No. 16-332

IN THE
Supreme Court of the United States

APOTEX INC., ET AL.,
Petitioners,

v.

AMGEN INC., ET AL.,
Respondents.

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

BRIEF FOR THE BIOSIMILARS COUNCIL AS AMICUS CURIAE SUPPORTING PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes:

Other Authorities:

BRIEF FOR THE BIOSIMILARS COUNCIL AS AMICUS CURIAE SUPPORTING PETITIONERS

INTEREST OF THE AMICUS CURIAE

The Biosimilars Council (the "Council"), a division of the Generic Pharmaceutical Association ("GPhA"), includes companies and stakeholder organizations working to develop biosimilar products for the United States pharmaceutical market.[1] Biosimilars are highly similar or interchangeable versions of branded biologic medicines licensed by the Food and Drug Administration ("FDA"), and an entity seeking FDA approval of a biosimilar is known as a biosimilar "applicant." A branded biologic in this context is known as a "reference product" and its licenseholder as the "Reference Product Sponsor." Congress established an expedited FDA approval pathway for biosimilars in 2010 in the Biologics Price Competition and Innovation Act ("BPCIA").[2]

The Council and its members supported the BPCIA and are deeply interested in its correct implementation and interpretation. To that end, the Council has participated in litigation as *amicus curiae* regarding the proper interpretation of the BPCIA,

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[1] The parties received timely notice of the Biosimilars Council's intent to file this brief and consented to the filing of this brief. No counsel for a party authored any part of this brief; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

[2] Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 119 (2010).

taking legal positions that reflect the position of the Council as an organization. The Council filed a brief in this case below and in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *petition for cert. pending*, No. 15-1039 (filed Feb. 16, 2016) ("*Sandoz*"). GPhA, the Council's parent organization, has likewise frequently participated in litigation as *amicus curiae* regarding patent and regulatory issues affecting pharmaceutical manufacturers. *See, e.g.*, *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

The Council also filed an amicus brief supporting the petition in *Sandoz Inc. v. Amgen Inc.*, No. 15-1039, and continues to believe that this Court should grant certiorari in that case. The Council has filed this brief to emphasize the distinct issues raised by this case that warrant review in their own right. This case, unlike *Sandoz*, involves a biosimilar applicant that engaged in the statutory procedure to exchange information with the Reference Product Sponsor (the "patent dance"). Nonetheless, the Federal Circuit held both that the biosimilar applicant must provide the sponsor with a *separate* notice of commercial marketing even after the patent dance, *and* (relying on its holding in *Sandoz*) that there can be no effective notice of commercial marketing until the biosimilar applicant receives a license.

The effect of these combined holdings is to give the sponsor a 12½-year period of exclusivity for its biologic, not the 12-year period the statute contemplates. Granting review and reversing on the question presented in *Sandoz* (which is also the second question presented here) would eliminate the extra

half-year entirely. Granting review and reversing on the first question presented here would at least eliminate the extra half-year where the biosimilar applicant participates in the patent dance.

In the Council's view, the Court would benefit from having before it all three potential interpretations of the BPCIA—are sponsors entitled to an extra half-year of exclusivity *always* (the holding below), *never* (if the Court were to agree with petitioners in *Sandoz*), or *sometimes* (if the Court were to agree with petitioners in this case but not in *Sandoz*)? The Council, like both sets of biosimilar-applicant petitioners, continues to believe that the correct answer is "never." But the Court's consideration will benefit from having both fact patterns and both legal questions before it. Accordingly, this brief focuses on the first question presented (whether notice was required), without retreating from the Council's view that the Federal Circuit *also* wrongly resolved the second question presented (when effective notice may be provided).

