No. 18-916

IN THE

Supreme Court of the United States

DEX MEDIA, INC.,

Petitioner,

v.

CLICK-TO-CALL TECHNOLOGIES, LP,

AND

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,

Respondents.

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

BRIEF OF *AMICUS CURIAE* THE ASSOCIATION FOR ACCESSIBLE MEDICINES IN SUPPORT OF THE PETITION FOR CERTIORARI

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INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing the interests of the leading manufacturers of generic and biosimilar medicines in the United States. Its members provide Americans with generic and biosimilar medicines that are as safe and effective as their brand-name counterparts, but are substantially more affordable. In 2017, generic medicines accounted for 90% of all prescriptions dispensed in the United States but only 23% of total spending. Generic medicines saved patients, taxpayers, and health care payers over $265 billion in 2017 compared to their brand-name counterparts.

AAM seeks to provide courts with the perspective of the generic and biosimilar pharmaceutical industry on important legal issues impacting its members, and to highlight the potential industry-wide consequences of significant pending cases.

AAM's members frequently participate in pharmaceutical patent litigation, at times involving dozens of patents purportedly protecting a single

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[1] Pursuant to Supreme Court Rule 37.2(a), AAM certifies that all parties have consented to this filing and that notice was provided at least ten days prior to filing. Pursuant to Rule 37.6, AAM certifies that no counsel for any party authored this brief in whole or in part, and no party, counsel for any party, or person other than *amicus curiae* or its counsel made a monetary contribution to preparing or submitting this brief.

pharmaceutical product. Relevant here, AAM's members also frequently take advantage of the *inter partes* review ("IPR") process, because the efficiency and speed of IPRs fit, and indeed further, the industry's mission of delivering generic and biosimilar alternatives to brand-name products to patients as soon and as cost-effectively as possible.

Limiting access to this critical administrative tool—as the Federal Circuit's decision below does here—reduces the opportunity for AAM's members to cancel improperly issued patents that undermine the legitimacy of the patent system, stifle competition, and impede consumers' access to lower-cost medicines. AAM's members thus have a significant interest in ensuring that unnecessary restraints are not improperly read into the IPR process, making it impossible for its members—and patients—to take advantage of this efficient patent challenge mechanism for both current and future drug products.

SUMMARY OF ARGUMENT

AAM supports Petitioner's challenge to the Federal Circuit's *en banc* decision, holding that the one-year bar in Section 315(b) applies to a patent infringement complaint that was dismissed without prejudice.[2] AAM will not repeat Petitioner's arguments on the merits of that decision. AAM submits this brief instead to highlight the

[2] AAM takes no position on Petitioner's arguments with respect to *Wi-Fi One*.

anticompetitive and unintended consequences of ignoring the fundamental purpose behind the one-year bar and extending that bar to voluntarily dismissed actions, particularly as they would play out as a result of a brand-name company's tactics to block competition from generic and biosimilar medicines.

IPR plays an important role in the pharmaceutical industry, for both traditional generic and biosimilar medicines. Congress created the IPR process to serve as an efficient and effective mechanism for the United States Patent and Trademark Office ("PTO") to reconsider its prior patentability decisions with input from interested third parties. Congress knew that many of the patents subject to challenge through the new IPR procedure would also be subject to ongoing or future patent infringement actions. Congress thus sought to reduce duplicative proceedings where district court litigation was long-underway, while simultaneously ensuring that IPR petitioners had the benefit of understanding the patent claims at issue in the litigation before filing an IPR. Balancing these interests, Congress gave prospective petitioners one year after being served with a complaint to identify the patents most relevant and best suited for an IPR challenge and to file an IPR petition. 35 U.S.C. § 315(b).

