No. 15-1039

IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* ADELLO BIOLOGICS, LLC IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was intended (a) to help speed biosimilars to market, while (b) assuring the reference biologic product a legislatively-prescribed 12 year period of exclusivity before the biosimilar is commercially sold. It provides a mechanism to allow potential patent disputes to be addressed before any commercial sale of the biosimilar. As part of this dispute resolution mechanism, § 262(*l*)(8)(A) of the BPCIA, the "notice provision", states that a biosimilar applicant shall provide notice to the reference sponsor of the biological product "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

Can a subsection (k) applicant provide its §262(*l*)(8)(A) notice before the biological product is licensed, or must the applicant await approval of the license, thereby effectively extending the exclusivity period provided by the BPCIA from the specified 12 years to 12.5 years?

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STATEMENT OF INTEREST OF THE *AMICUS CURIAE*[1]

Adello Biologics, LLC ("Adello") is a company that produces biologic products and brings them to market.

According to the U.S. Food and Drug Administration ("FDA"), biologics are "isolated from a variety of natural sources – human, animal, or microorganism – and may be produced by biotechnology methods and other cutting-edge technologies."[2]

The Patient Protection and Affordable Care Act ("Affordable Care Act") amends the Public Health Service Act ("PHS Act") to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to an FDA-licensed

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[1] Pursuant to Supreme Court Rule 37.3, Adello Biologics, LLC, through counsel, has timely notified the parties of its intent to file an *amicus curiae* brief and the parties have consented. Pursuant to Rule 37.6, undersigned counsel also certify that: (1) no counsel for a party authored this brief in whole or in part; (2) no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and (3) no person or entity – other than *amicus curiae*, its members, and its counsel – contributed money intended to fund the preparation or submission of this brief.

[2] U.S. Food and Drug Administration, "What is a biological product?", http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm.

biological product.[3] This pathway is provided in the part of the Affordable Care Act known as the Biologics Price Competition and Innovation Act ("BPCIA").

According to FDA, a biosimilar is "a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product." *Id.* The BPCIA allows for the filing of an abbreviated biologics licensure application ("aBLA") for biosimilars, and allows the aBLA to rely on the reference product's licensure. Given this streamlined pathway to approval, biosimilars cost less than the reference biologic product to which they are "similar."

Adello has a pipeline of biosimilar products to be submitted for licensure under the BPCIA. Adello is committed to providing patients access to biosimilars in a timely and affordable manner. Thus, the proper interpretation of the BPCIA has a significant impact on the ability of Adello, and indeed the biosimilar industry, to promptly bring biosimilars to the public.

If left uncorrected, the Federal Circuit's reading of Section 262(*l*)(8)(A) — to require that a product actually be licensed before notice of the date of first commercial marketing can be given — will

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[3]U.S. Food and Drug Administration, "Information on Biosimilars",www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ Biosimilars/.

needlessly delay the availability of biosimilars for at least six months longer than intended by Congress. Pharmaceutical companies, such as *amicus*, will bear the financial consequences of this additional delay in bringing their products to market, and therefore have an interest in ensuring that §262(*l*)(8)(A) is properly interpreted and applied. The consequences of an additional 180-day delay in the introduction of biosimilar-products will also be felt by patients, who would benefit from biologic therapies being made available sooner at lower cost, and by health care payers (including the Federal Government as a payer) and taxpayers who would bear the burden of higher Medicare and Medicaid costs resulting from a six-month delay in bringing lower-cost biosimilars to market.

INTRODUCTION AND BACKGROUND

As explained by FDA, 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."[4] However, these "cutting-edge" and life-saving therapies frequently come at an exorbitant cost to patients "often exceeding tens of thousands of dollars per year."[5] [6]

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[4] U.S. Food and Drug Administration, "What is a biological product?, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm.

[5] Federal Trade Commission, *Follow-On Biologics Workshop*, Tr. 8 (Feb. 4, 2014) (statement of FTC Chairwoman Edith Ramirez); and Steven Kozlowski et al., *Developing the Nation's*

(continued...)

