No. 16-712

IN THE

Supreme Court of the United States

OIL STATES ENERGY SERVICES, LLC,

Petitioner,

v.

GREENE'S ENERGY GROUP, LLC, *et al.*,

Respondents.

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

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

JULIE SIMON MILLER
MICHAEL S. SPECTOR
AMERICA'S HEALTH INSURANCE PLANS
601 Pennsylvania Ave., NW
Washington, DC 20004

ANNA-ROSE MATHIESON
Counsel of Record
BEN FEUER
CALIFORNIA APPELLATE LAW GROUP LLP
96 Jessie Street
San Francisco, CA 94105
(415) 649-6700
annarose@calapplaw.com

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BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

The undersigned respectfully submits this amicus curiae brief in support of respondents.[1]

INTEREST OF AMICUS CURIAE

America's Health Insurance Plans (AHIP) is a national association whose members provide coverage for health care and related services to millions of Americans every day. These offerings improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. AHIP is committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

As AHIP and its members are uniquely aware, increases in prescription drug costs are a leading driver of rising health care costs that burden consumers. Because of AHIP's commitment to practical solutions that reduce consumer costs and increase patient access to needed medication, AHIP has a strong interest in preventing drug manufacturers from securing improper patents or engaging in conduct that artificially prolongs monopoly power over critical medications past the time intended by Congress.

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[1] No counsel for any party authored this brief in whole or in part, and no person other than amicus or its counsel have made any monetary contribution intended to fund the preparation or submission of this brief. Letters of consent from all parties to the filing of amicus curiae briefs are on file with the Clerk's Office.

Because the merits briefs filed by the Solicitor General and Respondent Greene's Energy Group thoroughly address the constitutional issues in this case, this amicus brief seeks to provide the Court with studies and data showing that inter partes review can be quicker, less costly, and better at facilitating the aims of the patent system than district court litigation alone. As explained below, inter partes review promotes a strong competitive market for prescription drugs, which in turn expedites access to affordable, lifesaving medicines for millions of American citizens.

SUMMARY OF ARGUMENT

Congress designed inter partes review as a quick and cost-effective way for the Patent Office to revoke patents that should never have issued. Congress succeeded. Inter partes review takes significantly less time than district court patent litigation, generally resolving disputes at least a year earlier.[2] The costs are dramatically lower. Inter partes review averages $451k through appeal, while the average federal court patent case costs between $627k to nearly $4 million.[3]

While some of petitioner's amici claim that inter partes review strikes down too many patents, the process is also impartial and accurate. Out of the 5,914 inter partes review proceedings resolved as of September 2017, in only 24% did the Patent Trial and Appeal Board ("PTAB") rule some or all of the claims were unpatentable.[4] The PTAB denied institution in 30% of cases (outright wins for the patent owner), 28%

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[2] Anne Layne-Farrar, *The Other Thirty-Percent: An Economic Assessment of Duplication in PTAB Proceedings and Patent Infringement Litigation* (June 28, 2017), *available at* https://ssrn.com/abstract=2994858; Philip Swain, *The Cost-Effectiveness of PTAB Proceedings*, PTAB Blog (Nov. 13, 2015), http://www.ptab-blog.com/2015/11/13/the-cost-effectiveness-of-ptab-proceedings/ (citing Lex Machina statistics).

[3] American Intellectual Property Law Association, *2017 Report of the Economic Survey* I-112-116, I-162-163 (June 2017).

[4] USPTO, *Trial Statistics: IPR, PGR, CBM* 11 (Sept. 2017), *available at* https://www.uspto.gov/sites/default/files/documents/Trial_Stats_2017-09-30.pdf.

settled, 12% were joined, dismissed, or otherwise resolved, and in 6% the PTAB upheld all challenged claims of the patent.[5]

While most petitions are resolved in favor of the patent owner, inter partes review still provides a speedy, cost-effective, and reliable way to weed out improper and costly patent monopolies. The United States Patent and Trademark Office ("USPTO") receives more than half a million patent applications every year. The system is structurally biased in favor of granting patents, and some improper patents slip through the examination process. The monopolies created by those patents harm consumers who have to pay higher prices for patented products, potential competitors unable to enter the market, and society as a whole.

The ills of improper patents are particularly acute for health care. Prescription drug prices spiral up at ever-increasing rates. Drugs protected by patent monopolies cause the bulk of this price growth.[6] While brand-name drugs comprise only 10% of all dispensed prescriptions in the United States, they account for 72% of drug spending.[7]

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[5] *Id*.

[6] IMS Institute for Healthcare Informatics, *Global Medicines Use in 2020: Outlook and Implications* (Nov. 2015), *available at* https://s3.amazonaws.com/assets.fiercemarkets.net/public/005-LifeSciences/imsglobalreport.pdf.

[7] Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316:8 JAMA 858, 860 (Aug. 2016).

As a recent article from the Journal of the American Medical Association explains, "the only form of competition that consistently and substantially decreases prescription drug prices occurs with the availability of generic drugs, which emerge after the monopoly period ends."[8] Yet drug makers have significant incentives to maximize their market exclusivity period by seeking additional patents on other aspects of their brand-name drugs (such as slightly different formulations or methods of administration) in order to block generic entry for as long as possible.[9] Many of these follow-on patents are improper, but the long time frame of district court litigation itself extends the patent monopoly and prevents consumers from accessing generic alternatives.