SUMMARY OF ARGUMENT

The Federal Circuit held in *Sandoz* that a biosimilar applicant is forbidden from commercially marketing its approved product for 180 days after providing a notice to the Reference Product Sponsor, *and* that the applicant must wait until the FDA approves its license application before providing that notice. The court of appeals thought the 180-day delay would serve to give the Reference Product Sponsor sufficient time, before marketing begins, to decide whether to bring an infringement action for injunctive relief. But the time crunch that the court of ap-

peals was concerned about was entirely of its own making—had the court properly interpreted the BPCIA to permit applicants to provide notice of commercial marketing *before* license approval, the time concern would not have arisen. Moreover, where, as here, the parties have engaged in the patent dance and the applicant has already provided the Reference Product Sponsor with confidential product and manufacturing information that would otherwise be available only in discovery, the Federal Circuit's reasoning fails even on its own terms: the purpose that the court ascribed to 42 U.S.C. § 262(*l*)(8)(A) has already been fully accomplished. What remains is a six-month wait for waiting's sake.

Furthermore, the court of appeals explicitly stated that its rule is "categorical" and does not "turn on" the facts of any particular case, such as whether the applicant and Reference Product Sponsor already engaged in the information exchange or whether the only unexpired patents were already the subject of pending litigation. Pet. App. 16a. That means that no further percolation is needed, or possible. The Federal Circuit will insist on six months' delay even where, as is the case now, the applicant *wins* the litigation sparked by the patent dance or where, as will often be true, no unexpired patents remain. In such instances, a *post-licensure* notice of commercial marketing serves no conceivable purpose, yet the Federal Circuit's holding will still give a Reference Product Sponsor an extra half-year of exclusivity beyond the lengthy 12 years it already enjoys.

Pharmaceutical companies that are developing or are considering developing biosimilars need certainty *now*. They need to know, at the outset, what the

BPCIA requires and at what point they may begin to recoup the substantial investments (hundreds of millions of dollars) that biosimilar development and manufacturing require so they can make informed decisions about whether to invest in these life-saving alternative therapies, and whether to engage in the patent dance by voluntarily turning over their confidential product and manufacturing information.

In sum, the Council continues to believe that the Court should grant the petition in *Sandoz* and hold that biosimilar applicants are *never* required to wait until license approval to provide a notice of commercial marketing with the failure to do so privately enforceable by a mandatory 180-day injunction. And if the Court grants review in *Sandoz*, it should consider granting the petition in this case as well, so that the Court can consider the various factual scenarios in which the notice issue arises. But even if this Court decides to deny review in *Sandoz*, it should take up the first question presented in this case to provide much-needed certainty to current and potential biosimilar manufacturers.

ARGUMENT

THIS COURT SHOULD REVIEW THE FEDERAL CIRCUIT'S DETERMINATION THAT ALL BIOSIMILAR APPLICANTS MUST PROVIDE A POST-LICENSURE NOTICE OF COMMERCIAL MARKETING EVEN IF THEY HAVE ALREADY ENGAGED IN THE "PATENT DANCE," THUS FULLY FULFILLING THE NOTICE FUNCTION.

By calling for the views of the Solicitor General in *Sandoz*, this Court recognized the significance of the

issues presented by that case. This case only reinforces the important considerations at issue in both petitions: the emerging biosimilars industry needs to know, *with certainty*, what rules will govern their efforts to develop and market safe, effective, and affordable alternatives to lifesaving biologic therapies. *See generally* Biosimilars Council Amicus Br., *Sandoz Inc. v. Amgen Inc.*, No. 15-1039.

Respondents' brief in opposition to Sandoz's petition identified this case as "closely related to Sandoz's question presented," and "bear[ing] directly on the issues presented [t]here." Amgen Br. in Opp. 4, 35, No. 15-1039. It recommended that the Court wait until the Federal Circuit directly confronted a case in which an applicant had refused to provide a post-licensure notice of commercial marketing and determined whether the notice requirement applies to applicants who have fully engaged in the patent dance. *See id.* at 4, 27, 31, 33-35. This is just such a case: it offers the Court an excellent opportunity to consider, either in this case alone or in conjunction with Sandoz's petition, the interplay among the BPCIA's 12-year exclusivity period, the pre-licensure dispute resolution mechanism, and the notice of commercial marketing provision. Indeed, the Federal Circuit's extension of the rule from *Sandoz* to the fact pattern here would likely influence the Court's careful consideration of Sandoz's petition in any event. And the first question presented here warrants review in its own right.

