WHAT LITIGATORS CAN TEACH THE PATENT OFFICE ABOUT PHARMACEUTICAL PATENTS[1]

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ABSTRACT

Pharmaceutical patents listed in the FDA's "Orange Book" are some of the most valuable patents in the world. Accordingly, for this valuable subset of patents, it is paramount that the Patent & Trademark Office (PTO) correctly issue valid patents and preclude invalid patents from issuing.

In this paper, we study what happens to those patents in litigation, reporting the results for every Orange Book patent case that resulted in a merits decision. We find that about 25% of active Orange Book patents were invalidated in court. Since these invalid patents could wrongly increase the costs of prescription drugs, we investigate what happens during prosecution of these patents at the PTO. Our study is the first to link the prosecution of Orange Book patents directly to litigation outcomes. Our goal is to determine if there are ways to identify and prevent the issuance of these later invalidated Orange Book patents.

We find that litigated Orange Book patents have unique characteristics that distinguish them from other pharmaceutical patents. They are issued by a relatively small number of examiners. Most litigated patents (90%) are "secondary" patents—minor alterations to an existing drug rather than a patent on a new chemical. The owners of these later-litigated patent applications treat them very differently than they do other patents in the same field. They are part of large patent families, suggesting that the applicants are trying to build a patent fence around a known product. They frequently employ a procedural device known as "Track One" to obtain

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quicker patent prosecution. They are more likely to be subject to rejections based on double-patenting. When initially rejected by the patent examiner, owners of these applications are more likely to fight back rather than amend their claims. All of this suggests that applicants enter prosecution with these patents knowing that they are important and likely destined for litigation, and that they are deliberately creating patent "thickets" to make it harder for generics to enter the market.

Remarkably, we find that while patent examiners already have more time to spend on Orange Book patents than on other patents, the prosecution histories of many of these invalidated patents are identical. That is, many of these invalidated patents have the same assignee, the same examiner, and the same prosecuting attorney. Furthermore, both examiners and applicants cut and paste rejections as well as responses, thus creating identical or very similar prosecution histories.

We also find that while the patents that end up being litigated are clearly distinguishable from other pharmaceutical patents during patent prosecution, there is little difference in the PTO between the patents that end up surviving a court challenge and the ones that are invalidated.

Our data offer important guidance for reforming the process of prosecuting Orange Book patents. We can and should take advantage of advance knowledge about the importance of these patents to give them a more thorough examination early on. At the same time, the experience with cut-and-paste rejections suggests that we cannot simply give examiners more time and hope that they will do a more thorough job. That not only helps inform the policy suggestions we offer, but it sheds light on a long-standing academic debate about how much time and money we should spend examining patents.

Further, our data highlight the importance of secondary patents and patent thickets in Orange Book litigation. We offer a number of suggestions to simplify and streamline patent prosecution and litigation to make it harder to exclude generic entry with a thicket of bad patents.

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INTRODUCTION

Pharmaceutical patents are at the center of a major health and public policy controversy. On the one hand, there is widespread consensus in the patent community that strong patents are important to encourage pharmaceutical innovation.[2] On the other hand, drug prices are out of

2. *See, e.g.*, COMM'N ON INTELL. PROP. RTS., INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 29 (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [https://perma.cc/ZBB6-2T2L] ("The pharmaceutical industry in developed countries is more strongly dependent on the patent system than most other industrial sectors to recoup its past R&D costs, to generate profits, and to fund R&D for future products."); Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 850–55 (2002) (summarizing the research and noting the consensus that "patents

control, and both scholars and Congress have pointed the finger at drug patents and at a variety of efforts by pharmaceutical companies to extend the life of their patents after their normal expiration date by patenting small changes in the product.[3]

Against this backdrop, it is critically important to distinguish good pharmaceutical patents that increase social welfare from nuisance patents that are created only to make it more difficult for competitors to enter the market. That is an important goal in all sectors, and it has generated a great deal of policy and scholarly debate in recent decades.[4] But it is particularly important for pharmaceuticals. Allowing bad patents means that many people do not get access to lifesaving medicines, and that those who do potentially pay tens of billions of dollars more than they should. Wrongly rejecting good patents has less immediate consequences, but it may undermine the incentive structure that drives the development of new drugs, making everyone worse off.

In this Article, we take a close empirical look at how the Patent and Trademark Office (PTO) decides whether to issue key pharmaceutical patents, and we tie that process to what ultimately happens to those patents in court. We identify every pharmaceutical patent in the FDA's Orange

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are a more critical stimulus factor for pharmaceutical innovation compared with their impacts in other high-tech industries"); Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 248, 266–76 (2012) (noting the passage of the Hatch-Waxman Act because of pharmaceutical companies' unique dependence on patents, and arguing it does not go far enough in incentivizing innovation); Michelle L. Ethier, *Permissible Product Hopping: Why a Per Se Legal Rule Barring Antitrust Liability Is Necessary to Protect Future Innovation in the Pharmaceutical Industry*, 3 AKRON INTELL. PROP. J. 323, 329–30 (2009) ("Without patent protection, brand-name drug companies would likely cease to invest in research and development as they would be undercut in the market and fail to recoup their initial costs."); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1581, 1616 n.132, 1676 n.383, 1684–87 (2003) (providing estimates of the cost and delay associated with regulatory approval, and arguing that they justify stronger patent protection in pharmaceuticals than in other industries).

3. *See generally, e.g.*, *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. (2019); *Examining the Actions of Drug Companies in Raising Prescription Drug Prices: Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. (2019); Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860–63 (2016) (noting that patents are the primary reason for high drug prices, and blaming manufacturers for using "product life-cycle management" to extend the life of the patent); I-MAK, AMERICA'S OVERSPEND: HOW THE PHARMACEUTICAL PATENT PROBLEM IS FUELING HIGH DRUG PRICES 1 (Oct. 2017), https://www.i-mak.org/wp-content/uploads/2020/10/Excess-Costs-Briefing-Paper-FINAL-2017-10-24-with-cover-rev.compressed.pdf [https://perma.cc/T76M-PB8V]. *But see* Johnathan J. Darrow, *Debunking the "Evergreening" Patents Myth*, 131 HARV. L. REC. 6 (2010), https://hls.harvard.edu/content/uploads/2009/10/2010-debunking-the-evergreening-patents-myth-harv-l-record.pdf [https://perma.cc/WT3E-27VY].

4. *See generally, e.g.*, Mark A. Lemley, Douglas Lichtman & Bhaven N. Sampat, *What to Do About Bad Patents?*, 28 REGUL. 10, 10–13 (2005); Jonathan D. Putnam & Andrew B. Tepperman, *Revisiting the Cost of Bad Patents: For Whom Is "Rational Ignorance" Rational?*, 11 INTELL. PROP. TODAY 17, 17 (2004); Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 STAN. L. REV. 613 (2015).

Book[5] that was litigated in court. We compare the patent prosecution record of those patents that were upheld to those that were invalidated, and we measure both groups against patents from the same fields of technology that were not enforced in court.

We find that the important patents—the ones that end up in the Orange Book and enforced in court—have a very different record in the PTO than their counterparts, suggesting that applicants know in advance which patents are the important ones. By contrast, there is very little in the current prosecution record that allows us to distinguish good from bad patents. We also find that having examiners spend more time on the important patents, as some have suggested,[6] is not likely to help much; examiners who get more time to work on important cases now do not do more work, but instead cut and paste their existing work from prior cases.

Our data allow us to suggest some targeted reforms to the patent process. We would require applicants to identify up front patents they intend to list in the Orange Book. Those applications should be subject to extra scrutiny—not by giving examiners more time, but by putting them into a special process similar to the PTO's Central Reexamination Unit.[7] If they survive that more intensive process, we should give those patents a stronger presumption of validity. These reforms should provide a cost effective and efficient means to reduce the number of duplicative invalid patents issued by the PTO in this critical area of technology.

Our data also highlight the difficulties with patent thickets in the pharmaceutical industry. Under current law, patent owners can game the regulatory system by obtaining multiple patents that are virtually indistinguishable from each other. By dramatically increasing the number of weak patents issued, brand firms are able to increase entry costs for generic competitors.[8] We suggest significant reforms both to how we grant patents in these large families and to how we regulate generic entry into pharmaceutical markets.

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5. The Orange Book (formally, the "Approved Drug Products with Therapeutic Equivalence Evaluations") is a list of drugs and pharmaceuticals that the FDA has approved as both safe and effective. The Orange Book also includes the patent numbers associated with each product and the calculated expiration dates of those patents.

6. Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 981 (2019); Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination* 4–7 (Nat'l Bureau of Econ. Rsch., Working Paper No. 27579, 2020).

7. *See also* Dmitry Karshtedt, Pharmaceutical Patents and Adversarial Examination (August 9, 2021) (unpublished manuscript) (on file with author) (arguing that the PTO should allow interested third parties to participate in the pharmaceutical patent examination process).

8. *See* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICIAL LEGAL STUD. 613, 615 (2011) (showing that "additional patents, even weak ones, generally strengthen a brand-name firm's ability to exclude").

In Part I, we discuss the regulatory structure of pharmaceutical patents and the Hatch-Waxman Act. We discuss our data and methodology in Part II. In Part III we present our results. Finally, in Part IV we offer policy recommendations and a critique of some other proposals based on our findings.

I. THE HATCH-WAXMAN BALANCE AND ORANGE BOOK PATENTS

Pharmaceutical patents are important.[9] Indeed, patents are probably more important in pharmaceuticals than anywhere else.[10] Drug patents are subject not only to the normal rules of patent law but to a complex regulatory regime under the Hatch-Waxman Act. In this section, we explain the background of that system.

A. The Patent Examination Process

When an application is sent to the PTO, it is first sorted for examination by technology type.[11] Each application is assigned to an "art unit" which is a group of patent examiners who examine applications related to a specific technology type.[12] Once in the art unit, a supervisory patent examiner (SPE) will then assign applications, for the most part randomly, to a reviewing examiner.[13] However, once an examiner receives an application, there is a much higher likelihood that the same examiner will examine any related family members.[14]

9. We define "pharmaceutical patents" as patents directed towards small molecules which are listed in the Orange Book. Biologic drugs are listed in a separate "Purple Book" that does not disclose patents, and were excluded from our study.

10. *See* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 109 (2008) ("Over one-half of the value of worldwide patents accrues to a small number of large pharmaceutical firms; over two-thirds accrues to firms in the chemical and pharmaceutical industries.").

11. *See* Mark A. Lemley & Bhaven Sampat, *Examiner Characteristics and Patent Office Outcomes*, 94 REV. ECON. STAT. 817, 818 (2012) ("Once applications arrive at the PTO, they are divided into technology classes . . . .").

12. Each hundreds unit (1600, 1700, 2100, 2400, 2600, 2700, 2800, 2900, 3600, and 3700) defines a large "Technology Center." For example, Technology Center 1600 covers biotechnology and organic chemistry, while Technology Center 2100 covers computer architecture, software and information security. Further, each tens unit narrows the technology and is defined as a "Workgroup." For example, Workgroup 1610 is directed to organic compounds and Workgroup 2110 is directed to computer architecture. Finally, the unit digit is the narrowest measure of technology and defined as an "Art Unit." For example, Art Unit 1611 is drug, bio-affecting and body treating compositions, while Art Unit 2111 deals with electrical computers and digital data processing systems. *See id.*

13. Some SPEs will assign applications on the basis of the last digit of the application serial number. *See id.* Other SPEs will assign based on docket management, giving the oldest unassigned application to the examiner who has finished examining a prior application. *See id.*

14. *See* Robert Lichter & Ryan Potts, *Patent Office Insights from Two Former Examiners*, IPWATCHDOG (July 21, 2020), https://www.ipwatchdog.com/2020/07/21/patent-office-insights-two-former-examiners/id=123414/ [https://perma.cc/D6F8-B762] (stating that "[c]ontinuation applications are more likely to be docketed to the same examiner as the parent application").

There are many programs at the USPTO that allow applicants to speed up the review process.[15] The most important for Orange Book applications is the "Track One" program.[16] The Applicant can petition for Track One status, which aims to give applicants a final disposition within twelve months from the Track One request grant. Importantly, applicants do not have to perform pre-examination search to qualify for Track One status.[17] The USPTO, however, has limited Track One status to only 15,000 applications per fiscal year.[18]

Substantive examination begins when the examiner reviews the specification and closely reviews the claims. The examiner may argue that the claims do not encompass patentable subject matter or do not meet the requisite utility requirement. The examiner then reviews the claims in light of the specification and determines if the claims: (1) have enough written description support; (2) meet the enablement requirement; and (3) meet the definiteness requirement. Each of these requirements usually do not require the examiner to search outside the four corners of the patent application.[19]

During the substantive examination process, the examiner conducts a prior art search. Examiners can search within databases such as prior U.S. patents or applications, foreign patents, and nonpatent literature such as scientific or technical journals, though they overwhelmingly rely on prior U.S. patents as prior art.[20] The examiner then assesses the novelty and nonobviousness of the claims in light of the prior art that was found and the prior art disclosed by the applicant.

