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 *AMICUS CURIAE* MYLAN PHARMACEUTICALS INC. IN SUPPORT OF RESPONDENT GREENE'S ENERGY GROUP, LLC

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INTEREST OF THE *AMICUS CURIAE*[1]

Mylan Pharmaceuticals Inc. ("Mylan") is one of the largest generic and specialty pharmaceutical manufacturers in the world. It is dedicated to providing greater public access to high-quality medicines by bringing lower-priced drugs and biologics to the market. Mylan has fought tirelessly to bring patients the earliest possible access to more affordable medicines. In approximately the last five years alone, Mylan's patent challenges in district courts and through *inter partes* review have allowed consumers to benefit from earlier access to generic competition for more than $35 billion of annual costs of branded drug products. To do so, Mylan has erased more than 285 years of life from invalid patent claims, which should never have issued and would otherwise have continued to block lower-priced competition.

To be sure, the pharmaceutical industry benefits from a patent system designed to fulfill the Constitutional command to "promote the Progress of Science and useful Arts." But the system has become clogged with a glut of patents that fail to meet the statutory standards for patentability, which should never have issued. Pharmaceutical manufacturers have powerful economic incentives to obtain and use

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[1] Per Supreme Court Rule 37.6, Mylan certifies that all parties have consented to this filing through blanket letters of consent. No counsel for any party authored this brief in whole or in part. 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.

these weak patents to maximize their monopolies. Mylan, therefore, often challenges the validity and patentability of weak patent claims before Article III district courts and the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office ("PTO" or "Agency") to invalidate, cancel, or reduce the scope of overly broad claims that unlawfully obstruct the stream of commerce and reduce the public's access to more affordable medicines.

Mylan, like the public at large, shares a vital interest in ensuring patent quality. Accordingly, Mylan has a significant interest in this Court confirming the constitutionality of *inter partes* reviews ("IPRs"). As discussed below, these post-issuance proceedings provide an efficient mechanism for the Agency to reexamine its earlier decision to issue a challenged patent, and to correct its own errors (when appropriate), by canceling unpatentable claims that unlawfully block generic and biosimilar competition.

SUMMARY OF ARGUMENT

Mylan takes no position on whether the rights conferred by an issued patent constitute "public" or "private" rights. Regardless of the decision on that point, the current statutory framework for *inter partes* review complies with both the separation of powers required by Article III of the Constitution and patent-holders' Seventh Amendment rights, for at least the reasons described in Respondents' briefing. (*See* Fed. Resp. Br. at 15-53; Resp. Br. at 26-54). Because the parties and others have

thoroughly briefed the constitutional issues, Mylan submits this brief to illuminate the purpose, benefits, and practical consequences of *inter partes* review in the context of the pharmaceutical industry. As the biopharmaceutical industry's most prolific *inter partes* review petitioner, Mylan has gained considerable experience with the issues surrounding *inter partes* review.

Inter partes review evolved from predecessor post-issuance proceedings (*ex parte* and *inter partes* reexaminations) which similarly allowed the PTO to reassess its earlier patentability decisions and correct mistakes where appropriate. Decades of precedent confirm the sound statutory and constitutional bases for allowing the PTO—as the administrative agency tasked with determining patentability—to continue the examination and reconsider a patent grant in further administrative proceedings. By creating *inter partes* review, Congress sought to improve patent quality, promote innovation, and reduce the number of improperly granted patents deterring or blocking competition.

The outcomes of patent cases litigated to final judgment in the years leading up to the 2011 passage of the America Invents Act ("AIA") demonstrated a need to improve patent quality. Studies suggest that courts had ruled more than half of all patents litigated to final judgment invalid by clear and convincing evidence. These results may be explained in part by the difficult administrative challenge facing the PTO throughout the 1990s and 2000s. During those decades, the demand for patents exploded and Agency resources could not keep pace.

Application backlogs and average pendency times ballooned, creating serious concerns about the PTO's ability to devote sufficient time and resources to ensure issuance of only truly innovative, high-quality patents. In view of the PTO's practical limitations, Congress created *inter partes* review to serve as an efficient and effective mechanism for the PTO to reconsider its prior patentability decisions with input from interested third parties.

Inter partes review plays an important role in the pharmaceutical industry. The statutory framework Congress provided to accelerate approval of generic drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch–Waxman") has worked well in many ways, but the automatic 30-month stay of FDA approval triggered by Hatch-Waxman litigation allows suspect patents to delay lower-priced generic competition regardless of the scope or strength of the patent. As discussed below, generic drug companies have defeated all challenged patents in at least 45% of the Hatch-Waxman cases litigated to final judgment. This statistic highlights the high costs improperly granted pharmaceutical patents impose on consumers and the economy by extending brand monopolies and delaying full and fair competition. It also illustrates the benefits of *inter partes* review, which provides an efficient, effective, and much less costly mechanism for the PTO to reconsider its decisions and cancel patents that should never have issued.

The availability of *inter partes* review may be even more vital to the emerging biosimilar industry, as branded biologics can be covered by hundreds of

patents. Under the Biologics Price Competition and Innovation Act ("BPCIA"), there is no way to determine all patents a branded company believes cover its product until years after the biosimilar company's initial investment, which often exceeds $100 million. *Inter partes* review allows the biosimilar company to challenge suspect patents that potentially cover the branded product before making such a substantial investment, and thus obtain legal certainty earlier in the development process. The availability of these proceedings—which allow limited and focused challenges on a predictable timeline—confers a considerable benefit to those companies, whatever the outcome. Mylan's experiences with *inter partes* review highlight the pro-competitive nature of *inter partes* review.

ARGUMENT

I. *Inter Partes* Review Benefits the Public as a Key Safeguard of a Strong Patent System Intended to Ensure High-Quality Patents and Reward True Innovation.