A. The Patent Dance Eliminates Any Conceivable Need For 180 Days Of Post-Licensure Notice.

The Federal Circuit held in *Sandoz* that a notice of commercial marketing cannot be effective until the biosimilar applicant receives a license from the FDA. And the court adhered woodenly to that rule on the different facts here, holding that the statute is "categorical" and "not dependent on" any variation in the pre-licensure facts. Pet. App. 16a. The court based that holding almost entirely on the purported need for Reference Product Sponsors to have sufficient time, before marketing of a biosimilar begins, to decide whether to seek preliminary injunctive relief based on patent infringement. *See Sandoz*, 794 F.3d at 1357-58; Pet. App. 15a-17a. But this rationale provides little support for the holding here.

First, in cases like this one, the Reference Product Sponsor already has all of the information it would need to decide whether to bring a patent infringement action. A biosimilar applicant's participation in the patent dance allows the Reference Product Sponsor access to, among other things, confidential information regarding the applicant's clinical studies, manufacturing process, and recommended conditions of use[3]—information otherwise available only through discovery, *after* filing a lawsuit. *See Sandoz*, 794 F.3d at 1356. The six-month wait will be equally pointless in cases where the parties have already litigated every remaining patent. Yet under the Fed-

[3] The patent dance requires the applicant to disclose to the Reference Product Sponsor the confidential information it submits to the FDA as described in 42 U.S.C. § 262(k)(2). *See id.* § 262(*l*)(1)(B), (2).

eral Circuit's holding, the Reference Product Sponsor would nevertheless receive 12½ years of exclusivity. Pet. App. 16a ("The language of (8)(A) is categorical in the sense relevant here.").

In this case, for instance, the patent dance sparked patent litigation, which has been resolved *in petitioners' favor*. Pet. 13. That eliminates any conceivable need for a further waiting period. Consider the analogous circumstance under the regulatory framework that governs generic drugs, the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetics Act.[4] Under Hatch-Waxman, when a brand-name company files a patent-infringement action against a generic applicant, the FDA is automatically prevented from approving the generic for 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Congress "borrow[ed] from" Hatch-Waxman in some respects in writing the BPCIA, *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1276 (Fed. Cir. 2014), but did not include an automatic stay on approval triggered by patent litigation. Yet even Hatch-Waxman's automatic stay is lifted once a generic applicant *wins* the patent litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I), (j)(5)(B)(iii)(II)(aa)(AA). Hatch-Waxman's 30-month stay also does not take effect unless a patent-infringement lawsuit *is actually filed*. *Id.* § 355(j)(5)(B)(iii).

There is no reason why the extra 180-day stay that the Federal Circuit created should extend to *all* cases, even cases in which (a) the only unexpired patent is already the subject of pending litigation be-

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[4] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)).

tween the Reference Product Sponsor and the applicant, as was the case when the Federal Circuit issued its decision in this action, *see* Pet. App. 11a-12a; (b) the patent litigation has already resulted in a favorable judgment for the biosimilar applicant, as is the case now, *id.* at 59a-67a; or (c) the Reference Product Sponsor has not and even *could not* file an additional patent infringement action because no unexpired patents remain. Yet the Federal Circuit has created a "categorical" rule that does not "turn on" whether the parties engaged in the patent dance or the status of patent litigation between them. *Id.* at 16a.[5]

Second, a 180-day delay in launching an approved biosimilar is not the appropriate way to deal with the court of appeals' concern that a contrary rule would result in rushed decisionmaking by parties and courts alike. Pet. App. 20a, 24a-25a. If there is a time crunch, it occurs because the Federal Circuit has wrongly held that notice of commercial marketing cannot precede licensure. Permitting notice to take effect *before* the FDA approves a biosimilar application would solve the problem.

