



Administrative Patent Challenges and Drug Prices

By Charles Duan

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Introduction

Patents figure prominently in the policy conversation over skyrocketing drug prices and the increasing unaffordability of American health care.¹ Commentators have raised questions about anticompetitive practices based on “thickets” of dozens or hundreds of patents and about whether many of those patents were correctly granted and represent substantial advances in medical innovation.² The overarching concern is that erroneously granted patents could unjustifiably suppress competition by blocking the introduction of generic drugs, resulting in artificially inflated drug prices without worthy justification.³ As a result, members

1. See, e.g., Erin H. Ward et al., “Drug Prices: The Role of Patents and Regulatory Exclusivities,” Congressional Research Service, Feb. 10, 2021, p. 1. <https://crsreports.congress.gov/product/pdf/R/R46679>; Charles Duan, “Biologics Patent Litigation: Reforms for Lowering Drug Prices,” *R Street Policy Study* No. 220, February 2021, pp. 1-2. <https://www.rstreet.org/wp-content/uploads/2021/02/Final-No-220-biologics-patents.pdf>.

2. See, e.g., S. Sean Tu and Mark A. Lemley, “What Litigators Can Teach the Patent Office About Pharmaceutical Patents,” *Washington Law Review* 99:1673 (Aug. 11, 2021), pp. 4-5. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513; Olga Gurgula, “Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies—Two Different Concepts Sharing Similar Features,” *International Review of Intellectual Property and Competition Law* 242 (Oct. 13, 2016), p. 385. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2852056.

3. See, e.g., C. Scott Hemphill and Bhaven N. Sampat, “When Do Generics Challenge Drug Patents?,” *Journal of Empirical Legal Studies* 379 (July 15, 2010), p. 613. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1640512.

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of Congress have repeatedly introduced bills and called on the U.S. Patent and Trademark Office (USPTO) and other parts of the executive branch to investigate reforms to correct for any negative effect that patents may have on drug prices.⁴

A key reform enacted over 10 years ago attempts such a correction. The America Invents Act (AIA) created two new pathways for administratively challenging the correctness of issued patents before panels of expert administrative patent judges who sit on the Patent Trial and Appeal Board (PTAB) within the USPTO.⁵ The intention of these proceedings was to create an efficient litigation alternative for addressing ongoing questions of patent quality, and the proceedings have been used by generic firms seeking to clear out invalid patents from pathways to drug market competition.⁶ Yet these proceedings have not been without controversy: They have attracted multiple Supreme Court cases, dozens of hearings, legislative proposals and administrative actions to cut back on their effectiveness as vehicles for challenging patents.⁷ With respect to drug patents in particular, there is an ongoing line of argument that PTAB patent challenges conflict with the preexisting and complex scheme of patent litigation in federal courts that takes place between generic firms and brand-name pharmaceutical manufacturers.⁸

Despite this ongoing controversy, surprisingly little attention is paid to how these proceedings affect the top-line question of drug pricing.⁹ Some initial studies have explored generic manufacturers' use of inter partes review.¹⁰ Others have investigated the relationship between such proceedings and federal court litigation.¹¹ The USPTO itself has also reviewed PTAB trials involving Orange Book-listed patents.¹² However, none of these studies have compared proceedings with the availability of generic drugs or consequent changes in drug pricing.

A preliminary study of that relationship was performed in an *amicus curiae* brief filed in the Supreme Court. But that brief was limited to a hand-selected set of examples of challenged drug patents.¹³ This study aims to be more comprehensive, considering the entire spectrum of relevant patents. It joins patent-challenge proceedings data from the USPTO, drug-formulation data from the U.S. Food and Drug Administration (FDA), and drug-pricing records collected by the Centers for Medicare and Medicaid Services (CMS) to assess how PTAB proceedings relate to changes in generic competition and consequent pricing.



The America Invents Act (AIA) created two new pathways for administratively challenging the correctness of issued patents before panels of expert administrative patent judges who sit on the Patent Trial and Appeal Board (PTAB) within the USPTO.

4. Kevin J. Hickey et al., "Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress," Congressional Research Service, March 31, 2021. <https://sgp.fas.org/crs/misc/R46741.pdf>.

5. America Invents Act (AIA), Pub. L. No. 112-29, sec. 6, 125 Stat. 284, pp. 299-313 (2011).

6. H.R. REP. NO. 112-98, pp. 45-48 (2011); Reed F. Beall et al., "Approximating Future Generic Entry for New Drugs," *Journal of Law, Medicine & Ethics* 47:1 (Spring 2019), pp. 177-182. <https://doi.org/10.1177/1073110519840499>.