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15. These programs include: (1) Track One, (2) accelerated examination, (3) petition to make special, (4) patent prosecution highway (PPH), (5) full first action interview pilot program (discontinued on January 15, 2021), (6) after final consideration pilot program (AFCP 2.0—program extended to September 30, 2021), and (7) quick path information disclosure statement (QPIDS) program.

16. 37 C.F.R. § 1.102(e) (2022); *see also* Changes to Implement the Prioritized Examination Track (Track I), 76 Fed. Reg. 59,050 (Sept. 23, 2011).

17. *See* USPTO, USPTO'S PRIORITIZED PATENT EXAMINATION PROGRAM (2021), https://www.uspto.gov/patents/initiatives/usptos-prioritized-patent-examination-program [https://perma.cc/4JBW-TGGW]. The only requirements for Track One status is that the application cannot contain or be amended to contain more than four independent claims, more than thirty total claims, or any multiple dependent claim. *See* 37 C.F.R. § 1.102(e) (2022).

18. 37 C.F.R. § 1.102(e) (2022); *see also* Increase of the Annual Limit on Accepted Requests for Track I Prioritized Examination, 84 Fed. Reg. 45,907 (Sept. 3, 2019). By way of context, the USPTO recieves approximately 600,000 per year and grants approximately 300,000 per year. *See* USPTO, U.S. PATENT ACTIVITY CALENDAR YEARS 1790 TO THE PRESENT, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.htm [https://perma.cc/5L5Y-TV6Y].

19. *See* 35 U.S.C. § 112(a)–(b).

20. Christopher A. Cotropia, Mark A. Lemley & Bhaven Sampat, *Do Applicant Patent Citations Matter?*, 42 RSCH. POL'Y 844, 844–46 (noting that 64% of the art used is prior U.S. patents or patent applications). For examples of common rejections made by examiners see S. Sean Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, 38 CARDOZO ARTS & ENT. L.J. 391 (2020) and Shine Sean Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, 2021 MICH. ST. L. REV. 411.

If there is no invalidating prior art, and the claims are properly described and enabled, the examiner will issue a notice of allowance. However, first action allowances are a relatively rare occurrence.[21] More commonly, the examiner will reject the claims for one of the reasons listed above.[22] The applicant then has no more than six months to respond to the Office Action. Usually, the applicant will take one or both of the following actions: (1) amend the claims to traverse the rejections and (2) traverse the rejection based on scientific or legal arguments.

If the examiner is persuaded by the response, they can allow the case. If the examiner is not persuaded, they can reject using the same rejections as in the first Office Action or reject based on new grounds. Depending on the arguments made by the applicant (and if the examiner was persuaded by the applicant's arguments), the examiner can then choose to make their next response either "final" or "non-final."[23] The applicant has six months to choose one of several common options: (1) file a request for continued examination (RCE) to continue examination, basically continuing prosecution where the examiner left off; (2) file a notice of appeal, appealing the rejections to the Patent Trial and Appeal Board (PTAB); (3) abandon the application; or (4) file a continuation application or continuation in part (CIP) application.[24] Filing a continuation or CIP application can be done in conjunction with filing an RCE, notice of appeal, or abandonment. The process then repeats itself until a patent is allowed or the applicant abandons the application.

B. Orange Book Procedure

The Hatch-Waxman Act attempts to optimize the balance between innovation and access to pharmaceuticals. It gives special rights to pharmaceutical patent owners, including longer patent terms[25] and the power to prevent a generic drug from getting FDA approval to enter the market for up to thirty months until any patent litigation is resolved—in effect, an automatic preliminary injunction.[26]

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21. *See* Lemley & Sampat, *supra* note 11, at 820 (finding that 18% of applications were granted on first office actions).

22. *See* Mark A. Lemley & Bhaven Sampat, *Examining Patent Examination*, 2010 STAN. TECH. L. REV. 2, ¶ 7 (finding that 86.5% of their data set had a first action non-final rejection).

23. *See* Shine Sean Tu, *Luck/Unluck of the Draw: An Empirical Study of Examiner Allowance Rates*, 2012 STAN. TECH. L. REV. 10, 14.

24. *See id.*

25. *See* 35 U.S.C. § 156.

26. *See* 21 U.S.C. § 355(j)(5)(B)(iii). By contrast, actual preliminary injunctions in patent cases are quite rare. High Tech Med. Instrumentation, Inc. v. New Image Indus., 49 F.3d 1551, 1554 (Fed. Cir. 1995) ("[A] preliminary injunction is 'not to be routinely granted.'" (quoting Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993))).

Patents subject to these rules are listed with the FDA in an FDA compendium commonly known as the Orange Book. New Drug Applications (NDAs)

> *shall* file with the application the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[27]

Most new drugs are protected by one or more patents, and those patents are required to be listed in the Orange Book. Specifically, the FDA requires patents that "consist of drug substance (active ingredient) patents, drug product (formulation and composition patents), and method-of-use patents" to be listed in the Orange Book.[28]

Importantly, the FDA does not substantively review the accuracy of the patent information before publishing. This is because the FDA interprets its role in listing patent information as "purely ministerial" and explained that it "lacks both the resources and the expertise to police the correctness . . . of every patent listing submitted by an NDA holder."[29]

Orange Book listed patents provide certain privileges for the patent owner. Specifically, companies seeking to market a generic version of the drug must make a certification (for each patent listed in the Orange book) that: (1) the NDA holder has not submitted patent information to the FDA for listing in the Orange Book; (2) the patent has expired; (3) the date the patent will expire; or (4) "[the] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[30] For generic firms, the Paragraph IV certification is the most important.[31] In making a Paragraph IV certification, the generic drug maker posits that the patent is: (1) invalid, (2) not infringed, or (3) unenforceable. If so, the generic company can enter the market before the patent expires. Filing a Paragraph IV certification is deemed by the law to be an act of infringement to which the brand-name firm can respond by filing a patent infringement suit. Accordingly, if the patent owner sues within 45 days of receiving notice of the Paragraph IV certification, a stay is triggered that

27. 21 U.S.C. § 355(b)(1) (emphasis added).

28. 21 C.F.R. § 314.53(b) (2022).

29. aaiPharma Inc. v. Thompson, 296 F.3d 227, 237 (4th Cir. 2002) (noting that the FDA does not substantively review the correctness of the patent information before publication); *see also* Teva Pharm., USA, Inc. v. Leavitt, 548 F.3d 103, 106 (D.C. Cir. 2008); Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1084 (D.C. Cir. 2001); 21 C.F.R. § 314.53(e) (2022).

30. 21 U.S.C. §§ 355(b)(2)(A)(iv), (j)(2)(A)(vii)(I)–(IV). This last is commonly referred to as a "Paragraph IV" certification.

31. *See* Hemphill & Sampat, *supra* note 8, at 624 fig.4 (showing that 299 out of 692 drugs were subjected to Paragraph IV challenges).

generally prevents the FDA from approving the generic drug for 30 months.[32]

On the generic side, the Act permits generic drug makers to file an Abbreviated New Drug Application (ANDA), relying on the data the patent owner submitted to the FDA to get quicker approval for a generic version of the same drug. It also encourages generics to challenge the branded patents before they expire when they believe that the relevant patents are either invalid or do not cover the generic product. As an added incentive to encourage generic firms to engage in "Paragraph IV" certifications, the first generic applicant who files a Paragraph IV certification is given a 180-day exclusive right to market its product in competition with the brand-name firm before other generic firms may enter the market.[33]

These challenges are expensive and complex, and they offer many opportunities for gamesmanship.[34] Patentees try to extend patent lifecycles by creating large patent thickets and "evergreening" their patents, adding new patents on minor variants as the basic patents expire.[35] For example, when the patents on Namenda and Tricor expired, the patent owners sought to force everyone to accept a minor change in formulation because they had patents on that minor change that expired later.[36] Those later patents are often weaker, and they are more frequently challenged by generic firms.[37] But the structure of the regulatory regime means that any patent, no matter how weak, poses a significant obstacle to generic market entry.

Interestingly, even though Hatch-Waxman carefully balances the interests between generic firms and branded firms, nothing in Hatch-Waxman addresses what could be done at the Patent Office to prevent the issuance of weak patents designed to create patent thickets or evergreening.

Some commentators have noted that administrative proceedings, such as the *inter partes* review (IPR) process, are designed to lower the costs of

32. *See* 21 U.S.C. § 355(c)(3)(C) (for 505(b)(2) NDAs); (j)(5)(B)(iii) (for ANDAs).

33. 21 U.S.C. § 355(j)(5)(B)(iv).

34. *See* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, *in* INNOVATION POLICY AND THE ECONOMY 145, 145–87 (A.B. Jaffe, J. Lerner & S. Stern eds., 2004); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006).

35. *See* Hemphill & Sampat, *supra* note 8, at 615 (noting that "[b]rand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug"); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 5–6, 27 (2005); Bronwyn Hall, Christian Helmers & Georg von Graevenitz, *Technology Entry in the Presence of Patent Thickets* (NBER Working Paper No. 21455, 2015) (showing that patent thickets raise entry costs and lead to less entry into technologies regardless of a firm's size).

36. New York *ex rel.* Schneiderman v. Actavis P.L.C., 787 F.3d 638 (2d Cir. 2015); Abbott Lab'ys v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006).

37. Hemphill & Sampat, *supra* note 8, at 615 (stating that "[w]eak patents make a challenge more likely . . . particularly if they expire later than the basic patents"); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012).

invalidating patents, so they might be a solution to the problem of bad follow-on pharmaceutical patents.[38] But IPRs may be inefficient when brand firms create a thicket of patents since only a single patent can be challenged in each IPR. And invalidating a patent in an IPR proceeding does not lift the thirty-month stay, and so it will not allow generics to enter the market.[39]

Michael Frakes and Melissa Wasserman have proposed that the PTO focus more attention on Orange Book patents by giving examiners more time to evaluate those patents.[40] They suggest that even if it generally makes sense not to do a full-fledged assessment of every patent application, since most of them turn out not to be important,[41] Orange Book patents are sufficiently important that they deserve extra attention.[42] That is consistent with a larger literature suggesting extra attention to patents that turn out to be important.[43] Our data allows us to evaluate the feasibility of that proposal and to consider other ways to improve the quality of pharmaceutical patents.

II. THE DATASETS

We created two unique datasets for this study: a litigation dataset as well as a corresponding patent prosecution dataset. Second, we identified each of the patents in those cases. For each patent, we hand-coded whether it was a primary patent on a new chemical entity or a secondary follow-on patent.[44] We also collected the full prosecution history for each patent. Some of that

38. *See, e.g.*, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 35 (2020) (summarizing proposed legislation); Francisco Javier Espinosa, *Big Pharma Versus Inter Partes Review: Why the Pharmaceutical Industry Should Seek Logical Hatch-Waxman Reform over Inter Partes Review Exemption*, 50 J. MARSHALL L. REV. 337, 338–40 (2017) (summarizing various advocates' stances on using IPRs to solve bad pharmaceutical patents).

39. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I) (stating that only a district court ruling may lift the stay); Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALA. L. REV. 59, 87 (2017) (noting that after a successful IPR, a district court would still have to concurrently enter a judgment). *But see* Sunand Kannappan, Jonathand J. Darrow, Aaron S. Kesselheim & Reed F. Beall, *The Timing of 30-Month Stay Expirations and Generic Entry: A Cohort Study of First Generics, 2013–2020*, 2021 CLINICAL & TRANSLATIONAL SCI. 1917, 1917 (arguing that "30-month stays are unlikely to delay the timing of generic entry"). Notwithstanding Kannappan et al., there is little doubt that generics are regularly held back from generic entry by the thirty-month stay.

40. Frakes & Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, *supra* note 6, at 4–7.

41. For debate on that issue compare Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001) with Frakes & Wasserman, *Irrational Ignorance at the Patent Office*, *supra* note 6, at 981.

42. Frakes & Wasserman, *Irrational Ignorance at the Patent Office*, *supra* note 6, at 4–7.

43. *See generally, e.g.*, Douglas Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45 (2007); Lemley et al., *supra* note 4, at 10–13.

