market that approved biosimilar, and then wait six months more before doing so. Had Congress intended such a scheme, it would have created it expressly instead of burying its intent in the word "licensed."

Permitting notice before approval advances subsection (*l*)(8)(A)'s purpose, which is to notify the sponsor that the biosimilar is at least 180 days from marketing and to lift any stay on any not-yet-litigated patents. That is consistent with the Biosimilars Act's focus on early resolution of patent disputes. Yet the

Federal Circuit's reading of the statute precludes certain litigation from even starting until after the FDA has approved a biosimilar.

II. Regardless of whether notice can be provided only after approval, the Federal Circuit independently erred by fashioning a private right of action for an extra-statutory injunction to enforce subsection (*l*)(8)(A). It is up to Congress, not the courts, to create private rights and remedies for their enforcement. The Biosimilars Act reflects no congressional intent to do so for the notice provision.

Congress created no private right in subsection (*l*)(8)(A). That provision plays only a procedural role by affecting the timing of certain patent infringement suits. Even if subsection (*l*)(8)(A) conferred a right, no extra-statutory remedy may be inferred for violating it. Congress already provided a remedy. Specifically, when an applicant engages in the information exchange process but does not provide notice of commercial marketing, "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect to certain patents. 42 U.S.C. § 262(*l*)(9)(B). And when an applicant does not initiate the information exchange process, the sponsor already can file suit on all its patents. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Regardless, there is only one result: patent litigation.

These express remedies should have precluded the Federal Circuit from crafting additional ones. The unavailability of an injunction to enforce the notice provision is confirmed by the fact that Congress made a *different* provision of subsection (*l*) (involving confidentiality) enforceable by injunction. Effect must be given to Congress's choice to provide that remedy there but not here.

The Federal Circuit's ruling disrupts the careful balance struck by Congress. In exchange for provisions to speed competing biosimilars to market, Congress granted sponsors 12 years of exclusivity from competition from biosimilars, regardless of whether the sponsor has any valid patent claims. The Federal Circuit's ruling gives sponsors an additional 180-day injunction beyond that statutory period—thus effectively rewriting a central provision of the Biosimilars Act. And it does so even where the sponsor has *no* patent protection for its product.

III. Finally, the Federal Circuit erred by transforming subsection (*l*)(8)(A) into a standalone requirement unconnected to the Biosimilars Act's patent resolution provisions. The notice provision plays a procedural role in the information exchange process: it lifts the subsection (*l*)(9)(A) stay on litigation of certain not-yet-litigated patents. But where the applicant never triggered the information exchange process by providing its application, the stay as applied to the sponsor *already* has been lifted, authorizing the sponsor to start patent litigation on any and all patents.

Accordingly, in that circumstance, subsection (*l*)(8)(A) has no role to play and does not apply.

ARGUMENT

The Federal Circuit made three errors that result in effectively providing sponsors with six extra months of exclusivity beyond the 12 years Congress deemed sufficient. Its judgment on the notice of commercial marketing provision should be reversed.

I. NOTICE OF COMMERCIAL MARKETING MAY BE PROVIDED BEFORE FDA APPROVAL

The text, context, and purpose of the Biosimilars Act's notice of commercial marketing provision all establish that notice may be given before FDA approval of the biosimilar. The Federal Circuit's contrary reading—under which notice cannot come until after the FDA has already publicly approved the biosimilar—strips the "Notice of commercial marketing" provision of any notice function and instead converts it into a tool for delay for delay's sake.

A. The Text And Context Of Section 262(*l*)(8)(A) Demonstrate That Notice Can Be Provided Before FDA Approval

1. Titled "Notice of commercial marketing," Section 262(*l*)(8)(A) provides: "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

The provision includes one and only one timing limitation: at least "180 days *before* the date of the first commercial marketing" of the biosimilar. *Ibid.* (emphasis added). So long as that "180 days before" condition is satisfied, so too is Section 262(*l*)(8)(A). Nothing in the statutory text requires the applicant to wait until after FDA approval, then provide notice that it intends to market, and then wait six months more before bringing the biosimilar to market.

This plain-text reading of subsection (*l*)(8)(A) is confirmed by several other aspects of the statute.

First, an immediately neighboring provision demonstrates that Congress knew how to require that an action be both "after" one event and "before" another. Subsection (*l*)(8)(B) authorizes the sponsor to seek a preliminary injunction "*[a]fter* receiving the notice [of commercial marketing] under subparagraph (A) and *before* such date of the first commercial marketing * * * ." *Id.* § 262(*l*)(8)(B) (emphases added). Congress easily could have used the same structure in subsection (*l*)(8)(A) by requiring that notice be given "*after* receiving FDA approval and 180 days *before* the date of the first commercial marketing." It did not do so, and that choice should be given effect. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("Had Congress intended to restrict § 1963(a)(1) to an interest in an enterprise, it presumably would have done so expressly as it did in the immediately following subsection (a)(2).").

Second, this interpretation is confirmed by Section 262(*l*)(8)(A)'s specification that it is the

"subsection (k) *applicant*" that provides the notice. 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). The provision thus contemplates that the notifying party need only have requested FDA approval, not have received it. Elsewhere in the statute, Congress refers to parties with approved applications as "holders." *See id.* § 262(m)(3) (referring to "the holder of an approved application"). If Congress had meant to allow notice only after approval, it would have used consistent language here and called the notifying party "the holder of an approved application."

Third, the permissibility of pre-approval notice is confirmed by the provision's authorization of notice "*not later than* 180 days" before commercial marketing. *Id.* § 262(*l*)(8)(A) (emphasis added). Congress made 180 days the *minimum* notice period; nothing in the statute precludes applicants from giving earlier notice. Again, this reflects the Biosimilars Act's consistent goal of expedition and early resolution.

2. Despite all this support for the permissibility of pre-approval notice, the Federal Circuit thought its contrary rule lurked in the word "licensed" in the phrase, "the biological product licensed under subsection (k)." *Ibid.* ("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)*." (emphasis added)). According to the Federal Circuit, Congress's use of the word "licensed" "means that notice, to be effective under this statute,

must be given only after the product is licensed by the FDA." Pet. App. 20a.

This reading of the statute is wrong for multiple reasons.

Most fundamentally, the Federal Circuit's overreading of the word "licensed" ignored this Court's admonition that Congress does not "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001). The Federal Circuit's construction of "licensed" effectively extended the period of protection reference products enjoy from biosimilar competition from 12 years to 12 and one-half years. That is so because FDA licensure can come only after the reference product's 12-year exclusivity period. 42 U.S.C. § 262(k)(7)(A). If notice cannot be provided until after licensure—and if a 180-day waiting period can then be enforced by injunction, *see* Pet. App. 26a, 31a; *infra* Section II—then the exclusivity period would be extended by six months. As the district court observed, "[h]ad Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." Pet. App. 76a.