Congress enacts the laws governing our patent system under the authority granted by Article I of the Constitution to "promote the Progress of Science and useful Arts" (the "Patent Clause"). *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014); U.S. CONST. art. I, § 8, cl. 8. Accordingly, patents confer rights that "exist only by virtue of statute." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 n.5 (1964); *Gayler v. Wilder*, 51 U.S. 477, 494 (1851) (observing that a patent monopoly "is created by the act of Congress; and no rights can be acquired in it unless authorized by statute, and in the manner the statute prescribes").

When crafting and interpreting patent law, Congress and the courts have consistently recognized that granting monopoly rights to so-called "inventions" already known or available to the public imposes considerable social costs, and undermines the Patent Clause's central goal to promote innovation. *See Bonito Boats, Inc. v. Thunder-Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (A monopoly on publicly known information "would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use"); *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from

the public domain, or to restrict free access to materials already available.").

This Court has recognized *inter partes* review as one means for the PTO to promote patent quality, intended to "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, 2135 (2016) (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

The various mechanisms for post-issuance patent review—including *inter partes* review—allow the PTO to check its work, often in light of new information and arguments, and efficiently weed out patents that should never have issued. These proceedings improve patent quality, and promote genuine innovation. In the words of a former PTO Director:

> Patents of the highest quality can help to stimulate and promote efficient licensing, research and development, and future innovation without resorting to needless high-cost court proceedings. Through correctness and clarity, such patents better enable potential users of patented technologies to make informed decisions on how to avoid infringement, whether to seek a license, and/or when to settle or litigate a patent dispute.

Michelle K. Lee, *Enhanced Patent Quality Initiative: Moving Forward*, DIRECTOR'S FORUM: A BLOG FROM USPTO'S LEADERSHIP (Nov. 6, 2015).[2]

When Congress enacted the AIA, various studies of litigation outcomes had shown the need to improve patent quality and the value in providing mechanisms for doing so. A study examining cases decided by the Court of Appeals for the Federal Circuit between 2003 and 2009 found that the court ruled 60% of challenged patents invalid. Ronald J. Mann & Marian Underweiser, *A New Look at Patent Quality: Relating Patent Prosecution to Validity*, 9 J. EMPIRICAL LEGAL STUD. 1, 7 (2012); *see also* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (finding 46% of litigated patents were invalidated).[3] These results and others discussed below indicate that the PTO has issued a substantial number of low-quality patents.

Focusing on the pharmaceutical industry, generic drug companies have successfully litigated to final judgment against at least 220 patents alleged to cover more than 100 branded drugs before federal district courts and the Federal Circuit since passage of the Hatch–Waxman Act. Indeed, since 1989, generic challengers have defeated all blocking patents cover-

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[2] https://www.uspto.gov/blog/director/entry/enhanced_patent_quality_initiative_moving

[3] These patents were ruled invalid despite the statutory presumption of validity and the enhanced evidentiary burden imposed on patent challengers.

ing a branded drug—opening the market to lower-priced generic competition—in at least 45% of Hatch-Waxman cases litigated to final judgment. And those numbers do not include the many more cases resolved by negotiated settlements or other dismissals (most dispositions), which also reflect commercially successful patent challenges by generic manufacturers. The invalidated patents should never have existed or been used to delay lower-priced competition.

Through the 1990s and the first decade of this century, the PTO was faced with significant resource-based challenges. The number of patent applications filed skyrocketed while the PTO's resources did not. These circumstances created an increase in the backlog of pending patent applications, a substantial increase in application pendency times, and led to concerns about the quality of issued patents. *See* Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent & Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 STAN. L. REV. 613, 651 (2015) ("Contemporaneous with this documented decline in the Agency's resource balance is naturally a substantial increase in the Agency's backlog of examinations . . . . While this backlog grew only 14% throughout the first five years of the 1990s, it grew a staggering 114% over the subsequent five years. It then grew a further 190% over the course of the 2000s."); U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL

YEAR 2010 18, 125 (Nov. 9, 2010)[4] (average application pendency of 35.3 months and a backlog of 726,331 applications in FY 2010); Jason D. Grier, *Chasing Its Own Tail? An Analysis of the U.S.P.T.O.'s Efforts to Reduce the Patent Backlog*, 31 HOUSTON J. INT'L L. 617, 626-27 (2009) ("[T]he tremendous demand for patents has swamped the limited resources of the USPTO, even with the hiring of more examiners. As a result, the USPTO faces a backlog of over 700,000 patent applications. This backlog has lengthened pendency . . . to an average of 31.3 months . . . . Both the backlog and pendency problem threaten the quality of patents and burden the courts with litigation over bad patents."). As the problems worsened with no resolution in sight, the need for significant reforms and additional Agency resources became clear.

After years of legislative wrangling, Congress created the current *inter partes* review system as one of the patent reform measures in the AIA. Among other things, *inter partes* review allows the PTO to efficiently revisit its initial patentability determination in proceedings strictly limited in scope and duration. Petitioners may challenge patentability only on anticipation (35 U.S.C. § 102) and/or obviousness (35 U.S.C. § 103) grounds, based only on prior art patents or other printed publications, and the reviews have strict deadlines requiring a decision within 18-24 months of the

[4] https://www.uspto.gov/sites/default/files/about/stratplan/ar/USPTOFY2010PAR.pdf

petition's filing date. 35 U.S.C. §§ 311(b), 314(b), 316(a)(11).

The public benefits from *inter partes* review as part of the statutory and regulatory framework designed by Congress to enhance patent quality and reward true innovation. H.R. REP. NO. 112-98, pt. 1, at 48 (2011) (Congress sought to provide "a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.").

II. Congress Created *Inter Partes* Review to Allow the PTO to Reconsider its Prior Administrative Decisions.

This Court has recognized *inter partes* review as a specialized agency proceeding having a purpose and procedures different from district court litigation. *Cuozzo*, 136 S. Ct. at 2143. In doing so, the Court rejected an argument that *inter partes* review was intended to establish trial-like procedures to adjudicate patentability. *Id.* at 2135. The Court observed:

> The name and accompanying procedures suggest that the proceeding ***offers a second look at an earlier administrative grant of a patent***. Although Congress changed the name from "reexamination" to "review," nothing convinces us that, in doing so, Congress wanted to change its basic purposes, namely, ***to reexamine an earlier agency decision***.