44. *Cf.* Frakes & Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, *supra* note 6, at 13 n.6 (listing all "drug substance" patents in the Orange Book dataset as primary patents). We coded a patent as primary if it had at least one independent claim to a new composition of matter, and secondary if it did not.

data is evident on the face of the patent or the PTO record itself, but we hand-coded important prosecution events as well as the prior art that was used during prosecution and the nature of individual PTO rejections and applicant responses. To ensure consistent coding as well as familiarity with the technology, only one author (Tu) coded all the datasets.[45]

A. Litigation Dataset

First, we collected all ANDA litigated cases that resulted in a final decision on validity or infringement using Lex Machina[46] and hand-coded for the basis for invalidation (including the prior art used). The litigation dataset was generated from all ANDA cases[47] pending from January 1, 2009 to January 15, 2021. The earliest case was filed on March 16, 2000[48] and the latest case was filed on December 27, 2018.[49]

We reviewed the final decisions from all 328 federal district court cases corresponding to 632 patents. We selected two groups for more detailed investigation: the eighty-two cases that contained a finding of invalidity and the 196 cases that contained a finding of no invalidity.

For each case that had a final validity ruling, we collected basic information such as: (1) filing date, (2) termination date, (3) length of litigation, (4) number of defendants, (5) number of asserted patents, (6) if the patent was a reissue patent, (7) district in which litigation occurred, (8) judges, and (9) magistrates. We also recorded the substantive outcome and the procedural posture (specifically whether the court issued a judgment as a matter of law, summary judgment, or after trial, and whether the case was appealed to the Federal Circuit). Finally, we hand-coded the basis for invalidation: § 101 patentable subject matter, § 102 anticipation, § 103 obviousness, § 112(a) written description, § 112(a) enablement, § 112(b)

45. S. Sean Tu's pertinent credentials are: B.S. in Microbiology and B.S. in Chemistry, University of Florida (1997); Ph.D. in Pharmacology, Cornell University (2003); Post-Doctoral Fellow, La Jolla Institute for Allergy and Immunology (2005); Associate with Foley & Lardner (Chemical, Biotechnology & Pharmaceutical Practice/Life Science and Nanotechnology Industry Team). We acknowledge that while this eliminates the problem of inter-coder reliability, it does not guarantee that someone else would make the same decisions Tu did.

46. LEX MACHINA, www.LexMachina.com [https://perma.cc/8RDK-TR6G].

47. The full search term used on Lex Machina was: terminated federal district court cases; with Patent: ANDA case tag; with Claim Defendant Win: Judgment as a Matter of Law, Claim Defendant Win: Judgment on the Pleadings, Claim Defendant Win: Summary Judgment, Claim Defendant Win: Trial, Claimant Win: Judgment as a Matter of Law, Claimant Win: Judgment on the Pleadings, Claimant Win: Summary Judgment, or Claimant Win: Trial as case resolutions; pending between 2009-01-01 and 2021-01-15.

48. Smithkline Beecham Corp. v. Zenith Gold Pharms., Inc., 71 F. App'x 64 (Fed. Cir. 2003) (mem.) (per curiam).

49. Biogen Int'l GmbH v. Banner Life Scis. L.L.C., 956 F.3d 1351 (Fed. Cir. 2020). Given that we include only suits that went to a final judgment, and given the thirty-month stay of ANDA approval when a suit is filed, the delay from 2018 to 2021 is not surprising.

definiteness, and obviousness type double patenting. If the patent was invalidated due to prior art under sections 102 or 103, we categorized each prior art reference as a U.S. patent, U.S. patent application, foreign patent/application, printed publication, public use, or on sale bar. Additionally, we identified each specific reference used to invalidate the patent so we could match this information up with the prosecution data.

B. PAIR Dataset

We created the second dataset by running the 632 Orange Book patents with a litigation outcome through PatentAdvisor.com to retrieve all PAIR information about the patent prosecution process.[50] From these 632 patents, we were able to retrieve PAIR data on 458 patents using PatentAdvisor.com. Not all patents were retrieved because some patents were filed before the PTO kept electronic records (pre-January 2003 records).

We created a control group with a random sample of 100 patents issued from the "average" examiner from workgroup 1610, the PTO art unit that includes almost all Orange Book patents.[51] This second control group serves as a baseline for comparing litigated patents to an "average" patent from Workgroup 1610.

For each patent in both groups, we coded general information such as: patent application number, patent number, filing date, issue date, art unit, class/subclass, assignee, assignee citizenship, and examiner name. Additionally, we recorded specific information about the prosecution history of the patent, such as: the number of appeals within the PTO, the total number of priority documents, the type of priority document (CON, DIV, CIP, Provisional, PCT or foreign patent/application), the total number of children, the number of independent claims, and the total number of claims.

We also related each patent to the examiner who allowed the patent. For each examiner, we recorded their allowance rate, Office Action to Grant

50. The Patent Application Information Retrieval (PAIR) system, which provides information regarding the application status as well as the prosecution history of the application.

51. For a detailed description of the "1610 Average" control group see Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, *supra* note 20, at 407 and Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, *supra* note 20. See also Section III(B) for a further discission regarding the "1610 average" control group. Additionally, the "average" 1610 examiner was chosen (as opposed to the "fast" or "slow" group) because most Orange Book examiners in the litigated dataset have characteristics associated with the "average" examiner.

We conducted a robustness check in which we re-ran each of our results against the subset of litigated patents that were prosecuted by fast and slow examiners. The direction and magnitude of our results did not change significantly. [The results are available from the authors on request].

Ratio (OGR),[52] and the total number of applications reviewed by the examiner over their career.

C. Invalid Orange Book Patent Dataset

Our third dataset is a subset of the first and focuses on litigated Orange Book patents that resulted in a ruling on validity. Because this study focuses on things that the PTO could do to prevent the issuance of invalid patents, we focused on the 142 invalidated patents by completing a much deeper analysis into the prosecution history of this subgroup of invalidated patents. As a control, we used a dataset of 100 patents from workgroup 1610. Patents from the 1610 control group represent patents that were issued from the "average" patent examiner.[53] Furthermore, we used a second dataset of approximately 400 patents from the "not invalid" litigated patents as an additional control group. We refer to "litigated" patents as the combination of both "invalid" and "not invalid" patents.

We delved into the prosecution of these patents in detail. We recorded a variety of general patent-related metrics for each patent in this group. Those include the examiner's name, workgroup, and art unit; the class and subclass of the patent; the assignee; the number of priority claims; whether the priority claim was to a U.S. priority document (CON, DIV, CIP, or provisional) or foreign priority document (PCT, foreign application, or foreign patent); the number of children; the application date, issue date, and duration of prosecution; the number of independent claims at grant, the number of words in each independent claim at grant, the total change in number of words from publication to grant; and whether the application was granted Track One status.

We also delved into the technology of the patent to determine if the patent is to an active ingredient (primary patent) or was a follow-on invention (secondary patent). To classify the patent as either primary or secondary, we reviewed every claim of each invalid and control patent. We defined independent claims to compositions of matter as primary patents[54]

52. For a detailed description of the OGR metric, see Shine Sean Tu, *Three New Metrics for Patent Examiner Activity: Office Actions per Grant Ratio (OGR), Office Actions per Disposal Ratio (ODR), and Grant to Examiner Ratio (GER)*, 100 J. PAT. & TRADEMARK OFF. SOC'Y 277 (2018).

53. Ten random patent examiners were chosen from a group of examiners who issue between twenty and fifty patents per year. Then ten random patents were taken from each of those ten examiners to create a dataset of 100 patents from the "average" examiner. For a detailed description of the "average" patent examiner in the 1610 control group, see Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, *supra* note 20, at 407 and Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, *supra* note 20.

54. We did not include polymorph or enantiomers as primary patents even though they are composition of matter claims because these claims are usually not considered as "breakthrough" as the initial composition of matter claims. Rather, they are standard variants on an existing chemical. For discussion of enantiomer patents, see Mark A. Lemley, *Expecting the Unexpected*, 92 NOTRE DAME L.

while patents with only method of use claims, new dosing strategies, or other follow-on technologies were deemed secondary patents.

For each examiner who examined one or more of these patents, we looked into their overall record at the PTO. We coded the examiner's allowance rate, OGR, the total number of office actions they issued, and the total number of abandoned, patented, and pending applications they supervised (and the share of each).

We collected details on the prosecution process of each patent in our study and control groups.[55] That data includes the number of non-final rejections, the number of final rejections, whether the application was a first action allowance, the total number of pages in each office action, the type of rejections the examiner employed (§§ 101, 112(a), 112(b), non-statutory double patenting, 102, and/or 103), the number of examiner interviews, and whether the application had a prosecution that was identical or very similar to another family member. For those rejections based on 35 U.S.C. §§ 102 and/or 103, we coded the total number of *unique* references used[56] as well as the type and number of each unique references used. Each reference was categorized as either: (1) a US patent, (2) a US patent application, (3) a foreign patent or application, (4) a printed publication, or (5) other.[57] This information helps us evaluate how detailed the examination was, as well as to compare the prior art cited in the PTO to that used in litigation.

We also looked at every response filed by the applicants to a non-final and final Office Action. For each rejection, we categorized the applicant's response based on the type of rejection.

For section 101 and 112 rejections (utility, patentable subject matter, enablement, written description, definiteness, and statutory double patenting) we determined if the applicant relied on a claim amendment or on argument. For non-statutory double patenting rejections we also included whether a terminal disclaimer was used to overcome the rejection.[58]

REV. 1369, 1377–94 (2017). *See also* Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2007 STAN. TECH. L. REV. 2.

55. *See* Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, *supra* note 20, at 407; Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, *supra* note 20.

56. "Unique references" are especially important for rejections based on obviousness under section 103. *See* 35 U.S.C. § 103. For example, if the examiner rejected claim one based on References A and B, and also rejected claim one based on References A and C, the study would only account for three references, not four. Furthermore, if the examiner used the same reference in any subsequent rejections, then that reference was not counted again.

57. "Other" references were references that did not neatly fit into any of the enumerated categories (for example, the examiner's use of official notice).

58. See also Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, *supra* note 20, for a deeper discussion of examiner's non-prior art rejections and applicant's traversal strategies.

For section 102 anticipation rejections based on prior art,[59] we coded for several types of applicant responses: (1) claim amendments, (2) missing element arguments, (3) no motivation to modify arguments, (4) prior art reference was not enabled arguments, (5) arguments that the reference is not prior art using a 131 declaration,[60] and (6) "other" arguments.[61] We also recorded the number of times a 132 declaration[62] was used to introduce new evidence in conjunction with the applicant's arguments.

Finally, for section 103 obviousness type rejections based on prior art, we coded for the following types of applicant responses: (1) claim amendments, (2) missing element arguments, (3) no motivation to modify arguments, (4) no motivation to combine arguments, (5) reference is not prior art using a 131 declaration, (6) prior art reference is not enabled arguments, (7) reference teaches away from invention arguments, (8) unexpected results arguments, (9) not obvious to try arguments, (10) no expectation of success arguments, and (11) "other" arguments.[63] We also recorded the number of times a 132 declaration[64] was used to introduce new evidence in conjunction with the applicant's arguments.

D. Statistical Significance

Because this is a population study that includes every litigated patent, by definition the results are statistically significant. Nonetheless, where we make individual comparisons among examiner groups we have conducted statistical inference tests of the sort that would be important if this were only a sample.

We used a Kruskal-Wallis test to test whether a variable is different among the three examiner groups.[65] If the p-value is below the threshold, that indicates that we can safely reject the null hypothesis that the samples

59. These include rejections based on section 102(a), (g), (e), and (b). No other section 102 prior art rejections were found in this dataset.

60. *See* 37 C.F.R. § 1.131(a) (2019).

61. The "'other' arguments" was used as a catch-all if the argument used in prosecution did not squarely fit in a previously mentioned category.

Note that some of those categories—enablement and 131 declarations—do not apply to an inventor's own prior art under section 102(b), and we have excluded those categories from 102(b) cases. *See also* Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, *supra* note 20.

62. *See* 37 C.F.R. § 1.132 (2022); *see also* U.S. DEP'T OF COM., PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 716 (9th ed. rev. 8, Jan. 2018) [hereinafter MPEP].

63. The "'other' arguments" category acted as a catch-all for those arguments used during prosecution that did not squarely fit into one of the ten preceding categories (for example, if a reference was not prior art because the examiner erroneously calculated the priority date). *See also* Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, *supra* note 20.

64. *See* 37 C.F.R. § 1.132 (2022); *see also* MPEP, *supra* note 62, at § 716.