Just as Congress intended, AAM's members frequently invoke the IPR pathway to clear "patent

thickets" protecting brand-name products.[3] Sponsors of brand-name pharmaceutical products are notorious for patenting every conceivable aspect of their products, from the manufacturing process to the formulation, to each and every approved use, including even minor, non-innovative changes to each. This, of course, includes classic "evergreening" strategies to pursue patents on trivial or non-therapeutic changes to an existing drug product, all with the ultimate goal of preventing lower-cost competition with the brand-name drug. Moreover, pharmaceutical patents are commonly asserted with respect to multiple drug products—including line extensions and other products covered by the same platform technology. It is often difficult to know (especially in the biologic and biosimilar space) which patents will be asserted with respect to any particular product. For any or all of these reasons, IPR is a critical tool in the arsenal of generic and biosimilar companies for knocking out improperly granted patents that never should have issued in the first place, and which block more affordable competition.

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[3] The term "patent thicket" is often used to describe an overlapping set of patents rights covering a single product—a strategy that increases litigation and development costs for would-be competitors. *See, e.g.*, Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL'Y & ECONOMY 119, 120-21 (2001) (describing a patent thicket as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology").

The Federal Circuit's *en banc* decision will inevitably constrain the rights of generic and biosimilar companies to use the IPR process to clear the pathway to market. The *en banc* court interpreted the time bar under 35 U.S.C. § 315(b) to prohibit a company that has been sued for patent infringement from filing an IPR after one year has passed from the date the complaint was served, *even when that suit is dismissed voluntarily without prejudice*. The anticompetitive and unintended consequences of this decision are manifest.

First, as Judge Dyk (joined by Judge Lourie) aptly recognized in the dissenting opinion, the decision provides an obvious mechanism for manipulation. That is, patent owners are now incentivized to file suit and voluntarily dismiss the complaint after service in order to start the one-year clock, which continues to tick even when the litigation is no longer pending. This, in turn, forces the defendant to use its IPR rights or forfeit them forever. It is an understatement to say, as Judge Dyk observed, that Congress could not have intended to provide a mechanism for such manipulation.

Second, even beyond the recipe for such gamesmanship, the unintended consequences of the *en banc* decision for the generic and biosimilar industries are startling. For many pharmaceuticals, patents often cover multiple brand-name products—this is especially true for biologics. In the event of a voluntary dismissal, a generic or biosimilar company must now decide whether to file an IPR against the dismissed patents to avoid losing that option altogether—not only for the medicine at issue in that

particular case, but for all future products that might be covered by those patents, including products not yet in development. Once again, this absurd interpretation results in unnecessary forfeiture of critical IPR rights that could block patient access to more affordable medicines and is inconsistent with the statutory structure and purpose and could not possibly have been what Congress intended.

In short, taking the IPR arrow out of the quivers of generic and biosimilar companies in these circumstances could have disastrous consequences for patients, healthcare payers, and taxpayers who rely on generic and biosimilar drug companies to provide safe and lower-cost alternatives to brand-name medicines.

AAM thus respectfully urges this Court to grant Petitioner's petition and review the Federal Circuit's *en banc* decision. Because the Federal Circuit has exclusive jurisdiction over these disputes, no other court of appeals will have an opportunity to correct this prejudicial ruling. 28 U.S.C. § 1295(a)(4). And unless Section 315(b) is given its proper reading, the harm to generic and biosimilar pharmaceutical companies *and* to patients will be immediate and costly.

ARGUMENT

I. THIS CASE PRESENTS AN OPPORTUNITY FOR THIS COURT TO CORRECT A HIGHLY PREJUDICIAL AND INCORRECT RULING THAT WILL RESULT IN HARMFUL AND COSTLY CONSEQUENCES TO IPR PETITIONERS AND PATIENTS IN THE U.S.

A. Generic and Biosimilar Medicines Save Money and Improve Patient Access to Critical Therapies.

Manufacturers of generic drugs have long ensured affordable access to medicines for millions of American consumers. Taxpayers, employers, insurance companies, and state and federal governments have benefited from trillions of dollars in savings from lower-cost alternatives to brand-name medicines. Biosimilar manufacturers are now starting to add to that considerable savings.