Id. at 2144 (discussing Congress' changes to the then-existing *inter partes* reexamination to create *inter partes* review under the AIA) (emphasis added).

Thus, *inter partes* review allows the Agency to revisit and reassess patents it may have issued in error in order to fulfill Congress' stated goal to "screen out bad patents while bolstering valid ones." 157 CONG. REC. H4220, H4425 (June 22, 2011) (remarks of Rep. Goodlatte). If the PTAB determines the challenged claims are patentable, it confirms the Agency's initial patentability decision, rejecting the asserted significance of prior art and arguments raised during the *inter partes* review. But if the PTAB finds some or all issued claims unpatentable, the Agency efficiently corrects its mistake by cancelling those that do not meet the statutory standards for genuine innovation. As described below, these PTAB decisions fall within the continued patent examination process conducted by the PTO—a specialized agency responsible for evaluating patent applications and only issuing patents that meet those standards.

A. The PTO First Assesses Patentability and Examines Applications *Ex Parte*, with Limited Resources.

Pursuant to its authority under the Patent Clause, Congress created the PTO as an agency with "special expertise in evaluating patent applications," with authority to issue a patent only if "it appears that the applicant is entitled to a patent" under federal law, which includes requirements for novelty and nonobviousness. *Kappos v. Hyatt*, 566 U.S. 431,

445 (2012); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95-96 (2011); 35 U.S.C. §§ 102, 103, 131.

After the Agency receives a patent application, an examiner analyzes the claimed inventions against the prior art in the relevant fields to decide whether the claims meet the statutory requirements for patentability. *Cuozzo*, 136 S. Ct. at 2136-37; *Graham*, 383 U.S. at 18 (recognizing that the "Patent Office is confronted with the most difficult task" because "the primary responsibility for sifting out unpatentable material lies in the Patent Office"); *see also* 35 U.S.C. § 131; 37 C.F.R. § 1.104(a)(1). The applicant and the PTO engage in a series of *ex parte* exchanges which culminate in the Agency decision to allow or reject the application.

If the examiner determines a proposed claim is unpatentable, the examiner rejects that claim and explains the rejection in an office action. 35 U.S.C. § 132(a). The applicant may then amend the claims, submit arguments to explain why the invention actually differs from the prior art, or both. 35 U.S.C. § 132(a); 37 C.F.R. § 1.111(b), (c). If the PTO issues a final rejection, the applicant has a statutory right to judicial review. *Cuozzo*, 136 S. Ct. at 1237; *Kappos*, 566 U.S. at 434; *see also* 35 U.S.C. §§ 141(a), 145.

During the initial examination, only the PTO and the applicant can participate; there are no established procedures for an interested third party to take part. Further, there is no mechanism, either through the PTO or in court, for a third party to appeal a patentability determination before patent issuance. Since there is no party adverse to the

applicant during the initial examination, the examiner provides the only counterbalance to the applicant's patentability assertions. And as a practical matter, patent examiners face a tremendous volume of new applications each year, which has led to a huge backlog of pending applications.[5] The resulting institutional pressures and Agency productivity metrics severely limit the time and resources each examiner can devote to any one application. The reality is that patent examiners must make decisions in a very short amount of time, often without the complete set of information necessary for a thorough analysis. *See generally* Shine Tu, *Patent Examiners and Litigation Outcomes*, 17 STAN. TECH. L. REV. 507, 516 (2014); FED. TRADE COMM'N, *Competition Perspectives on How Procedures and Presumptions Affect Patent Quality* in TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 9 (Oct. 2003) ("FTC 2003").

A recent study reported that on average "an examiner spends only nineteen (19) hours reviewing an application, including reading the patent application, searching for prior art, comparing the prior art with the patent application, writing a

[5] While the application backlog and average pendency times have declined in recent years, they remain a significant problem for the Agency and the patent system. *See* U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2016 3, 61 (Nov. 14, 2016), https://www.uspto.gov/sites/default/files/documents/USPTOFY16PAR.pdf. (showing average application pendency of 25.3 months and a backlog of 537,655 applications in FY 2016).

rejection, responding to the patent applicant's arguments, and often conducting an interview with the applicant's attorney." Michael D. Frakes & Melissa F. Wasserman, *Is The Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, NW. L. & ECON. RES., PAPER NO. 14-16 (July 18, 2014) ("Frakes 2014"). Moreover, it is commonly known that "the great weight of the case law . . . stands for the proposition that while an inventor must disclose all material information to the patent examiner, he is not required to make sure the patent examiner understands that information." *Nevro Corp. v. Boston Sci. Corp.*, No. 16-cv-06830, slip op. at 2 (N.D. Cal. Oct. 4, 2017).

PTO examiners work under a quota system which assigns a set standard number of hours within which a patent examination should be completed. UNITED STATES PATENT AND TRADEMARK OFFICE, *Examination Time and the Production System* (2016).[6] The Agency uses this performance metric system to assess annual evaluations, retention, and bonuses. PATENT OFFICE PROFESSIONAL ASS'N, *Changes to the Patent Examiner Performance Appraisal Plan, Extension of the Pendency Award, Renewal of the Count System Initiatives, and Other Issues* (June 18, 2015).[7] As a result, the examiner

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[6] https://www.uspto.gov/sites/default/files/docments/Examination%20Time%20and%20the%20Production%20System.pdf (link published at 81 Fed. Reg. 73,383, 73,384 (Oct. 25, 2016))

[7] http://www.popa.org/static/media/uploads/uploads/CSI_PendencyAward_2016PAP_Agreement.pdf

stands at a significant disadvantage when facing a motivated, well-resourced applicant; the Agency's limited review sometimes results in issued patents failing to meet patentability requirements. *See* Frakes 2014 at 14-16.