Contrary to the Federal Circuit's view, the phrase, "the biological product licensed under subsection (k)," does no more than identify the product whose commercial marketing is relevant to measuring the 180-day period. Congress's use of "licensed" reflects the simple fact that, by the time the biosimilar is commercially marketed, it will be "licensed under subsection (k)." *See* 42 U.S.C. § 262(a)(1)(A); *see also* Pet. App. 75a

("'Before' modifies 'first commercial marketing'; 'licensed' refers only to 'biological product'—not the appropriate time for notice.").

This understanding is confirmed by another part of the Biosimilars Act, which provides the FDA with the "same" authority with respect to risk evaluation and mitigation strategies for "biological products *licensed under this subsection*" (*i.e.*, the biosimilar approval pathway) that the FDA has for "biological products licensed under subsection (a)" (*i.e.*, the traditional pathway). 42 U.S.C. § 262(k)(5)(C) (emphasis added). Despite the use of this "licensed under" phrasing, Congress expressly provided that the FDA could exercise this authority *before* approval. *See* 21 U.S.C. § 355-1(a)(1). Specifically, the FDA may require a company submitting an application under either subsection (a) or subsection (k)—"as part of such application"—to propose a strategy to ensure that the benefits of the proposed drug outweigh the risks. *Ibid.*; *cf. id.* § 355-1(a)(2) (separately authorizing FDA to require such a strategy after approval under certain circumstances if it becomes aware of new safety information). In other words, the phrase, "biological products licensed," in Section 262(k)(5)(C) imposes no temporal limitation on the provision's applicability. The FDA may require the applicant to develop mitigation strategies before approval, for use after the biologic is "licensed." Section 262(*l*)(8)(A) uses the phrase in the same way—notice may be given before approval of intent to commercially market a biosimilar once it is "licensed."

Section 262(k)(5)(C) also undermines the Federal Circuit's reliance on the word "licensed" in another respect. As just noted, the provision refers to both "biological products licensed under this subsection" (*i.e.*, the biosimilar approval pathway) and "biological products licensed under subsection (a)" (*i.e.*, the traditional pathway). 42 U.S.C. § 262(k)(5)(C). The Biosimilars Act uses these phrases and their equivalents to distinguish between the two different ways that a biologic product can be licensed. Elsewhere, for example, the statute provides that a biologic cannot be marketed unless "a biologics license under this subsection [*i.e.*, subsection (a)] or subsection (k) is in effect for the biological product." *Id.* § 262(a)(1)(A). The statute also defines a "reference product" as a "biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." *Id.* § 262(i)(4). The phrase, "the biological product licensed under subsection (k)," in subsection (*l*)(8)(A) is simply one way the statute refers to a biosimilar, as opposed to a biologic licensed under the traditional pathway.

B. Amgen's Textual Arguments Lack Merit

None of Amgen's additional textual arguments in support of the Federal Circuit's interpretation of Section 262(*l*)(8)(A) withstands scrutiny.

First, Amgen contends that if Congress had intended to permit pre-approval notice, subsection (*l*)(8)(A)

would have labeled the biosimilar " 'the biological product that is the subject of' the subsection (k) application"—a phrase used elsewhere in Section 262(*l*)—instead of "the biological product licensed under subsection (k)." Amgen Opp. 17; *accord* Pet. App. 20a. Unlike the provisions that use the "subject of" formulation, however, Section 262(*l*)(8)(A) is pegged to a specific point in time at which commercial marketing will take place and the biologic will therefore be "licensed." *See* Pet. App. 75a ("It would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its 'first commercial marketing' a biosimilar must, in all instances, be a 'licensed' product.").

Second, Amgen posits that the Biosimilars Act's interchangeability provisions support its view that notice cannot be provided until after FDA approval. *See* Amgen Opp. 18. Under those provisions, a second biosimilar cannot be certified as interchangeable until the earliest of five dates. 42 U.S.C. § 262(k)(6).[6] Amgen observes that one of those dates "is one year after the first commercial marketing of the interchangeable

[6] The FDA will certify a biosimilar as "interchangeable" if it "can be expected to produce the same clinical result as the reference product in any given patient" and if "the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." 42 U.S.C. § 262(k)(4). An interchangeable biosimilar "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." *Id.* § 262(i)(3).

biosimilar, while another is eighteen months after the approval of that biosimilar." Amgen Opp. 18-19 (citing 42 U.S.C. § 262(k)(6)(A) and *id.* § 262(k)(6)(C)(ii)). Amgen then posits that comparison of these two triggering events "suggest[s] that first commercial marketing will not occur on the heels of FDA approval, but rather will follow that approval by some 180 days." *Ibid.*

These provisions have nothing to do with the notice of commercial marketing, and the obscure inference Amgen seeks to draw from them cannot overcome the lack of straightforward evidence for Amgen's post-approval timing requirement. As an initial matter, if Congress had meant to link these disparate concepts, it would have made the second triggering date "one year plus 180 days" after approval rather than "eighteen months" after approval—180 days is shorter than six months. Moreover, Section 262(k)(6) envisions that these end dates will be *different*: it calls for the end of interchangeability exclusivity on "the earlier of" a series of dates, including the two highlighted by Amgen. 42 U.S.C. § 262(k)(6). Yet Amgen's theory depends on the two periods being essentially the same. In any event, these provisions have nothing to do with commercial marketing of a biosimilar as a *biosimilar*. Rather, they apply when the first biosimilar meets the separate, more-demanding requirements of *interchangeability*. As the FDA has explained, approval of a biologic as interchangeable is a separate step that will typically take place subsequent to its approval as a biosimilar. *See* Draft Guidance, FDA, *Biosimilars:*

Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 6-7 (May 2015).[7] The time periods for calculating interchangeability exclusivity are thus beside the point.

Third, Amgen asserts that permitting notice before FDA approval renders Section 262(*l*)(9)(A) "meaningless." Amgen Opp. 19. That provision imposes a stay on litigation "[i]f a subsection (k) applicant provides" its biosimilar application to the sponsor, with the stay lifted when notice of commercial marketing is provided. 42 U.S.C. § 262(*l*)(9)(A). Amgen posits that "[i]f Sandoz were correct and an Applicant could give notice of commercial marketing as soon as it files its [application], the period in subparagraph 262(*l*)(9)(A) would end before it even began, rendering it meaningless." Amgen Opp. 19.

Amgen is wrong that the existence of this hypothetical would render Section 262(*l*)(9)(A) meaningless. In the specific fact pattern posited by Amgen, the applicant simply accelerates the parties' ability to move straight to litigation. *See* 42 U.S.C. § 262(*l*)(9)(A) (provision of notice lifts bar on declaratory judgment actions); *id.* § 262(*l*)(8)(B) (allowing sponsor to seek preliminary injunction on certain patents). The ability of a party in the information exchange process to choose one option over another does not render the forgone option superfluous. In any event, Amgen

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[7] http://www.fda.gov/downloads/Drugs/Guidances/UCM273001.pdf.

never explains why an applicant would behave so irrationally—providing its application to the sponsor (thus triggering the process meant to narrow and allow it to control the scope of immediate litigation) while simultaneously eliminating the value of that narrowing process by providing its notice of commercial marketing (thus inviting immediate litigation on any and all patents).