7. *United States v. Arthrex, Inc.*, 141 S. Ct. p. 1970 (2021); *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. p. 1365 (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. p. 2131 (2016); Greg Reilly, "The PTAB's Problem," *Texas Intellectual Property Law Journal* 31 (May 31, 2019), pp. 35-41. <https://tipj.org/wp-content/uploads/Volumes/v27/Reilly.pdf>.

8. See, e.g., Francisco Javier Espinosa, "Big Pharma Versus Inter Partes Review: Why the Pharmaceutical Industry Should Seek Logical Hatch-Waxman Reform over Inter Partes Review Exemption," *John Marshall Law Review* 50:2 (Winter 2017), p. 363. <https://repository.law.uic.edu/lawreview/vol50/iss2/7>.

9. *Ibid.*, pp. 370-372.

10. Beall et al. <https://doi.org/10.1177/1073110519840499>.

11. Tulip Mahaseth, "Maintaining the Balance: An Empirical Study on Inter Partes Review Outcomes of Orange Book Patents and its Effect on Hatch-Waxman Litigation," Self Published, Nov. 29, 2018. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3188995.

12. United States Patent and Trademark Office, "PTAB Orange Book patent/biologic patent study," June 2021. <https://www.uspto.gov/sites/default/files/documents/PTABOBbiologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf>.

13. "Brief of the Coalition Against Patent Abuse as *Amicus Curiae* in Support of No Party," pp. 9-21, *United States v. Arthrex, Inc.*, 141 S. Ct. p. 1970 (Dec. 1, 2020). https://www.supremecourt.gov/DocketPDF/19/19-1434/162265/20201201162003002_brief-arthrex.pdf.

This study is intended to be a preliminary start to potentially much more detailed research on the role of administrative patent challenge proceedings. Every drug, patent and generic-firm challenge is unique and cannot be fully characterized by summary statistics. Nevertheless, this preliminary investigation arrives at two key findings. First, successful challenges to drug patents before the PTAB correlate with increases in the number of approved drug competitors and with decreases in price: A drug formulation with a successful patent challenge typically has seven additional products approved within five years and a price drop of around 20 percent. Indeed, within three years of a successful patent challenge, 16 percent of drug formulations experience a price drop of 75 percent or more. These results suggest that administrative patent challenge proceedings are closely tied to generic competition and lower prices. Second, these administrative proceedings are likely not the sole cause of these outcomes; the proceedings are likely acting as an adjunct to existing federal court litigation pathways rather than as a replacement for them.

Patents, Generics and Drug Prices

Generic drugs are central to the policy goal of lowering drug prices. By being approved to be therapeutically equivalent to more expensive, brand-name drugs, generics provide head-to-head competition that lowers prices and offers consumers choice.¹⁴ Indeed, every state provides some level of substitutability between brand-name and generic drugs at the pharmacy level.¹⁵ Multiple researchers, including the FDA, have observed that drug prices decrease rapidly when generics enter the market, particularly if there are six or more competing products.¹⁶

The primary limitation on generic entry is patent protection. A U.S. patent gives the inventor of a new technology an exclusive right to that technology for a period of about 20 years, along with the ability to sue others who make or use similar products or services during that time.¹⁷ Most new drugs are covered by at least one patent and often multiple patents.¹⁸ Because generic drugs are required to be identical to their brand-name counterparts in several respects, generics will often infringe patents on those brand-name drugs and thus cannot enter while those patents are in force.

In the abstract, the arrangement of patents and generics makes sense. The brand-name innovator earns patent-backed monopoly profits on a new drug for a period of time that Congress has determined to be sufficient to compensate for the research and development costs of the drug. After the patent term expires, the drug is exposed to ordinary free-market competition that lowers prices and increases consumer welfare.¹⁹

In practice, though, the complexities of patents paint a more problematic picture. For a single drug, multiple patents can be issued not just on the active ingredient, but also on dosage regimens, excipient combinations, formulation specifications and methods

price
DROP
↓
of **75%**

Within three years of a successful patent challenge, 16 percent of drug formulations experience a price drop of 75 percent or more.

14. See, e.g., Richard G. Frank, "The Ongoing Regulation of Generic Drugs," *New England Journal of Medicine* 357:20 (Nov. 15, 2007), pp. 1994-1995. https://www.researchgate.net/profile/Richard-Frank-2/publication/5842975_The_Ongoing_Regulation_of_Generic_Drugs/links/09e415065005652275000000/The-Ongoing-Regulation-of-Generic-Drugs.pdf.

15. Jesse C. Vivian, "Generic-Substitution Laws," *U.S. Pharmacist* 33:6 (June 19, 2008), p. 30. <https://www.uspharmacist.com/article/generic-substitution-laws>; Yan Song and Douglas Barthold, "The effects of state-level pharmacist regulations on generic substitution of prescription drugs," *Health Economics* 27:11 (November 2018), p. 1717. <https://pubmed.ncbi.nlm.nih.gov/29992674>.