Because of these time and resource constraints, examiners have only limited ability to locate the most relevant prior art, which may include U.S. patents, foreign patents, patent applications, and non-patent literature published anywhere in the world, in any language, before the priority date at issue. Indeed, on average, the initial examination includes less than eight hours of searches for prior art. U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-479, INTELLECTUAL PROPERTY: PATENT OFFICE SHOULD STRENGTHEN SEARCH CAPABILITIES AND BETTER MONITOR EXAMINERS' WORK 55 (June 2016); *see also id.* at Appendix III (Tbl. 12) (wherein examiners in the biotechnology and organic chemistry technology office reported only spending on average 5.2 hours per prior art search). Therefore, the most relevant prior art is often not identified until after the patent issues, when would-be competitors and other third parties unable to participate in the initial examination can evaluate the issued patent and the scope of its claims. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (observing that "the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity."). Those third parties and would-be competitors know the industry's history and technology—likely to a greater extent than the

examiner—and have incentives, economic and otherwise, to invest resources in a prior art search more extensive and complete than the Agency could reasonably conduct.

In sum, Congress has tasked the PTO with broad and critically important responsibilities to evaluate applications and determine patentability. But the *ex parte* structure of initial examination creates an asymmetry of time and resources biasing the examination process towards issuing patents, even invalid ones. *See* Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?,* 58 EMORY L. J. 181, 193 (2008) (calculating a patent grant rate between 72% and 76% as of April 2008); FTC 2003 at 6 ("[T]he PTO's grant rate, defined in terms of applications allowed as a percentage of application disposals, reached 98% in 2000, considerably higher than in Europe (67%) and Japan (64%)."); Cecil D. Quillen, Jr., et al., *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office – Extended*, 12 FED. CIR. B. J. 35, 38 (2002) (calculating an 85% grant rate). Various studies use different definitions to reach different conclusions on the precise patent grant rate, but none dispute the heavy administrative burden on the PTO's limited resources. Due at least in part to the Agency's constrained resources and individual examiners' heavy workloads, mistakes inevitably happen and ineligible claims are allowed.

B. *Inter Partes* Review, Like Other Post-Issuance Proceedings, Exercises the PTO's Clear and Broad Responsibility to Examine Patentability.

The PTO not only possesses legal authority to grant patents, but for nearly 40 years has had the authority to review patents that may have been issued in error. *Cuozzo*, 136 S. Ct. at 2137 ("For several decades, the [PTO] has also possessed the authority to reexamine—and perhaps cancel—a patent claim that it had previously allowed.").

Interested third parties have long been able to petition the PTO to request further examination of an issued patent through *ex parte* and *inter partes* reexamination. *Cuozzo*, 136 S. Ct. at 2137. These petitions were accompanied by patents or printed publications alleged to show a substantial new question of patentability which could cause the PTO to cancel the patent (or certain claims). These petitions often identified prior art not considered during the initial examination.

Congress first authorized post-issuance proceedings allowing the Agency to revisit patentability decisions in 1980 (*ex parte* reexamination). *See* Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 301-307). Any party can challenge the patentability of an issued patent by notifying the PTO of prior art "bearing on the patentability of any claim of [the] patent." 35 U.S.C. §§ 301(a)(1), 302. The requesters, however, cannot participate after filing the request, having no right to

present additional evidence or respond to statements by the patent owner or Agency. As during initial examination, the patent owner may seek judicial review of an adverse *ex parte* reexamination decision, but a third party petitioner has no right to appeal an Agency decision confirming patentability. 35 U.S.C. § 306.

In 1999, Congress created *inter partes* reexamination (since superseded by *inter partes* review) to give third parties a greater role in identifying erroneously issued patents. *See* American Inventors Protection Act, Pub. L. No. 106-113, Div. B. § 1000(a)(9), 113 Stat. 1536, 1501A–567 (Sec. 4604(a)) (codified as amended at 35 U.S.C. §§ 311-318 (2006)). This statute permitted third party requestors to participate in the PTO's reexamination by filing "comments" and supporting declarations after any patent owner response to their request. 35 U.S.C. §§ 314, 315 (2000). After 2002, the requester also had the right to participate in any appeal. *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1332 (Fed. Cir. 2008). But *inter partes* reexamination still provided no discovery or cross-examination of declarants.

It eventually became clear that *inter partes* reexaminations were rarely used, in part because of the long and unpredictable timeframes to resolution. On average, an *inter partes* reexamination took roughly thirty-six months from filing through certificate issue date—with even more time lapsing if the patentholder appealed an adverse decision. UNITED STATES

PATENT & TRADEMARK OFFICE, INTER PARTES REEXAMINATION FILING DATA (Mar. 31, 2010)[8]; *see also* Alison J. Baldwin & Aaron V. Gin, *Inter Partes Review and Inter Partes Reexamination: More Than Just a Name Change*, 11 SNIPPETS 11, 11-12 (2013) (noting it "took an average of three years to reach a final decision that could be appealed to the Court of Appeals for the Federal Circuit"). Moreover, no law or regulation sets deadlines for the PTO to conclude an *inter partes* reexamination. Simply put, those proceedings proved to be an ineffective and inefficient way to challenge the patentability of issued claims with no predictable timeline.

Against this backdrop, Congress in 2011 modified (and renamed) *inter partes* reexamination to create *inter partes* review, thereby designing a faster, more efficient proceeding to examine the same questions of patentability. *Cuozzo*, 136 S. Ct. at 2137; 157 CONG. REC. S5347, S5375 (Sept. 7, 2011) (*inter partes* reviews are "hardly novel but rather are based on longstanding procedures established by Congress and repeatedly recognized as constitutional by the Federal Circuit"). In doing so, Congress sought to strike an appropriate Constitutional balance:

> One manner in which Congress has fulfilled this mandate to strike the proper balance is through the existing reexamination procedures, which provide a mechanism for removing

[8] http://www.ptolitigationcenter.com/wp-content/uploads/2010/02/2010-03-31-Inter-Partes.pdf

> patents that should never have been granted by the PTO because they did not meet the requirements for a valid patent set by Congress in the Patent Act. As the Federal Circuit has observed, "[t]he reexamination statute's purpose is to correct errors made by the government, to remedy defective governmental (not private) action, and if need be to remove patents that should never have been granted." A determination that a patent should never have been granted is no more a "taking" than is a determination that a putative landowner suffers a defect in title.