65. *See* William H. Kruskal & W. Allen Wallis, *Use of Ranks in One-Criterion Variance Analysis*, 47 J. AM. STAT. ASS'N 583, 595–97 (1952). Kruskal-Wallis is preferable to an ANOVA test where, as here, we have abnormal distributions.

come from the same distribution. That tells us that there is at least one of the three groups of patents (1610 control, invalid, valid) that is different from the others on that particular metric and which group is larger.[66] But it doesn't tell us which group or groups are different in a statistically significant way.

Because we have three groups to compare, we supplemented Kruskal-Wallis with Dunn's test, which considers all the groups as a whole when finding ranks of the numbers.[67] The combination allows us to test whether there is significant difference in a certain variable among any of the three examiner groups. The chi-squared test and p-value show how the examiners are different regarding a certain variable.

We report the results of both the pairwise and cross-group Dunn comparisons in the Statistical Appendix.[68] Where we report data in the text, we indicate the significance (or lack thereof) of that data.

III. RESULTS

Because our goal is to learn how the PTO might improve its processes and weed out mistakes in pharmaceutical patents, we focus our attention on the outcomes of litigated patents, with particular attention to the patents ultimately held invalid in court. We discuss the basic descriptive results of our patents of interest in Section A. We then turn in Section B to the relationships we observe between different variables in our study.

A Litigation Outcomes[69]

There were 328 ANDA cases resolved during the years of our study (suits filed from 2000 through 2018). We present the results of those cases in Figure 1.

66. SMD represents "Score Mean Difference," which is calculated from the ranks of the numbers from the whole dataset. The formula for SMD is:

SMD = {Sum of group 1 scores - 0.5}/n1 - {Sum of group 2 scores + 0.5}/n2.

A positive SMD represents that the first group has larger scores than the second, while a negative SMD represents that the second group has larger scores. A p-value that is less than 5% shows that the difference is significant.

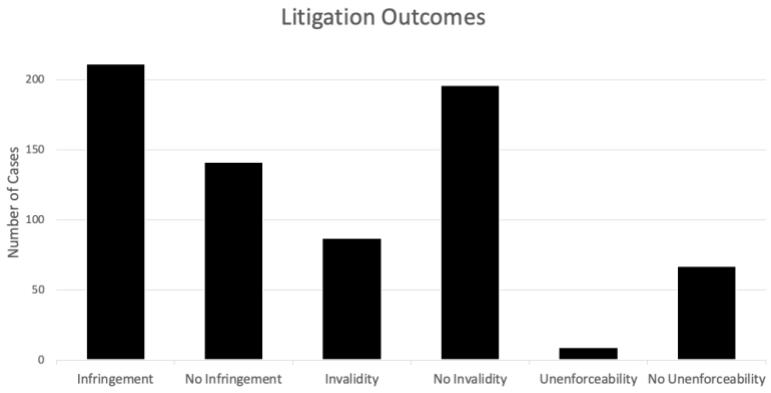
67. *See* Olive Jean Dunn, *Multiple Comparisons Among Means*, 56 J. AM. STAT. ASS'N 52, 52 (1961).

68. If not listed, the results are not statistically significant to a p-value of less than 0.05.

69. We are conscious of the problem of selection bias in any study of litigation outcomes. *See* John R. Allison, Mark A. Lemley & David Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073 (2015) (discussing potential biases in detail). But we think they are less of a problem in this study, because our findings focus on how patent prosecution differs for litigated and unlitigated patents, not on the (relatively modest) differences between valid and invalid patents. Further, in the pharmaceutical industry cases tend to be litigated rather than settling before any suit is filed.

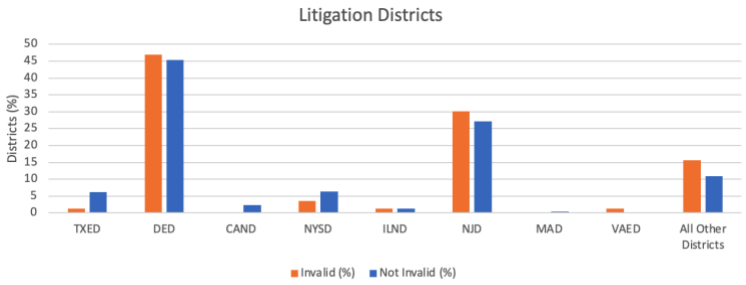
Nonetheless, in an ideal world we would also have a comparison set of litigated but settled Orange

Figure 1



Those cases are concentrated in just two courts – the District of Delaware and the District of New Jersey.[70]

Figure 2



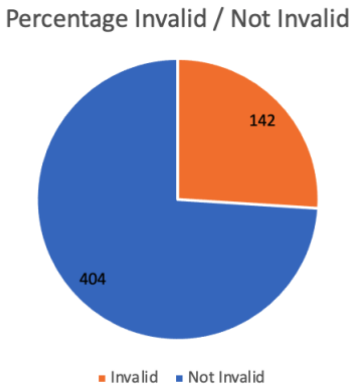
Of particular interest for our purposes, eighty-two cases corresponding to 142 unique patents resulted in invalidation. 196 cases corresponding to 404 unique patents are held not invalid. That represents an invalidity rate of just 26%, well below the overall patent invalidation rate of 43%.[71]

Book patents. Cases that settle might do so because the patents seemed stronger than normal, or conversely because the patents seemed weaker than normal. To have a clear theory on the basis for settlement we would have to know the terms of that settlement. But that information is confidential.

70. Many, though not all, pharmaceutical companies are based in those districts. *See* John R. Thomas, *Hatch-Waxman's Renegades* 1 (working paper 2021) (stating that "Delaware and New Jersey[] adjudicate the vast majority of patent contests between brand-name and generic manufacturers").

71. *See* John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1801 (2014). Pharmaceuticals in general fare better in

Figure 3



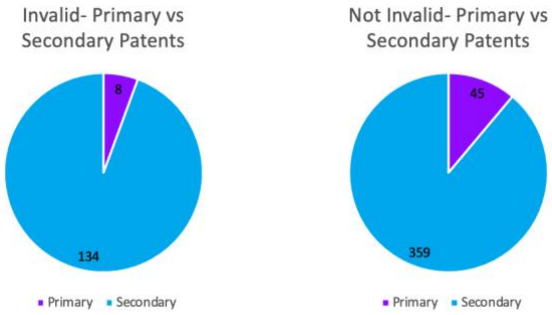
The overwhelming majority of litigated Orange Book patents are not "primary" patents directed to new chemical entities, but follow-on patents that claim changes in formulation, dissolution profile, new uses, and the like. Various scholars have pointed to the problems with evergreening and the building of patent thickets around secondary patents, which tend to be less important inventions that are used to extend the life of a basic patent.[72] 134 (94%) of the 142 invalid patents and 359 (89%) of the 404 valid patents were secondary patents.[73]

court than other sorts of patents. Allison et al., *supra* note 69, at 1111. Orange Book/ANDA patents—the ones we consider here—are a subset of all pharmaceutical patents.

72. *See* Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, *supra* note 37, at 327; Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171 (2016); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009). These problems are not limited to the pharmaceutical industry. *See* Cesare Righi & Timothy Simcoe, *Patenting Inventions or Inventing Patents? Strategic Use of Continuations at the USPTO* (NBER Working Paper No. 27686, 2021). But they are most significant in pharmaceuticals because they trigger regulatory exclusivities.

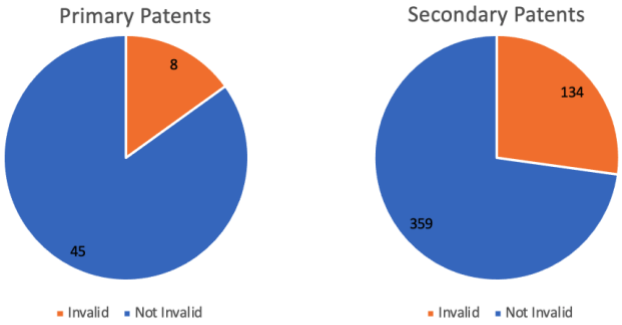
73. *See also* Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, *supra* note 37, at 328 (finding that generics are more likely to challenge secondary patents).

Figure 4



Secondary patents were somewhat more likely to be invalidated than primary patents. Only 15% of primary patents litigated were invalidated, while 27% of secondary patents were invalidated.

Figure 5



Notably, however, even the numbers for secondary patents involve a much higher win rate than for non-pharmaceutical patents.[74]

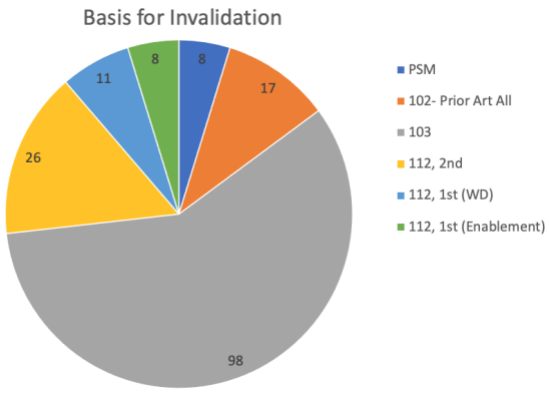
The basis for invalidating patents is broken down in Figure 6.[75] Most patents were invalidated on obviousness grounds. Additionally, the prior art used for these obviousness invalidations were mostly "printed publications." (Appendix 9). But more than a quarter were invalidated under

74. *See* Allison et al., *Understanding the Realities of Modern Patent Litigation*, *supra* note 71, at 1801.

75. We hand-coded this data. We also collected Lex Machina's reason codes for invalidation, which used a somewhat different set of categories but came to very similar results.

section 112, a constellation of requirements that polices inadequate disclosure in the patent. Consistent with prior work,[76] we find that Orange Book patents are significantly more likely to be invalidated under section 112 than other types of patents.

Figure 6



B. The Prosecution Process

For each of the invalidated patents, we delved deeply into the patent prosecution process to try to figure out what went wrong. We did a comparable analysis for the control sample of patents held valid and for a randomly selected group of patents prosecuted in PTO art group 1610, where most of the litigated patents were prosecuted.[77]

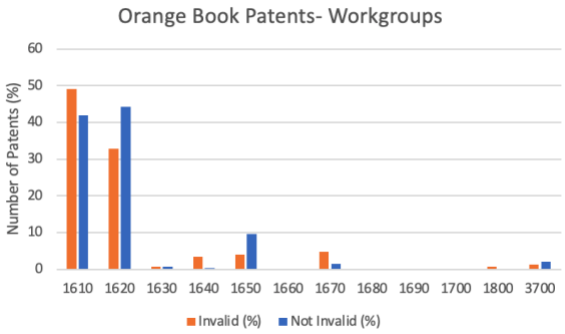
76. *See* Allison et al., *Understanding the Realities of Modern Patent Litigation*, *supra* note 71. Karshtedt, Lemley, and Seymore have argued that pharmaceutical genus claims in particular have fared very poorly at the Federal Circuit in the last two decades. Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, HARV. J.L. & TECH. 1 (2021).

77. The 1610 workgroup covers art units relating to "Drug, Bio-Affecting and Body Treating Compositions." The 1620 workgroup covers art units relating to "Organic Compounds" as well as also covering "Drug, Bio-Affecting and Body Treating Compositions."

The fact that most litigated Orange Book patents are coming from these workgroups is unsurprising because most Orange Book patents (3,641 patents) from our dataset come from these workgroups. *See* Appendix 1.

Because some litigated patents came from outside the 1610 art unit, we conducted a robustness check in which we re-ran each of our results against the subset of litigated patents that were prosecuted in 1610. The direction and magnitude of our results did not change significantly, except in a few instances noted below, each of which strengthened our results. [The results are available from the authors on request.] That gives us some comfort that the control group is appropriately matched to the litigated patents.

Figure 7



1. Patent Family Characteristics and Family Size

We find that litigated patents have significantly different characteristics than other patents from the nonlitigated control group.

First, litigated patents tend to come from large families of related patents.[78] By contrast, unlitigated patents almost never do. Litigated patent families frequently have the same assignee and the same examiner. Specifically, from the 142 invalidated patents, there were only forty-seven unique assignees and only sixty-two unique examiners who issued these invalidated patents. Similarly, of the 295 patents held not invalid for which we had examiner information,[79] there were only eighty unique assignees and only 112 unique examiners. This is consistent with prior literature suggesting that the most valuable patents often come from large families, as applicants are willing to spend more time and money and seek greater insurance against the risk that any one patent is invalidated.[80]

Many firms that assert Orange Book patents are asserting multiple Orange Book patents from the same family. More than half (73.0%) of all invalid patents had at least one other family member that was also found

78. Because patent applicants can file "continuations"—new applications that claim priority to original "parent" applications—many patents can issue from the same original application. *See* Mark A. Lemley & Kimberley A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 66–71 (2004). Those related applications are called families.