The principal difference between generic or biosimilar medicines and brand-name prescription drugs or biologic products is cost.[4] Generics account for 90% of prescriptions dispensed in the United States, but only 23% of total drug costs.[5] In total, generic medicines generated $265.1 billion in savings for the

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[4] ASS'N FOR ACCESSIBLE MEDICINES, GENERIC DRUG ACCESS & SAVINGS IN THE U.S.: ACCESS IN JEOPARDY 24 (2018) ("GENERIC DRUG ACCESS 2018").

[5] *Id.* at 10.

American healthcare system in 2017, and $1.79 trillion in savings over the last decade.[6]

But the benefits of more affordable generic and biosimilar medicines extend beyond mere cost savings. Generic drugs reduce the problem of lack of adherence because new patients are three times less likely to stop taking generic medications than brand-name drugs.[7]

All of these benefits flow directly from the competition that generic and biosimilar medications provide to brand-name drugs that would otherwise enjoy monopoly status. The more competitors there are, the greater the savings: The entry of a second generic manufacturer into the market reduces the average generic price to nearly half the brand-name price, and for medicines that attract a large number of generic manufacturers, the average generic price falls to less than 20% of the branded price.[8]

Not only is the generic marketplace good for patients, but it benefits taxpayers, too. Although brand-name drugs account for only around 10% of prescriptions dispensed in the U.S., they account for

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[6] *Id.* at 11.

[7] *Id.* at 16.

[8] U.S. FOOD & DRUG ADMIN., *Generic Competition and Drug Prices* (Nov. 28, 2017), https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

more than 75% of total drug spending.[9] One of the largest subsidizers of pharmaceutical prescriptions is the federal government, which contributes more than $70 billion dollars annually to subsidize Medicare Part D premiums.[10] In 2015, the U.S. government paid roughly 43% of all retail prescription drug costs—29% through Medicare and 10% through Medicaid.[11] Medicare and Medicaid saved $82.7 billion and $40.6 billion, respectively, in 2017 due to savings associated with lower-cost, generic drug options.[12] This equates to an average annual savings of $1,952 per Medicare enrollee and $568 per Medicaid enrollee.[13] With health expenditures climbing 5.8% in 2015 and accounting for 17.8% of Gross Domestic Product, the savings associated with generic drug options has become an indispensable component of national health policy.[14]

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[9] GENERIC DRUG ACCESS 2018 at 10.

[10] *See* JULIETTE CUBANSKI & TRICIA NEUMAN, KAISER FAMILY FOUNDATION, THE FACTS ON MEDICARE SPENDING AND FINANCING 6 (2018).

[11] Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, BROOKINGS INST. (Apr. 26, 2017), https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/.

[12] GENERIC DRUG ACCESS 2018 at 4.

[13] *Id*.

[14] ASS'N FOR ACCESSIBLE MEDICINES, GENERIC DRUG ACCESS & SAVINGS IN THE U.S. 8 (2017).

B. IPR Is A Critical Tool For Clearing The Patent Thickets Used To Protect Brand-Name Product Monopolies.

Before a generic or biosimilar product can enter the market and start saving patients and payers money, it often must cut through a patent thicket protecting the brand-name company's monopoly.[15] One way is through costly and time-consuming patent litigation. But litigation often takes several years and several millions of dollars to resolve. Another way is through the IPR process created by Congress in the America Invents Act ("AIA"). Pub. L. No. 112-29, § 6, 125 Stat. 284, 299-305 (2011). Consistent with Congressional intent, IPRs have become a critical tool for clearing away brand-name drug and biologic patents that never should have issued and that unnecessarily delay lower-cost generic and biosimilar competition.