The court suggested that pre-licensure notice was not permitted because "we believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufac-

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[5] Because Hatch-Waxman explicitly created a 30-month stay to give time for patent litigation before launch and the BPCIA contains no similar provision, the Council believes that no such stay should be read into the BPCIA. But even if such a function were necessary under the BPCIA when a biosimilar applicant refuses to engage in the pre-licensure dispute resolution process, no stay is necessary once the patent dance performs this function.

turing processes are fixed" because at that point there is a "fully crystallized controversy." *Sandoz*, 794 F.3d at 1358. But the court cited no basis in the text, structure, or legislative history of the statute for that "belie[f]," and there is every indication that Congress actually intended exactly the opposite. Congress created a *pre-licensure* dispute resolution process and built in substantial incentives for litigants to avail themselves of that process. Pet. App. 8a, 10a, 25a. Congress also created "an artificial 'act of infringement'" that permits "infringement suits based on a biosimilar application prior to FDA approval and prior to marketing" if an applicant fails to engage in the patent dance altogether. *Sandoz*, 794 F.3d at 1352 (citing 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6)). If Congress intended patent litigation to occur only after there was a "fully crystallized controversy" post-licensure, it would not have permitted—indeed, encouraged—infringement lawsuits to be filed shortly after an applicant submits an abbreviated biosimilar application ("aBLA") and certainly long before approval. And the pre-licensure dispute-resolution process will go a long way toward "crystalliz[ing]" the controversy; it is unlikely Congress built in more time to ensure every single dispute has reached diamond hardness.

Furthermore, the court's concern with the waste of resources that could result from patent litigation over products that may never obtain FDA approval or that may be changed during the approval process, *Sandoz*, 794 F.3d at 1358, is simply unfounded. As an initial matter, the same could be said about lawsuits over yet-to-be-approved generic drugs as well, yet the entire premise of Hatch-Waxman litigation is that litigation occurs *while* the FDA is considering

approving a generic drug. The statute powerfully encourages brand-name drug sponsors to sue *immediately* after the generic applies for FDA approval, and the litigation and the FDA approval process thereafter proceed in tandem, during the statutory 30-month stay on final FDA approval. That is by design. Channeling patent litigation to the period *before* FDA approval and commercial marketing takes the threat of damages (especially lost-profits damages) off the table. That encourages generic drug companies to file applications and resolve patent disputes during the FDA process. So too here. Both Hatch-Waxman and the BPCIA intentionally encourage applicants to resolve these issues after an abbreviated application is filed but before FDA approves it—after the patent dispute is sufficiently "crystallized" for a court to determine validity and infringement, yet before a launch could result in millions in damages and declines in a name-brand's market share.

The court of appeals' other timing concern—that if a notice of commercial marketing could be provided before the FDA made a licensing decision, the Reference Product Sponsor would have to guess "when commercial marketing would actually begin," *Sandoz*, 794 F.3d at 1358—likewise contemplates a false problem. The same is true of not-yet-approved generic drugs, yet Hatch-Waxman encourages brand-name drug companies to sue for patent infringement during the FDA approval process despite this inherent uncertainty. Furthermore, the FDA's decisionmaking timeline for biosimilars is hardly a black box. The agency has expressly stated that biosimilars "will generally have a 10 month review clock," with the agency aiming to reach final decisions with-

in 10 months in 90% of applications. *See* FDA Media Briefing, First Biosimilar Approval in the United States 9 (Mar. 6, 2015), http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM437548.pdf.[6]

Finally, if Congress had wanted to ensure that patent litigation was resolved after licensure but before launch, forbidding pre-licensure notice of marketing and imposing a *180-day* marketing stay following that notice would have been a particularly odd way to go about achieving this goal. If patent litigation were commonly resolved in under six months, then there would be no need for a *30-month* stay under Hatch-Waxman. And if Congress's concern were with an opportunity to seek preliminary relief, 180 days is far more time than needed to resolve any preliminary-injunction motion.

In sum, the Federal Circuit's rule was animated by wholly mistaken "belie[fs]" about Congress's intentions, and reasoning that does not hold water—particularly when, as in this case, the BPCIA's notice requirement is adequately served by the parties' involvement in the patent dance.

B. This Issue Will Not Decline In Significance.

Respondents opposed the *Sandoz* petition on the ground that further percolation was needed, and the Federal Circuit opined in this case that the issues presented would decline in significance over time.