C. Permitting Notice Before FDA Approval Advances Section 262(*l*)(8)(A)'s Purpose

1. The purpose of Section 262(*l*)(8)(A) is manifest from its terms and express role in the statute: to provide the sponsor with "notice" that commercial marketing will commence in at least 180 days, *id.* § 262(*l*)(8)(A), so that, when the parties have been engaging in the information exchange process, the sponsor can seek a preliminary injunction based on any patents that have not yet been litigated, *id.* § 262(*l*)(8)(A)-(B), (9)(A). That purpose is advanced by permitting notice before FDA approval so that any remaining patent litigation can start—and litigation as to at least the merits of any patent-based preliminary injunction can finish—*before* expiration of the sponsor's 12-year exclusivity period.

In various ways, the Biosimilars Act promotes early resolution of patent disputes so that biosimilars can be available to patients as soon as the reference product's exclusivity ends. Congress made that purpose concrete by creating new artificial infringement

actions to allow patent suits before any actual infringement has occurred, long before FDA approval. *See* 35 U.S.C. § 271(e)(2)(C). Indeed, the mere filing of the biosimilar application allows the parties to start resolving patent disputes—through either the information exchange process followed by patent litigation, 42 U.S.C. § 262(*l*)(2)-(8), (9)(A)-(B); 35 U.S.C. § 271(e)(2)(C)(i), or immediate patent litigation, 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

Critically, it is the notice that triggers the sponsor's ability to seek a preliminary injunction on any patents that the sponsor has not yet been able to litigate through the information exchange process. *See* 42 U.S.C. § 262(*l*)(8)(B). Yet under the Federal Circuit's interpretation of the statute, that litigation cannot even *begin* until after FDA approval in *every* situation where the parties participate in the information exchange process. Nothing in the statute supports that result, which is entirely inconsistent with a statute structured to facilitate early resolution of patent disputes so that biosimilars can quickly reach patients. *See N.Y. State Dep't of Social Servs. v. Dublino*, 413 U.S. 405, 419-20 (1973) ("We cannot interpret federal statutes to negate their own stated purposes."). Moreover, the Federal Circuit's automatic six-month delay beyond FDA approval would apply even when there are *no* patents left to litigate—a particularly perverse outcome for a process that is all about patent rights. *See* Apotex Cert. Amicus Br. 13 (noting that in Amgen's litigation with Apotex *all* patents on the (*l*)(3) list were

litigated immediately after the information exchange, leaving nothing to be litigated under (*l*)(8)(B)).

2. The Federal Circuit's rule permitting "notice" only after FDA approval also deprives Section 262(*l*)(8)(A) of any *notice* function. There is no need for special notice after approval. FDA licensure of a biosimilar is a public act—the FDA itself provides public notice that a biosimilar may be commercially marketed. *See*, *e.g.*, Press Release, FDA, *FDA Approves First Biosimilar Product Zarxio* (Mar. 6, 2015) (announcing approval of Sandoz's application for filgrastim);[8] *see also* FDA, Center for Drug Evaluation and Research, List of Licensed Biological Products;[9] FDA, Drugs@FDA: FDA Approved Drug Products.[10]

The Federal Circuit thought that "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." Pet. App. 21a. While the merits of that policy-based rationale can be debated, there is no basis for it in the text of the statute, which contemplates patent litigation well before (possibly *many years* before) FDA approval.

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

[9] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.

[10] http://www.accessdata.fda.gov/scripts/cder/daf/.

The Biosimilars Act's amendments to the patent laws establish a crystallized patent dispute upon the filing of a biosimilar application with the FDA and either non-provision of the application to the sponsor or the creation of a patent list. *See* 35 U.S.C. § 271(e)(2)(C); *see also Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014) (observing that in the artificial infringement actions created by the statute, it is the application that "circumscribes and dominates the assessment of potential infringement"). That can occur as early as *eight years* before the sponsor's exclusivity period expires. 42 U.S.C. § 262(k)(7)(A)-(B). And the first phase of patent litigation—which, at the applicant's option, can include *all* of the sponsor's asserted patents, 42 U.S.C. § 262(*l*)(5)(B)(i)(I), (ii)(II), & (6)(B)—commences no later than 250 days after the applicant is notified of acceptance of its biosimilar application. *See id.* § 262(*l*). If the applicant does not provide its application to the sponsor, the statute contemplates patent litigation on all the sponsor's patents even earlier. *See id.* § 262(*l*)(9)(C). All of these provisions permitting (indeed, encouraging) early resolution of patent claims cut against the Federal Circuit's interpretation of the notice provision to require the opposite result.

II. THE FEDERAL CIRCUIT ERRED BY INVENTING AN EXTRA-STATUTORY RIGHT OF ACTION AND INJUNCTION TO "ENFORCE" THE NOTICE OF COMMERCIAL MARKETING PROVISION

A. This Court's Precedents Foreclose Adding Judicially Created Remedies To Those In The Biosimilars Act

After concluding that the 180-day notice could not be given until after FDA approval, the Federal Circuit fashioned an injunctive remedy not specified in the Biosimilars Act and layered it on top of the remedies the statute does provide. In particular, the court of appeals created a private right of action for an automatic injunction to specifically enforce the notice of commercial marketing provision. Pet. App. 25a-26a, 31a; *see Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060-61, 1063-65 (Fed. Cir.), *cert. denied*, 137 S. Ct. 591 (2016). This independent error provides a basis for reversal even if the Federal Circuit correctly decided that notice could not be provided until after FDA approval.

An injunction to enforce the Biosimilars Act's notice provision would be warranted only if supported by a showing of congressional intent to create "not just a private right" in that provision "but also a private remedy" for that right's violation. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001); *see Gonzaga Univ. v. Doe*, 536 U.S. 273, 283-84 (2002) (private right of action can be implied only when "Congress intended to create a federal right" *and* intended "to create a private remedy"

for its enforcement (emphasis omitted)). Amgen can make neither showing.

1. The notice of commercial marketing provision creates no private right

The Biosimilars Act reflects no congressional intent to create any "private right" in Section 262(*l*)(8)(A). The notice of commercial marketing provision "lack[s] the sort of 'rights-creating' language critical to showing the requisite congressional intent to create new rights." *Gonzaga*, 536 U.S. at 287 (quoting *Sandoval*, 532 U.S. at 288-89). That is consistent with the purely procedural role the provision plays in the statute. Where the parties are engaged in the information exchange process, the notice authorizes the sponsor to file suit on listed patents not previously litigated. *See* 42 U.S.C. § 262(*l*)(8)(B), (9)(A). The only *substantive* rights involved are patent rights—and the only injunction contemplated by subsection (*l*)(8) is a "preliminary injunction" based on a showing of the strength of any such patents and the traditional requirements for injunctive relief. *Id.* § 262(*l*)(8)(B). Subsection (*l*)(8)(A) creates no substantive "right" to notice.