16. See, e.g., Ryan Conrad and Randall Lutter, "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," U.S. Food and Drug Administration, December 2019, p. 2. <https://www.fda.gov/media/133509/download>; Frank, p. 1995. https://www.researchgate.net/profile/Richard-Frank-2/publication/5842975_The_Ongoing_Regulation_of_Generic_Drugs/links/09e415065005652275000000/The-Ongoing-Regulation-of-Generic-Drugs.pdf.

17. 35 U.S.C. § 154(a)(2); § 271(a).

18. Lisa Larrimore Ouellette, "How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing," *Michigan Telecommunications and Technology Law Review* 17:1 (2010), pp. 314-315. <https://repository.law.umich.edu/mttlr/vol17/iss1/7>.

19. Ward et al., pp. 3-4. <https://crsreports.congress.gov/product/pdf/R/R46679>.

of use. These so-called “secondary patents” are typically sought and obtained years or decades after the discovery and patenting of the active ingredient, such that those patents expire later and effectively extend the length of time that the brand-name drug is insulated from generic competition.²⁰

Furthermore, not all patents issued on a drug are valid. For an inventor to receive a patent, the invention must be “novel” and “nonobvious,” meaning in essence that the invention was unknown prior to the inventor’s work and that it represents a nontrivial step beyond the cutting edge of science and technology at the time the patent application was filed.²¹ Particularly with respect to secondary patents on drugs, many invalid patents are issued by the USPTO, as constraints on the agency’s capacity and resources limit its ability to examine patent applications with complete accuracy.²² With a valid patent, the theoretical advance in technology outweighs the temporary loss of competition, but where a patent aims to secure obvious advances over existing knowledge, the suppression of competition is difficult to justify. And yet even patents of great economic importance are often invalid, with studies finding that courts invalidate about 40 percent of patents tested in litigation.²³

The prevalence of invalid patents that can improperly suppress generic competition means that there is an urgent need for mechanisms through which to challenge the validity of drug patents. To the extent that generic manufacturers correctly invalidate patents on drugs, they not only advance their own interests but also the public interest in general, as other firms can also enter and compete once the manufacturing pathway has been cleared of improper patents.²⁴ The two primary mechanisms for disputing patent validity are described below.

Hatch-Waxman Litigation

Conventionally, challenges to drug patent validity have been brought under the Hatch-Waxman Drug Price Competition and Patent Term Restoration Act.²⁵ Enacted in 1984, Hatch-Waxman created the accelerated pathway for FDA approval of generic drugs, commonly called an abbreviated new drug application (ANDA).²⁶ Hatch-Waxman also devised a structured procedure for litigating drug patents. The procedure starts with the approval process for the patented brand-name drug, where the applicant for approval is required to identify all patents covering the drug.²⁷ Each year, the FDA publishes a listing of all such patents identified as an appendix to its listing of approved drug products titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”²⁸ When a generic manufacturer seeks approval for a generic version of a listed drug with active patents in the Orange Book, the generic manufacturer must certify that it will not violate those patents either because its product is different (for example, the patents cover excipients that the



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20. Tahir Amin and Aaron S. Kesselheim, “Secondary Patenting of Branded Pharmaceuticals,” *Health Affairs* 31 (2012), p. 2286. <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2012.0107>; Amy Kapczynski et al., “Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents,” *PLoS One* 7:12 (Dec. 5, 2012). <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470>.

21. 35 U.S.C. § 102; § 103.

22. Hemphill and Sampat. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1640512.

23. John R. Allison et al., “Our Divided Patent System,” *University of Chicago Law Review* 82:3 (2015), p. 1100. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2510004.

24. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. p. 313, p. 350 (1971); Megan M. La Belle, “Patent Law as Public Law,” *George Mason Law Review* 20 (2012), pp. 42-43. <https://www.law.msu.edu/ipic/workshop/2012/papers/PatentLawasPublicLaw2.pdf>.

25. Hatch-Waxman Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at Federal Food, Drug, and Cosmetic Act (FFDCA) § 505, 21 U.S.C. § 355).

26. FFDCA § 505(j).

27. *Ibid.* § 505(b)(1)(viii).

28. *Approved Drug Products with Therapeutic Equivalence Evaluations*, Food and Drug Administration, 2022. <https://www.fda.gov/media/71474/download>.

generic does not use) or because the patents are invalid.²⁹ That certification triggers a special form of federal court litigation between the brand-name drug patent holder and the generic manufacturer.³⁰ In that litigation, the federal court reviewing the case can declare the patents at issue invalid, opening the door for the FDA to approve not just the litigating generic’s product but also others.

