



Yale Journal of Health Policy, Law, and Ethics

Volume 19 | Issue 1

Article 3

Battling Over Patents: The Impact of Oil States on the Generic Drug Industry

Jonathan J. Darrow

S.J.D., LL.M., J.D., M.B.A., Assistant Professor, Harvard Medical School.


Ameet Sarpatwari

Ph.D., J.D., Assistant Professor, Harvard Medical School.

Gregory Curfman

M.D., Deputy Editor, Journal of the American Medical Association.

Follow this and additional works at: <https://digitalcommons.law.yale.edu/yjhple>

 Part of the [Health Law and Policy Commons](#), and the [Legal Ethics and Professional Responsibility Commons](#)

Recommended Citation

Jonathan J. Darrow, Ameet Sarpatwari & Gregory Curfman, *Battling Over Patents: The Impact of Oil States on the Generic Drug Industry*, 19 YALE J. HEALTH POL'Y L. & ETHICS ().

Available at: <https://digitalcommons.law.yale.edu/yjhple/vol19/iss1/3>

This Article is brought to you for free and open access by Yale Law School Legal Scholarship Repository. It has been accepted for inclusion in Yale Journal of Health Policy, Law, and Ethics by an authorized editor of Yale Law School Legal Scholarship Repository. For more information, please contact julian.aiken@yale.edu.

Battling Over Patents: The Impact of *Oil States* on the Generic Drug Industry

Jonathan J. Darrow, Ameet Sarpatwari, Gregory Curfman *

Abstract:

In the 2018 case of *Oil States Energy Services v. Greene's Energy Group*, the U.S. Supreme Court upheld the constitutionality of *inter partes* review, a non-judicial proceeding for challenging patents that was created by Congress as part of the 2011 Leahy-Smith America Invents Act. By establishing *inter partes* review, Congress hoped to rebalance patent policy to make it faster and less costly to invalidate erroneously granted patents in all fields of technology. In the pharmaceutical industry, generic drug companies have embraced *inter partes* review, filing hundreds of challenges in the first five years after its creation, with moderate success. Biologics, which make up a growing class of pharmaceutical products, are sometimes covered by dozens or scores of patents. As more of these complex therapeutics are developed and approved, *inter partes* review is expected to play an increasingly important role.

In 2018, the Supreme Court upheld the constitutionality of a new non-judicial proceeding for challenging patents, called *inter partes* review, in *Oil States Energy Services v. Greene's Energy Group*.¹ *Oil States*, the owner of a

* Jonathan J. Darrow, S.J.D., LL.M., J.D., M.B.A., Assistant Professor, Harvard Medical School, 1620 Tremont St., Suite 3030, Boston, MA 02120 Phone: 347-792-2246, Fax: 617-232-8602, Email: jjdarrow@bwh.harvard.edu. Ameet Sarpatwari, Ph.D., J.D., Assistant Professor, Harvard Medical School. Gregory Curfman, M.D., Deputy Editor, Journal of the American Medical Association. From the Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital. LL.M. "waived" upon admission to the S.J.D. program. This research was supported by Arnold Ventures, with additional support from the Harvard-MIT Center for Regulatory Science and the Engelberg Foundation.

1. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018).

patent on hydraulic fracturing (“fracking”) technology that was invalidated in a challenge before the U.S. Patent and Trademark Office (USPTO), an administrative agency, argued that *inter partes* review unconstitutionally deprived patent owners of their right to be heard in a court, as guaranteed by Article III of the U.S. Constitution, and of their right to a trial by jury, as guaranteed by the Seventh Amendment. In *Oil States*’ view, the private property rights embodied in its patent should not have been subject to abrogation by a non-judicial body whose members answered to a political appointee.

Although *Oil States* addressed a patent directed to technology in the energy industry, the failed challenge to the *inter partes* review procedure has implications for any field of technology in which patents play an important role, including pharmaceuticals. More than 1,100 drug products are protected by at least one patent, with an average of more than three patents for each patent-protected drug.² The battle over patents in the pharmaceutical industry has a long history, the modern portion of which began in 1984 with the enactment of the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman Act”). Under the Hatch-Waxman Act, litigation over patents can trigger a 30-month stay of approval of a generic drug application in order to provide time for the litigation to resolve, potentially allowing even weak patents to have an important exclusive effect in the market. The Act also provides brand-name manufacturers with the ability to extend the expiration date of one patent per drug product for up to five years, to make up for time lost during clinical testing and U.S. Food and Drug Administration (FDA) review.