2. No injunctive remedy to enforce the notice provision is permissible

Even if Section 262(*l*)(8)(A) conferred a "right" on sponsors to receive a notice of commercial marketing (whether before or after licensure), no extra-statutory remedy for that right's "violation" may be inferred. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392

(2006) ("[T]he creation of a right is distinct from the provision of remedies for violations of that right."); *Sandoval*, 532 U.S. at 286. The remedy is provided by the Biosimilars Act itself. The Federal Circuit had no business adding its own remedy—a 180-day injunction against commercial marketing—to the one expressly provided by Congress.

"Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Sandoval*, 532 U.S. at 286. Without a showing of congressional intent to create a private remedy, courts are not at liberty to fashion one. *Id.* at 286-87; *see Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 508 n.9 (1990) (limits on inferring rights of action "reflect[] a concern, grounded in separation of powers, that Congress rather than the courts controls the availability of remedies for violations of statutes"). Because "implied causes of action are disfavored," *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009), this Court is extremely reluctant to recognize them.

The demanding standard for implying a cause of action not expressly created by Congress is not satisfied here. Indeed, neither the Federal Circuit nor Amgen has cited *any* evidence of congressional intent to create a private injunctive remedy to enforce the notice provision—and there is none. Such a remedy is unavailable for that reason alone. But there is much more.

a. The statute's express remedies foreclose adding others

Where "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989). "In such cases, '[i]n the absence of strong indicia of contrary congressional intent, we are compelled to conclude that Congress provided precisely the remedies it considered appropriate.'" *Ibid.* (quoting *Middlesex Cty. Sewerage Auth. v. Sea Clammers*, 453 U.S. 1, 15 (1981)).

Here, Congress specified that when an applicant engages in the information exchange process, yet does not provide notice of commercial marketing, "the reference product sponsor, but not the subsection (k) applicant, may bring" an action for a "declaration of infringement, validity, or enforceability" with respect to certain patents identified earlier in the information exchange process and any newly obtained patents. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, *inter alia*, *id.* § 262(*l*)(8)(A)). And when an applicant has not initiated the information exchange process, its failure to provide the sponsor with its biosimilar application has *already* triggered the sponsor's ability to file suit on all its patents. *Id.* § 262(*l*)(9)(C).

These specified remedial consequences are consistent with Congress's approach throughout subsection (*l*). Instead of providing for judicial enforcement of the provision's steps through injunctions, the Biosimilars Act provides its own, patent-based remedies.

As Judge Chen correctly observed, "Entitled 'Patents,' § 262(*l*) of the BPCIA concerns one thing: patent litigation." Pet. App. 45a (Chen, J., dissenting). The actions or inactions of the applicant and sponsor under the Section 262(*l*) provisions all lead to only one result: a possible pre-approval patent infringement suit. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(C). Moreover, the statute expressly provides that patent-based remedies "are the *only remedies* which may be granted by a court" for the artificial acts of infringement created by the Biosimilars Act. 35 U.S.C. § 271(e)(4) (emphasis added); *see ibid.* (exception only for attorneys' fees). With one significant exception discussed below, *see infra* Section II.A.2.b, the Biosimilars Act's express injunctive remedies all require a showing of possible infringement of a valid patent, as well as the traditional factors for an injunction. *Id.* § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(8)(B); *see eBay*, 547 U.S. at 394.

The statute's grant of these specific remedies should have precluded the Federal Circuit from crafting additional ones. *See Karahalios*, 489 U.S. at 533; *see also Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209 (2002) (noting that a statute's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly" (internal quotation marks and citation omitted)).

Amgen contends that the Biosimilars Act's express remedies are insufficient and that enforcement

by injunction is therefore necessary to effectuate "Congressional purposes" behind the notice provision. Amgen Supp. Cert. Br. 9. Amgen's policy arguments are irrelevant. Absent congressional intent to create a remedy, that remedy "does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Sandoval*, 532 U.S. at 286-87. In any event, in a scheme that "concerns one thing: patent litigation," Pet. App. 45a (Chen, J., dissenting), offering patent-based remedies is fully sufficient to effectuate the statute's purposes.

Amgen raises the specter that an applicant without any securities-law disclosure obligations might "keep secret" its application, not provide notice, and somehow "surprise" the sponsor by commercially marketing the biosimilar. Amgen Supp. Cert. Br. 1. Again, Amgen's policy concerns with the remedies provided by Congress are immaterial. *See Sandoval*, 532 U.S. at 286-87. In any event, there is "no reason to believe that Congress feared" this unlikely scenario. *See Reynolds v. United States*, 132 S. Ct. 975, 984 (2012) (refusing to read statutory language "unnaturally" to avoid an "unrealistic possibility"). Indeed, Congress authorized a sponsor to file an infringement suit when the applicant does not provide its application, 35 U.S.C. § 271(e)(2)(C)(ii), reflecting its assumption that the sponsor would know about the filing of the application even when the applicant did not provide a copy. That understanding was correct. Filing a biosimilar application is a significant financial event—developing

a biosimilar requires eight to ten years and "between $100 and $200 million." FTC Report at 14.[11] All companies with approved biosimilars issued press releases upon filing their applications, including Amgen, which has its own biosimilars.[12] These companies also disclosed the application in their next securities filing.[13]

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[11] By contrast, it typically takes three to five years and costs $1 to $5 million to develop a generic version of a chemically synthesized drug. FTC Report at 14.

[12] Amgen, FDA Accepts Amgen's Biosimilar Biologics License Application For ABP 501 (Jan. 25, 2016), http://tinyurl.com/zkyhhgu; Novartis, FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept (Oct. 2, 2015), http://tinyurl.com/plq5ebj; Celltrion, Celltrion files for US FDA approval of Remsima® (Aug. 11, 2014), http://tinyurl.com/gvbf9jz (approved under the name Inflectra®); Novartis, FDA accepts Sandoz application for biosimilar filgrastim (July 24, 2014), http://tinyurl.com/grl3p3o. Applicants with still pending applications have also issued press releases. *See*, *e.g.*, Apotex, Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Pegfilgrastim (Dec. 17, 2014), http://tinyurl.com/nvxywql; Amgen, Amgen And Allergan Submit Biosimilar Biologics License Application For ABP 215 To U.S. Food And Drug Administration (Nov. 15, 2016), http://tinyurl.com/junhlnz.