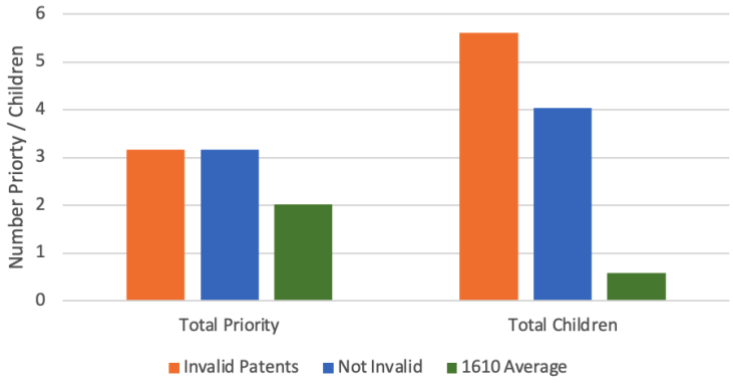
79. There are only 295 patents in this group, instead of 404 patents, because not every patent had examiner information associated with the patent. These patents were patents that were filed before the USPTO kept electronic prosecution histories. Additionally, not every patent was associated with a recorded assignment.

80. *See* John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435, 456–58 (2004).

invalid. Interestingly, 58.6% of the group held valid also had at least one family member that was also found valid.[81]

Litigated Orange Book patents claim almost 1.5 times as many priority documents compared to the 1610 control group.[82] Even more pronounced is the fact that these invalid and not-invalid (litigated) patents have approximately nine and seven times as many children as patents in the control group, respectively.[83]

Figure 8
Priority and Child Data



2. Applicant Management of the Prosecution Process

There are other indications of significant differences between litigated and unlitigated patents. Those differences suggest that applicants are aware from an early stage that the applications that end up in litigation will be important. They treat those applications very differently.

Litigated patents were much more likely to use "Track One," an accelerated process for patent prosecution.[84] Valid and invalid patents use

81. Prior work has shown that patent claims litigated together often stand or fall together. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 252 (1998).

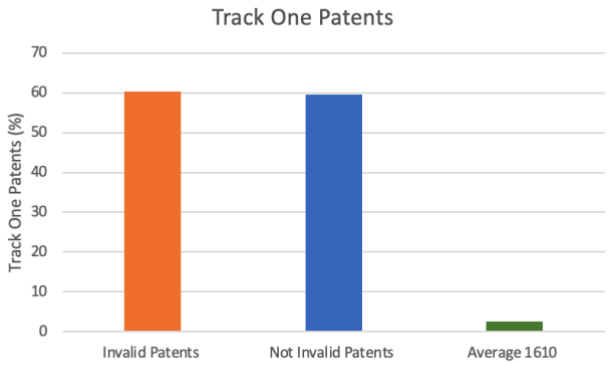
82. Also, these litigated patents are claiming priority to other U.S. patents, and not foreign patents or PCT applications. *See infra* Appendix 2.

83. In our robustness check, 1610 litigated patents had even more children per application than overall litigated patents (6.42 per parent, or eleven times that in the control group).

84. *See* 37 C.F.R. § 1.102(e) (2022); Track One is prioritized examination that attempts to get to final disposition within about twelve months. Track One gives the application special status with fewer requirements than the accelerated examination program and without having to perform a pre-examination search. Track One was implemented in a final rule published on September 23, 2011. *Changes To Implement the Prioritized Examination Track (Track I)*, 76 Fed. Reg. 59,050, 59,050–55 (Sept. 23, 2011). *See also* USPTO, *supra* note 17. Accordingly, this analysis excludes any applications filed before the September 23, 2011 date.

Track One 60.3% and 59.6% of the time, respectively. In contrast, the 1610 control group used Track One only 2.6% of the time. That may in part explain the faster consideration litigated patents received. But it is somewhat surprising, given that speed to issuance is not generally thought to be a major concern with pharmaceutical patents.[85] It may be that applicants want secondary patents quickly because the timing of their listing can block generic ANDA approval.

Figure 9



Litigated patents make it through the patent office more quickly than control group patents.[86]

Litigated patents are also more likely to have examiner interviews.[87] Coupled with fewer office actions, this is consistent with the idea that applicants are more actively steering their patents. Applicants often use examiner interviews to obtain patents that examiners are otherwise unwilling to grant.[88] Despite the requirement that examiners make a record

85. *See* Lemley & Moore, *supra* note 78, at 85–86 ("[T]he highest percentage of continuations [are] filed in the Biotechnology and Chemical areas."). Also, Table 2 shows that Biotechnology and Organic Chemistry patents experience the longest length of prosecution. *Id.*

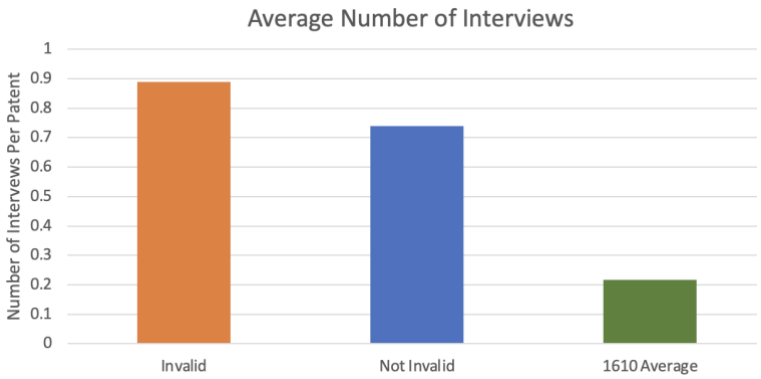
86. The prosecution duration for invalid patents is 2.45 years (898 days). In contrast the prosecution duration for valid patents is 2.68 years (979 days) and the unlitigated control group spent approximately 2.93 years (1071 days) in prosecution. Each of those differences is statistically significant.

87. Litigated patents overall had significantly more interviews than the control group, but the difference between valid and invalid patents was not significant. The result was even more pronounced in the litigated 1610 subgroup, with examiner interviews rising from 0.9 per case to 1.11 per case, nearly ten times the rate of interviews in the control group.

88. During these interviews applicants can dispute the merits of any rejection with the examiner. These interviews are usually done alone with the examiner and usually with a limited written record. Interviews often lead to allowance, and the reason for allowance is unclear since much of the discussion is not recorded or described in great detail. *See generally* S. Sean Tu, *Patent Examination and Examiner Interviews*, 49 FLA. ST. U. L. REV. ONLINE 1, 12–13 (2021) (Figure 1, showing that it takes only approximately 2.0 Office Actions to get to allowance for cases with interviews versus an average of 3.6

of the interview, they tend to create only very pro-forma records of the outcome, allowing applications without the same written record an office action would.

Figure 10



3. Examiner Responses to Litigated Patents

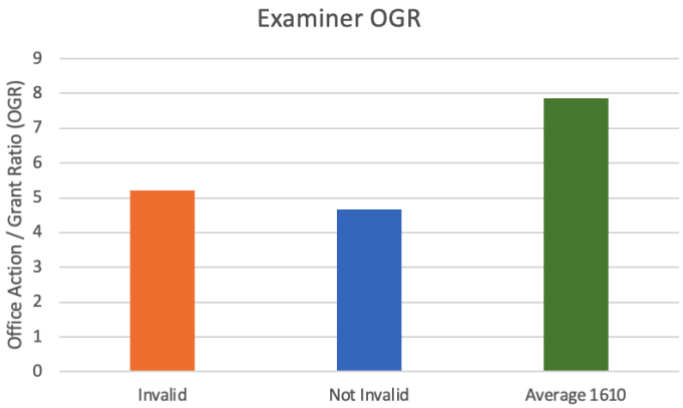
Examiners also treat applications that are ultimately litigated differently than ordinary pharmaceutical patents.

Examiners approve litigated patents after having issued fewer office actions than they do with unlitigated patents. For litigated patents it takes approximately five office actions before allowance. In contrast, for the average, it takes approximately eight office actions before an allowance. [89]

Office Actions). *See also id.* at 17–18 (arguing that the rationale for interviews may be: (1) to bridge the gap between the examiner's concerns and/or confusion with the invention/prior art or (2) signal to the examiner that the application is important to the inventor/assignee and the applicant will not easily abandon the application).

89. We measure the work per application by the Office Action/Grant Ratio (OGR), the number of substantive office actions an examiner issues for each patent that examiner grants.

Figure 11



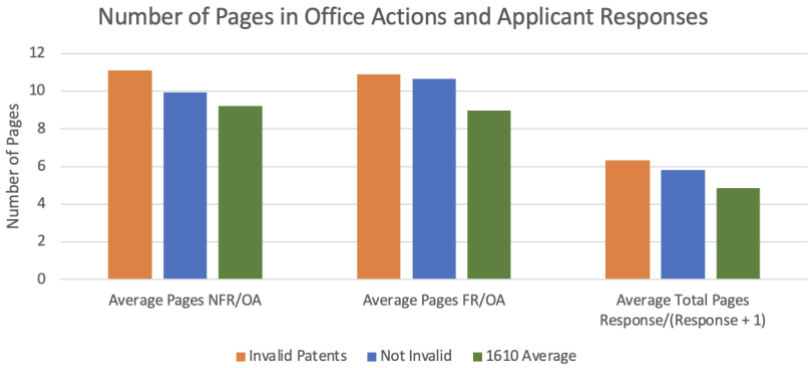
We also measure the number of pages of each Office Action as a refinement to the number of office actions as a proxy for the amount of work the examiner is doing. As shown in Figure 12, the average number of pages in an Office Action for an invalid patent is two pages longer than the Average 1610 control group. Interestingly, the number of pages in the applicant responses are approximately the same for both invalid patents and the control group. These longer office actions are mainly due to longer obviousness rejections in litigated cases based on a much higher number of prior art references.

While the office actions are longer, applicants write somewhat shorter responses for these litigated patents compared to the Average 1610 control group.[90] This may seem surprising. One explanation is that because the applicant knows that these are valuable patents, it will most likely strive to keep the responses shorter to avoid limiting itself with statements in the prosecution history.[91]

90. Applicant responses are significantly longer in the control group than in valid litigated patents, but neither is significantly different than the middle group—invalid litigated patents.

91. The denominators for the applicant response graphs are the total number of responses plus one. This is to account for first action allowances.

Figure 12



Here the evidence suggests—at least at first blush—examiners are doing somewhat more work on litigated patents. If so, that would be good news. Many scholars have sought to encourage examiners to concentrate more attention on the small subset of patents that turn out to be important.[92] Patents litigated to judgment certainly fit that category.[93]

In fact, however, longer office actions may not indicate that the examiner is devoting more attention to the critical patents. As we have seen, litigated patents come from much larger families than unlitigated patents. Those family members frequently include similar if not identical prosecution histories. By that, we mean that the back-and-forth filings between the patentee and the examiner make the same arguments and cite the same references. Indeed, in many cases the same text is literally cut and pasted from one patent file to another. Not only are the examiner's rejections similar or identical, but the applicant responses are also identical. This is somewhat unsurprising since (1) many claims are similar and (2) applicants would want to avoid inconsistent arguments that could lead to estoppel or inequitable conduct issues.

For example, a family of over fifty patent applications was filed to an invention dealing with compositions and methods of using L-lysine-d-amphetamine. More than a dozen of these patents ended up in litigation.[94] Each of these litigated patents has a similar or identical prosecution history. In fact, during the prosecution of this family, the examiner noted that there

92. *See, e.g.*, Lemley, *supra* note 41; Lemley, Lichtman & Sampat, *supra* note 4, at 10–13 (2005); Frakes & Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, *supra* note 6, at 4–7.

93. Allison et al., *supra* note 80, at 436 n.9.

94. U.S. Patent Nos. 7,655,630; 7,659,253; 7,659,254; 7,662,788; 7,671,030; 7,671,031; 7,764,774; 7,678,770; 7,678,771; 7,687,467; 7,713,936; 7,718,619; 7,723,305.

were forty-four continuations (of which the examiner had twenty-five and would "likely be docketed the remaining 19")[95] as well as another ten related applications that were undergoing examination (only one of which was with another examiner). Each of these patents were either allowed in a first action allowance or allowed quickly after an examiner interview to overcome an obviousness rejection and filing a terminal disclaimer to overcome an obviousness-type double patenting rejection.