Inter partes review allows the swift correction of inappropriately-issued pharmaceutical patents that block lower-cost generic drugs.[10] Without inter partes

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[8] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 7, at 861.

[9] References to "prescription drugs" or "drugs" in this brief include biologics, complex medications that "are generally derived from living material—human, animal, or microorganism." U.S. Food & Drug Administration, *Frequently Asked Questions About Therapeutic Biological Products*, https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/ucm113522.htm (last visited Oct. 25, 2017). References to "generics" include biosimilars.

[10] Because the Court's grant of certiorari focuses on inter partes review, this brief does as well, but most of the discussion applies to post-grant review and covered business method proceedings. USPTO, *Trial Statistics*, *supra* note 4, at 3.

review, companies will funnel funds towards obtaining spurious patents instead of investing in development of new medications. Many challenges to improper patents will never occur. And even if a challenger has the funds to proceed with district court litigation, consumers will bear the higher costs created by these extended patent monopolies.

These costs and delays cause very real harms to American citizens. They mean that consumers must pay higher prices, both through direct payments for prescription medications and through increased insurance premiums. For those who cannot afford expensive branded medications, these delays may mean no access at all to needed treatments.

ARGUMENT

I. Congress Designed Inter Partes Review to Correct Inappropriate Patent Monopolies, Which (Among Other Harms) Drive Up Drug Prices

A recent national poll found "that the affordability of prescription drugs continues to be at the top of the public's priority list for the President and Congress."[11] From patients who cannot afford life-saving medications, to consumers who pay higher and higher premiums because of rising drug prices, to hardworking taxpayers who fund public programs like Medicaid

[11] Bianca DiJulio, Jamie Firth, and Mollyann Brodie, *Kaiser Health Tracking Poll: October 2015* (Oct. 28, 2015), http://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/. Priorities include "'making sure that high-cost drugs are affordable to those who need them' and 'government action to lower prescription drug prices.'" *Id*.

and Medicare, rising prescription drug costs impose a heavy burden on Americans. As explained in this section, Congress designed the inter partes review system to address these harms and prevent improper patent monopolies that drive up drug prices.

A. Patents on prescription drugs significantly and directly affect health plan premiums and consumer costs

The United States spends 18% of our gross domestic product on health care, up from just 7% in 1970.[12] A significant portion of that spending—and the fastest growing portion—goes towards prescription drugs. Our nation spent more than $324 billion on prescription drugs in 2015.[13] That represents a 9%

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[12] Center for Sustainable Health Spending, *Insights from Monthly National Health Spending Data Through December 2015* 1 (Feb. 16, 2016), *available at* https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Spending-Brief_February_2016.pdf; Medicaid and CHIP Payment and Access Commission, *Report to Congress on Medicaid and CHIP* 3 (June 2016), *available at* https://www.macpac.gov/wp-content/uploads/2016/06/June-2016-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

[13] Centers for Medicare & Medicaid Services, *National Health Expenditures 2015 Highlights* 2 (2015), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf; *see also* Office of the Assistant Secretary for Planning and Evaluation, Department of Health & Human Services, *Observations on Trends in Prescription Drug Spending* (Mar. 8, 2016), https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending (estimating the United States spent $457 billion on prescription drugs in 2015).

increase over 2014, and outpaced the growth rate for all other areas of health care spending.[14]

And it continues to increase. Global spending on medicine is projected to reach $1.4 trillion by 2020.[15] Our nation's spending on prescription drugs will likely reach between $560 billion and $590 billion in 2020, a 34% increase over 2015.[16]

These trends have significant impacts on both private citizens and the public sector. For individuals paying for prescriptions out of their own pockets, rising drug prices take a direct and obvious toll. For those with insurance the costs are just as substantial, although less obvious, because health insurance premiums have a direct relationship with costs of inputs such as pharmaceuticals.[17] Nearly a quarter of every dollar spent on health insurance premiums goes to pay for prescription drugs.[18] This is more than the

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[14] Centers for Medicare & Medicaid Services, *National Health Expenditures*, *supra* note 13, at 2.

[15] IMS Institute for Healthcare Informatics, *Global Medicines Use in 2020*, *supra* note 6, at 9.

[16] *Id*., at 16. These figures are on an invoice price basis.

[17] *See, e.g.*, Bradford R. Hirsch, Suresh Balu & Kevin A. Schulman, *The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs*, 33:10 HEALTH AFFAIRS 1714 (Oct. 2014).

[18] AHIP, *Where Does Your Premium Dollar Go?* (March 2, 2017), https://www.ahip.org/health-care-dollar/. The figures in this study actually *understate* the impact of prescription drugs on insurance premiums, because drugs administered in hospital inpatient settings were excluded.

amount spent on physician services, inpatient hospital services, or outpatient hospital services.[19]

On the public side, about a quarter of the entire federal budget goes to Medicare and Medicaid.[20] Spending for drugs in the Medicare Part D prescription drug program rose to $137 billion in 2015, a 13% increase from 2014.[21] Similarly, spending for drugs covered under the Medicare Part B program (which include outpatient prescription drugs that are administered by physicians rather than by patients themselves) totaled $24.6 billion, a 14% increase from 2014.[22]

The bulk of this spiraling price growth is caused by drugs protected by patent monopolies. Although brand-name drugs comprise only 10% of all dispensed prescriptions in the United States, they account for 72% of drug spending.[23] Prices for existing brand-name drugs reached a double-digit growth rate in 2015 for the fourth consecutive year, while prices for

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[19] *Id.*, at 4.