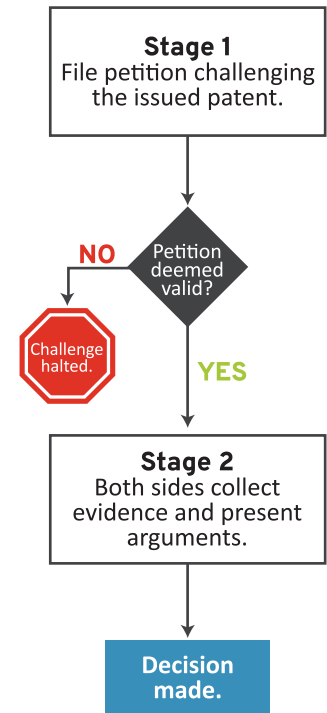
Although Hatch-Waxman litigation has been widely used to challenge drug patent validity, it faces a number of limitations. First and most importantly, litigation in federal court is typically drawn-out and expensive—often several million dollars.³¹ While the duration problem can be solved in district courts with expedited procedures for this specialized form of litigation, expedited procedures do not necessarily keep costs down. Second, the fact that the litigation considers both invalidity and noninfringement of the patents forces the litigants to make choices about their arguments and tactics that can lead to less-than-clear invalidity defenses being presented.³² This latter problem is exacerbated when the litigation involves a large number of patents, each of which requires separate analysis, attention and arguments. As a result, Hatch-Waxman litigation is an incomplete solution to the problem of invalid drug patents preventing generic competition.

Administrative Patent Review Proceedings

In 2011, Congress enacted the first major revision to patent law in half a century: the AIA. Among other things, the law created two new administrative procedures for challenging patent validity, called “inter partes review” and “post-grant review.”³³ These proceedings are held before a branch of the USPTO called the PTAB, and they are often collectively called PTAB trials or AIA trials.³⁴ The two proceedings differ regarding the invalidity arguments that may be made and how long after patent issuance they may be brought, but they follow largely the same two-stage procedure. In the first stage, the challenger of a patent files a petition detailing the reasons why the challenged patent was wrongly issued.³⁵ If a panel of the PTAB decides that the petition demonstrates a substantial likelihood that the patent is invalid, then the panel orders institution of a trial proceeding, moving on to the second stage.³⁶ There, the patent owner and the challenger collect evidence and present arguments in an administrative trial before the PTAB panel, which renders a decision on the validity of the patent.³⁷ That decision, which may be appealed in the federal appellate courts, results in the USPTO issuing a certificate canceling any of the claims of the disputed patent deemed to be unpatentable.³⁸

Compared to Hatch-Waxman litigation and federal court patent litigation in general, PTAB trials have several distinct advantages. First, because they lack the overhead of federal courts, PTAB trials are significantly less expensive and more efficient. A

PTAB Patent Challenge Procedure



29. FDCA § 505(j)(2)(A)(vii)(IV).

30. 35 U.S.C. § 271(e)(2)(A).

31. See, e.g., Branka Vuleta, “25 Patent Litigation Statistics—High-Profile Feuds about Intellectual Property,” Legaljobs, Aug. 6, 2021. <https://legaljobs.io/blog/patent-litigation-statistics>.

32. Roger Allan Ford, “Patent Invalidity versus Noninfringement,” *Cornell Law Review* 99:1 (November 2013), pp. 93-103. <https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=4614&context=clr>.

33. 35 U.S.C. § 311; § 321.

34. 35 U.S.C. § 6(b)(4).

35. § 312(a)(3); § 322(a)(3).

36. 35 U.S.C. § 314(a); § 324(a).

37. 35 U.S.C. § 316(c); § 326(c).

38. 35 U.S.C. § 318(b); § 328(b).

survey of patent practitioners finds that those trials cost about \$250,000 in legal fees, compared to several million for Hatch-Waxman trials.³⁹ Second, the administrative patent judges who sit on the PTAB generally have training in science and engineering, meaning that they are likely to render informed decisions on the technical subject matter of patents—an expectation perhaps confirmed by the generally high affirmance rate of the PTAB decisions on appeal.⁴⁰ Third, because the PTAB can only decide matters of patent validity and not infringement, litigants in such proceedings avoid some of the tactical considerations that would otherwise impede the presentation of fully formed invalidity arguments. Because of these advantages, generic manufacturers are using PTAB trials, inter partes review in particular, as a component of their patent litigation strategies.

Data and Methods

This study relied primarily on three types of data: information about administratively challenged patents; drug pricing; and records of drugs associated with patents. For the purposes of transparency, replicability and follow-on research, all data used in this study is publicly available free of charge. All data was retrieved during May and June 2022.