That cut-and-paste approach is even more likely among the patents that were invalidated. More than 50% of the invalidated patents came from families with similar prosecution histories, compared with 40% of the patents held valid.[96]

We note that most of the patents that undergo litigation are not "original" patents.[97] As shown in Table 1, only 21% of invalidated patents are original, while 73% of invalidated are continuation applications and only 4% are divisional applications. In contrast, the 1610 control group contains 43% original applications with only 35% continuation applications and 15% divisional applications. Importantly, litigated patents are not divisional applications, which usually arise from a restriction requirement imposed by the examiner. Accordingly, these large patent thickets are being created by brand-firms on their own volition and not created by patent examiners.[98]

Table 1

	Continuation	Continuation in Part	Divisional	Original
Invalid	73%	3%	4%	21%
Not Invalid	60%	5%	8%	27%
1610 Control	35%	8%	15%	43%

95. *See* Non-Final Office Action Dated June 24, 2009, page 3 (present in U.S. Patent Nos. 7,659,253; 7,659,254; 7,671,030; 7,687,467; 7,713,936; 7,723,305).

96. The y-axis in Figure 13 is the percentage of each group in each category. The numbers for each category add to 100%.

97. Original patents are defined as patents that do not claim priority to a parent application.

98. Divisional applications are usually filed in response to a restriction requirement issued by an examiner, while continuation and continuation in part applications are usually filed by applicants to capture subject matter that was not claimed in the parent application or to seek to persuade the examiner to change their mind and issue a patent. *See* Lemley & Moore, *supra* note 78.

Figure 13

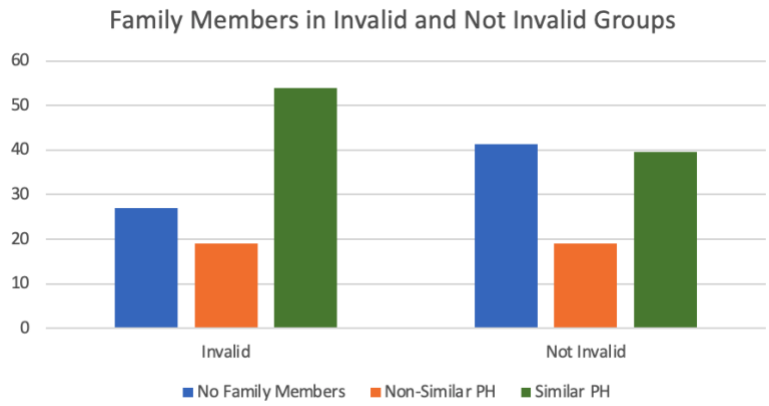
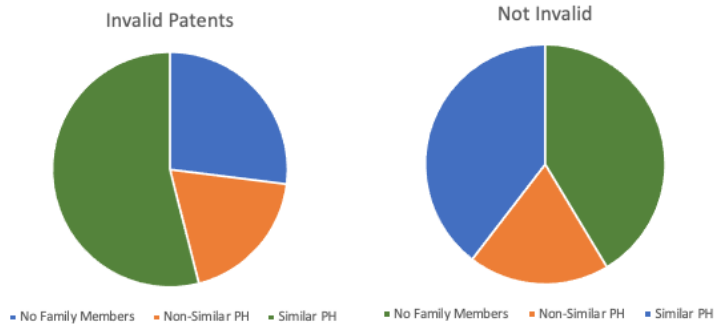


Figure 14



Of the 126 invalid patents with prosecution histories there were sixty-eight patents (53.96%) which had either identical or near identical prosecution histories (same rejections by the same examiner cut and paste into different office actions and the same responses by applicants cut and paste into the response).[99] The examiner rejections are not only usually identical but are usually sent out close in time (the Office Actions are sent out only a few days from each other).[100] So while examiners are writing

99. There were only 126 invalid patents in this group instead of 142 because sixteen patents were removed because they had no image file wrapper and thus the prosecution history could not be analyzed.

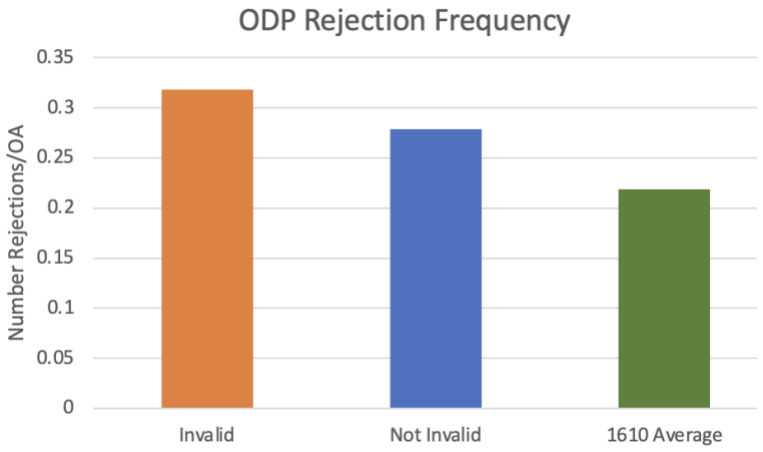
100. For example, for the L-lysine-d-amphetamine family of patents, six of the thirteen patents had office actions sent out on June 24, 2009 and an additional identical office action sent out on June 26, 2009.

longer office actions, they are often reusing the same work across multiple patents in the same family rather than spending more time on those patents.

On the substantive merits of patent prosecution, there are many similarities between litigated patents and the control group. These similarities include: (1) the number of restriction requirements / species elections, and the number of traversals for those restriction requirements; (2) the number of § 112(b) indefiniteness rejections, and the strategies used to traverse these § 112(b) rejections (claim amendments); (3) the number of § 112(a) written description rejections, and the strategies used to traverse these § 112(a) rejections (claim amendments); (4) the number of § 101 statutory double patenting, utility and patentable subject matter rejections, and the strategies used to traverse these § 101 rejections (claim amendments).[101]

There are, however, a few significant differences between the prosecution histories of litigated and unlitigated patents. Figure 15 shows that litigated patents face many more obviousness-type double patenting rejections.[102] When it comes to prior art, Figure 16A shows that litigated patents face fewer anticipation-based prior art rejections (both § 102(b) and § 102(a/e)). Additionally, Figure 16B shows that litigated patents exhibit significantly more obviousness rejections than unlitigated patents.[103]

Figure 15



101. *See infra* Appendices 6–8.

102. The difference between valid and invalid patents is not significant, but the difference between litigated patents and the control group is.

103. Again, the difference between valid and invalid patents is not significant, but the difference between litigated patents and the control group is.

Figure 16A

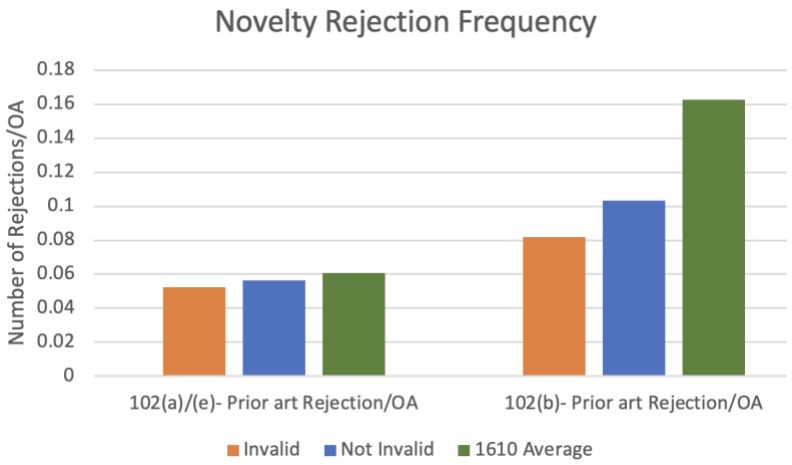
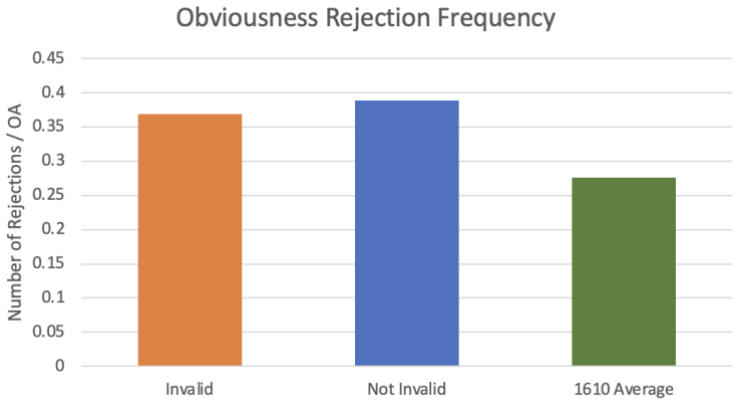


Figure 16B

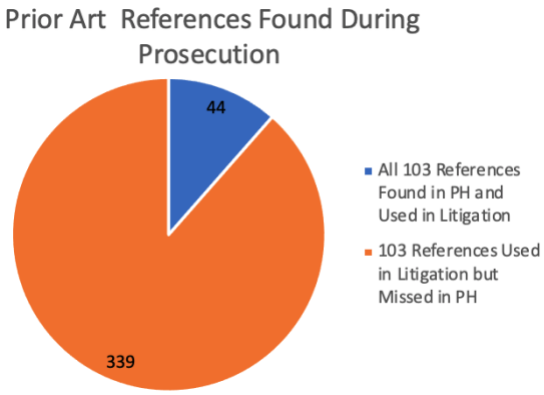


The obviousness-type double patenting rejections are not surprising, because as we have seen most of the Orange Book patents are directed towards follow-on technology and they tend to come from large families of related patents. Those are the situations in which we would expect to see an obviousness-type double patenting rejection.

The fact that litigated patents, and especially those that are held invalid, were less likely to be rejected on novelty grounds and more likely to be rejected on obviousness grounds is interesting. That would ordinarily signal that those patents are stronger than the patents in the control group, particularly since we also find that the obviousness rejections tend to combine multiple different prior art references, which commentators have

noted is associated with a weaker obviousness challenge.[104] Many of those patents were ultimately invalidated, though our data also show that those invalidations were overwhelmingly based on different prior art not before the examiner.[105]

Figure 17



4. Applicant Responses to Examiner Rejections

Applicants differed in how they responded to examiner rejections. For example, Figure 18 shows that litigated patents rely heavily on terminal disclaimers to traverse obviousness-type double patenting rejections.[106] That means they chose to allow the patent but limit how long its term runs rather than change the patent claims or dispute the obviousness of the new claims over other patents.[107]

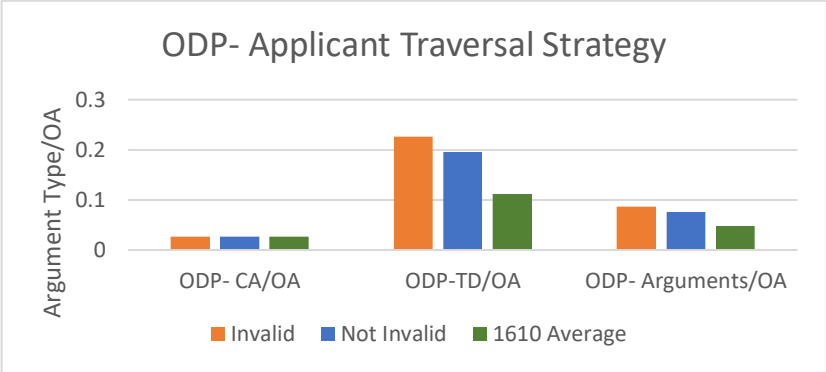
104. *See, e.g.*, *In re* Enhanced Sec. Rsch., L.L.C., 739 F.3d 1347, 1355 (Fed. Cir. 2014) (The examiner cannot "stitch together an obviousness finding from discrete portions of prior art references" without being cautious of hindsight bias.). *Compare* MPEP, *supra* note 62, at § 2144.05 (saying multiple prior art references may sometimes be acceptable "depending on the specific facts of the case"), *with* MPEP, *supra* note 62, at § 2144.08 (noting when a "single prior art reference" discloses a genus but not a species, examiners should take further efforts to find additional prior art to show obviousness).

105. We caution against making too much of this data. While it might indicate that the PTO did a poor job of finding the most important references, there are other possible explanations. Defendants often seek prior art that was not before the PTO because it is easier to tell a story that the examiner missed the key reference than to persuade the factfinder to overturn the examiner's decision on a reference they did consider. *See* Allison & Lemley, *supra* note 81, at 231–34.

106. The difference between valid and invalid patents is not significant, but the difference between litigated patents and the control group is.