[20] This represents a dramatic increase since those programs were enacted in 1965. *See* Medicaid and CHIP Payment and Access Commission, *Report to Congress on Medicaid and CHIP*, *supra* note 12, at 3-5.

[21] Centers for Medicare & Medicaid Services, *Update to the Medicare Drug Spending Dashboard* (Nov. 14, 2016), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-14.html.

[22] *Id.*

[23] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 7, at 860.

generic drugs increased less than 1%.[24] And this trend is expected to continue.[25]

B. Patent monopolies reflect a policy judgment that higher costs are worthwhile for a short time, after which consumers will benefit from less costly alternatives

Congress's decision to provide for a limited term of patent monopoly reflects a policy judgment that the higher costs borne by consumers are necessary to provide short-term incentives for true innovation. As the Federal Trade Commission put it, "[p]atent protection enables biotechnology firms to increase their expected

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[24] Anne B. Martin et al., *National Health Spending: Faster Growth in 2015 as Coverage Expands and Utilization Increases*, 36:1 HEALTH AFFAIRS 166, 174-175 (Jan. 2017). In 2014, brand-name drugs prices grew by 15.4% while prices for generics grew by only 0.2%. S&P Dow Jones Indices, *Healthcare Expenditures for Commercial Plans up 3.2% in the Year to February 2014: S&P Healthcare Claims Indices* (June 30, 2014), *available at* http://press.spglobal.com/2014-06-30-Healthcare-Expenditures-for-Commercial-Plans-up-3-2-in-the-Year-to-February-2014-S-P-Healthcare-Claims-Indices?asPDF=1.

[25] Divya Grover, *Costly Drugs to Weigh on U.S. Employers' Expenses in 2018: Survey*, Reuters (Sept. 18, 2017), http://www.reuters.com/article/us-usa-healthcare-survey/costly-drugs-to-weigh-on-u-s-employers-expenses-in-2018-survey-idUSKCN1BT1FR (citing Mercer, *Mercer Survey Finds Employers Hold Health Benefit Cost Increases to 4.3%, Maintaining Stable Growth* (Sept. 18, 2017), https://www.mercer.us/our-thinking/healthcare/mercer-survey-finds-employers-hold-health-benefit-cost-increases-to-43-maintaining-stable-growth.html).

profits from investments in R&D, thus fostering innovation that would not occur without patents' exclusionary rights."[26]

The expected trade-off, though, is that at the end of the patent monopoly consumers should be able to benefit from the entry of lower cost alternatives. As this Court explained decades ago, "[b]y the patent laws Congress has given to the inventor opportunity to secure the material rewards for his invention for a limited time, on condition that he make full disclosure for the benefit of the public of the manner of making and using the invention, and that upon the expiration of the patent the public be left free to use the invention." *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945).

That careful balance only functions when patents are novel, non-obvious, and otherwise proper. When a patent is inappropriately issued, it does not spur innovation but instead saddles consumers with the costs of a sham patent monopoly until the patent is invalidated.

The pharmaceutical industry provides a stark example of how this plays out in the real world. While some drugs "are important clinical breakthroughs and may even be relatively cost-effective; others are merely costly, with prices that are difficult to justify

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[26] Federal Trade Commission, *Emerging Health Care Issues: Follow-On Biologic Drug Competition*, at v (June 2009), *available at* https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report.

in relation to their actual contributions to patient outcomes."[27] Studies have found that "[t]he only form of competition that consistently and substantially decreases prescription drug prices occurs with the availability of generic drugs, which emerge after the monopoly period ends." [28]

Americans overwhelmingly favor making it easier for generic drugs to come to market.[29] And for good reason. For typical drugs, the presence of generic medications can cut prices by half or even more.[30] "Drug prices decline to approximately 55% of brand-name drug prices with 2 generic manufacturers making the product, 33% with 5 manufacturers, and 13% with 15 manufacturers."[31] Indeed, a 2012 government study estimated that "generic drugs . . . saved

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[27] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 7, at 859.

[28] *Id*., at 861.

[29] Henry J. Kaiser Family Foundation, *Public Opinion on Prescription Drugs and Their Prices*, at slide 11, http://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices (last visited Oct. 24, 2017); *see also* Office of the Assistant Secretary for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending*, *supra* note 13 (discussing results of Kaiser poll).

[30] Judith A. Johnson, *FDA Regulation of Follow-On Biologics* 2 (Cong. Research Serv., Apr. 26, 2010), https://primaryimmune.org/wp-content/uploads/2014/05/Biosimilars_Congressional_Research_Service_Report.pdf .

[31] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 7, at 861.

the US health care system $1 trillion during the previous decade."[32]

Unsurprisingly, companies with valuable patents do everything they can to avoid competition from generics. Most relevant here, many companies attempt to game the patent system to keep their monopoly even after the expiration of their original patent. As explained more fully in Section III.B, strategies used by brand-name drug manufacturers include obtaining follow-on patents "of questionable validity" with slight variations in formula or methods of administration, and then "engaging in frequent and costly patent litigation."[33]

Challenging defective patents in a district court lawsuit can cost millions of dollars and take three years or more. As explained below, Congress enacted the inter partes review process to provide a faster and less expensive process for correcting abuses of the patent system.