While biosimilars are, by definition "similar" to their reference biologic, they are not necessarily identical to it. Biologic molecules are very large, and it is difficult to provide an exact copy. Accordingly, development of a biosimilar version of a biologic is still expensive and time consuming — much more expensive and time consuming than, for example, the development of a generic version of a typical small-molecule drug. As Sandoz noted, an FTC report estimates that biosimilars are "likely to take eight to ten years to develop, and their development will likely cost between $100 and $200 million" — in contrast to the three to five years and $1 to $5 million it typically costs to develop a generic version of most small molecule drugs.[7]

(continued...)
Biosimilars Program, 365 New Eng. J. Med. 385, 385 (Aug. 4, 2011) http://www.nejm.org/doi/pdf/10.1056/NEJMp110728.

[6] Third party data collection company QuintilesIMS reports that Neupogen's estimated sales totaled about $397,000,000 in the six months prior to the launch of Zarxio (Sandoz's biosimilar product). National Sales Perspectives, Neupogen, February 13, 2017, *available at* IMS Smart MVP Solutions, https://websolutions.imshealth.com/EB2/User/Validate_UserID.aspx?TARGET=SMhttp://customerportal.imshealth.com/portal/site/imsportal. The six month revenue from sales for this single product provides a strong indication of the significance of postponing competition by delaying the commercial marketing of biosimilar drugs for an additional six months.

[7] Pet. at 2, *citing* FTC Report, *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, iii (June 2009) [hereinafter *FTC Report*], https:// www.ftc.gov/sites/default/files/ documents/reports/ emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

Despite these costs, biosimilars save money.[8] The record before Congress showed that more competition in the biologics market could save government and private payers tens of billions of dollars.[9] To this end, Congress wanted to bring biosimilar drugs to market quickly. In order to do this, Congress proposed a mechanism designed to swiftly and efficiently deal with the expected patent litigation initiated against the biosimilar developer that could otherwise delay the public's access to biosimilars for much longer. The BPCIA represents an effort to create a balance between promoting innovation and competition while addressing potential delays in biosimilars reaching the market.

That balance is explicit in the BPCIA. The BPCIA prohibits FDA from making its approval of the aBLA effective earlier than 12 years after the first licensing of the reference product. 42 U.S.C. § 262(k)(7)(A), which guarantees the reference product 12 years of exclusivity. At the same time, the BPCIA seeks to expedite the introduction of biosimilars by the conclusion of the exclusivity period.

There are three major hurdles involved in bringing a biosimilar to market: (1) obtaining approval from FDA; (2) the 12 years of marketing

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[8] Pet. at 2 ("When Congress passed the BPCIA, purchases of biologics represented 21% of the $307 billion spent annually on medicines, and spending on biologics was increasing materially". CA JA A389-A391).

[9] *E.g.*, Judith A. Johnson, Cong. Research Serv., RL34045, FDA Regulation of Follow-On Biologics 4 (2010).

exclusivity given to the reference biologic product's sponsor ("RPS") which prevents FDA from licensing any biosimilar until that time period is up (42 U.S.C. § 262(k)(7)(A)); and (3) navigating patents and patent litigation. Thus, while actual FDA approval is critical to bringing a biosimilar to market, the 12-year non-patent exclusivity and potentially various patents imparting their own exclusivity are equally important when launching a biosimilar.

To further the overriding goal of bringing biosimilars to market quickly once the 12 years of exclusivity have run, the BPCIA provides a central mechanism for the early resolution of patent claims by establishing an "artificial" patent-infringement claim. 35 U.S.C. § 271(e)(2)(C)(ii). This artificial infringement claim may be litigated while FDA is still reviewing the aBLA and prior to its approval.

As described by the Acting Solicitor General, section 262(*l*) sets out this process in four phases. See 42 U.S.C. §§ 262(*l*)(2)-(8). *See* United States Br. 4-7.

(1) In the Information phase, the applicant for the aBLA ("subsection (k) applicant") "shall provide" the RPS with a copy of both the aBLA and manufacturing-process information. 42 U.S.C. § 262(*l*)(2)(A). If the subsection (k) applicant does not comply and timely provide this information, the subsection (k) applicant's submission of its aBLA is deemed an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii).

(2) In the Comprehensive List Phase, the RPS and applicant produce a list of the patents on which infringement claims could reasonably be asserted. 42 U.S.C. § 262(*l*)(3). The subsection

(k) applicant's submission of its aBLA is an artificial act of infringement "with respect to a patent that is identified in the list of patents described in section [262](*l*)(3)," i.e., in the Comprehensive List. 35 U.S.C. § 271(e)(2)(C)(i).