To collect information about administratively challenged patents, the USPTO database was searched, as it contains data on all trial decisions rendered by the PTAB.⁴¹ Only PTAB trials that had reached a post-institution final decision were considered in this study. The USPTO database includes metadata on the types of challenges, the patents involved and the dates of decision. However, it does not identify the specific outcomes of individual challenges. Instead, outcomes were determined by extracting the text of the Board's opinions and pattern-matching phrases indicating dispositions of proceedings, such as "claims X of U.S. Patent No. Y are held to be unpatentable." Each decision was thus assigned to one of three categories:

- **Unpatentable:** One or more of the challenged claims was held unpatentable.
- **Not unpatentable:** The Board declined to hold one or more of the claims unpatentable, or reached no decision because the proceeding settled or was not instituted.
- **Mixed:** Some of the claims were unpatentable, and others were held not unpatentable.

Further litigation in the Federal Circuit was not considered in this study and is potentially a worthwhile area for future research. For drug pricing data, this study used the CMS's National Average Drug Acquisition Cost (NADAC). CMS developed the NADAC as an alternative to proprietary drug pricing data of questionable accuracy and has published the resulting data since November 2013. To compute pricing, CMS surveys retail pharmacies on a weekly basis for their drug purchase prices. NADAC data is thus limited to pharmacy-purchasable drugs and does not cover, for example, injectables that are dispensed and administered in hospitals.⁴²

Advantages of PTAB Trials

- ✓ Trial costs are cheaper.
- ✓ Patent judges have training in science and engineering.
- ✓ PTAB decides on patent validity and not infringement.

39. Josh Landau, "Inter Partes Review: Five Years, Over \$2 Billion Saved," Patent Progress, Sept. 14, 2017. <https://www.patentprogress.org/2017/09/14/inter-partes-review-saves-over-2-billion>.

40. Matthew G. Sipe, "Experts, Generalists, Laypeople—and the Federal Circuit," *Harvard Journal of Law & Technology* 32:2 (Spring 2019), p. 578. <https://jolt.law.harvard.edu/assets/articlePDFs/v32/32HarvJLTech575.pdf>.

41. "PTAB API v2," United States Patent and Trademark Office Open Data Portal, last accessed July 19, 2022. <https://developer.uspto.gov/api-catalog/ptab-api-v2>.

42. "Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs," Centers for Medicare & Medicaid Services, January 2021, pp. 3-4. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf>.

Linking challenged patents to drug pricing was achieved using two FDA databases. The first was the Orange Book, the FDA’s compendium of approved drugs.⁴³ Each drug formulation in the Orange Book is identified by the four elements the FDA considers for pharmaceutical equivalence: active ingredients, drug form (tablet, solution, etc.), route of administration (oral, injectable, etc.) and dosage strength. For each formulation, the Orange Book lists each manufactured product approved for that formulation, along with the FDA’s assessment of the therapeutic equivalence of the product to others of the same formulation, namely whether the product will be absorbed into a patient’s body in the same manner as other drugs of the same formulation. Those that the FDA deems therapeutically equivalent receive “AB” or similar codes, which pharmacies often will rely on to determine substitutability of drugs.⁴⁴

Drug manufacturers can also identify patents covering their products, which the Orange Book lists. As a result, the Orange Book links patents both to a specific manufacturer’s drug formulation and to therapeutic equivalents of that formulation (generics).⁴⁵ However, matching Orange Book records with NADAC prices requires an additional step, because the Orange Book uses FDA application numbers and product codes to identify products, whereas NADAC uses the National Drug Code (NDC). Bridging that gap requires the FDA’s NDC database, which identifies manufactured products by FDA application number, active ingredient, drug form, administration route and dosage strength.⁴⁶ Unfortunately, the FDA’s naming conventions for the latter four elements are not consistent between the NDC database and the Orange Book, requiring substantial reconciliation by text pattern matching in order to link Orange Book product records to NDCs and thus NADAC pricing records.

Further complicating matters, the FDA deletes records from both the Orange Book and the NDC database when drugs are no longer being marketed. Because patented drugs often are pulled off the market, sometimes as part of product-hopping schemes, these deleted records contain information important to this study. Thus, to ensure completeness, historical copies of Orange Book and NDC data were obtained from the Internet Archive’s copies of the FDA’s website. At least one archived version of each database was obtained for every year between 2012 and 2022, which was determined to be sufficient to capture all deleted records based on the reasonable assumption that any marketed drug was available for at least one calendar year.