C. Congress designed inter partes review to reexamine inappropriately issued patents quickly and cost-effectively

Recognizing the societal costs of inappropriately issued patents, Congress created the inter partes re-

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[32] *Id*.

[33] Alfred B. Engelberg, Aaron S. Kesselheim, and Jerry Avorn, *Balancing Innovation, Access, and Profits — Market Exclusivity for Biologics*, 361 NEW ENG. J. MED. 1917 (Nov. 12, 2009), *available at* http://www.nejm.org/doi/full/10.1056/NEJMp0908496#t=article.

view system to identify and cancel inappropriately issued patents that can cause significant public harms. *See* Leahy-Smith America Invents Act, 35 U.S.C. §§ 100 et seq. As this Court put it, "in addition to helping resolve concrete patent-related disputes among parties, inter partes review helps protect the public's 'paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.'" *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)).

In enacting inter partes review, Congress sought "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 112-98, pt. 1, at 40 (2011), *reprinted in* 2011 U.S.C.C.A.N. 67, 69; *id.* at 39-40 (inter partes review provides a method "for challenging patents that should not have issued"); 157 Cong. Rec. 9778 (2011) (remarks of Rep. Goodlatte) (goal of inter partes review is to "screen out bad patents while bolstering valid ones"); S. Rep. No. 110-259, at 20 (2008) (inter partes review is "a quick, inexpensive, and reliable alternative to district court litigation").

The need for more robust post-grant review makes sense given the size and scope of the USPTO's task. The USPTO receives over half a million patent applications each year, and has a backlog of over a million more.[34] Given the huge volume of applications and

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[34] U.S. Patent & Trademark Office, *Performance and Accountability Report Fiscal Year 2016* 178, 180 (Nov. 14, 2016), https://www.uspto.gov/sites/default/files/documents/USPTOFY16PAR.pdf.

intense pressures to resolve them quickly, the USPTO grants some questionable patents. This summer, for instance, the USPTO granted a patent to HP for the use of reminder messages on a computer, even though those reminders have been around for at least a decade.[35] Ford received a patent for the design of a fairly ordinary windshield.[36] And someone received a patent for how to swing on a swing.[37]

Some of the improperly-issued patents slip through because of the structure of the patent examination system, which "is structurally biased towards

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[35] Electronic Frontier Foundation, *Stupid Patent of the Month: HP Patents Reminder Messages* (July 31, 2017), https://www.eff.org/deeplinks/2017/07/stupid-patent-month-hp-patents-reminder-messages (discussing United States Patent No. 9,715,680, *available at* https://www.eff.org/document/united-states-patent-no-9715680).

[36] Electronic Frontier Foundation, *Stupid Patent of the Month: Ford Patents a Windshield* (May 31, 2017), https://www.eff.org/deeplinks/2017/05/stupid-patent-month-ford-patents-windshield.

[37] Free Patents Online, *Method of Swinging on a Swing*, http://www.freepatentsonline.com/6368227.html (last visited Oct. 24, 2017) (discussing United States Patent No. 6,368,227).

The patent office did not, however, grant Halliburton's application to patent a method for patent trolling. Halliburton, *Patent Acquisition and Assertion by a (Non-Inventor) First Party Against a Second Party* (April 27, 2007), *available at* https://www.google.com/patents/US20080270152; *see* Theo Francis, *Can You Get A Patent On Being A Patent Troll?*, NPR (Aug. 2, 2012), http://www.npr.org/sections/money/2012/08/01/157743897/can-you-get-a-patent-on-being-a-patent-troll.

allowing patents."[38] If a patent examiner rejects a patent application, the party seeking the patent receives several chances to refine its application—so there is little penalty for seeking an overbroad patent to begin with. 35 U.S.C. § 132(a). If the examiner denies a patent, the applicant can contest that denial before the PTAB and can then seek judicial review from the Federal Circuit. 35 U.S.C. §§ 141(a), 145. When the USPTO grants a patent, by contrast, that decision is unappealable.

In addition to the structural pressures towards granting patent applications, the initial system for granting patents suffers from a lack of information. A patent examiner usually considers patent applications with little or no input from potentially affected competitors. 35 U.S.C. § 122(e); 37 C.F.R. § 1.291.

Congress recognized these problems, and designed inter partes review so third parties could alert the patent office to prior art that the patent office may not have located when granting the patent. The party challenging the patent bears the burden of persuasion to prove that the claims are not patentable, though, and that burden never shifts to owner of the patent. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378-79 (Fed. Cir. 2015); 35 U.S.C. § 316(e).

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[38] PTAB Bar Association Amicus Br. 13-14. That amicus brief provides a detailed overview of these structural constraints that drive the issuance of patents.

II. Inter Partes Review Successfully Reexamines Improper Patents

A. Inter partes review yields reasonable, appropriate results

Petitioner's amici argue that the PTAB acts as a "death squad" for patents, stifling innovation. Not so.