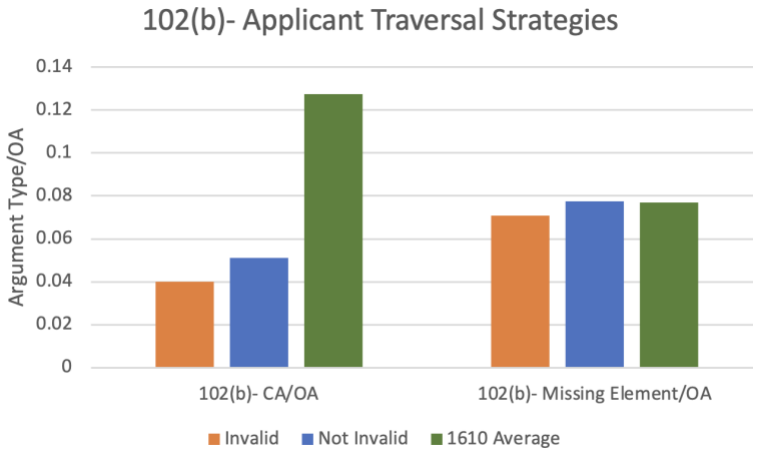
107. That fact has implications for patent policy. If patentees are attempting to quickly create a patent thicket, then speedy prosecution is critical. If the technology has significant overlap with prior patents, then overcoming the rejection by simply filing a terminal disclaimer is the most reasonable response for a patentee who wants a large number of patents to create a fence. In contrast, if applicants

Figure 18



When it comes to prior art, litigated patent owners, especially those whose patents turn out to be invalid, are more likely to respond to a rejection with an argument for why the claims should be allowed as is, rather than following the common practice of amending the claim to narrow it.[108]

Figure 19



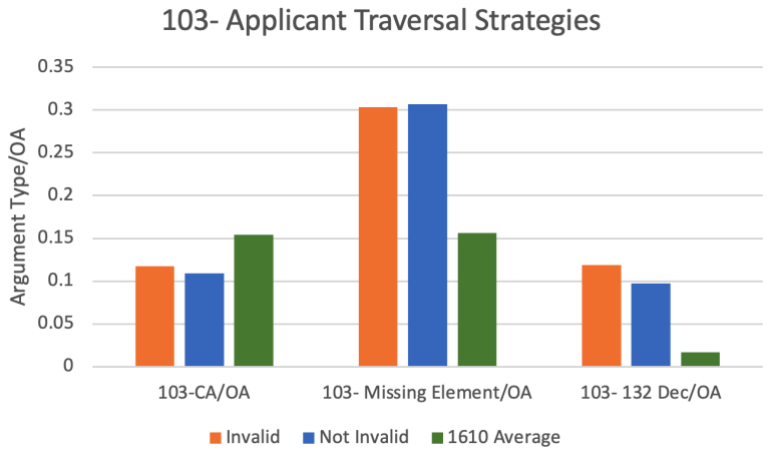
were attempting to evergreen patents and thus attempting to extend the life of a prior parent patent, filing a terminal disclaimer, which ties the expiration date to a prior patent, would undermine that strategy.

This result was even more dramatic in the subset of litigated 1610 patents, where the proportion of terminal disclaimers was higher than in the control group.

108. The control group had significantly more amendments than litigated patents, but there was no significant difference between valid and invalid patents. See Lemley & Sampat, *supra* note 22, at ¶¶ 11–26 on how common narrowing amendments are.

Similarly, Figure 20 shows that in response to § 103 rejections invalid patentees are much more likely to use a missing elements argument or unexpected results argument. They are also more likely to submit a 1.132 declaration (providing outside evidence to support their case) than are the owners of unlitigated patents.[109]

Figure 20



The owners of litigated patents are less willing to give up claim scope than ordinary pharmaceutical patentees. This is consistent with the idea that the owners of those applications know they have something valuable and are willing to fight to preserve it.[110]

IV. IMPROVING PHARMACEUTICAL PATENT LITIGATION

Our data offer several insights about how to improve pharmaceutical patent quality. First, we have shown that most pharmaceutical patents litigated to judgment are not core patents on new chemical entities, but secondary or follow-on patents of the type often used to extend patent life after the expiration of the core patent. Second, our data provide strong

109. In each case, the difference between valid and invalid patents is not significant, but the difference between litigated patents and the control group is.

110. We can't prove causation runs this way, though; it could be that the patents that survive without amendment turn out to be the valuable ones in litigation. Two factors lead us to believe that isn't the explanation, though. First, the phenomenon is more pronounced with invalidated patents than those held valid, suggesting that it's not simply that litigants are choosing the best patents based on prosecution. Second, as we have seen, other evidence suggests that applicants are targeting these patents for special treatment early in prosecution, meaning that they are aware of the potential litigation use of the patent at the time they make prosecution decisions.

evidence that the owners of those patents know quite early in the process which patent applications will ultimately end up in Paragraph IV litigation, and they treat those applications very differently than they do counterpart applications in the same art unit. They seek a quicker prosecution, and they are more likely to fight back against examiner demands that they narrow the scope of the patent. Third, those litigated patent applications are filed in much larger families, and they are frequently prosecuted in groups by the same examiner. Fourth, the PTO is doing a pretty good job of evaluating those patents. Only 26% of ANDA patents litigated to judgment are invalidated, well below the overall invalidity rate of 43%. Finally, even though patent examiners frequently know of the importance of these applications through the Track One process and have more time to evaluate them, they commonly cut and paste rejections from examination to examination rather than focusing more attention on these families.

Those facts suggest some things that won't work to improve pharmaceutical patent examination and open the door to others that might. They also suggest some strategies for changing pharmaceutical patent litigation.

A. Do We Need to Do Anything?

One might reasonably question whether we need to change anything at all given our data. Our data shows that issued Orange Book patents hold up pretty well in court, certainly better than patents in other fields.[111] Perhaps we should simply leave well enough alone.

But we think the high cost of invalid patents in the pharmaceutical space justifies the additional expenditure. Frakes and Wasserman do a good job of showing the value of weeding out invalid Orange Book patents.[112] Further, the owners of strong patents should also benefit from additional scrutiny, since as we suggest below surviving that scrutiny should make it easier to defend the patent in court.

Our data also show a different concern. Overwhelmingly, litigated Orange Book patents are not primary patents on new chemical entities but

111. *See supra* note 71 and accompanying text; *see also* Allison et al., *Understanding the Realities of Modern Patent Litigation*, *supra* note 71, at 1801. Pharmaceuticals in general fare better in court than other sorts of patents. Allison et al., *supra* note 69, at 1111.

112. *See* Frakes & Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, *supra* note 6, at 34–42 (estimating those costs); *cf.* Hemphill, *supra* note 34, at 1568–73 (exploring the costs of pharmaceutical patent settlements); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009) (studying the social costs of pay-for-delay settlements); *see also* David Miller, Benedic Ippolito, Inmaculada Hernandez & Benjamin Davies, *The Costs of Delayed Generic Drug Entry: Evidence from a Controversial Prostate Cancer Drug Patent*, J. GEN. INTERNAL MED. (July 13, 2021) (showing that an inappropriately awarded secondary patent cost consumers $2 billion).

secondary, follow-on patents aimed at complicating generic entry and extending patent life. And patent owners frequently obtain multiple secondary patents from the same family, often obvious variants of each other. Because of the Hatch-Waxman regulatory framework, obtaining multiple patents can delay or prevent entry by a generic competitor regardless of whether those patents are valid.[113] As a result, issuing multiple secondary Orange Book patents is a problem independent of the risk of issuing bad patents.

B. Targeting Examiners: Review by a Team of Examiners

Two decades ago, one of us argued that it did not make economic sense for the PTO to carefully review every patent application it received because 95% of the patents it issued never amounted to much. Their validity did not matter in the real world.[114]

Frakes and Wasserman question the rational ignorance hypothesis more generally,[115] but they also argue that even if it were true in general, the rational ignorance story should not apply to Orange Book patents.[116] Because Orange Book patents are litigated at a much higher rate than the average patent, perhaps they should not be subject to the rational ignorance critique. One way to improve the patent examination process, therefore, would be to target these patents *ex ante* at the examination stage. This would take the form of a more comprehensive review at the PTO.

Frakes and Wasserman's argument makes logical sense in the abstract. If we have a subset of patents we know are more important, the PTO should pay more attention to those patents. That is consistent with Lemley's original argument, and with the development of administrative revocation procedures like Inter Partes Review (IPR) that focus more attention on patents once their importance becomes clear.[117] The fact that (as we have shown) the applicants generally know early on that their Orange Book patents are important gives the PTO an opportunity to pay more attention to those patents. We could go further in identifying these important patents. Applicants whose patent claims will be listed in the Orange Book if the patent issues should be required to disclose this information to the PTO

113. For a discussion of how this regulatory framework is gamed, see generally 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW ch. 16 (2001); Dogan & Lemley, *supra* note 72.

114. *See* Lemley, *supra* note 41.

115. Frakes & Wasserman, *Irrational Ignorance at the Patent Office*, *supra* note 6.

116. *See* Frakes & Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, *supra* note 6.

117. *See* 35 U.S.C. § 311. For an argument for greater attention to a subset of patents, see Lemley, *supra* note 41, at 1523–24; Lemley, Lichtman & Sampat, *supra* note 4.

before examination starts. Thus, the PTO would know *ex ante* if the application could correspond to an Orange Book listed patent.

But our data also gives us reason to question how much that will help. First, our data show that there is not much difference in prosecution between the patents held valid and those held invalid. As a result, it may not be as easy as they suggest to weed out the bad patents while continuing to issue the good ones simply by spending more time on each patent. Second, Frakes and Wasserman assume that giving examiners more time to review patents will itself increase patent quality.[118] Our data directly contradict this hypothesis. Examiners that issue invalidated patents are *already* given more time than other examiners since they are reviewing similar patents in the same family. An examiner reviewing three patents with an identical specification and similar claims is given additional "credit" for these office actions in the form of additional "counts."[119]

However, instead of writing better office actions or searching the prior art for additional references, our evidence shows that examiners are simply cutting and pasting their rejections from other patent applications in the same family.[120] This leads us to question whether giving examiners more time to review applications will produce more careful analysis or searching. Our data do not show that. It might simply increase the cost of patent prosecution with little to no public benefit.

That does not mean we should ignore what we have learned about the importance of these patents. But just throwing more time/money (and examiner time) at the problem will not necessarily help.[121] Instead, we suggest a structural change in how the PTO examines Orange Book patents. We would require the applicant to disclose to the PTO that the application is likely to be listed on the Orange Book.[122] Once the applicant discloses that the application is an Orange Book patent application, the patent

118. Frakes & Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, *supra* note 6, at 26–28.

119. *See* Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, *supra* note 20, at 397–99 (2020) (giving a detailed description of the count system); *see also* Naira Rezende Simmons, *Putting Yourself in the Shoes of a Patent Examiner: Overview of the United States Patent and Trademark Office (USPTO) Patent Examiner Production (Count) System*, 17 J. MARSHALL REV. INTELL. PROP. L. 32 (2017).

120. Nor is there evidence that these examiners are doing extra work on these application families with their extra time and producing a much better office action that they then copy for each family member. To the contrary, despite having several times as many hours to devote to the family patents, examiner office actions are only slightly longer than for those without similar prosecutions. And those litigated patents with cut-and-paste responses are more likely to be ultimately held invalid.

121. *See* Greg Reilly, *The Complicated Relationship of Patent Examination and Invalidation*, 69 AM. U. L. REV. 1095 (2020) (detailing other structural reasons why additional examiner time won't necessarily improve examination).

122. This disclosure alone would be valuable, because it would allow greater coordination between the PTO and the FDA. *See* Robin C. Feldman, David A. Hyman, W. Nicholson Price & Mark J. Ratain, *Negative Innovation: When Patents Are Bad for Patients*, 39 NATURE BIOTECH. 914 (2021).

application should go to a new art unit that focuses specifically on Orange Book patent applications. These applications would not be reviewed by only one examiner, but a team of three examiners, in a framework similar to the Central Reexamination Unit (CRU).[123] This new art unit would be staffed with senior primary patent examiners and supervisory patent examiners that have technical expertise as well as advanced patent legal knowledge.

Examination by a team of examiners, instead of just a single examiner, will allow for not only better searching for prior art references, but better perspectives when reviewing the prior art for obviousness and anticipation issues.[124] Examination by a group of three examiners will help prevent interpretation errors by improving prior art searching and allowing examiners to approach the art they find from multiple perspectives. Each examiner on the team could separately assess the validity of the patent and then deliberate about the identified divergences.[125]

We could impose other requirements as part of this heightened scrutiny. For example, applicants should have to rank order cited prior art references to reveal most relevant prior art references, in a framework similar to the accelerated examination program.[126] 37 C.F.R. § 1.56 already requires a duty of candor to disclose information material to patentability.[127] However,

123. See *Central Reexamination Unit*, USPTO, https://www.uspto.gov/about-us/organizational-offices/office-commissioner-patents/office-deputy-commissioner-patent-37 [https://perma.cc/TJ6R-8UYD] for details on the CRU.