(3) In the Round 1 Litigation Phase, the subsection (k) applicant and the RPS identify patents for Round 1 Litigation. 42 U.S.C. §§ 262(*l*)(4)-(6). The RPS then "shall bring an action for patent infringement" for each patent on the Round 1 lists within 30 days. *Id.* If the subsection (k) applicant and RPS successfully complete these steps, then the Round 1 litigation will be filed about 250 days or less after FDA accepts the aBLA for review. *Id.* §§ 262(*l*)(2)-(6).

(4) The Round 2 Litigation Phase addresses the patents on the Comprehensive List not addressed in Round 1. *Id.* §§ 262(*l*)(8)(B)(i) and (ii) (remaining patents). If the subsection (k) applicant has timely provided the RPS with the information required in the Information Phase, neither the RPS nor the subsection (k) applicant may bring a declaratory-judgment action based on a Round 2 patent before the subsection (k) applicant provides advance notice of the first commercial marketing of its biosimilar. *Id.* § 262(*l*)(9)(A).

Section 262(*l*)(8)(A) ("the notice provision"), at issue here, governs the timing of that notice. It provides that the "applicant shall provide notice" to the RPS "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." *Id.* § 262(*l*)(8)(A).

One further clarification of the statutory procedure is appropriate here. FDA approval of a biosimilar product does not create an immediately operative license to market the biosimilar product. The application for licensure (the aBLA) can, of course, be submitted by the subsection (k) applicant during the term of the reference product's period of exclusivity. FDA then reviews (and hopefully approves) the biosimilar's aBLA – during the exclusivity period. However, FDA approval does *not* confer an immediately operative license to commercially market the biosimilar product. The approved license cannot be made *effective* until the 12-year exclusivity period has expired. 42 U.S.C. § 262(k)(7)(A).

SUMMARY OF ARGUMENT

The BPCIA was intended by Congress to speed biosimilars to market, while preserving incentives for innovation by providing a 12 year period of exclusivity — a balance that is disrupted by the Federal Circuit's ruling. The Federal Circuit's reading of §262(*l*)(8)(A) of the BPCIA ignores the plain language of the statute, as well as Congress's intent in drafting it.

Congress provided 12 years of market exclusivity to the RPS. 42 U.S.C. § 262(k)(7)(A). By holding that the notice cannot be given until the biosimilar product has been licensed, the Federal Circuit decision impermissibly converts this statutory 12-year exclusivity period into a 12.5-year period. Under the Federal Circuit's erroneous reading, the notice given by a subsection (k) applicant under § 262(k)(7)(A) would extend the 12-

year period of exclusivity by 180 additional days, every time.

The notice provision is explicit in stating that an *applicant* can give notice – negating any suggestion that only a subsection (k) applicant whose application has been approved can do so. If Congress wished to allow notice to be given only after FDA had approved the application, it would have required the "holder" – meaning a subsection (k) applicant whose application had been approved – to provide the notice. The notice provision's reference to the notice being provided with respect to the date of commercial marketing of the "licensed" product should not be read to mean that notice can be given only for a previously-licensed biosimilar product. To the contrary, it refers to the elementary fact that at the time of commercial marketing, the product will necessarily be licensed.

ARGUMENT

I. A Subsection (K) Applicant May Give Notice Prior To FDA Licensure Of The Biosimilar Product

The Federal Circuit concluded that a subsection (k) applicant cannot provide the 180-day notice of first commercial marketing of its biosimilar pursuant to § 262(*l*)(8)(A) until after FDA licensure of the biosimilar product. *Amicus* agrees with Petitioner that the Federal Circuit erred in this interpretation of §262(*l*)(8)(A). The subsection (k) applicant may provide notice of commercial marketing – and thus trigger the 180 day period — prior to FDA licensure. That understanding is consistent with both the text of § 262(*l*)(8)(A), and the broader purposes of the BPCIA to allow the

biosimilar product to expeditiously reach market, while allowing the reference product a 12 year exclusivity period and fair notice and opportunity to assert any patent rights it might have. Thus, the subsection (k) applicant may give notice of first commercial marketing before FDA approves the aBLA application. Indeed, if subsection (k) applicants must wait until FDA licenses the biosimilar product before giving notice, the 12 year period of exclusivity at the heart of the statute would always be converted to 12.5 years.