Inter partes review is a two-step process. At the initial stage, the PTAB reviews the petition and decides whether to institute inter partes review at all. Although the PTAB instituted review in 87% of cases in its first year, that rate has steadily declined over the past four years, and dropped to 63% during the 12 months ending September 2017.[39] The decision to deny review is not reviewable on appeal, 35 U.S.C. § 314(d), which means that in 37% of cases this year the patent owner won outright without any further litigation.

Out of all the 7,557 inter partes review petitions that have been filed since the procedure became available in 2012, 5,914 petitions reached some conclusion by September 2017.[40] Of those, the PTAB denied institution in 30% of cases, 28% settled, and another

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[39] USPTO, *Trial Statistics*, *supra* note 4, at 7; Ryan Davis, *Inter Partes Reviews Becoming Friendlier to Patent Owners*, Law 360 (March 1, 2017) https://www.law360.com/articles/894916/inter-partes-reviews-becoming-friendlier-to-patent-owners.

[40] USPTO, *Trial Statistics*, *supra* note 4, at 11. As of September 2017, of the 7,557 total petitions filed, 918 are open pre-institution and 725 are open post-institution.

12% were joined, dismissed, or otherwise resolved before final judgment.[41] In 6% of the total cases the PTAB upheld all challenged claims of the patent in a final written decision, in 5% the PTAB upheld some of the claims, and in 19% the PTAB ruled all of the claims were unpatentable.[42]

Some of petitioner's amici focus on the small subset of petitions resolved at the final written decision stage, arguing that the PTAB is biased since it struck down some or all of the patent claims in 81% of those cases.[43] But that narrow focus makes no sense—it would be like assessing district court outcomes after excluding all cases where the defendant won on a motion to dismiss or summary judgment. Out of all 5,914 inter partes review petitions that have reached resolution, in only 1,440 (24%) did the PTAB find *any* claims were unpatentable.[44] Indeed, even if all settlements are excluded from the calculations and we consider only petitions that were resolved in favor of one party or the other, the PTAB's total invalidation rate

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[41] *Id*.

[42] *Id*.

[43] *Id*.

[44] *Id*. This figure is computed by adding the cases where all instituted claims were found unpatentable (1,153) and those where some claims were found unpatentable (287), and dividing by the total cases that have reach a disposition (5,914).

is only 34%.[45] The patent owner entirely prevailed in 52% of cases.[46]

Congress built judicial review into the system as well. Final written decisions of the PTAB are reviewable by the United States Court of Appeals for the Federal Circuit. 35 U.S.C. §§ 141(c), 319. A recent study of more than 100 inter partes review appeals filed to the Federal Circuit since this Court's June 2016 ruling in *Cuozzo* found that the Federal Circuit affirmed 82% of inter partes review appeals, reversing in only 18%.[47]

Despite claims by some of petitioner's amici that this low reversal rate indicates the Federal Circuit's abdication of responsibility for inter partes review, that figure is solidly in line with the court's general reversal rates for other decisions (and, indeed, solidly

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[45] *Id.*; *see also* Monica Grewal, James Hill, and Kathryn Zalewski, *Trends in Inter Partes Review of Life Sciences Patents*, 92 BNA'S PAT., TRADEMARK, & COPYRIGHT J. 4 (June 17, 2016), *available at* https://www.wilmerhale.com/uploadedFiles/Shared_Content/Editorial/Publications/Documents/2016-06-07-Trends-in-Inter-Partes-Review-of-Life-Sciences-Patents.pdf.

[46] USPTO, *Trial Statistics*, *supra* note 4, at 11; *see also* Grewal et al., *Trends in Inter Partes Review of Life Sciences Patents*, *supra* note 45. In 8% of cases the proceeding was joined to another petition, and in the remaining 6% of cases a party requested an adverse judgment—often because the patent owner was seeking reissuance of a modified version of the patent in a separate proceeding.

[47] Christopher A. Suarez, American Bar Association: Section of Intellectual Property Law, *Navigating Inter Partes Review Appeals in the Federal Circuit: A Statistical Review*, 9 LANDSLIDE MAGAZINE No. 3, at 1-2 (2017).

in line with reversal rates of other courts of appeals).[48] Moreover, many of the inter partes review appeals were by the party challenging the patents—in two-thirds of the reversals, the decision favored the patent owner.[49] The Federal Circuit is taking its review responsibilities seriously, and ensuring that any issues in this relatively new review system get corrected swiftly.

B. Results for biopharmaceutical inter partes review generally track district court results for patent cases

When focusing on pharmaceutical and life sciences patents, the claims that the PTAB is a patent "death squad" are even more unfounded. In only 11% of petitions resolved through March 2016 did the PTAB find *any* claims unpatentable.[50] Even considering

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[48] U.S. Court of Appeals for the Federal Circuit, *Appeals Filed, Terminated, and Pending*, Table B-8, *available at* http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/FY16_Appeals_Filed_Terminated_and_Pending_2.pdf (showing the Federal Circuit's overall reversal rate for 12-month period ending September 30, 2016 was 11%, and reversal rate for review of U.S. District Court decisions was 16%); *see also, e.g.*, U.S. Court of Appeals for the Ninth Circuit, *2015 Ninth Circuit Annual Report* 59 (2015), *available at* http://www.ce9.uscourts.gov/publications/AnnualReport2015.pdf ("The court's overall reversal rate was 10.9 percent, compared to a national average of 8.3 percent.").