[13] Amgen, Form 10-K (Feb. 16, 2016) ("In January 2016, we announced that the FDA accepted for review our Biologics License Application (BLA) for ABP 501, a biosimilar candidate to Humira® (adalimumab)."), https://www.sec.gov/Archives/edgar/data/318154/000031815416000031/amgn-12312015x10k.htm; Novartis, Form 20-F (Jan. 27, 2016) ("The FDA and European Medicines Agency confirmed acceptance of our applications for etanercept, a proposed biosimilar to Amgen's Enbrel®, which treats autoimmune diseases such as rheumatoid arthritis and psoriasis."), https://www.sec.gov/Archives/edgar/data/1114448/000104746916009872/a2227040z20-f.htm; Celltrion, Form 10-K (Feb. 12, 2015) ("In August 2014, our partner Celltrion submitted an infliximab biosimilar application to the FDA for approval in the U.S."), https://

Furthermore, most applicants are conducting clinical trials to prove, among other things, biosimilarity. *See* 42 U.S.C. § 282(j); FDA, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry (Apr. 2015).[14] Certain of these trials must be publicly reported on a federal web site: clinicaltrials.gov. *See* Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,982, 64,982 (Sept. 21, 2016) (codified at 42 C.F.R. Part 111). Indeed, dozens of ongoing trials by biosimilar applicants and prospective applicants are now disclosed there.[15] Moreover, the FDA has held public advisory committee meetings before approval of biosimilars. *See*, *e.g.*, Oncologic Drugs Advisory Committee; Notice of Meeting, 79 Fed. Reg. 73,326, 73,326-27

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www.sec.gov/Archives/edgar/data/1274057/000127405715000012/hsp-201410xk.htm; Novartis, Form 20-F (Jan. 27, 2015) ("In the US, Sandoz completed Phase III trials, and the FDA accepted Sandoz's BLA for filgrastim, which was filed under the biosimilar pathway of the BLA."), https://www.sec.gov/Archives/edgar/data/1114448/000104746915000433/a2222787z20-f.htm.

[14] http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.

[15] *E.g.*, A Study Comparing SB8 and Avastin® in Patients With Advanced Non-squamous Non-small Cell Lung Cancer (currently recruiting participants) (last verified Feb. 2017), https://clinicaltrials.gov/ct2/show/NCT02754882?term=bevacizumab+AND+biosimilar&recr=Open&rank=1; Immunogenicity and Pharmacodynamic of B12019 and Neulasta® in Healthy Subjects (currently recruiting participants) (last verified Sept. 2016), https://clinicaltrials.gov/ct2/show/NCT02912377?term=biosimilar&recr=Open&rank=8; Assessment of Pharmacokinetics (PK) and Safety of M834 and Orencia®, in Healthy Subjects (currently recruiting participants) (last verified Feb. 2017), https://clinicaltrials.gov/ct2/show/NCT02923583?term=biosimilar&recr=Open&rank=11.

(Dec. 10, 2014) (providing notice of advisory committee meeting in January 2015 to consider Sandoz's biosimilar filgrastim application, which was ultimately approved in March 2015); CA JA A1575-A1576 (news article about meeting).

Finally, even were it possible to "surprise" a sponsor by commercially marketing without notice, no rational applicant would do so in the face of potentially viable patents. This case proves that point: given the expense of entering the market and the harm of being removed by a patent injunction, Sandoz provided notice in an effort to litigate any potential patent claims before approval—even though Amgen had publicly announced it had no more patent coverage. Pet. App. 8a-9a; CA JA A915, A960.

b. Congress elsewhere provided for a mandatory injunction but not in subsection (l)(8)

Where Congress provides a particular type of remedy in one portion of a statute but not another, that choice must be given effect. *See Touche Ross & Co. v. Redington*, 442 U.S. 560, 571-72 (1979). In only one instance did Congress make a provision of Section 262(*l*) enforceable by injunction. When an applicant chooses to provide its biosimilar application to a sponsor, the Biosimilars Act extends certain confidentiality protections to the application. *See* 42 U.S.C. § 262(*l*)(1)(A)-(G). The statute expressly provides an injunctive remedy when these provisions are violated: "The disclosure of

any confidential information in violation of" the confidentiality rules "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." *Id.* § 262(*l*)(1)(H).

Nowhere else did Congress create a cause of action for either the applicant or the sponsor to obtain an injunction to compel the other party to comply with any of the provisions of Section 262(*l*). That absence is dispositive.

Section 262(*l*)(1)(H) highlights a second error in the Federal Circuit's analysis: the court enjoined Sandoz without regard to traditional equitable factors. This Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination" of a statutory violation. *eBay*, 547 U.S. at 392-93. The Court insists on clear evidence of congressional intent to depart from the "long tradition of equity practice" rejecting automatic injunctions. *Id.* at 395 (Roberts, C.J., concurring) (citation omitted). The text of the expressly mandatory injunction in Section 262(*l*)(1)(H) provides evidence of such intent. Congress provided no injunctive remedy at all to enforce the Biosimilars Act's other procedural provisions, much less a mandatory one like Section 262(*l*)(1)(H).

3. The authority cited by the Federal Circuit in Apotex *does not support creation of an extra-statutory injunction*

The Federal Circuit here offered no justification for the injunctive remedy it added to the Biosimilars Act. Although the court subsequently attempted to do so, its analysis is incorrect. *See Apotex*, 827 F.3d 1052.

The court in *Apotex* concluded that a 180-day injunction against commercial marketing is available because Section 262(*l*)(9)(B), which specifies the consequence for failing to comply with the notice provision, has no "text providing for exclusivity." *Id.* at 1064 ("There is no language that excludes other remedies for the conduct described.").

This approach—under which judicially fashioned remedies are allowed so long as not expressly foreclosed by Congress—is the opposite of the one mandated by this Court. In *Touche Ross*, this Court rejected the argument that where "Congress did not express an intent to deny a private cause of action [in a statute], this Court should infer one." 442 U.S. at 571. The Court held that "implying a private right of action on the basis of congressional silence is a hazardous enterprise." *Ibid.* Without evidence of Congress's affirmative intent to create the right of action in question, such an action is unavailable—whether or not Congress included a statement expressly foreclosing added remedies. *See ibid.*; *Sandoval*, 532 U.S. at 286.

The decisions the *Apotex* court cited lend no support to its inverse rule. *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), does not stand for the proposition that courts are free to fashion injunctive remedies to enforce statutory provisions unless Congress specifically directs them not to do so. *Contra Apotex*, 827 F.3d at 1064. In that case, Congress expressly authorized the federal government to obtain an injunction against violations of a price-control statute and to obtain any "other order" in such proceeding. *Porter*, 328 U.S. at 397 (quoting Emergency Price Control Act of 1942, § 205(a), 56 Stat. 22, 33). The Court held that an order for restitution was an "other order" within this broad and express grant of equitable authority. *Id.* at 399. And because the statute was enforceable by the United States, the "public interest [was] involved," and the "equitable powers" of the district court "assume[d] an even broader and more flexible character than when only a private controversy is at stake." *Id.* at 398.

Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288 (1960), is similar. *See Apotex*, 827 F.3d at 1064 (citing *DeMario Jewelry*). In that case too, Congress had granted district courts broad equitable jurisdiction to permit the federal government to enforce the Fair Labor Standards Act. *DeMario Jewelry*, 361 U.S. at 289 (citing 29 U.S.C. § 217). The Court held that this express authority included not only the power to issue injunctions but also the power to order reimbursement for lost wages after an illegal discharge. *Id.* at 291-93. And, as in *Porter*, the Court relied on the principle that the courts' equitable powers are broader when invoked

by the government, as opposed to "when only a private controversy is at stake." *Id.* at 291 (quoting *Porter*, 328 U.S. at 398).

This case is fundamentally different. The Biosimilars Act confers no "comprehensive[] * * * equitable jurisdiction" to enforce its procedural provisions, *cf. Porter*, 328 U.S. at 398, nor has it "entrust[ed] to an equity court the enforcement" of the notice provision or the information exchange process, *cf. DeMario Jewelry*, 361 U.S. at 291. Moreover, disputes between sponsors and applicants under the statute are purely "private controvers[ies]" without the governmental enforcement element that this Court invoked in *Porter* to support the availability of broad remedial tools. *Cf. Porter*, 328 U.S. at 398; *DeMario Jewelry*, 361 U.S. at 291.

United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483 (2001), is even further afield. *Contra Apotex*, 827 F.3d at 1064. That decision addressed courts' ability to consider the public interest when deciding whether to grant an injunction. The Court explained that "when district courts are properly acting as courts of equity, they have discretion" to consider the public interest "unless a statute clearly provides otherwise." *Oakland Cannabis*, 532 U.S. at 496. Here, Congress did not direct district courts to "act[] as courts of equity" to enforce the Biosimilars Act's procedural provisions. *Cf. ibid.*

Finally, the *Apotex* court thought there was support for its position in the fact that subsection "(9)(B) does not make declaratory judgments exclusive and

thereby wipe out the remedies expressly provided for in 35 U.S.C. § 271(e)(4)." 827 F.3d at 1064-65 & n.4. The presence of expressly granted remedies does not support the Federal Circuit's analysis. Quite the opposite. The Biosimilars Act's express and interwoven remedies leave no room for courts to add their own. *See Karahalios*, 489 U.S. at 533.

B. By Delaying The Market Entry Of Every Biosimilar Product By Six Months, The Federal Circuit's Ruling Disrupts The Careful Balance Struck By Congress

The Federal Circuit's interpretation of the Biosimilars Act effectively rewrites key provisions and disrupts the careful balance struck by Congress. In enacting the statute, Congress sought to facilitate prompt access to cost-saving biosimilars while promoting innovation in biologics. Biosimilars Act § 7001(b), 124 Stat. at 804. To speed competing biosimilars to market, Congress allowed approval of biosimilar products to be based in part on previous approvals of reference products. Pet. App. 5a-6a; 42 U.S.C. § 262(i)(2), (k). In exchange, Congress granted sponsors up to 12 years of exclusivity from competition from biosimilars—regardless of whether the sponsor has any valid patent claims. 42 U.S.C. § 262(k)(7)(A).

Specifically, in a section titled "Exclusivity for reference product," Congress provided that the FDA's "[a]pproval of [a biosimilar] application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the

reference product was first licensed." *Ibid.* Under the clear terms of this provision, the FDA may issue an "effective" approval after the expressly granted exclusivity period has run. The biosimilar applicant should then be able to market immediately, absent the successful assertion by the sponsor of any valid patent claims.

Contrary to the statutory design, the Federal Circuit's ruling renders that "effective" approval *ineffective* for six months. The applicant must obtain FDA approval, then give notice (of the self-evident fact) that it intends to market that approved biosimilar, and then wait 180 days before marketing. Pet. App. 20a. Here, for example, the FDA licensed Sandoz's biosimilar on March 6, 2015, but the Federal Circuit blocked it from entering the market until September 3, 2015, based on no patent showing by Amgen. Pet. App. 8a-9a, 26a, 31a. As Judge Chen explained, this reading of the notice of commercial marketing provision gives the sponsor an "extra-statutory exclusivity windfall"—"a 180-day injunction beyond the express twelve-year statutory exclusivity period." Pet. App. 43a-44a (Chen, J., dissenting). The Federal Circuit's interpretation of the statute effectively gives all sponsors a six-month preliminary injunction after approval for every biosimilar—even if they have no patents covering the product—without meeting the high burden for obtaining such an injunction. But "[i]f Congress intended to create a 180-day automatic stay it understood how to do so." Pet. App. 52a-53a (Chen, J., dissenting). Indeed, Congress expressly extended the exclusivity period

to "12 years and 6 months rather than 12 years" for sponsors that successfully complete pediatric studies. 42 U.S.C. § 262(m)(2)(A).

Congress also "could have tied FDA approval to the notice provision" by providing that FDA approval cannot be effective until 180 days after notice is given. Pet. App. 53a (Chen, J., dissenting); *cf.* 21 U.S.C. § 355(j)(5)(B)(iii) (Hatch-Waxman Act's 30-month stay of effectiveness of FDA approval). Congress did not do so. Instead, it expressly directed that an approval after the expiration of the statutorily defined exclusivity period is "effective." 42 U.S.C. § 262(k)(7)(A).

The Federal Circuit attempted to downplay the significance of its holding by suggesting that the extra 180 days of exclusivity "will not likely be the usual case, as [applications] will often be filed during the 12-year exclusivity period for other products." Pet. App. 22a. That would not cure the problem created by its decision, even if there were a factual basis for that assertion. The Federal Circuit held that the "licensed product" language in subsection (*l*)(8)(A) means that notice cannot be given until the biosimilar is "licensed." Pet. App. 20a. But the biosimilar cannot be "licensed" until the 12 years of statutory exclusivity has run. *See* 42 U.S.C. § 262(k)(7)(A); Draft Guidance, FDA, *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* 2 (Aug. 2014) (explaining that the 12-year exclusivity period is "the period of time" during which the "FDA is not permitted to *license*" a

biosimilar (emphasis added)).[16] Thus, under the Federal Circuit's decision, an effective notice of commercial marketing cannot come until expiration of the 12-year exclusivity period. Pet. App. 20a. That would delay *all* biosimilars by 180 days.

For this same reason, the Federal Circuit's subsequent assertion in *Apotex* that the FDA could someday avoid providing sponsors with an extra six months of exclusivity fails. *See* 827 F.3d at 1062. According to the court of appeals, the FDA could in the future "issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." *Ibid.* But the Federal Circuit held that notice may not be given until the biosimilar is "licensed." Pet. App. 20a. Once a product is licensed, it can be marketed. *See* 42 U.S.C. § 262(a)(1). Nothing the FDA does during the reference product's exclusivity period can "license" a biosimilar to be sold. *See* 42 U.S.C. § 262(k)(7)(A). Such an action therefore could not trigger the applicant's ability to provide notice under the Federal Circuit's reading of the provision.