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[6] *See also* FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017, at 3-4, *available at* http://bit.ly/2ecO0Yw.

Neither of those contentions is correct, and neither justifies denying review.

1. Respondents' brief in opposition to Sandoz's petition argued that this Court should not grant review "because these issues are still being developed" and this Court should "wait . . . until the law has evolved further." Amgen Br. in Opp. 31, 32, No. 15-1039. The decision in this case eliminates any doubt that now is the appropriate time to grant review. The court of appeals explicitly stated in this case that the rule announced in *Sandoz* is "categorical" and does not "turn on" the facts of any particular case, such as whether the applicant and Reference Product Sponsor already engaged in the information exchange or whether the applicant declined to participate in the patent dance altogether. Pet. App. 12a. This case confirms both that the Federal Circuit is locked into its position and that the issue will recur. In any case in which a biosimilar applicant could provide notice more than 180 days before licensure, the Federal Circuit's erroneous interpretation will treat that notice as ineffective.

2. The court of appeals opined that in the future, the FDA will more often make its licensing decision at least six months before the end of the exclusivity period, because future biosimilar manufacturers can file applications "long before the 12-year exclusivity period is up"—even "a mere four years after licensure of the reference product." Pet. App. 17a.[7] But

[7] That rationale is obviously inapplicable to the dozens of cases in which biosimilar applicants seek FDA approval where the relevant biologic has already been on the market for more than 12 years. *See* FDA, Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity

while the *legal bar* to submitting an application lasts only four years, 42 U.S.C. § 262(k)(7)(B), that hardly means that biosimilar applications take only four years to prepare. Biosimilars are not developed as quickly and cheaply as generic small-molecule drugs. Indeed, the FTC reported that "[biosimilar] products are likely to take eight to ten years to develop," in contrast with "small-molecule generic drugs, which typically take three to five years to develop." FTC, *Emerging Health Care Issues: Follow-On Biologic Drug Competition*, at iii (June 2009), *available at* http://bit.ly/2dz4ADM (hereinafter "FTC, *Follow-on Biologic Drug Competition*").

Thus, contrary to the Federal Circuit's assumption, this timeline is likely to place approval of many biosimilars close to the 12-year exclusivity period, *and* close to or after the end of patent protection given the time it takes to develop biologics. *See* Erwin A. Blackstone & P. Fuhr Joseph, Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 470 (2013) ("There is often a lag of many years between patent approval and FDA approval to market a drug; therefore, a patent may run out before the exclusivity expires."). And after any applicable patents have expired, a 180-day post-licensure exclusivity extension to allow a biologic license holder "to make a decision about seeking relief based on yet-to-be litigated patents," Pet. App. 18a, serves no conceivable purpose, yet it would seem to be available under the Federal Circuit's decision below.

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or Interchangeability Evaluations, http://bit.ly/2dOo0DP (listing dozens of biologics that were licensed more than twelve years ago). In these situations, the Federal Circuit's rule creates market exclusivity where the statute itself does not.

C. Clarification Now Will Provide Much-Needed Certainty To Pharmaceutical Manufacturers.

The Federal Circuit's rule affects not just cases already in litigation, but every potential biosimilar applicant deciding whether and when to submit an aBLA. Applicants decide whether to engage in the patent dance at the front end of the application process. *See* 42 U.S.C. § 262(*l*)(2) (patent dance must begin within 20 days of the FDA's acceptance of an aBLA). And to make that decision intelligently, they need to know whether and to what extent voluntarily disclosing their confidential manufacturing and development information will work to their advantage at the back end. The success of the "patent dance" relies on the incentives created by the BPCIA's statutory framework. A biosimilar applicant faced with the decision in this case may very well decide not to engage in the patent dance because doing so will provide no protection from the six-month automatic exclusivity extension created by the Federal Circuit.[8] Clarification is needed *now*, for the benefit of the numerous biosimilar applicants that are still in the development process.