The IPR pathway was designed "to ensure that the poor-quality patents can be weeded out through administrative review rather than costly litigation" to "improve patent quality and limit unnecessary

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[15] Press Release, Food & Drug Admin., Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan (Jul. 18, 2018); (acknowledging that brand-name companies commonly use patent thickets to discourage competition and raise the overall cost of entering the market); *see also* I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 6 (2018) (finding brand-name companies for the top 12 grossing drugs of 2017 have sought on average 38 years of patent protection to block generic competition).

and counterproductive litigation costs."[16] Indeed, the IPR process offers many advantages over litigation. For one, Congress designed the IPR process to be fast and efficient. The statute requires the Patent Trial and Appeal Board ("PTAB") to complete an IPR within 12 months of institution, absent good cause. 35 U.S.C. § 316(a)(11). The PTAB's final decision is reviewable solely by the Federal Circuit. 35 U.S.C. §§ 319, 141(c). Further, IPRs are overseen by a panel of at least three PTAB members—senior personnel required by law to be qualified in both "legal knowledge and scientific ability." 35 U.S.C. § 6. In short, IPRs serve a distinct and crucial role in a healthy patent system, allowing the PTO to take a second look at its patentability decision.

IPRs are particularly important in the pharmaceutical and biologic context, where brand-name companies routinely seek dozens, if not hundreds, of patents covering a single brand-name drug or biologic and use second-, third-, and even fourth-generation patents to extend a monopoly.[17] What's more, IPRs are working as intended to knock out blocking pharmaceutical patents that never

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[16] 157 CONG. REC. S5409 (daily ed. Sept. 8, 2011) (statement of Sen. Schumer); 157 CONG. REC. S1349 (daily ed. Mar. 8, 2011) (statement of Sen. Leahy).

[17] *See, e.g.*, Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. Times, July 15, 2016, https://nyti.ms/2kUxW18 (noting that the manufacturer of Humira "amassed more than 70 newer patents, mostly in the last three years, covering formulations of the drug, manufacturing methods and use for specific diseases").

should have issued in the first place. In the small-molecule context alone, the PTO reports that 66% of IPRs challenging Orange Book[18] patents are instituted, with 49% of those IPRs resulting in final written decisions finding at least one claim unpatentable.[19] In fact, according to a recent study, between September 2012 and April 2017, generic drug manufacturers used the IPR process to challenge 198 patents covering 134 different drugs and, in 43% of the cases, generic drug makers succeeded in canceling all patent claims that were challenged.[20] All told, many decades of patent life that never should have blocked competition in the first instance have been eliminated, paving the way for more affordable medicines.

Extending Section 315(b)'s one-year bar to petitioners whose suits have been voluntarily dismissed will take away their option to use this valuable tool for patents that may cover a number of different products. The harm will be felt not only by generic and biosimilar companies, but also by patients, who rely on such challenges to lower prices.

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[18] The "Orange Book" is an FDA publication that, among other things, lists patents that purportedly cover and protect a brand-name drug.

[19] U.S. PATENT & TRADEMARK OFFICE, CHAT WITH THE CHIEF: ORANGE BOOK-LISTED PATENT STUDY 43, 45 (Mar. 2018).

[20] Jonathan J. Darrow et al., *The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents*, 17 APPLIED HEALTH ECONOMICS & HEALTH POLICY 47, 50-51 (2019).

C. The Federal Circuit's *En Banc* Decision Leads To Absurd And Prejudicial Results.

The Federal Circuit's *en banc* decision has the very real potential to have a disparate impact on generic and biosimilar companies given the sheer volume of patents that purportedly protect brand-name products, and will inevitably lead to absurd results. On the one hand, the decision provides a recipe for overt manipulation by patent owners. But even beyond that, the natural and unintended consequences of the *en banc* decision would likely be just as severe, due to the regular overlap of patents covering multiple products.

1. The Federal Circuit's Decision Provides an Incentive and "Mechanism for Manipulation."

As observed in the dissenting opinion, the Federal Circuit's *en banc* decision opens the door to, and indeed incentivizes, manipulation by patent owners who may seek to bar future IPR challenges by filing—and then dismissing—suits after serving the complaint. App. at 105a-106a. Judge Dyk explained:

> Finally, ***the purposes of section 315(b) will be defeated if the patentee plaintiff is allowed to manipulate the filing of infringement actions in order to bar a future IPR challenge.*** Indeed, if dismissals without prejudice did not nullify the underlying complaint, patent owners would have an incentive to file

> suits alleging infringement and subsequently voluntarily dismiss these suits without prejudice after service of the complaint. Such actions would effectively begin the one year clock for the accused infringer to file an IPR, even where there was no longer an underlying infringement action. ***Congress could not have intended to provide a mechanism for such manipulation.***

App. at 105a-106a (emphasis added).