157 CONG. REC. S5347, S5375 (Sept. 7, 2011) (quoting *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 604 (Fed. Cir. 1985)).

Similar to *inter partes* reexamination, an *inter partes* review begins with a third party petition challenging patentability for lack of novelty (anticipation) or obviousness, based on prior art patents or printed publications. 35 U.S.C. §§ 311(b), 312(a). Anyone can petition for *inter partes* review, but a party sued for patent infringement must file any petition against the asserted patent(s) within a year. 35 U.S.C. §§ 311(a), 315(b).

The patent owner may file a response within three months of the filing date the PTO accords to the petition, 35 U.S.C. § 313, and within another three months, the PTAB must decide whether there

is a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(b).

If the PTAB institutes an *inter partes* review, the proceedings continue on a strict schedule with limited opportunities for either party to supplement their original filings with additional evidence or arguments. 37 C.F.R. § 42.123. Discovery is restricted by statute and regulation, and generally limited to deposing witnesses who submitted declarations. 35 U.S.C. § 316(a)(5); 37 C.F.R. § 42.51(b). The statute also allows patent owners to move to amend the challenged claims. 35 U.S.C. § 316(d).

The statute requires the PTAB to complete an *inter partes* review within 12-18 months of institution—half the average time for an *inter partes* reexamination. 35 U.S.C. § 316(a)(11). The PTAB's final decision is reviewable by the Court of Appeals for the Federal Circuit. 35 U.S.C. § 319. An adverse decision estops the unsuccessful challenger from relying in later litigation on prior art that it "raised or reasonably could have raised" in the *inter partes* review. 35 U.S.C. § 315(e).[9]

Inter partes reviews offer many advantages over *inter partes* reexaminations. As to timing, the proceedings move much more quickly. Further, *inter partes* reviews are overseen by a panel of at least

[9] Courts are still considering the precise scope of estoppel under 35 U.S.C. § 315(e).

three PTAB members—senior personnel required by law to be qualified in both "legal knowledge and scientific ability"—while *inter partes* reexaminations were overseen by a lone examiner from the same technology unit which performed the initial examination. 35 U.S.C. § 6. Finally, *inter partes* review allows more information and argument from diverse voices to come before the PTAB to inform its patentability analysis.

The evolution of *inter partes* review from longstanding reexamination procedures shows that, like other post-issuance proceedings, *inter partes* review operates as a continued examination of an issued patent, allowing the PTO to continue to exercise its broad authority to evaluate patentability. The agency entrusted by Congress to make patentability determinations should also have the right to review and correct its own mistakes if appropriate.

C. Continued Agency Examination in *Inter Partes* Review Differs in Purpose and Function From Litigation in Article III Courts.

Patent litigation in Article III courts typically involves claims, defenses, and other legal issues which cannot be heard within the narrower confines of an *inter partes* review. These include, among others, infringement, invalidity for reasons other than anticipation or obviousness based on prior art publications (*e.g.*, prior public use, prior public knowledge or offers for sale, lack of written description, lack of enablement, lack of utility, or improper inventorship

under 35 U.S.C. §§ 101, 102, 112, 256), unenforceability due to inequitable conduct, other equitable defenses, damages, and the propriety of an injunction. By contrast, the AIA limits *inter partes* reviews to evaluating patentability under 35 U.S.C. §§ 102 (anticipation) and 103 (obviousness) based solely on printed prior art—the same limitations imposed on *inter partes* and *ex parte* reexaminations.

Beyond the radically different scope of the proceedings, the different standards applied show their different purposes. *See In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008) ("'reexamination[s are] conducted according to the procedures established for initial examination,' 35 U.S.C. § 305, and PTO examination procedures have distinctly different standards, parties, purposes, and outcomes compared to civil litigation.") (quoting *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985)). As in reexaminations, the PTAB applies the same burdens of proof, presumptions, and claim construction standards during *inter partes* reviews as during the initial examination; consistent with their function as continued examination.

In district courts, patents are presumed valid, with clear and convincing evidence required to prove otherwise, whereas in *inter partes* review the petitioner has "the burden of proving a proposition of unpatentability by a preponderance of the evidence." *Cuozzo*, 136 S. Ct. at 2144 (comparing 35 U.S.C. § 316(e) with *Microsoft*, 564 U.S. at 95). The presumption of validity and heightened evidentiary standard in litigation arise from deference to the

PTO's specialized expertise. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (courts presume validity because "the PTO, in its expertise, has approved the claim"). But deference to administrative expertise is not an issue during initial examination, reexamination, or *inter partes* review when the Agency reviews its own work to correct its own mistakes.

Similarly, construing claims using the broadest reasonable interpretation standard during initial examination, reexaminations, and *inter partes* reviews reflects the PTO's statutory role as the gatekeeper of patentability:

> [T]he broadest reasonable interpretation standard increases the possibility that the examiner will find the claim too broad (and deny it), use of that standard encourages the applicant to draft narrowly. This helps ensure precision while avoiding overly broad claims, and thereby helps prevent a patent from tying up too much knowledge, while helping members of the public draw useful information from the disclosed invention and better understand the lawful limits of the claim.

Cuozzo, 136 S. Ct. at 2144-45 (citing *Nautilus*, 134 S. Ct. at 2129; *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)).