For clarity in the following discussion, the following terms are used below. A *formulation* is a combination of active ingredients, dosage strength, form and route of administration that identifies a class of therapeutic equivalents. (To compensate for typographical errors and minor changes in different editions of the Orange Book, several “formulations” may be considered identical if they cover the same product or contain substantively identical content.) An *application* is a New Drug Application or Abbreviated New Drug Application filed with the FDA for the purposes of approval of one or more products. Each application covers one or more *products*, which are specific instances of formulations that a manufacturer intends to produce and market. Multiple products may share the same formulation, even products from the same manufacturer in cases in which the FDA requires separate applications for approval of the same formulation for different indications.



The Orange Book links patents both to a specific manufacturer’s drug formulation and to therapeutic equivalents of that formulation (generics).

43. *Approved Drug Products with Therapeutic Equivalence Evaluations*. <https://www.fda.gov/media/71474/download>.

44. *Ibid.*, pp. xiii-xx.

45. *Ibid.*, p. AD2.

46. “National Drug Code Database Background Information,” U.S. Food and Drug Administration, March 20, 2017. <https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information>.

Results

The initial data for this study comprised 9,541 PTAB decisions involving 6,597 patents, as well as Orange Book records covering 7,495 patents, 24,465 applications for FDA approval and 42,266 approved products. However, most patents challenged before the PTAB do not involve drugs, and most Orange Book patents are not challenged in that forum. During the period studied, 370 PTAB proceedings considered the patentability of 226 Orange Book patents.

Of the 226 patents challenged, 61 (27.0 percent) had all considered claims deemed unpatentable. (The terms “unpatentable” and “invalid” are used interchangeably below; they have a technical difference irrelevant to this study.) The number of challenged patents had at least one claim survive challenge, either because the Board found the evidence of unpatentability insufficient, the proceeding settled before final disposition or the Board refused to institute a proceeding. Dispositions of PTAB trials by year and outcome are shown in **Table 1**. As this data shows, consistent with the USPTO’s findings, Orange Book patents are not frequently invalidated in PTAB trials.

Patents challenged before the PTAB are associated with 384 drug products approved by the FDA and listed in the Orange Book. However, even successful PTAB challenges would rarely leave drug products patent-free. For the vast majority of drug products with challenged patents (351 products, or 91.4 percent), at least one patent covering the product was never challenged before the PTAB. There were only three drug products for which every Orange Book-listed patent was challenged and held unpatentable in PTAB trials: abiraterone (Zytiga, one patent) for treatment of prostate cancer; tavaborole (Kerydin, six patents) for fungal infections; and difluprednate (Durezol, one patent) for ocular inflammation, pain, and uveitis.

Subsequent Generic Entry

Assessing characteristics of generic entry requires grouping approved products by formulation, as described above. The Orange Book contains 9,220 different formulations, of which 3,533 have one or more associated patents, and 365 have one or more PTAB-challenged patents.

To estimate the number of available generics for a given formulation, the number of approved products for each formulation can be counted. Although this measure is imperfect because manufacturers occasionally will submit multiple applications for the same product, it gives an approximate size of the competitive market for a drug formulation.

Table 2 presents statistics on how many approved products the Orange Book listed for various subsets of formulations. Given the caveats noted above, these statistics generally suggest that: (1) patented formulations face fewer competing products than unpatented ones, but (2) successful PTAB challenges to Orange Book patents correlate with greater generic entry. Interestingly, mixed PTAB outcomes (where part of the challenged patent is upheld and part held unpatentable) are associated with significantly fewer competing products, but failed challenges to patents do not significantly correlate with the number of products.

Another metric of generic entry following PTAB proceedings is to track the number of generic products approved in the years following a decision. As seen in **Figure 1**, the number of approved A-rated generic products increases rapidly after a PTAB decision

Table 1

PTAB Trial Outcomes for Orange Book Patents, by Year

	Not Unpatentable	Unpatentable	Mixed
2013	1	0	0
2014	9	0	0
2015	43	9	0
2016	77	39	0
2017	74	14	1
2018	37	9	0
2019	13	8	1
2020	10	13	2
2021	6	0	1
2022	2	1	0

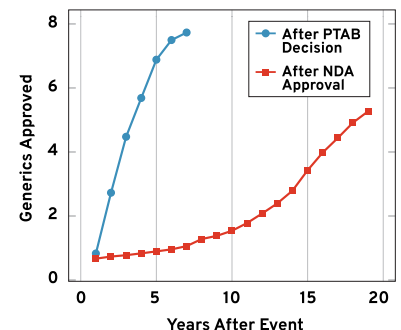
Table 2

Statistics on Numbers of Approved Products Per Drug Formulation, for Various Subsets of Drug Formulations

Formulations	Mean	Standard Deviation	n
All	4.58	6.12	9220
Patented	4.1	5.44	3533
PTAB Challenged	4.29	5.63	365
Held Unpatentable	5.8	7.56	107
Not Patentable	4.46	5.93	309
Mixed Outcome	2.13	1.85	30

Figure 1

Average Number of Generics Approved Following a PTAB Decision or Initial Drug Approval



is rendered, with an average of seven new products within five years of the decision. Surprisingly, this increase in generic entry is observed regardless of the outcome of the proceeding: Generic entry follows in the years immediately after PTAB decisions upholding patents just as it follows after decisions invalidating them.