There are, in fact, any number of ways in which such manipulation could play out. A patent owner could, for example, serve a complaint alleging infringement of several patents purporting to cover the brand-name company's reference biologic product, only to voluntarily dismiss some, if not all, of the patents shortly thereafter to start the clock running. The dismissal then leaves the biosimilar sponsor guessing which, if any, of the patents could be asserted later, and whether to expend the money and resources now to challenge such patents in an IPR. The clock, moreover, is also running for future products that might be implicated by those same patents, thereby substantially increasing the penalty to any defendant who fails to invoke IPR. Patent owners could make the decision even harder by purposefully waiting to dismiss their patent claims until a date nearing the end of the one-year period, effectively eliminating IPR as a viable option altogether.

Judge Taranto, in his concurrence, dismissed this possibility as "purely hypothetical," having been presented with no evidence of this occurring. App. at 89a. But that is no surprise. Until the decision below, all parties *and* the Board operated on the principle that suits that had been voluntarily dismissed did not, in fact, trigger the one-year time bar for filing a petition.[21] The settled expectation was that a voluntarily dismissed action without prejudice was a complete nullity.[22] Now, settled expectations of all stakeholders that were once in accord have been turned on their head in a manner that not only upsets decades of understanding regarding the impact of a dismissal without prejudice, but creates a perverse incentive to manipulate the bar.

It is clear that the decision will foster and encourage gamesmanship of the process that will defeat the purposes of the AIA. By way of another example, a patent owner could file an objectively baseless lawsuit, only to voluntarily dismiss the action to start the one-year clock running. This tactic would be particularly appealing to a company that may believe it has relatively weak infringement claims with

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[21] *See, e.g.*, *Apple Inc. v. Rensselaer Polytechnic Inst.*, No. IPR2014-00319, 2014 WL 2735064, at *3 (P.T.A.B. Jun. 12, 2014); *Macauto U.S.A. v. BOS GmbH & KG*, No. IPR2012-00004, 2013 WL 5947694, at *7-8 (P.T.A.B. Jan. 24, 2013).

[22] *Oracle Corp. v. Click-to-Call Techs. LP*, IPR2013-00312, 2013 WL 11311788, at *7 (P.T.A.B. Oct. 30, 2013), citing *Graves v. Principi*, 294 F.3d 1350, 1356 (Fed. Cir. 2002).

respect to a currently-approved product, but whose patents could be asserted in connection with future line-extensions as well. In one fell swoop, a patent owner could effectively insulate its patents from IPR, for all time, and for all products—even where "there is a reasonable likelihood that [a] petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See* 35 U.S.C. § 314(a).

A patent owner could achieve the same effect by asserting numerous patents in its original complaint, and then dropping several patents in an amended complaint. Under the *en banc* court's expansive interpretation, it may not matter that such patents were dismissed via amended complaint rather than a Rule 41(a) dismissal. Under the current ruling, *any* complaint that was served triggers the one-year bar, "irrespective of subsequent events." App. at 47a.

When companies have billions of dollars in annual revenue at stake, brand-name companies have every incentive to take advantage of this judicially-created loophole. It would certainly not be the first time a brand-name drug company engaged in sham litigation to protect its monopoly. *See, e.g.*, *FTC v. AbbVie Inc.*, No. 14-cv-05151, 2017 WL 4098688, at *12 (E.D. Pa. Sept. 5, 2017) (granting summary judgment "on the objective[ly] baseless[] element of the sham litigation prong of [FTC's] monopolization claim").

A statutory interpretation that provides such an obvious mechanism for manipulation, as described by

Judge Dyk, could not possibly have been what Congress intended.