The patent owner's opportunity to amend challenged claims during *inter partes* review also shows that the Agency continues to examine patentability. 35 U.S.C. § 316(d) (patent owners may file one motion to amend as of right, and the PTAB has discretion to allow others). In district court proceedings, by contrast, the patent claims are fixed, and courts may not modify them. *See Hill-Ram Servs. v. Stryker Corp.*, 755 F.3d 1367, 1374 (Fed. Cir. 2014) ("claim terms . . . cannot be rewritten by courts to save their validity"); *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("We have also admonished against judicial rewriting of claims to preserve validity.").

Congress also granted the Agency the discretion to continue *inter partes* reviews under certain circumstances even after the original petitioner settles and drops out. *See Cuozzo*, 136 S. Ct. at 2140; 35 U.S.C. § 317(a). District court cases terminate when the parties settle. Congress' decision to allow the Agency to correct its mistakes even without the interested third party petitioner shows Congress viewed *inter partes* review primarily as continued examination in the public interest, rather than a dispute between two private parties.

D. *Inter Partes* Review Does Not Preclude Adjudication By Article III District Courts.

Petitioner argues that *inter partes* review extinguishes patent rights without access to Article III courts, and allows third parties to remove patent

challenges from Article III courts without the patent owners' consent. (*See* Pet. Br. at 2, 17, 41). Not so.

First, all final written decisions from *inter partes* review may be appealed to the Court of Appeals for the Federal Circuit, an Article III Court.[10] 35 U.S.C. §§ 318(a), 319. During the appeal, the court reviews "the PTAB's factual findings for substantial evidence and its legal conclusions *de novo*." *Novartis AG v. Noven Pharm. Inc.*, 853 F.3d 1289, 1291 (Fed. Cir. 2017) (quoting *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015)).

Second, *inter partes* reviews do not bar a patent owner from filing or continuing to litigate a parallel infringement suit in district court. In Mylan's experience, most *inter partes* reviews are initiated while district court litigation is ongoing, and patent owners continue to litigate even patents the PTAB rules unpatentable until the Federal Circuit resolves the appeal. Further, neither filing an *inter partes* review petition, nor the institution of a petition for review, automatically stays a district court litigation involving the same patent—patent owners are free to advocate for concurrent proceedings.

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[10] As an administrative proceeding, *inter partes* reviews do not include a jury. But jury trials are also unavailable in many district court patent infringement cases. For example, cases brought under Hatch-Waxman or BPCIA typically do not involve juries because only equitable remedies are at issue. *In re Apotex, Inc.*, 49 F. App'x 902, 903 (Fed. Cir. 2002) (holding that a generic drug manufacturer is not entitled to a jury where only equitable remedies are at issue).

Third, as noted above, estoppel prevents any unsuccessful *inter partes* review challenger from relying on prior art in district court litigation that the challenger raised or reasonably could have raised in the *inter partes* review. 35 U.S.C. § 315(e). Thus, any party filing a petition for *inter partes* review must consider its potential estoppel effect. If the PTAB affirms patentability over the prior art raised in the *inter partes* review, the patent owner lands in a more favorable position than before the review.

Petitioner is wrong to claim that *inter partes* review bars patent owners' access to Article III courts or meaningful Article III review.

III. Mylan's Experience Confirms *Inter Partes* Reviews are an Important Tool to Promote Patent Quality and Competition in the Pharmaceutical Industry.

Inter partes reviews, either as stand-alone actions or in conjunction with district court litigation, have become increasingly common in the pharmaceutical industry and play an important role in business and legal strategy. Pharmaceutical companies often use *inter partes* review to secure patent certainty during the early stages of developing a small-molecule or biologic product, occasionally before any suit and sometimes even before filing a product application. The availability of *inter partes* review is important to corporate decision-making. This administrative process operates within a strict, statutorily-mandated timeframe, which provides the legal certainty necessary for product development decisions, potentially expediting the introduction of

life-saving medicines. Indeed, the patent certainty provided by *inter partes* review has great value even if the Agency confirms patentability.[11]

Nearly every branded drug or biologic product is covered by multiple patents which a potential competitor must assess (and perhaps challenge) on a patent-by-patent, or even claim-by-claim, basis. Given the thicket of patents often purporting to protect a brand monopoly, a company usually cannot launch a generic pharmaceutical or biosimilar product simply because it obtains a ruling that a single patent or patent claim is unpatentable or invalid. *Inter partes* reviews allow companies to present focused challenges to individual patents (or claims) they believe were improperly granted, and are often used along with Article III litigation.

More specifically, generic and biosimilar companies (like all potential accused infringers) benefit from the availability of both *inter partes* review and district court litigation because there may be strong defenses to certain patents which can only be heard and resolved by a district court (*e.g.*, non-infringement, § 112 invalidity, §§ 102 or 103 invalidity defenses not based on written prior art, and equitable defenses). At the same time, strong claims of unpatentability under §§ 102 or 103 based

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[11] Patent certainty and resulting projected market entry dates are crucial to the pharmaceutical industry; companies use this valuable information in earnings forecasts, and to make budget allocations, manufacturing bandwidth preparations, and pipeline development decisions.

on written prior art are well-suited for the continued examination provided by *inter partes* review, where the PTAB's technical expertise allows for efficient reconsideration of the Agency's patentability decision. Eliminating *inter partes* review would force pharmaceutical companies to forgo an efficient, focused vehicle to challenge patentability with no corresponding societal benefit—while stifling lower-priced competition.

A. *Inter Partes* Reviews Help Promote Generic and Biosimilar Competition by Weeding Out Improperly Granted Patents.

Branded drug companies employ many strategies to maximize their patent protection and extend the commercial lifecycle for franchise products. For example, in a process known as "evergreening," a company seeks to extend its market monopoly by obtaining patent coverage for even the most minor changes to a known and patented product. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECONOMICS 327, 327-28 (2012). Despite the questionable patentability of many of these later-issued, later-expiring patents, they frequently delay generic competition under the Hatch-Waxman Act or the BPCIA.