Moreover, the FDA has no authority to issue a non-effective biologic "license." By contrast, the Hatch-Waxman Act expressly provides the FDA the power to grant tentative approval for generic small-molecule drugs. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd). That demonstrates that Congress acts expressly when it wishes to confer such authority to the FDA. It did not

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[16] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf.

do so in the Biosimilars Act. In any event, the FDA does not consider a tentative approval under the Hatch-Waxman Act to be a license. *See* 21 C.F.R. § 314.107(b)(4) ("Tentative approval of a[ ] [new drug application ("NDA")] or [abbreviated new drug application ("ANDA")] does not constitute 'approval' of an NDA or ANDA and cannot, absent an approval letter from the Agency, result in an approval under paragraph (b)(3) of this section.").

That the Federal Circuit perceived the need to contort other statutory provisions in an attempt to soften the blow of its interpretation of the notice of commercial marketing provision "should have alerted" the court "that it had taken a wrong interpretive turn." *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014). It is not permissible "to adopt unreasonable interpretations of statutory provisions and then edit other statutory provisions to mitigate the unreasonableness." *Ibid.* (internal citation, quotation marks, and ellipses omitted) (applying this principle to the EPA).

III. THE FEDERAL CIRCUIT ERRONEOUSLY DIVORCED THE NOTICE OF COMMERCIAL MARKETING PROVISION FROM THE PATENT RESOLUTION SCHEME

Even putting aside the questions of when notice may be given and whether courts may enforce the provision by automatic injunction, the Federal Circuit erred by transforming the notice provision into a standalone requirement unconnected to the Biosimilars Act's patent resolution provisions. *See FDA v.*

Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). As Judge Chen correctly concluded, the notice provision does not apply at all where, as here, the parties did not engage in the Biosimilars Act's information exchange process.

As outlined above, *see supra* pp. 12-16, the Biosimilars Act establishes an elaborate, multi-step process for resolving patent disputes—with options for patent litigation interwoven throughout. When a party declines to take one of the information exchange steps, the only result is an effect on the scope and timing of patent litigation. Indeed, the Biosimilars Act contemplated that the applicant might not initiate the process at all—giving the sponsor the unilateral right to initiate immediate patent litigation on the patents of its choosing. *See* 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii); Pet. App. 18a. When the parties' actions trigger that litigation-only path, the statutory context makes clear that the rest of the exchange process, including the notice provision, falls away.

In keeping with the rest of Section 262(*l*), the notice provision is "part and parcel to, and contingent upon, the preceding steps in the (*l*)(2)-(*l*)(8) litigation management regime." Pet. App. 50a (Chen, J., dissenting). In particular, the notice provision plays a role in the sequencing of litigation for parties that are engaging in, or that have completed, the information exchange process. As part of that process, declaratory judgment actions on certain patents are barred.

42 U.S.C. § 262(*l*)(9)(A). But when the applicant provides the notice of commercial marketing, the bar is lifted, and the sponsor may seek a preliminary injunction based on any patents that have not yet been litigated. *See id.* § 262(*l*)(8)(B), (9)(A). If the applicant declines to provide the notice, the stay is removed for the sponsor, but not the applicant. *See id.* § 262(*l*)(9)(B). "Thus, the entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that [a sponsor] will be able to assert all relevant patents before the (k) applicant launches its biosimilar product." Pet. App. 48a (Chen, J., dissenting).

Both parts of Section 262(*l*)(8) therefore rest on the "express assumption that the parties have already performed the steps in (*l*)(3), and (*l*)(4)-(*l*)(5)." Pet. App. 49a (Chen, J., dissenting). "Without first engaging in these procedures, (*l*)(8) lacks meaning." *Ibid.* In particular, when the applicant did not trigger the information exchange process at all, providing the notice of commercial marketing cannot lift the stay on litigation of "remaining" patents. That is because the non-provision of the application *already* lifted the stay on litigation as to *all* patents, freeing the sponsor to file suit on any and all of them. *See* 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Under that scenario, there are not two separate phases of litigation over different sets of patents (with the applicant getting to limit the scope of the first phase). There is only one phase, whose timing and scope is entirely up to the sponsor.

The Federal Circuit observed that the statutory consequence specified for non-provision of the notice of commercial marketing "is a declaratory judgment action brought by the [sponsor] based on 'any patent included in'" the patent list it provided to the applicant. Pet. App. 25a; *see* 42 U.S.C. § 262(*l*)(9)(B). The court further observed that where, as here, the applicant did not trigger the information exchange process, no such list exists. Pet. App. 25a. The court perceived this supposed gap as a reason to allow for specific enforcement of the notice provision through an injunction. *Ibid.*

But this is a feature of the statute, not an inadvertent gap in its design. When the applicant does not trigger the information exchange process by providing its application, a sponsor "does not need the remedy in (*l*)(9)(B)" for failure to provide the notice "because (*l*)(9)(C) and [Section] 271(e)(2)(C)(ii) already grant the right to file, immediately, an unrestricted patent infringement action." Pet. App. 51a (Chen, J., dissenting). That Congress provided no separate consequence for failure to provide the notice in the non-information-exchange scenario simply shows that the notice provision is inapplicable.

CONCLUSION

The portion of the judgment involving the Biosimilars Act's notice of commercial marketing provision should be reversed.

Respectfully submitted,

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APPENDIX A

TITLE 28—JUDICIARY AND JUDICIAL PROCEDURE

PART VI—PARTICULAR PROCEEDINGS

CHAPTER 151—DECLARATORY JUDGMENTS

§ 2201. Creation of 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.

§ 2202. Further relief

Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

APPENDIX B

TITLE 35—PATENTS

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

CHAPTER 28—INFRINGEMENT OF PATENTS

§ 271. Infringement of patent

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

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

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

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his

having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

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

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

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

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

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

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

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

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

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

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

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

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

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided

the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

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

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

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

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

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

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

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

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

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

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

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

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

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent,

no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

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

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

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

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

APPENDIX C

TITLE 42—THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

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

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

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

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

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

(iii) the expiration date of the biological product.

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

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

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

(i) on the basis of a demonstration that—

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

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

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

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

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

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

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

(c) Inspection of establishment for propagation and preparation

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

(d) Recall of product presenting imminent hazard; violations

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

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

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

(f) Penalties for offenses

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

(g) Construction with other laws

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

(h) Exportation of partially processed biological products

A partially processed biological product which—

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

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

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

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

(i) "Biological product" defined

In this section:

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

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

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

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

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

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

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

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

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

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

(2) Content

(A) In general

(i) Required information

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

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

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

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

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

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

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed

for the biological product have been previously approved for the reference product;

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

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

(ii) Determination by Secretary

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

(iii) Additional information

An application submitted under this subsection—

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

(II) may include any additional information in support of the application, including publicly-available

information with respect to the reference product or another biological product.