As a comparison, the lower plot on **Figure 1** shows the average rate of generic entry in the years after approval of all patented drug products. The rate is significantly slower, with the average patented drug having fewer than seven generic competitors even 20 years after approval. PTAB proceedings conclude on average 9.08 years after first approval of a drug product covered by the challenged patent, meaning that PTAB-challenged drug products typically face robust market competition more quickly than other products.

Drug Prices

As discussed above, NADAC data is used to compute drug prices over time. For any drug formulation identified in the Orange Book, the price on a given day is calculated by choosing the lowest price effective that day among all products on the market matching that formulation. For PTAB-litigated formulations, those prices are benchmarked relative to the lowest price effective on the day of the PTAB decision. In theory, there are 754 unique pairs of drug formulations and decision dates to explore (larger than the number of PTAB-challenged formulations because many formulations have multiple patents and multiple challenges), but sufficient NADAC data is not available for all of them. There are 300 formulation-date pairs with price data three years after the decision date, and 186 pairs with data five years thereafter.

Figure 2 shows how drug prices change following a PTAB decision. On average, PTAB-challenged drug formulations drop modestly in price by 6.2 percent after the decision. When the Board reaches a decision of unpatentability, prices drop on average 25.0 percent within five years. By contrast, when a patent on a formulation is upheld, prices drop by only 2.0 percent.

However, these averages obscure a strong bimodality in pricing for drug formulations with successful PTAB patent challenges. As shown in **Figure 3**, most formulations increase in price three years after a PTAB decision of unpatentability, but a substantial fraction—16.3 percent—experience price drops of 75 percent or more. Additionally, large price increases (of 25 percent or more) are fairly rare for formulations with PTAB-invalidated patents, accounting for only 4.1 percent of observations. By contrast, as shown in **Figure 4**, a PTAB decision upholding a patent does not produce a substantially bimodal distribution of prices. And many more drug formulations with PTAB-upheld patents experience large price increases.

Discussion

The findings of this study support a potential relationship between administrative PTAB patent challenges and generic drug competition. Challenges that lead to the cancellation of patent claims are associated with a larger number of approved products for associated drug formulations, and new generic approvals follow rapidly in succession after the PTAB decisions. Furthermore, successful patent challenges correlate with somewhat lower prices on average and dramatically lower prices for a notable fraction of challenged drug formulations.

Figure 2

Relative Drug Price Changes Following PTAB Decisions

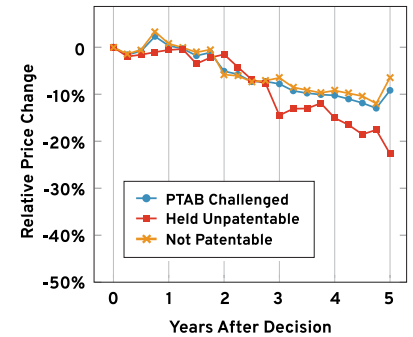


Figure 3

Distribution of Relative Price Changes for Drug Formulations Three Years After PTAB Decisions Invalidating Patents

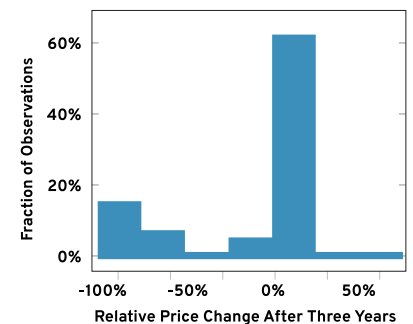
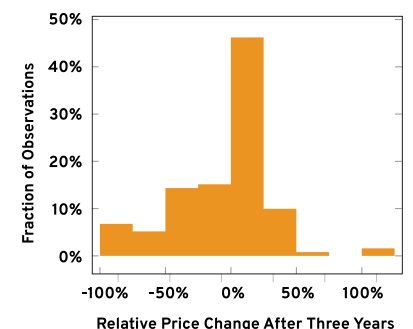


Figure 4

Distribution of Relative Price Changes for Drug Formulations Three Years After PTAB Decisions Upholding Patents



These findings are subject to several limitations arising from the data used in this study. First, it is not clear whether the USPTO's data on PTAB trials is complete; other scholars report a larger number of challenged Orange Book patents, although they consider challenges that resulted in no final decision, which this study does not consider.⁴⁷ The NADAC pricing data is known to be incomplete. If the omissions are nonrandom, then that may affect results. Also, the use of heuristic pattern-matching strategies to determine PTAB outcomes and drug formulation identities could introduce potential data errors. Additionally, the FDA and NADAC data sources were assumed to have consistent data field definitions over time.