To incentivize challenges to weak patents that were delaying generic competition, the Act provided the first generic drug manufacturer that brought a patent challenge with the possibility of obtaining a 180-day period during which no other generic drug company could enter the market.³ But bringing suit in federal court was (and remains) expensive and time-consuming for patent challengers, in all fields of technology. Where more than \$25 million is at stake—as is the case for virtually all litigated pharmaceutical patents—the costs of asserting or defending a Hatch-Waxman patent dispute average approximately \$1.1 million or more per litigant.⁴

In the mid-2000s, Congress began to consider whether a rebalancing of

2. Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECHNOLOGY 142, 143 tbl.1 (2018).

3. Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman Act”), Pub. L. No. 98-417, 98 Stat. 1585, 1589 (1984).

4. Donika P. Pentcheva & Frank L. Gerratana, AIPLA 2017 REPORT OF THE ECONOMIC SURVEY 42 (2017). The \$1.1 million median figure represents a dramatic decline from 2013 and 2015, when medians of \$6 million and \$5 million, respectively, were reported. *Id.* It is not clear whether the decline represents a trend, or whether it is related to *inter partes* review.

patent policy was necessary to ensure a favorable market environment.⁵ After six years of hearings and deliberation, it concluded that “flaws in the [patent] system . . . have become unbearable,” and that change was needed to appropriately respond to the “growing sense that questionable patents are too easily obtained and . . . too difficult to challenge.”⁶ The culmination of Congress’s deliberations was the 2011 Leahy-Smith America Invents Act,⁷ which made a number of changes to the patent laws, including the establishment of a new type of administrative proceeding called *inter partes* review. The new proceeding allowed the USPTO to reconsider its previous decision to grant a patent and was intended to be faster and less expensive than court litigation.⁸

Congress also reconstituted the USPTO’s Board of Patent Appeals and Interferences, an administrative tribunal that addressed matters such as appeals from patent rejections by examiners, into a new Patent Trial and Appeal Board. Like its predecessor, the PTAB comprised administrative patent judges who sat in 3-judge panels to make determinations about patent validity without involving juries. But *inter partes* review allowed patent challengers to participate in patent challenge proceedings to a greater extent than had previously been possible, as part of an adversarial process that resembled litigation.⁹

From the perspective of the patent challenger, *inter partes* review had a number of advantages over litigation. Estimated costs of the new proceeding were approximately ten percent as much as litigation, and the PTAB was generally required to make a judgment within one year of its decision to begin review.¹⁰ A patent’s obviousness could be established by a mere preponderance of the evidence, rather than by clear-and-convincing evidence, as would be required in court,¹¹ and patent claims would be interpreted according to their broadest reasonable interpretation rather than according to their ordinary meaning, increasing the probability that a claim would be invalidated as obvious over the prior art. In contrast with federal lawsuits, in which generic drug manufacturers generally seek to demonstrate patent invalidity only after brand-name manufacturers have sued for patent infringement, *inter partes* review proceedings may be brought by any party at virtually any time. This allows pro-

5. See H.R. REP. NO. 112-98, pt. 1, at 57 (2011), reprinted in 2011 U.S.C.C.A.N. 67, 88 (listing relevant Congressional hearings on patent reform beginning in 2005).

6. *Id.* at 39.

7. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

8. See generally Evan J. Wallach & Jonathan J. Darrow, *Federal Circuit Review of USPTO Inter Partes Review Decisions, by the Numbers*, 98 J. PAT. & TRADEMARK OFF. SOC’Y 105 (2016) (summarizing the background that motivated the America Invents Act).

9. *Id.* at 109.

10. 35 U.S.C. § 316(a)(11) (2018).

11. Jonathan J. Darrow, Reed F. Beall & Aaron S. Kesselheim, *Will Inter Partes Review Speed US Generic Drug Entry?*, 35 NATURE BIOTECHNOLOGY 1139, 1139 (2017).

active challenges by generic drug firms and expands the list of prospective challengers to include public interest groups, other competing generic manufacturers, or even hedge funds seeking to profit from patent invalidation by betting against a company's stock.¹²