(B) Interchangeability

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

(3) Evaluation by Secretary

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

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

(i) is biosimilar to the reference product; or

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

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

(4) Safety standards for determining interchangeability

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

(A) the biological product—

(i) is biosimilar to the reference product; and

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

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

(5) General rules

(A) One reference product per application

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

(B) Review

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

(C) Risk evaluation and mitigation strategies

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

(6) Exclusivity for first interchangeable biological product

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

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

(B) 18 months after—

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

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

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

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

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

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

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

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

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

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

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

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

delivery system, delivery device, or strength; or

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

(8) Guidance documents

(A) In general

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

(B) Public comment

(i) In general

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

(ii) Input regarding most valuable guidance

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

(C) No requirement for application consideration

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

(D) Requirement for product class-specific guidance

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

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

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

(E) Certain product classes

(i) Guidance

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

(ii) Modification or reversal

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

(iii) No effect on ability to deny license

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

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

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

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

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

(II) In-house counsel

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

(iii) Patent owner access

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

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the

prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

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

(E) Ownership of confidential information

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

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the

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

(G) Rule of construction

Nothing in this paragraph shall be construed—

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

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

(H) Effect of violation

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

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

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

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

(3) List and description of patents

(A) List by reference product sponsor

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

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

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

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

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

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a

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

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

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

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

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

(C) Description by reference product sponsor

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

(4) Patent resolution negotiations

(A) In general

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

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of

which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

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

(B) Exchange of patent lists

(i) In general

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

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

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes

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

(ii) Number of patents listed by reference product sponsor

(I) In general

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

(II) Exception

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

(6) Immediate patent infringement action

(A) Action if agreement on patent list

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

(B) Action if no agreement on patent list

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

(C) Notification and publication of complaint

(i) Notification to Secretary

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

(ii) Publication by Secretary

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

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product

sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

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

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

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before

the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

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

(ii) not included, as applicable, on—

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

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

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product

sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

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

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

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

(3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

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

(m) Pediatric studies

(1) Application of certain provisions

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

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to

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

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

(B) if the biological product is designated under section 526 [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.

(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.

(4) Exception

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

* * *

APPENDIX D

Public Law 111-148
111th Congress

An Act

Entitled The Patient Protection
and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * *

TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

Subtitle A—Biologics Price Competition and Innovation

SEC. 7001. SHORT TITLE.

(a) IN GENERAL.—This subtitle may be cited as the "Biologics Price Competition and Innovation Act of 2009".

(b) SENSE OF THE SENATE.—It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

SEC. 7002. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following:

"(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

"(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

"(2) CONTENT.—

"(A) IN GENERAL.—

"(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

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

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

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

"(cc) a clinical study or studies (including the assessment

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

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

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

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

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

the biological product continues to be safe, pure, and potent

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

"(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

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

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

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

"(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the

Secretary shall license the biological product under this subsection if—

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

"(i) is biosimilar to the reference product; or

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

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

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

"(A) the biological product—

"(i) is biosimilar to the reference product; and

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

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

"(5) GENERAL RULES.—

"(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

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

"(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

"(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on

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

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

"(B) 18 months after—

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

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

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

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

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

"(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

"(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

"(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

"(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

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

"(ii) a subsequent application filed by the same sponsor or manufacturer of

the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

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

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

"(8) GUIDANCE DOCUMENTS.—

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

"(B) PUBLIC COMMENT.—

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

"(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish

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

"(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

"(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

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

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

"(E) CERTAIN PRODUCT CLASSES.—

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

"(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

"(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

"(l) PATENTS.—

"(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

"(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the 'subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the 'reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

"(B) IN GENERAL.—

"(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause

(ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information').

"(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

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

"(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

"(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference

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

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

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

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

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

"(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

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

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

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

"(2) SUBSECTION (K) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

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

"(B) may provide to the reference product sponsor additional information requested

by or on behalf of the reference product sponsor.

"(3) LIST AND DESCRIPTION OF PATENTS.—

"(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

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

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

"(B) LIST AND DESCRIPTION BY SUBSECTION (K) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

"(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a

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

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

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

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

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

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

"(4) PATENT RESOLUTION NEGOTIATIONS.—

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

"(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference

product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

"(5) PATENT RESOLUTION IF NO AGREEMENT.—

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

"(B) EXCHANGE OF PATENT LISTS.—

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

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

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

"(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

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

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

"(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

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

"(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

"(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

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

"(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

"(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

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

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

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

"(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

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

"(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

"(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by

the subsection (k) applicant under paragraph (3)(B); and

"(ii) not included, as applicable, on—

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

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

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

"(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

"(A) SUBSECTION (K) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, 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, United States Code, 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, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.".

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking "In this section, the term 'biological product' means" and inserting the following: "In this section:

"(1) The term 'biological product' means";

(2) in paragraph (1), as so designated, by inserting "protein (except any chemically

synthesized polypeptide),” after “allergenic product,”; and

(3) by adding at the end the following:

“(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).”.

(c) CONFORMING AMENDMENTS RELATING TO PATENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking "or" at the end;

(ii) in subparagraph (B), by adding "or" at the end; and

(iii) by inserting after subparagraph (B) the following:

"(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,"; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)), by striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product";

(B) in paragraph (4)—

(i) in subparagraph (B), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking "and" at the end;

(ii) in subparagraph (C), by—

(I) striking "or veterinary biological product" and inserting ", veterinary biological product, or biological product"; and

(II) striking the period and inserting ", and";

(iii) by inserting after subparagraph (C) the following:

"(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."; and

(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking "and (C)" and inserting "(C), and (D)"; and

(C) by adding at the end the following:

"(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.".

(2) CONFORMING AMENDMENT UNDER TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: ", or section 351 of the Public Health Service Act".

(d) CONFORMING AMENDMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) CONTENT AND REVIEW OF APPLICATIONS.—Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: "or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies".

(2) NEW ACTIVE INGREDIENT.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by adding at the end the following:

"(n) NEW ACTIVE INGREDIENT.—

"(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

"(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.".

(e) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

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

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

(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle as the "Secretary") before the date of enactment of this Act; or

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

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

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

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

(f) FOLLOW-ON BIOLOGICS USER FEES.—

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the

Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS.—Section 735(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)(B)) is amended by striking "section 351" and inserting "subsection (a) or (k) of section 351".

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

(C) AUDIT.—

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

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

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

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

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

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

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(m) PEDIATRIC STUDIES.—

"(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (*l*), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the

same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

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

> "(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 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of

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

"(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 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

"(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.".

(2) STUDIES REGARDING PEDIATRIC RESEARCH.—

(A) PROGRAM FOR PEDIATRIC STUDY OF DRUGS.—Subsection (a)(1) of section 409I of the Public Health Service Act (42 U.S.C.

284m) is amended by inserting ", biological products," after "including drugs".

(B) INSTITUTE OF MEDICINE STUDY.—Section 505A(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355b(p)) is amended by striking paragraphs (4) and (5) and inserting the following:

"(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009 and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

"(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

"(6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.".

(h) ORPHAN PRODUCTS.—If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with,

such reference product may be licensed by the Secretary only after the expiration for such reference product of the later of—

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

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

SEC. 7003. SAVINGS.

(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle.

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

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