2. The *En Banc* Decision Would Have Drastic Unintended Consequences On Generic And Biosimilar Companies And Patients.

Unfortunately, the potential for gamesmanship merely scratches the surface of what is at stake if the Federal Circuit's *en banc* decision is not reversed.

As noted above, brand-name companies routinely build a "patent thicket" around their brand-name drug or biologic, patenting every aspect, from the compound, the formulation, dosage forms and strengths, uses, delivery devices, and line extensions, including combination products containing the same active ingredient. Many of these patents often cover more than one brand-name product.

For instance, two of the patents listed in FDA's Orange Book for Gilead's Truvada® tablets, an HIV medication, also are listed for *nine* other Gilead products, plus an *eleventh* HIV product held by Janssen. Significantly, not all of these products were approved at the same time; these approvals span the course of 15 years—from 2003 to 2018. This illustrates the problem with closing off a defendant's IPR options when litigation over one product is voluntarily dismissed. Even if that defendant diligently searches for related products covered by the same patents-in-suit during the one-year period after the original complaint is served, its search could come up empty, and any failure to file an IPR

at that time could unknowingly prejudice its rights with respect to later-approved products.

The problem is amplified for biologic products, for which the patent thicket is even more imposing.[23] In addition to product- and use-based patents, biologic companies obtain numerous patents covering various platform technologies, including laboratory diagnostics, testing devices, and different forms of gene therapy or gene sequencing technologies, just to name a few.[24] Biologic products also are typically protected by large numbers of method-of-manufacturing patents, including, for example, patents directed to methods of purifying antibodies, methods of refolding proteins, and methods of producing antibody compositions using certain host cells. Moreover, these patents may be licensed to multiple manufacturers, and thus may cover not just a single company's portfolio, but multiple portfolios.

Interpreting Section 315(b) to prevent companies who were sued over one product from being able to petition for IPR with respect to other future products if the original litigation is dismissed will have a disparate impact on the generic and biosimilar

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[23] For example, at least 16 of the patents asserted against companies seeking approval for a biosimilar to Herceptin® have also been asserted against companies seeking approval for a biosimilar to Avastin®. Of these 16 patents, 14 have also been asserted against companies pursuing approval for a Rituxan® biosimilar.

[24] *See* Jacob S. Sherkow, *Protecting Products Verses Platforms*, 34 NATURE BIOTECHNOLOGY 462 (2016).

industries and hamper the ability of such companies to utilize this important tool.

Voluntary dismissals entered under Rule 41(a) are common in pharmaceutical and biologic patent litigation. Patent owners often drop asserted patents for a variety of strategic, evidentiary, practical, and cost reasons. Beyond that, parties might agree to settle litigation with respect to one accused product, even where the patents at issue cover other approved products or future products in development that have not yet been approved. Moreover, a generic or biosimilar company may decide to discontinue pursuing approval for a particular product, once again leading to the voluntary dismissal of any pending litigation. Simply put, even without overt gamesmanship, dismissals without prejudice are frequent throughout pharmaceutical patent litigation.

Under the *en banc* ruling, if the original litigation is dismissed before the one-year deadline, the generic or biosimilar company would nevertheless be forced to decide whether to spend the resources to file an IPR, solely because that patent could cover a separate product one day in the future. Indeed, the generic or biosimilar company could be forced into this Hobson's choice even before any such separate product has been added to that company's research and development portfolio. This complicates the decision further because, if the company has not yet begun development for such future products, it might not have constitutional standing to appeal any unfavorable IPR decision. There is no legitimate

reason to snuff out IPR rights in these circumstances—and even less reason to believe that Congress intended to do so.

These manifestly absurd results cannot be squared with Congress's intent in enacting Section 315(b).