A. Section 262(*l*)(8)(A) Allows the 180-Day Notice to be Given "not later than 180 days before the date of commercial marketing," Regardless of the Date of FDA Licensure

The notice provision at issue is designed to provide a 180-day time period during which the RPS can consider whether to assert, and in fact assert, its rights prior to the commercial marketing of the reference product. It provides that:

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

42 U.S.C. § 262(*l*)(8)(A). A plain reading of that section indicates that notice should be given not *later* than 180 days before the date of the first commercial marketing, and a commonsense reading indicates that the notice can be given at any time before, provided that it is given by a subsection (k) applicant. That is clear enough from the fact that the benchmark date is the date of "first commercial

marketing." The BPCIA is quite clear about when the earliest date of first commercial marketing may be: 12 years after the date the reference product was approved, *i.e.*, at the end of the 12-year period of exclusivity and no longer.

The statute certainly does not say that notice can only be given 180 days after FDA licensure of the biosimilar product, nor does the statute use the date when the biosimilar product is licensed as the benchmark for that notice. To the contrary, the statutory reference to the product being licensed is simply part of specifying the actual benchmark: Q. What is it that is being first commercially marketed at that time? The answer is "the biological product licensed under subsection (k)."

If the Federal Circuit were correct, the requirement that the product must be licensed before the notice is given would be an important precondition to that notice. But it is extremely unlikely that Congress would bury such an important precondition to giving notice as part of an adjectival phrase.

There is nothing illogical in the understanding that notice of the "date of the first commercial marketing of the biological product licensed under subsection (k)" can be provided before the license has been issued. The Federal Circuit itself did not suggest that it would be an unreasonable or ungrammatical reading of the notice provision. To the contrary, "licensed" as used in the statute is not a precondition to giving notice, but instead simply and accurately describes what the product will be at the "date of its first commercial marketing." 42 U.S.C. § 262(*l*)(8)(A). The date of first commercial

marketing can only be of a licensed product. The biosimilar product cannot be marketed until FDA licenses it. Therefore, the reference to the licensed product makes perfect sense in the notice provision.

The Federal Circuit's alternative reading would not permit a mere subsection (k) applicant, who has not yet received approval of its application, to give notice. That reading, however, conflicts with the specific words of the notice provision; Section 262(*l*)(8)(A) expressly authorizes a "subsection (k) applicant" to provide notice. *Id*. The notice provision thus contemplates that the notifying party need only have requested FDA approval; *i.e.*, that the notifying party be a subsection (k) *applicant*.

Indeed, if Congress intended to allow notice to be given only by someone who was already permitted to market, or who had their application approved, then Congress would have said so. Elsewhere in the same statute, Congress refers to parties who have had their application approved as "holders." *E.g. id*. § 262(m)(3) (referring to "the holder of an approved application"). If Congress had meant to require approval before the notice is given, it would have used consistent language and called the notifying party in §262(*l*)(8)(A) "the holder of an approved application."

Crucial here is the fact that FDA approval of a biosimilar product does not automatically create an operative license to market the biosimilar product. This is because the approval itself is not effective, and one cannot fairly say that the biosimilar product has been licensed, until the 12-year period has expired. The statute is explicit on this point:

> [a]pproval 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).

Id. § 262(k)(7)(A).

Thus, the approved license becomes effective only after the expiry of the 12 year exclusivity period. Prior to the approved license becoming effective, the biosimilar cannot be marketed.

Congress appears to have chosen its language carefully in allowing a subsection (k) applicant to give notice. Use of the term "applicant" is broad enough to encompass all of the following: a mere applicant; someone who was an applicant and who is now a "holder" of an approved license; and someone who already has an operative license made effective by FDA upon the expiration of the 12-year exclusivity period. All three circumstances are included within the term "applicant". If Congress had intended another, for example more limited meaning, it would have used the word "holder", or "licensee", which would have excluded mere applicants from giving notice.