Similarly, clarification *now* will provide much-needed certainty to pharmaceutical manufacturers deciding whether to engage in biosimilar development at all. Developing and manufacturing biosimilars is particularly expensive and time consuming—far beyond the cost and time it takes to develop and

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[8] The Federal Circuit correctly held in *Sandoz* that the patent dance is not mandatory. (Amgen has cross-petitioned for review of that holding.) But the statute does *encourage* participation even if it does not *require* participation.

manufacture generic small-molecule drugs. As the FTC reported in 2009, development of each biosimilar will cost between $100 million and $200 million and take between eight and ten years, in comparison with small-molecule generic drugs, "which typically take three to five years to develop and cost between $1 and $5 million." FTC, *Follow-On Biologic Drug Competition*, at iii. This cost and time commitment are on top of the $250 million to $1 billion investment that is required for drug companies "to build, equip and qualify their own manufacturing facilities," *id.* at 14, which the FDA takes about four years to approve, *see* John R. Thomas, Cong. Research Serv., Follow-On Biologics: The Law and Intellectual Property Issues 15 (Jan. 15, 2014), *available at* https://www.fas.org/sgp/crs/misc/R41483.pdf; *see also id.* ("In addition, the cost of materials to manufacture biologics may be 20 to 100 times more than chemical drugs."). Companies determining whether and when to undertake these substantial efforts need to have full knowledge of the statutory requirements and the ways in which their ability to market and sell their products will be hampered.

The extra six months of extra-textual market exclusivity might, upon initial glance, not seem significant. But for a company that has spent or is considering spending half a billion dollars to build an appropriate manufacturing facility and successfully develop a biosimilar, the need to recoup that investment is very real. As the FTC has observed, given the high costs of entering the biosimilars market, the number of potential entrants is limited. FTC, *Follow-On Biologic Drug Competition* at 15. The Federal Circuit's creation of an additional six-month delay before these companies can begin to recover their

substantial investments is likely to shrink the universe of potential candidates still further.

In the world of pharmaceuticals, uncertainty dampens or even kills the incentives to enter the market, to compete, and if necessary to litigate. The public, faced with the high costs of biologics (and rising insurance costs as a result), cannot afford the uncertainty or delay caused by the Federal Circuit's decisions in *Sandoz* and this case.[9] The Court should grant certiorari *now* to resolve this important issue.

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The court of appeals noted that the BPCIA "contains no words that make the applicability of its notice rule turn on whether the applicant took the earlier step of giving the (2)(A) notice that begins the § 262(*l*) information-exchange process." Pet. App. 16a. But the Federal Circuit adopted its hard-and-fast rule that notice must *always* come after licensure without considering the following fact patterns:

- In some cases, there will not be any unexpired patents that remain at the time the aBLA is filed or FDA approval is granted.
- In some instances, as was the case here, by the time the FDA grants approval of the biosimilar, every unexpired patent will already be the subject of litigation, or will already be re-

[9] *See* Judith A. Johnson, Cong. Research Serv., FDA Regulation of Follow-On Biologics at 1 (Apr. 26, 2010), *available at* http://bit.ly/2dTKKoX (noting the "prohibitively high" costs of commonly used biologics for diseases such as rheumatoid arthritis, breast cancer, multiple sclerosis, and Crohn's disease, which can cost tens of thousands of dollars per year).

> solved through litigation, as a result of the patent dance.

The extra six months serves no purpose in these cases, cases that will become increasingly common. The Federal Circuit felt bound by its decision in *Sandoz* to stick to the inflexible rule it had laid down. This Court, of course, is not so constrained. The pointlessness of the six-month delay in a case like this one demonstrates either that the Federal Circuit's underlying rule is wrong, or at a minimum that the Federal Circuit was wrong in not distinguishing cases like this one. In either event, this Court should step in.

CONCLUSION

The petition for a writ of certiorari should be granted, irrespective of the disposition of *Sandoz*. If this Court grants certiorari in *Sandoz*, the petition in this case should be granted as well. If this Court opts to grant only one of the two petitions, the other should be held pending the Court's consideration, and then disposed of as appropriate in light of the Court's decision.

Respectfully submitted.

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