II. SECTION 315(b) SHOULD NOT BE INTERPRETED IN A WAY THAT DEFEATS THE PURPOSE AND STRUCTURE OF THE STATUTE.

Where, as here, an interpretation of a statute produces unreasonable—if not absurd—results, this Court can, and should, look beyond the words of the statute to interpret its meaning, consistent with Congress's intent and the overall statutory scheme. This Court has recognized that "a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning -- or ambiguity -- of certain words or phrases may only become evident when placed in context." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000) (internal quotations and citations omitted); *see also King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (A court's "duty, after all, is to construe statutes, not isolated provisions," therefore, "when deciding whether the language is plain, [courts] must read the words in their context and with a view to their place in the overall statutory scheme.") (internal quotations and citations omitted); *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 320 (2014) (finding EPA's statutory interpretation "incompatible" with "the substance of Congress'

regulatory scheme") (internal quotations and citations omitted).

Turning to the statutory scheme and legislative history here, it becomes clear that the real world implications of the Federal Circuit's *en banc* decision "plainly contradict[s] congressional policy" and is incompatible with the "substance of Congress' regulatory scheme." *Brown & Williamson*, 529 U.S. at 139, 156. The one-year deadline imposed by Section 315(b) is grounded in concerns over duplicative proceedings before federal courts and the patent office. As Judge Dyk observed in the dissenting opinion, "one of the purposes of section 315(b) in setting a one year time period was to bar the filing of an IPR when, typically, the district court action would have already consumed the time and attention of the court and parties." App. at 105a. Congress feared that IPRs could be used to harass patent owners through duplicative litigation and administrative actions.[25]

To address this concern, Congress set a one-year deadline for a defendant served with a complaint to file an IPR petition. Congress selected this time period in recognition of the "multiple patents with large numbers of vague claims" that were regularly asserted against defendants.[26] Congress acted to ensure that defendants had a "reasonable

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[25] H.R. REP. NO. 112-98, pt. 1, at 48 (2011).

[26] 157 CONG. REG. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl).

opportunity to identify and understand the patent claims that are relevant to the litigation" before the one-year bar went into effect.[27]

Importantly, as explained in the dissenting opinion, these concerns are no longer implicated when the underlying district court litigation is dismissed without prejudice. App. at 104a-105a. At that point, the patent owner has chosen not to continue asserting its patent, and the parties are no longer using the resources of the court. Moreover, to the extent the one-year bar conveys some notice-conferring purpose to help reduce the need for dual proceedings, the entry of a dismissal without prejudice in the underlying litigation effectively eliminates the need for that bar. Thus common sense dictates that Congress did not intend the one-year bar to insulate a patent from PTAB review where there is no concurrent proceeding.

The *en banc* court concerns itself with the "ordinary, contemporary, [and] common meanings" of the terms "served" and "complaint" in Section 315(b), relying on definitions supplied by Black's Law Dictionary as support. App. at 47a. But the meaning of Section 315(b) cannot be ascertained without looking further at the particular objective of that provision within the context of the statutory scheme. This Court previously has explained that "it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of

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[27] *Id.*

the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.'" *Public Citizen v. United States Dep't of Justice*, 491 U.S. 440, 454-55 (1989) (quoting *Cabell v. Markham*, 148 F.2d 737, 739 (2d Cir. 1945)). "Looking beyond the naked text for guidance is perfectly proper when the result it apparently decrees is difficult to fathom or where it seems inconsistent with Congress' intention." *Public Citizen*, 491 U.S. at 455; *see also Kasten v. Saint-Gobain Performance Plastics Corp.*, 563 U.S. 7, 11 (2011).

As explained above, interpreting Section 315(b) without reading in the context, structure, and purpose of the entire statute will inevitably lead to unreasonable, if not patently absurd, results that cannot be squared with the purpose behind the one-year bar, let alone the underlying purpose of the IPR pathway to create an efficient mechanism to review patents that should not have issued in the first place.

CONCLUSION

This case presents a critical issue of first impression that can be addressed and corrected only by this Court. Absent review, the Federal Circuit's *en banc* decision will have a disparate impact on the generic and biosimilar industry, which will face unnecessary barriers to utilizing the IPR process to strike down improperly-issued patents that keep brand-name products at monopoly prices. The petition for *certiorari* should be granted.

FEBRUARY 13, 2019 Respectfully submitted,

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