The Federal Circuit's alternative interpretation is based on its elevation of the word "licensed" in the adjectival phrase into a full-scale limitation on when notice must be provided. In so holding, the Federal Circuit appeared to recognize that if its construction of the notice provision converted §262(k)(7)(A)'s 12-year period of exclusivity into a 12.5-year period (12 years, plus 180 days for notice), that would create a "conflict" that would counsel against such a construction. Pet. App. 22a. The 12 year exclusivity

period is at the core of the statute. The Federal Circuit ultimately dismissed that concern by suggesting that this would not happen in the "usual case," *id.*, and the 12 year period would be converted to 12.5 years only in some circumstances:

> [i]t is true that in this case, as we decide *infra*, Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product. Amgen had more than an "extra" 180 days, but that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products."

Id.

The Federal Circuit apparently conceived that the biosimilar product could, in fact, be licensed long before the 12-year exclusivity period had expired. Therefore, "in the usual case," notice could be provided and the 180 day period could run after license approval without extending the 12 year exclusivity period. The premise of that argument is that an application could be approved long before the 12-years expired, and thus the product would be licensed as soon as the agency gave its approval – before the end of the period of exclusivity.

But that view is demonstrably wrong under the statute. One can surely apply for a license before the 12 years have expired. And one can surely conceive that FDA might indicate its approval of that application before the 12 years have expired. But, as discussed above, the approval is not *effective*

and the biosimilar product is not actually licensed until the 12-year period has expired. 42 U.S.C. § 262(k)(7)(A).[10]

Thus, the actual result under the Federal Circuit's reading is that in *every* case, instead of a 12-year period of exclusivity, the period of exclusivity would be 12.5 years (or, for reference biologic products with approval dates more than 12 years prior to the passage of the BPCIA, at least an extra 6 months of exclusivity).[11] Given that

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[10] The Federal Circuit simply failed to comment on this provision specifying when approval becomes effective.

[11] It is conceivable that the Federal Circuit's erroneous reading of the notice provision would not only delay the market entry of a first biosimilar, but also could delay the ability of second and subsequent biosimilars from receiving a designation of interchangeability from FDA.

There is a subset of biosimilars known as "interchangeables" which, in addition to meeting the requirements of being "biosimilar" to a reference product, are so similar that they may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. 42 U.S.C. § 262(i)(3). The interchangeability determination is typically done by FDA after the approval as a biosimilar. Once FDA has determined that a first biosimilar is an interchangeable, it receives a period of exclusivity where it is the only interchangeable on the market. *Id.* § 262(k)(6). The shortest period of exclusivity for the first interchangeable provided by the statute is one year. *Id.* (FDA "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 [262(k)(6)(A)-(C)]- (A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product…").

(continued...)

Congress's intent was to help speed biosimilars to market and clearly set a 12-year exclusivity period – points that no one disputes, and which reflect the overall tone and tenor of the statute – the Federal Circuit's reading leads to an inconsistent and unrealistic result. 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.

B. Notice Before Licensure Provides a Well-Crystalized Controversy

The Federal Circuit posited that its approach to the notice provision makes sense because "[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystalized controversy regarding the need for injunctive relief." Pet. App. 21a. While striving for a more crystallized controversy is laudable, the Federal Circuit's position unreasonably elevates any hypothesized benefit at the expense of the BPCIA's language and more fundamental purposes. Indeed,

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(continued...)
Under the Federal Circuit's holding, if the first biosimilar has also been designated as an interchangeable by FDA, and is ready to market as an interchangeable as of the date of licensure – but is required to wait until the date of licensure before notifying the RPS – this first interchangeable's commercial marketing is delayed by 180 days. And, as an interchangeable meriting one year (or more) of being the only interchangeable on the market, this one year (or more) of exclusivity begins 180 days later than it otherwise would have, and the designation of a second biosimilar as interchangeable in the marketplace is thus delayed by one year plus 180 days.

waiting until after licensure to create a "crystallized controversy" for litigation is exactly what Congress intended to avoid by making the mere submission of an aBLA itself an "act of infringement." 35 U.S.C. § 271(e)(2)(C).