Available statistics show that competitors typically target precisely such follow-on patents for *inter partes* review. Nearly three-quarters of all *inter partes* review petitions related to biologic products challenge method-of-treatment (49%) or formulation

(24%) patents, which are often considered less innovative than the underlying composition-of-matter patents. John Molenda & Richard Praseuth, *Current Trends in Biologics-Related Inter Partes Reviews*, Law360 (July 20, 2017).[12] Formulation, dosing, and indication patents also comprise the overwhelming majority of small-molecule patents challenged in *inter partes* review. *See* IPD ANALYTICS, LLC, *Updated IPR Statistics In the Pharmaceutical Sector*, 9 (Apr. 29, 2016).

Moreover, not only do generic drug and biosimilar companies use *inter partes* review—many historically branded companies have petitioned for review of patents owned by competitors. Just like their generic and biosimilar counterparts, branded companies use *inter partes* review to challenge patents of questionable patentability that may block new or competitive products and impede the availability of life-saving medicines. *Inter partes* reviews have become an important tool used by the pharmaceutical industry to challenge patents which the PTO never should have issued.

1. *Inter Partes* Review Allows Generics To Challenge Patents That Could Unlawfully Delay Competition Under The Hatch-Waxman Act.

To obtain approval for a new drug, a branded pharmaceutical company must submit a New Drug

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[12] https://www.law360.com/articles/942459/current-trends-in-biologics-related-inter-partes-reviews

Application ("NDA") to the Food and Drug Administration ("FDA") showing the safety and efficacy of its proposed product. *See* 21 U.S.C. § 355(b)(1). The NDA-holder must also submit information to FDA concerning any patent it asserts "claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1); *see also* 21 U.S.C. § 355(c)(2). After approving an NDA, FDA publishes the related patent information in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). *See* 21 C.F.R. § 314.53(e). When listing these patents, FDA operates in a purely ministerial role, making no determination as to the scope or validity of the patent, but instead, relying wholly on the NDA holder to accurately provide patent information. *Apotex Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (noting that 21 C.F.R. § 314.53(f) "codifies FDA's position that its duties with respect to Orange Book listings are purely ministerial.").

Under the Hatch-Waxman Act, to obtain FDA approval to market a generic version of a brand-name drug product, an applicant must file an Abbreviated New Drug Application (ANDA). The ANDA must contain a "certification" to any patent information listed in FDA's Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The Hatch-Waxman Act provides four certification options, including the "paragraph IV certification" which indicates the ANDA-filer seeks immediate approval and asserts the subject patent is invalid, not enforceable, and/or will not be infringed by the proposed generic drug

product or its approved use. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Thus, an ANDA applicant seeking FDA approval before an Orange-Book listed patent expires generally must submit a paragraph IV certification. Submitting an ANDA containing a paragraph IV certification constitutes a technical act of infringement, and grants the district courts subject matter jurisdiction over a resulting patent infringement suit. *See* 35 U.S.C. § 271(e)(2)(A).

Branded pharmaceutical companies almost always sue for patent infringement under the Hatch-Waxman Act in response to a paragraph IV ANDA filing. 21 U.S.C. § 355. If the brand files suit within the statutory window, FDA may not grant final approval to the applicant's ANDA for 30 months unless the district court holds the patent invalid or not infringed before that stay expires. *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013); 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Since FDA does not review the merits of the patent information the brands provide, the statutory mechanisms unique to the Hatch-Waxman Act allow brand pharmaceutical companies to automatically block generic competition for up to 30 months by merely listing a patent in the Orange Book and then suing over a paragraph IV certification, ***regardless of the strength or scope of the listed patent.*** Brand companies have every incentive to maximize the benefits of the automatic 30 month stay by delaying the district court litigation and suing in slower jurisdictions. The generic competitors have correspondingly strong interests in resolving patent issues

as quickly as possible. *Inter partes* review provides precisely such a means to challenge the patentability of Orange Book patents comparatively quickly and efficiently, either before or during Hatch-Waxman litigation.

Importantly, generic companies can also use *inter partes* review to challenge patents purportedly covering a branded product which cannot be listed in the Orange Book, including patents claiming methods of manufacture, product packaging, or process intermediates. *Inter partes* review provides a narrowly-focused mechanism to efficiently address the patentability of such patents which are outside the scope of the Hatch-Waxman framework and cannot be litigated until after the FDA approves the generic product.

2. *Inter Partes* Review Also Allows Biosimilar Applicants To Clear The Patent Thicket.

Similar to the Hatch-Waxman Act, the BPCIA provides an abbreviated pathway for FDA approval of biosimilar products referencing licensed biologics. 42 U.S.C. § 262(k). The BPCIA "also provides procedures for resolving patent disputes between biosimilar manufacturers (applicants) and manufacturers of reference products (sponsors)." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1666 (2017). Under the BPCIA, submitting a biosimilar application is an act of "artificial infringement," which allows the reference product sponsor and biosimilar applicant to liti-

gate patent disputes. *Sandoz*, 137 S. Ct. at 1666 (citing 35 U.S.C. § 271(e)(2)(C)(i), (ii)).

Biologics are complex products that may be protected by hundreds of patents covering at least the "biologic, its therapeutic uses, and the processes used to manufacture it." *Sandoz*, 137 S. Ct. at 1670. A biosimilar applicant on average spends "7 to 8 years to develop a biosimilar, at a cost of between $100 million and $250 million." Erwin A. Blackstone, Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH DRUG BENEFITS 469, 471 (2013) (compared to the average cost of $1 million to $4 million to develop a small molecule generic).