[49] Suarez, *Navigating Inter Partes Review Appeals, supra* note 47, at 3.

[50] Grewal et al., *Trends in Inter Partes Review of Life Sciences Patents*, *supra* note 45, at 4. The PTO tracks claims by "technology centers," and assigns code 1600 to patents in biotechnology and organic fields. *See* USPTO, *Patent Technology*

only petitions that reach the final written decision stage, the PTAB finds more claims patentable than not patentable.[51] Indeed, at the final decision stage more than twice as many claims are found patentable than for other types of technology.[52] In the vast majority of inter partes review proceedings for pharmaceutical patents, the patent emerges completely unscathed.

These figures undercut any argument that the PTAB's system of having the same judges decide on institution and the merits is structurally biased against the patent owner. If the invalidation of claims was a forgone conclusion once the judges decide on in-

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Centers Management (Aug. 16, 2017), https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management. These patents represent about 11% of inter partes review petitions in the last year. USPTO, *Trial Statistics*, *supra* note 4, at 4.

[51] USPTO, *Patent Trial and Appeal Board Statistics* 14 (Mar. 31, 2017), *available at* https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf; Corinne E. Atton & April M. Breyer, Biologics/HQ Fitzpatrick, *Drug Patents May Fare Better Than Other Technologies In IPR Proceedings* (June 12, 2017), http://www.biologicshq.com/wp-content/uploads/2017/06/Drug-Patents-May-Fare-Better-Than-Other-Technologies-In-IPR-Proceedings.pdf.

[52] USPTO, *Patent Trial and Appeal Board Statistics, supra* note 51, at 14.

stitution, there wouldn't be a disparity where life sciences patents win two to three times as often as other patents at that stage.[53]

Indeed, a recent study that examined claims involving life sciences patents and Abbreviated New Drug Application cases found relatively close results before the PTAB and district court.[54] There is simply no warrant to conclude that inter partes review yields unfair results in any cases, and certainly not for pharmaceutical and life sciences patents.

Branded drug-makers have been the beneficiaries of a generous USPTO and patent system that is biased in favor of granting patents for decades. These patents come at the expense of patients and tax payers, working real harm to consumers across the nation. Inter partes review provides a relatively speedy and cost-effective method to restore a long-overdue balance to the patent system.

III. Eliminating Inter Partes Review Will Spur Patent Abuse and Harm Consumers

A. Inter partes review takes significantly less time and money than district court litigation

While inter partes review has not had long to establish its benefits, data from the first five years show

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[53] Josh Landau, *IPR Statistics—Success Is Sector Specific*, Patent Progress (June 23, 2017), https://www.patentprogress.org/2017/06/23/ipr-statistics-success-sector-specific/.

[54] Ramy Hanna, Liane M. Peterson & Rebecca J. Pirozzolo-Mellowes, *Comparing the PTAB and District Court for Life Sciences Patents*, Mondaq (July 20, 2017), http://www.mondaq.com/article.asp?articleid=611670&friend=1.

it is significantly less expensive, and quicker, than district court litigation. This means inter partes review can efficiently root out improper patents, providing access to generic alternatives and ensuring consumers are not overpaying for medications.

According to 2017 statistics compiled by the American Intellectual Property Law Association based on a survey of practitioners, the average cost for post-grant proceedings (including inter partes review) was only $451,000 through appeal:[55]

Costs of Post-Grant Review[56]	
Through filing petition	$124k
Through end of motions practice	$223k
Through PTAB hearing	$324k
Through appeal	$451k

Patent infringement litigation in a district court can cost up to eight times as much, depending on the amount in controversy, and even the smallest cases still cost nearly 40% more than the average for all post grant review proceedings:

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[55] American Intellectual Property Law Association, *2017 Report of the Economic Survey*, *supra* note 3, at 1, I-163. Unlike district court litigation, the survey did not break the data for post-grant proceedings down by amount in controversy.

[56] *Id.* at I-162-163. All of these post-grant review figures were slightly lower than the costs of the comparable inter partes review proceedings in 2015. American Intellectual Property Law Association, *2015 Report of the Economic Survey*, at 1, I-139-140 (June 2015).

Costs of District Court Patent Litigation[57]				
Amount at stake	<$1 million	$1-$10 million	$10-$25 million	>$25 million
Through discovery & claim construction	$306k	$702k	$1,230k	$2,000k
All costs	$627k	$1,456k	$2,374k	$3,831k

If costly district court litigation is the only option to challenge an improper patent, some challenges will not be filed, leaving improper patent monopolies in place without generic alternatives to drive down prices. Even if the developer of a potential generic alternative does decide to take on the expense of filing a district court suit, the additional costs may be passed on to consumers, and pharmaceutical companies will have to spend funds on litigation rather than investing in innovation and development. The availability of inter partes review yields clear benefits to consumers.

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[57] American Intellectual Property Law Association, *2017 Report of the Economic Survey*, *supra* note 3, at I-112-116. These figures are all dramatically lower than the costs of district court litigation in 2015, when the upper end of federal court patent litigation was estimated to average $6,341,000. American Intellectual Property Law Association, *2015 Report of the Economic Survey*, at I-105-108. Reports attributed this significant price drop to the availability of inter partes review, which avoided some of the most cost-intensive district court litigation. Malathi Nayak, *Cost of Patent Infringement Litigation Falling Sharply*, Bloomberg BNA (Aug. 10, 2017), https://www.bna.com/cost-patent-infringement-n73014463011/.