By the time the Supreme Court rendered its decision in *Oil States*, more than 7,500 petitions for *inter partes* review had been filed, resulting in the partial or complete invalidation of more than 1,600 patents across a broad range of technologies.¹³ In the pharmaceutical sector, at least 198 patents covering 134 small-molecule drug products had already been challenged in *inter partes* review, with approximately half of completed challenges resulting in at least partial victory for the patent challenger.¹⁴ In 2018 alone, almost 100 patents in the biopharmaceutical space were challenged,¹⁵ and the number of drug patents challenged each quarter has been approximately four times as high as the number of new drugs approved each quarter.¹⁶

Although the patent in *Oil States* did not directly concern the pharmaceutical industry, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade group, filed an amicus brief in support of *Oil States*. PhRMA warned the Court that pharmaceutical companies invest “hundreds of billions of dollars” in drug development, and that these investments, on which future innovations rely, “make sense only because the resulting intellectual property is respected as property.”¹⁷ In essence, PhRMA's position as to *inter partes* review echoed the age-old battle over the patent system more generally, which has persisted at least since the patent abolition movement of the 1800s.¹⁸ The basic arguments are relatively straightforward: Those favoring stronger, broader, or longer patent protection suggest that patents are needed to adequately incentivize the initial creation of new inventions, while those favoring more limited patent protection or opposing it altogether emphasize the restrictions on use that accrue

12. *Id.* at 1139–40.

13. U.S. PATENT & TRADEMARK OFFICE, TRIAL STATISTICS IPR, PGR, CBM: PATENT TRIAL AND APPEAL BOARD, Feb. 2018, at 3, 11 (2018), https://www.uspto.gov/sites/default/files/documents/trial_statistics_20180228.pdf.

14. Jonathan J. Darrow et al., *The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents*, 17 APPLIED HEALTH ECON. & HEALTH POL'Y 47, 51 (2019).

15. U.S. PATENT & TRADEMARK OFFICE, TRIAL STATISTICS IPR, PGR, CBM: PATENT TRIAL AND APPEAL BOARD, June 2019, at 4 (2019), https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2019-06-30.pdf.

16. Darrow et al., *supra* note 14, at 53.

17. Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioner at 6, *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018) (No. 16-712).

18. See generally Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1 (1950); Mark D. Janis, *Patent Abolitionism*, 17 BERKELEY TECH. L.J. 899 (2002) (describing the patent controversy in the nineteenth century).

once inventions have been created.

Notwithstanding PhRMA's argument, this larger policy question was not at issue in *Oil States*, which instead required the Court to resolve whether Congress could constitutionally delegate the *inter partes* review function to a non-judicial body.¹⁹ The Court upheld Congress's action, rejecting Oil States' challenge in a 7-to-2 decision. The Court explained that although Article III generally prohibits Congress from conferring judicial power on entities outside of the traditional court system, Congress has greater latitude when public rather than private rights are involved. According to the Court, *inter partes* review "falls squarely within the public rights doctrine," which covers matters that arise between the government and those subject to its authority.²⁰ Specifically, the grant of a patent is a matter between the government, which grants a public franchise in the form of a patent, and the patentee, which discloses its invention in return. Because *inter partes* review is simply a reconsideration of the original patent grant, the Court ruled that Congress permissibly assigned authority to the PTAB. The Court emphasized that its ruling was limited and did not speak to whether a proceeding similar to *inter partes* review would be constitutional if used to settle patent infringement (as opposed to invalidity) cases, which might be more likely to involve private rights, or if it were not subject to review by an Article III court. The Court found that the Seventh Amendment's right to a trial by jury also had not been offended by the creation of *inter partes* review. Under Supreme Court precedent, once Congress properly assigned responsibility for adjudication to a non-Article III body such as the PTAB, the Seventh Amendment posed no independent bar.

Regarding PhRMA's concern that post-grant administrative invalidation could upset the legitimate, investment-backed expectations of businesses, the Court observed that patents confer only those rights that the statute prescribes, and that at the time of grant these rights are subject to the qualification that the U.S. Patent and Trademark Office may reexamine and even cancel a patent's claims at a later time if it determines statutory criteria were in fact not met. Even before the creation of administrative patent review, a patent did not guarantee a particular duration of exclusivity, since it could be challenged and invalidated by the judiciary.

Justice Gorsuch and Chief Justice Roberts dissented, echoing the concern of Oil States that political appointees may be more likely than independent judges to issue decisions that follow political interests, potentially undermining "much hard work and no little investment"²¹—a concern magnified in 2019 when the

19. See Petition for a Writ of Certiorari Question 1, at i, *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018) (No. 16-712).

20. *Oil States*, 138 S. Ct. at 1368.