Moreover, unlike small molecule drugs regulated under the Hatch-Waxman Act, there is no corresponding Orange Book listing for biologics, making it harder for a biosimilar applicant to identify patents the reference product sponsor believes cover its product. Indeed, under the BPCIA, a biosimilar applicant may not actually know which patents the reference product sponsor believes it can assert until years after the applicant's initial investment, when the parties exchange information to negotiate which patents to litigate and when. *See generally Sandoz*, 137 S. Ct. at 1671-72. *Inter partes* review can alleviate this delay. Unlike district court challenges, an *inter partes* review petitioner need not have Article III standing, which enables petitioners to challenge blocking patents well before they could otherwise do so in district courts. *Inter partes* reviews provide a valuable mechanism for biosimilar companies to make early challenges to key patents and obtain le-

gal certainty earlier in the development process to help guide their investment decisions.

B. Mylan's *Inter Partes* Review Petitions Have Resulted in the PTO Canceling Improperly Issued Patents, and Potential Earlier Entry of Lower Cost Generic and Biosimilar Products.

To expedite public access to more affordable generic and biosimilar medicines, generic drug companies challenge many patents purportedly protecting branded drugs and biologics from competition. Mylan has effectively used *inter partes* review, often in conjunction with district court litigation, to challenge weak blocking patents. In many cases, Mylan has identified relevant and invalidating prior art never previously before the patent examiner.

Mylan participates in more *inter partes* reviews than any of its pharmaceutical competitors. Among the 25 largest biopharmaceutical companies (calculated by 2016 Rx Sales),[13] Mylan has filed 88 petitions for *inter partes* review, as compared to 50 petitions by the next closest company. Mylan has used *inter partes* review as a critical tool in its development strategy and mission to provide more affordable medicines, challenging patents covering 37 different drug products. Mylan continually

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[13] *See* Michael Christel, *Pharm Exec's Top 50 Companies 2017*, 37 PHARMACEUTICAL EXECUTIVE (June 28, 2017), http://www.pharmexec.com/pharm-execs-top-50-companies-2017.

analyzes additional drug products and biologics for potential future *inter partes* review challenges.

When assessing which patents to challenge via *inter partes* review, Mylan selectively targets improperly granted, overbroad patents where cancellation could allow earlier market entry of low-cost generic drugs and biosimilar products. As just one example, Mylan and other petitioners recently prevailed before the PTAB in IPR2016-00297, in which the PTAB ruled unpatentable an Orange Book patent covering APRISO® (mesalamine) Capsules which expires 12 years after any other listed APRISO® patent. *See GeneriCo, LLC v. Dr. Falk Pharma GmbH*, IPR2016-00297 (P.T.A.B. May 19, 2017) (holding challenged claims of U.S. Patent No. 8,863,688 unpatentable, which expires May 1, 2030).[14] Exercising its right to Article III review, the patent owner appealed the PTAB's decision to the Federal Circuit. *Dr. Falk Pharma GmbH v. GeneriCo, LLC*, No. 17-2312 (Fed. Cir.). If the Federal Circuit upholds the PTAB decision, Mylan's petition will have erased 12 years of improperly granted patent protection for a drug with almost $150 million in annual revenues, ultimately saving consumers hundreds of millions of dollars. VALEANT

[14] Mylan also recently won a non-infringement verdict in the parallel district court litigation. *Salix Pharm., Inc. v. Mylan Pharm. Inc.*, No. 15-cv-00109-IMK (N.D.W. Va.), D.I. 256 – Sept. 12, 2017 Judgment (the parties stipulated to dismiss claims regarding '688 patent invalidity after the PTAB's unpatentability decision, before the court tried validity).

PHARMS. INT'L, INC., *4Q and FY 2016 Financial Results* at 27 (Feb. 28, 2017).[15]

The strength of arguments included in an *inter partes* review petition can also provide useful settlement leverage leading to a negotiated market entry date for a generic or biosimilar product earlier than would otherwise have been possible. This pro-competitive benefit of *inter partes* review was not available prior to the AIA because *inter partes* and *ex parte* reexaminations could not be terminated by settlement. *See, e.g.*, David Holt & Karl Renner, *Settlement Doesn't Guarantee End of Post-Grant Proceeding*, Law360 (Feb. 14, 2014)[16] (noting that settlement was not an option before because pre-AIA reexaminations were often continued by the reviewer, even after the third-party requester had dropped out of the proceeding).

Several other Mylan *inter partes* review challenges have resulted in favorable settlements allowing Mylan to cumulatively shave decades off patent life with corresponding benefit to consumers. Such results appear to be consistent across the industry; nearly 22% (44/204) of all *inter partes* review petitions filed by generic drug companies have resulted in settlement, presumably granting an earlier-than-patent-expiry market entry date. *See* Stephen B. Maebius & Wenhua Yu, *Key Trends in*

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[15] http://ir.valeant.com/~/media/Files/V/Valeant-IR/reports-and-presentations/q4-fy2016-vrx-02282017-v1.pdf

[16] https://www.law360.com/ip/articles/507081/settlement-does n-t-guarantee-end-of-post-grant-proceeding

Pharmaceutical IPRs Filed by Generic Petitioners, PTAB Trial Insights (May 15, 2017).[17]

In sum, *inter partes* review provides a valuable administrative mechanism for the PTO to reconsider its patentability decisions. These proceedings are consistent with the underlying goals of the Hatch-Waxman Act and the BPCIA by leading to the cancellation of improperly granted patents that unlawfully delay lower-priced generic and biosimilar competition. Eliminating *inter partes* review would have significant anti-competitive effects in the pharmaceutical industry.

CONCLUSION

Inter partes review, like other post-issuance proceedings, operates as continued examination under the PTO's broad responsibility to assess patentability and issue lawful patents. Decades of precedent affirm the PTO's authority to review and correct its own mistakes. *Inter partes* review plays a particularly important role in the pharmaceutical industry, where dubious patents can automatically delay full and fair competition, thereby blocking public access to lower-priced generic and biosimilar medications. *Inter partes* review is a constitutional and efficient administrative means to promote genuine innovation.

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[17] https://www.ptabtrialinsights.com/2017/05/keytrends-in-pharmaceutical-iprs-filed-by-generic-petitioners

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