Inter partes review has also been fulfilling Congress's goal of providing a speedy resolution to disputes. Congress built strict time limits into the statutory framework for both the institution of inter partes review, 35 U.S.C. § 314(b); 37 C.F.R. § 42.107(b), and the issuance of the PTAB's final written decision, 35 U.S.C. § 316(a)(11). The longest the entire review process can ever go is just over two years, and that is only with "good cause" for the delay. 35 U.S.C. § 316(a)(11). As a result of these requirements, "the average time for final decision in the PTAB, from filing of the petition until final decision by the PTAB, is one year, six months (531 days)."[58]

By contrast, district court patent trials "can be very lengthy affairs. It is not uncommon that a trial does not even begin until 3 or more years after the initial complaint is filed."[59] Nationally, "the median time from filing to trial for a patent infringement case is approximately two years, three months (814 days)," and later phases can add another year or more.[60]

This difference in timing between inter partes review and district court litigation has serious ramifications not only for the companies involved but for all consumers who might benefit from generic medications. As explained below, drug companies often seek

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[58] Swain, *The Cost-Effectiveness of PTAB Proceedings*, *supra* note 2 (citing Lex Machina statistics).

[59] Layne-Farrar, *The Other Thirty-Percent*, *supra* note 2, at 2.

[60] Swain, *The Cost-Effectiveness of PTAB Proceedings*, *supra* note 2; Layne-Farrar, *The Other Thirty-Percent*, *supra* note 2, at 2.

additional patents that can extend the product franchise by several years beyond the expiration of the original patent. Without some swift reexamination method these patents can effectively extend the patent monopoly by another three to five years.[61] Every day that a drug is protected by improper patents causes serious harms to consumers.

B. Eliminating inter partes review would reward patent abuse

Without inter partes review, promising new generics will be kept from the market, harming millions of citizens and keeping many from accessing needed medications.

The monopoly power of a patent confers huge benefits. Companies do everything they can to retain that power even after the expiration of their original patents, including "seeking and obtaining many patents of questionable validity" and "engaging in frequent and costly patent litigation" for improper purposes.[62] Most relevant here is the technique of evergreening, which is when "brand-name companies patent 'new inventions' that are really just slight modifications of old drugs."[63]

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[61] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 7, at 861.

[62] Engelberg et al., *Balancing Innovation, Access, and Profits*, *supra* note 33.

[63] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASS'N J. E385, E385 (June 11, 2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/.

Consider, for example, the medication Humira (adalimumab), which treats rheumatoid arthritis and other inflammatory conditions. It costs over $50,000/year and is the top selling medication in the world, with approximately $17.6 billion projected sales in 2017.[64]

Humira was first approved by the FDA in 2002.[65] The original patent expired in 2016, and the FDA has already approved a biosimilar (generic) version.[66] Yet the company that owns Humira has acquired a web of over 70 other ancillary patents to protect Humira, the "vast majority" of which it obtained within the last two years before its original patent expired.[67] The company's stated goal is to use these new patents to

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[64] Johnson, *FDA Regulation of Follow-On Biologics*, *supra* note 30, at 1; Amy Brown, Evaluate Grp., *EP Vantage 2017 Preview* 5 (Dec. 2016), *available at* info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[65] U.S. Food & Drug Administration, *FDA Approves Amjevita, a Biosimilar to Humira* (Sept. 23, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm.

[66] *Id*. Humira is a "biologic," which as explained above is a relatively new category of high-priced specialty medications made from living material. *See supra* note 9.

[67] Dan Stanton, *AbbVie: Humira's Patent Maze Will Keep US Biosimilars Away Until at Least 2022*, BioPharma Reporter (Nov. 3, 2015), http://www.biopharma-reporter.com/Markets-Regulations/AbbVie-Humira-s-patent-maze-to-keep-US-biosimilars-at-bay-until-2022; *see also* Andrew Pollack, *New Patents Aim to Delay Generics of Biologics*, N.Y. Times, July 15, 2016, at B1, *available at* https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html?mcubz=1.

extend its monopoly; as AbbVie's CEO told investors on an earnings report conference call, "[a]ny company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate, which AbbVie intends to enforce vigorously. . . . [W]e believe the litigation process and our intellectual property estate will protect Humira from biosimilar entry until 2022."[68]

The follow-on patents AbbVie obtained for Humira include 22 patents for method of treatment (*e.g.*, giving Humira to patients by injection), and 24 patents on different ways to make Humira.[69] The company is attempting to use these patents to "cocoon Humira by tying up competitors in expensive and lengthy court battles."[70] AbbVie already sued a potential competitor for patent infringement, and the district court trial wasn't scheduled to begin until 2019.[71]

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[68] The Street, *AbbVie (ABBV) Earnings Report: Q3 2015 Conference Call Transcript* 11 (Oct. 30, 2015), *available at* https://s.t.st/media/xtranscript/2015/Q4/13346337.pdf.

[69] Stanton, *Humira's Patent Maze*, *supra* note 67.