A correlation between the PTAB challenges and lower prices does not show that patent challenges are the direct cause of price-lowering competition. It is more likely that certain drug formulations are especially worthwhile for generics to challenge because the potential market is large and/or the relevant patents are particularly questionable, and the initiation of PTAB proceedings is part of a larger litigation strategy to enable generic competition. This is consistent with two other findings in this study. First, PTAB proceedings alone rarely appear to be sufficient to enable generic entry for any drug because not all of the patents on that drug are challenged. In other words, PTAB trials are not being used to supplant Hatch-Waxman litigation, but instead are likely being used as an adjunct to that litigation, simplifying issues and reducing the number of patents to be disputed in a more expensive district court proceeding.

Second, the actual outcome of a PTAB trial may not be as important as the act of adjudicating the trial. Although successful PTAB challenges correlated with the largest increases in generic entry and drops in price, similar changes were observed, particularly with respect to the number of approved generics, for unsuccessful challenges. There are several potential explanations for this. One reasonable explanation is that PTAB proceedings simplify issues and streamline the adjudicative process overall. Another is that generic firms are reaching settlements with patent holders that permit, immediately or later, the generic to enter. Settlements of litigation between generics and patent-holding branded drug firms have attracted some controversy in recent years.⁴⁸ But administrative patent challenge settlements differ in a crucial way: Unlike with Hatch-Waxman litigation, the first generic to administratively challenge a patent does not win a regulatory exclusivity benefit, and other generics are free to challenge the patent again.

Recommendations

Given the findings of a relationship between PTAB challenges and price-lowering generic competition, this study suggests caution for policy changes that might limit the availability of such challenges or raise barriers to initiating them. If PTAB challenges are a component of generic firms' strategies to create competition in drug markets, then limitations on such challenges could discourage that activity and leave improvidently granted patents and associated monopoly pricing intact. Thus, proposals to disallow PTAB challenges on Orange Book patents or rules that permit discretionary denials of PTAB challenges with copending federal court litigation could end up undermining the bipartisan goals of lowering drug prices and making health care more affordable for all Americans.



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47. See, e.g., Mahaseth, p. 17. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3188995.

48. See, e.g., Michael A. Carrier, "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality," *Michigan Law Review* 108 (2009), p. 37. <https://repository.law.umich.edu/mlr/vol108/iss1/2>.

This study also suggests a need for further conversation about and investigation of the uses of administrative patent challenges. The current conversation about the PTAB has focused almost entirely on allegations of abuse and harm to inventors on the side of detractors and on non-practicing entities and software patents on the side of proponents. Yet PTAB proceedings implicate a much wider cross-section of policy interests, at least encompassing the health care space. There is a need for dialogue that extends past the current talking points and looks more broadly at the public interest considerations that administrative patent challenges, and the patent laws generally, encompass.

Additional avenues of further research should be apparent from the preliminary nature of this study. A finer analysis of distinctions between PTAB dispositions of proceedings, particularly denials of institution and settlements, could further explain outcomes for generic entry and drug pricing. Further comparative analysis of challenged versus unchallenged patents on drugs may be worthwhile, as may be comparisons between PTAB-challenged and Hatch-Waxman-challenged patents. In addition, the differentiation of patent types as registered in the Orange Book, for example, method-of-use patents, may provide further information, particularly on the role of PTAB proceedings with respect to secondary patents.

Conclusion

Using publicly available patent, pricing, and drug approval data from the USPTO, FDA and CMS, this study has looked at the effects of post-grant administrative patent challenges on generic entry and drug prices. It finds that PTAB challenges to drug patents, particularly successful ones, correlate with more generic competitors, speedier generic entry and drug price drops that are often substantial. It also finds that generics tend not to bring PTAB challenges against all of the patents on a drug formulation, suggesting that administrative patent challenges are part of broader litigation strategies intended to enable generic entry. These findings suggest that, today, PTAB challenges to drug patents play an important role in the health care ecosystem, helping enable the entry of cost-saving generic drugs. Legislation that might limit the usability or availability of PTAB challenges must account for this important role.



PTAB challenges to drug patents play an important role in the health care ecosystem, helping enable the entry of cost-saving generic drugs.

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