The Federal Circuit's theory is that a "crystallized controversy" does not exist until the biosimilar product, as well as its manufacturing and use, are licensed; *i.e.*, fixed and unchangeable. By this reasoning, all litigation which takes place before licensure is premature. And that logic conflicts with the Federal Circuit's own statements in the same opinion concerning the fundamental objective of the statute, which was to allow patent litigation to proceed even before licensure and commercial marketing. Pet. App. 6a. As the Federal Circuit explained, the "BPCIA amended the Patent Act to create an artificial 'act of infringement' and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to the marketing of the biological product." *Id.*

The BPCIA expressly contemplates litigation before licensure, as it provides for a situation where all relevant patents can be placed in Round 1 litigation. See 42 U.S.C. §§ 262(*l*)(5)(B), and (6)(B), *supra* p. 7. If the parties follow the schedule in Section 262(*l*), Round 1 litigation will begin no later than about 250 days after FDA accepts the aBLA for review. See *id.* §§ 262(*l*)(2)-(6), *supra* p. 7.

Given that an aBLA may be submitted, and accepted by FDA for review, a full eight years before FDA could grant an effective license (*see* §§ 262(k)(7)(A) & (B)), it is clear that Congress intended that patent litigation on all relevant

patents could begin as early as about 7 years before the aBLA is approved by FDA (8 years less 250 days).

The Federal Circuit's expressed concern for crystallizing controversies for suit is even more unrealistic when one imagines a situation where there are no relevant patents to be placed at issue. This scenario is entirely possible, as patents may have expired by the time of licensure, or any patent disputes may have already been resolved between the parties. Yet, the 180-day windfall mandated by the Federal Circuit's reading would apply even in situations like these where the RPS has no infringement claim to "justify" the delay. Thus, the marketing of the biosimilar would be delayed for 180 days to protect a "fully crystalized controversy" that in fact would not exist.

C. The Federal Circuit's Interpretation Undermines the BPCIA's Overriding Purpose

The Federal Circuit's interpretation is squarely at odds with the broader purpose of the BPCIA in bringing biosimilar products to market as soon as possible.

Nowhere in the BPCIA is there evidence that Congress wanted biosimilar patent suits filed after licensure. If Congress had wanted that, the creation of the artificial act of infringement under Section 271(e)(2)(C), and the mechanism for patent resolution prior to licensing set forth in Section 262(*l*), would have been unnecessary. A way to resolve patent disputes after licensure already existed: a RPS could bring a declaratory judgment action and seek a preliminary injunction under the

Patent Act, including 35 U.S.C. § 271(a) and (g); *see MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

But Congress did not want that. Congress wanted to resolve patent disputes early. This desire led Congress to make the *submission* of an aBLA an artificial act of infringement in order to allow for litigation shortly after the aBLA submission. In fact, the aBLA may be submitted up to 8 years before FDA can license it, providing time to commence patent litigation as early as seven years before licensure. 42 U.S.C. §§ 262(k)(7)(A) and (B).

A practical application of the Federal Circuit's reading of the notice provision is helpful here. When the subsection (k) applicant and the RPS are engaging — or have engaged — in the patent exchange process of the Comprehensive List phase, only the agreed-upon patents may be litigated in Round 1 litigation. If the parties participate in the patent dispute mechanism of § 262(*l*), the litigation of any remaining patents in Round 2 is postponed by the BPCIA until notice is given. *Id.* § 262*(l)*(9)(A). Thus, it may be the 180-day notice that allows Round 2 litigation to commence. *Id.*

Yet, under the Federal Circuit's approach, in every situation where the parties participate in the patent dispute mechanism of § 262(*l*), any litigation on the Round 2 patents must wait until the biosimilar product is licensed and then until notice is given by the subsection (k) applicant.

The notice provision is thus properly viewed as providing the RPS an opportunity to bring suit on the Round 2 patents that it previously could not bring while the subsection (k) applicant was

following the litigation mechanism of Section 262(*l*) prior to the licensure of the biosimilar. The notice provision, rather than standing alone, assumes that the parties have already engaged in the preceding steps: The "entirety of (*l*)(8), including (*l*)(8)(A)'s notice provision, serves to ensure that an RPS will be able to assert all relevant patents before the (k) applicant launches its biosimilar product." Pet. App. 48a (Chen, J. dissenting).

CONCLUSION

The judgment of the Federal Circuit should be reversed.

Respectfully submitted,

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