21. *Id.* at 1380 (Gorsuch, J., dissenting).

Federal Circuit held that members of the PTAB could be removed without cause.²² The dissent cautioned that important constitutional protections are often inefficient, such as the need to obtain a warrant before a search or conduct a jury trial before a criminal conviction, and that the expediency of PTAB review is not a justification for dispensing with constitutional safeguards. Despite these concerns, a majority of the Court found *inter partes* review constitutionally permissible, and the new proceeding survived its day in court.

The *Oil States* decision has important implications across all industries but may be particularly significant with respect to timely access to affordable generic drugs. Most drug patents that have been challenged in *inter partes* review are directed to aspects of the drug product other than its active ingredient.²³ Because these “secondary” patents may have expiration dates that extend well beyond the end of primary patents’ expiration dates, challenging those that should not have issued because they were obvious could significantly advance the date of generic entry. The filing of a petition for *inter partes* review also does not trigger the 30-month stay available under the Hatch-Waxman Act, potentially shortening the time to generic drug entry for those products protected only by weak patents that would be found invalid if challenged.

Although some commentators have asserted that *inter partes* review makes little difference on the timing of generic drug entry,²⁴ circumstantial evidence suggests otherwise. Hedge funds have challenged drug patents in *inter partes* review in combination with shorting a company’s stock, a stratagem that would result in profits only to the extent the market believes the challenge will impact generic entry. Generic drug firms quickly embraced the proceeding, filing 274 challenges in the pharmaceutical space between September 16, 2012 and April 24, 2017.²⁵ And the branded drug industry has vigorously opposed *inter partes* review, not only as reflected in PhRMA’s amicus brief in *Oil States*, but by proposals that drug patents be exempted from eligibility for *inter partes* review altogether.²⁶

The Court’s vindication of Congress’s choice to streamline patent challenges

22. *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1338 (Fed. Cir. 2019).

23. Jonathan J. Darrow et al., *The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents*, 17 APPLIED HEALTH ECON. & HEALTH POL’Y 47, 51 (2019).

24. Sarah Karlin-Smith, *Patent Review: Not Super Effective in Speeding Early Generic Entry*, POLITICO (August 1, 2016, 12:00 PM), <https://www.politico.com/tipsheets/prescription-pulse/2016/08/part-d-premiums-remain-stableptos-patent-review-isnt-speeding-many-genericsportman-calls-for-more-opioid-funding-215637>.

25. Darrow et al., *supra* note 23, at 51.

26. Letter from James C. Greenwood, President and CEO, BIO, and John J. Castellani, President and CEO, PhRMA, to Chuck Grassley, Chairman, Senate Judiciary Committee, et al. (July 15, 2015), <http://phrma-docs.phrma.org/sites/default/files/pdf/joint-phrma-bio-letter-on-ipr-071515.pdf>.

before an administrative body may be especially important for the rapidly growing class of biologic drugs. These drugs are not subject to the regulatory scheme of the Hatch-Waxman Act, including its 180-day generic drug exclusivity incentive, so an inexpensive means of challenging patents may be particularly critical. Although a one-year exclusivity provision is available for “interchangeable” biosimilars, this higher standard has not yet been met for any product, and follow-on biologics have so far been approved only as ordinary biosimilars that do not benefit from the one-year non-patent exclusivity provision. Some biologics, such as the blockbuster tumor necrosis factor-alpha monoclonal antibody adalimumab (Humira), have been protected by veritable intellectual property “fortresses” made up of 100 or more patents.²⁷ In these cases, the impact of *inter partes* review is more complex. Although the cost of the administrative proceeding is generally lower if only one patent is at issue, this benefit may erode for drugs protected by larger numbers of patents. Only a single patent can be challenged in each *inter partes* review proceeding, in contrast to court litigation where multiple patents can be addressed at once.

Overall, however, the Supreme Court’s preservation of an efficient administrative procedure for challenging weak patents can only benefit generic drug and biosimilar manufacturers that seek to enter the market sooner. When these challenges successfully lead to earlier entry by competitors, they can be expected to bring down prices, including those on some of the most expensive drugs and biologics in the world. Following the Court’s decision in *Oil States*, *inter partes* review will help to ensure that invalid patents are not preventing patient access to important new medicines.

27. Complaint at 1, AbbVie Inc. v. Amgen Inc., No. 16-cv-00666 (D. Del. Aug. 5, 2016), ECF No. 1, *dismissed*.