[70] Kristen Schorsch, *How AbbVie Has Won the Humira Fight—So Far*, Crain's Chicago Business (Nov. 5, 2016), http://www.chicagobusiness.com/article/20161105/ISSUE01/311059994/how-abbvie-has-won-the-humira-fight-so-far. Or, as a recent article put it, "Abbvie has built a thick patent fence around its cash cow." Mari Serebrov, *Amgen-Abbvie Agreement Erases Uncertainty for Humira Biosimilar*, BioWorld, http://www.bioworld.com/content/amgen-abbvie-agreement-erases-uncertainty-humira-biosimilar-0 (last visited Oct. 25, 2017).

[71] The companies just announced a settlement that allows the competitor to sell a biosimilar version in Europe in 2018, but

The long duration of district court litigation is a key part of the strategy of companies seeking ways to protect their expiring patents. As the CEO of AbbVie told investors, "[a]s you evaluate the time frame for a potential US biosimilar market entry, it is important that you consider the legal process and the likely timeline for resolution. While it's always difficult to estimate the precise duration of the litigation process, the average time to trial for a patent action is nearly three and a half years. Appeals to the federal circuit court usually take one year, so based on similar cases, the total litigation timing may be as long as four or five years."[72]

But inter partes review is beginning to whittle down AbbVie's attempt to evergreen Humira. Several competitors have filed inter partes review challenges to AbbVie's ancillary patents for Humira, claiming those follow-on patents were obvious in light of numerous prior sources (including, in some instances, Humira's own 2003 label).[73] Several of these challenges have succeeded, eliminating improper patent

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not enter the U.S. market until 2023. Serebrov, *Amgen-Abbvie Agreement Erases Uncertainty*, *supra* note 70.

[72] The Street, *AbbVie (ABBV) Earnings Report*, *supra* note 68, at 10.

[73] Courtenay C. Brinckerhoff, *Coherus Challenges One AbbVie Humira Patent In Four PTAB Proceedings*, PharmaPatents (July 18, 2017), https://www.pharmapatentsblog.com/2017/07/18/coherus-challenges-abbvie-humira-patent-in-four-ptab-proceedings/.

claims that AbbVie otherwise could have used to block prospective competitors.[74]

This Court has long made clear that "any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws." *Scott Paper Co.*, 326 U.S. at 256. Yet companies with valuable patents are throwing research and development funding into gaining ancillary patents that they can use to "cocoon" their lucrative brand-name drugs even after the original patent expires.

These ancillary patents shield brand-name drugs from potential competition, harming consumers by increasing costs. And as explained below, these improper patents further harm consumers by diverting funds that could otherwise be spent researching and developing potentially beneficial new drugs.

C. Improper patents can stifle competition and deter innovation

In addition to the significant consumer costs imposed by inappropriately issued patents, eliminating inter partes review would chill innovation and undermine the core purpose of the Constitution's Intellectual Property Clause.

As explained above, resources from companies with valuable patents are being directed towards

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[74] Arlene Weintraub, *Key Humira Patent Gets Struck Down for the Second Time in as Many Months*, FiercePharma (July 7, 2017), http://www.fiercepharma.com/legal/key-humira-patent-gets-struck-down-for-second-time-as-many-months.

gaming the patent system rather than true innovation to develop new life-saving medications. Perhaps even more significantly, other scientists may be chilled from innovative research for fear of legal issues created by the invalid patents.

In a survey of clinical laboratory directors, more than half reported deciding not to develop a new clinical genetic test because of concern about an existing patent or license, and a quarter reported that they had stopped performing a genetic test because of a patent or license.[75] Even the "knowledge that a patent application has been filed can influence the decision to spend the time and resources to develop a clinical test because of the uncertain risk that a patent holder will later prevent the laboratory from continuing to provide this service."[76] By contrast, an inter partes review petition "could allow a biosimilar developer to clear blocking patents (or at least determine the strength of patent protection covering the reference

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[75] Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 7 (Feb. 2003), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1907368/#__ffn_sectitle; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (May 1, 1998), *available at* http://science.sciencemag.org/content/280/5364/698.full.

[76] Jon F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 CLINICAL CHEMISTRY 324, 327 (March 1999), *available at* http://clinchem.aaccjnls.org/content/45/3/324.full.

product) earlier in the biosimilar development pathway, before making a major investment in developing a biologic."[77]

Without inter partes review, many challenges to inappropriately-issued patents will be barred by time or money. Resources that could be used for innovation will be devoted to patent gamesmanship, and potential competitors will be blocked from innovation. The American public will bear the higher costs created by these improperly extended patent monopolies.

CONCLUSION

Amicus respectfully urges this Court to affirm the decision of the Federal Circuit and reject the challenges to inter partes review.

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[77] Michael T. Siekman & Oona M. Johnstone, *Impact of Post-Grant Proceedings on Biologics and Biosimilars*, BioProcess International (Jan. 19, 2017), http://www.bioprocessintl.com/business/intellectual-property/impact-of-post-grant-proceedings-biologics-biosimilars/.

Respectfully submitted,

JULIE SIMON MILLER
MICHAEL S. SPECTOR
AMERICA'S HEALTH
INSURANCE PLANS
601 Pennsylvania Ave., NW
Washington, DC 20004

ANNA-ROSE MATHIESON
Counsel of Record
BEN FEUER
CALIFORNIA APPELLATE
LAW GROUP LLP
96 Jessie Street
San Francisco, CA 94105
(415) 649-6700
annarose@calapplaw.com

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