124. Evidence suggests that the change from single-examiner reexamination to the CRU was effective in improving reexaminations. *See* Robert Greene Sterne, Jon E. Wright & Lori A. Gordon, *Reexamination Practice with Concurrent District Court Litigation or Section 337 USITC Investigations*, 10 SEDONA CONF. J. 115, 158–65 (2009); Dmitry Karshtedt, *Contracting for a Return to the USPTO: Inter Partes Reexaminations as the Exclusive Outlet for Licensee Challenges to Patent Validity*, 51 IDEA 309, 330 (2011) (noting that the CRU is better at applying the "person having ordinary skill in the art" standard); The PTO gave extra scrutiny to business method patents for a short period under a program called Second Pair of Eyes review (SPER). As its name suggests, patents in the program were evaluated independently by a second examiner. The grant rate for patents in the program fell precipitously. John R. Allison, Emerson H. Tiller, Samantha Zyontz & Tristan Bligh, *Patent Litigation and the Internet*, 2012 STAN. TECH. L. REV. 3; John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 BERKELEY TECH. L.J. 729 (2006) (noting decline but also observing that patent applicants changed their characterization of patents to avoid being included in the program). *Cf.* Colleen V. Chien, *Rigorous Policy Pilots the USPTO Could Try*, 104 IOWA L. REV. ONLINE 1 (2019) (suggesting more evaluation of SPER as a model).

125. *See, e.g.*, Daniel E. Ho, *Does Peer Review Work? An Experiment in Experimentalism*, 69 STAN. L. REV. 1 (2017) (showing that when two food safety inspectors separately assessed code violations and deliberated about divergences, they were able to increase the violations detected and improve the consistency of inspections).

126. *See* Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination, 71 Fed. Reg. 36,323 (June 26, 2006) (stating that the applicant must conduct a preexamination search and must cite "each reference deemed most closely related to the subject matter of each of the claims").

127. *See* MPEP, *supra* note 62, at § 2001. To counter concealment of the most relevant prior art references, the PTO states that "no patent will be granted on an application in connection with which

many applicants comply with this requirement by sending the PTO an avalanche of references, thereby concealing the most important references in a list of dozens, sometimes hundreds, of references.[128] Applicants should identify the references they consider most important to facilitate evaluation.

Finally, examiner interviews for these applications should be recorded and made part of the prosecution history. Interviews are used much more frequently with Orange Book patents than in the average 1610 control group. Unfortunately, the prosecution history created by interviews is usually very limited and does not adequately describe the arguments used by the applicant. It would be relatively easy for the PTO to simply record and transcribe the audio for the interviews and make that part of the prosecution history. This would help fairly reflect any unwritten claim limitations used to overcome the examiner's rejections.[129]

In return for this more comprehensive review, applicants would receive automatic Track One status if requested at no additional cost. Applicants should also have the choice to avail themselves of expedited review. This would allay applicant's fears that a more comprehensive review would delay prosecution duration.

An additional benefit that applicants could receive is a higher presumption of validity for the two or three references specifically identified by the applicant as the most relevant prior art considered by the examiners.[130] The presumption of validity might even be conclusive as to those key pieces of prior art. Furthermore, we could apply the current clear and convincing evidence presumption from litigation to IPR proceedings.[131] This would also help encourage applicants to disclose the most relevant prior art references during prosecution.

A risk associated with heavier presumption of validity is that if the examiner interprets the prior art incorrectly it may be harder to invalidate the patent. However, balancing this against the fact that most examiners are not finding the correct prior art, we believe this is an acceptable trade off. Specifically, examiners only found forty-four out of the 383 references

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fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct." *Id.*

128. *See, e.g.*, Robert Brendan Taylor, *Burying*, 19 MICH. TELECOMM. & TECH. L. REV. 99 (2012); Molins P.L.C. v. Textron, Inc., 48 F.3d 1172 (Fed. Cir. 1995) (rejecting an inequitable conduct claim for burying, but noting the practice).

129. Bernard Chao, *Making Examiner Interviews Transparent*, PATENTLY-O (Apr. 13, 2014), https://patentlyo.com/patent/2014/04/examiner-interviews-transparent.html [https://perma.cc/6EP7-Q27S]; Tu, *supra* note 88. *Contra* John R. Thomas, *On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation*, 47 UCLA L. REV. 183 (1999).

130. For a similar suggestion, see Lemley, Lichtman & Sampat, *supra* note 4; see also Lichtman & Lemley, *supra* note 43.

131. There is currently no such presumption. *See* 35 U.S.C. § 314.

(11%) used to invalidate patents based on obviousness.[132] Further, we propose changes in who evaluates these patents and the effort the PTO spends in doing so. The benefits of earlier and fuller evaluation by a new art unit at the PTO may outweigh the risk of weakening court challenges.

This additional review by a small team of examiners would not cost the PTO (or applicants, who pay the fees) much more than the current review process. This is because these patents are already being reviewed by examiners who simply cut and paste previous rejections into rejections for other family members. Thus, instead of giving multiple counts for cutting and pasting identical office actions into similar applications, our team approach may give a better initial rejection that could also be used for subsequent Orange Book family members. Accordingly, PTO counts would be spread among two or three examiners instead of just one but the costs to the PTO would be roughly similar to current costs, at least for the majority of Orange Book patents that come from large families.

C. Targeting the Multiplicity of Patents Covering a Drug

Secondary patents are litigated at a much higher rate than primary patents.[133] One rationale for branded firms to file many of these weaker secondary patents is to evergreen or extend the life of their primary patents. Evergreening imposes significant costs on society, delaying the entry of cheap generic drugs.[134] Our second set of recommendations involves ways to limit evergreening and consolidate patent examination and litigation to prevent patent thickets.

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132. As noted above, however, there could be some selection bias when finding prior art. Specifically, litigators may be selecting references that were not considered during prosecution for litigation purposes.

133. *See supra* Section III(A); *see also* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE e49470 (2012).

134. *See, e.g.*, Lemley & Moore, *supra* note 78; Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009); Robin Feldman, '*One-and-Done' for New Drugs Could Cut Patent Thickets and Boost Generic Competition*, STAT (Feb. 11, 2019), https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/ [https://perma.cc/D3FA-3MYQ]; Tahir Amin & Aaron Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could be Extended for Decades*, 31 HEALTH AFFS. 2286 (2012); Reed Beall & Aaron Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECH. 142 (2018) (showing that drug-device combination products prolong the expiration date of primary and secondary patents on the drug itself).

We acknowledge that not all secondary patents are intended to support evergreening. Sometimes secondary patents on things like dosages are filed and expire at the same time as the patent on the new chemical entity. But that is the exception, not the rule.

1. Terminal Disclaimers

One way to prevent evergreening of secondary patents is for examiners to use the obviousness type double patenting rejection. Under the judicially created doctrine of obviousness-type double patenting (ODP), a patentee may not have a later-issued patent with claims directed to an obvious variation of the subject matter claimed in an earlier-issued patent. Most frequently, during prosecution an applicant will obviate an ODP rejection simply by filing a terminal disclaimer. The terminal disclaimer will tie the term of the later-issued patent to the term of the earlier-issued patent. The two patents will expire at the same time and also requires that the two patents remain under common ownership.[135] Terminal disclaimers prevent the most common harm from evergreening—obtaining weak follow-on patents that delay generic entry into the market.

Training examiners to judiciously use ODP rejections will help prevent brand firms from evergreening their patents because most of these patents will expire at the same time. If we forced applicants to disclose the fact that they will list their patents in the Orange Book, the PTO could consolidate all the listed Orange Book-relevant applications together in an Orange Book examination group. Patent examiners in this group could then review previous Orange Book family members to better determine if an ODP rejection is appropriate.[136]

Not every applicant will know up front that its application is relevant to an Orange Book filing, so this isn't a perfect solution. But applicants should have a duty to update the PTO, and late-listed patents should get extra scrutiny, either under the three-examiner system we propose or under something similar to the PTO's Central Reexamination Unit for reexamination applications.

2. Consolidating Applications into a Single Patent

While this solution may help with the evergreening problem, it does not address the fact that brand firms may still be using these secondary patents to create a patent thicket devised to increase the costs of litigation.

Orange Book patent owners increasingly file very large patent families to increase costs for generic manufacturers when challenging their Orange Book listed patents.[137] For example, the blockbuster drug icosapent ethyl

135. *See* Emily A. Evans & Jill A. Jacobson, *Double Patenting Recapitulated*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 625 (2005).

136. *See* ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES 106 (2019) (arguing for greater use of obviousness-type double patenting and terminal disclaimers).

137. *See* Carrier & Shadowen, *supra* note 72; Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1. *Cf.* Lisa L. Ouellette, Note, *How Many Patents Does*

(Vascepa) had sixty-one patents listed in the Orange Book.[138] These large families increase costs in several ways. First, patent thickets increase costs by rendering inefficient the use of IPRs to invalidate these weak secondary patents. This is because IPRs need to be instituted on a patent-by-patent basis, and it would be difficult and more costly to challenge 100 different patents rather than one patent with many claims. Second, in the face of this large patent family, juries as well as judges may be overwhelmed by the information needed to invalidate each patent, rather than each claim in one patent. Third, later secondary patents can be added to a lawsuit before it is resolved, or even added after the original patent is invalidated, restarting the Paragraph IV process and delaying generic entry.

These patent thickets seem particularly problematic when multiple patents stem from the same parent patent application.[139] It seems unfair that a procedural tool allowing firms to file multiple continuation patents from the same family should give such a large benefit to the brand firm.

By increasing direct costs through PTO fees as well as making it equitable for the public to challenge these secondary patents through IPR we can help bring balance to the Hatch-Waxman bargain. One solution to this problem is to allow firms to file multiple secondary patents and continuation applications but have the claims that issue from these applications added to the original patent.[140] This system would only be

It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing, 17 MICH. TELECOMM. & TECH. L. REV. 299 (2010).

138. *See* Jonathan J. Darrow & Daniel T.C. Mai, An Orange Book Landscape: Drugs, Patents, and Generic Competition (unpublished manuscript) (showing that when competitors sought to market generic versions of Vascepa, the NDA holder asserted only six of these patents, with the court invalidating all asserted claims as obvious); Amarin Pharma, Inc. v. Hikma Pharm. USA Inc., No. 2:16-cv-02525, 2020 WL 1517568 (D. Nev. Mar. 30, 2020), *aff'd*, 819 F. App'x 932 (Fed. Cir. Sept. 3, 2020), *cert. denied*, 141 S. Ct. 2794 (June 21, 2021). The problem is even greater in biologics, which can have hundreds of patents covering a single drug. *See* Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93 (2019).

139. *See* Johnathan 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 250 (2019); *see also* Beall & Kesselheim, *supra* note 134, at 143 tbl.1.

140. Common patent practice requires new claims to be put in a new patent. But there is no statutory requirement that claims can't be added to an existing patent. Indeed, the statute permits patents to reissue with new claims. *See* 35 U.S.C. §251(a). Section 251(b) provides that "[t]he Director may issue several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents." The reference to the applicant's "demand" could be read to mean that the patentee can have multiple reissued patents if they want them, but the use of the word "may" suggests the better reading of the statute is that the PTO has discretionary power to grant more than one patent, but only if the applicant asks for it. Customarily reissue practice is used to correct an error in the patent. However an error can include things most people would not view as errors: changes driven "by reason of the patentee claiming more or less than he had a right to claim in the patent." 35 U.S.C. §251(a). The PTO should decline to exercise that discretion where doing so creates a patent thicket.

The PTO may still wish to charge higher fees associated with this consolidated application that corresponds with the filing of these additional claims. For example, if the firm files an original

applied to patents where applicants would otherwise use a terminal disclaimer to obviate an obviousness-type double patenting rejection. If the claims are truly non-obvious over the parent application, those new claims should be worthy of additional patent protection and additional patent life.

This solution also comports with the end goal of using a terminal disclaimer without creating a second patent directed to obvious improvements over the parent patent. First, similar to a terminal disclaimer, this solution would allow for all of the related subject matter to expire at the same time. Second, this solution would tie all related subject matter under common ownership.

If, however, the application would be obvious over the parent patent and the applicant is willing to make the two patents expire at the same time, the applicant should not get the benefit of creating a second patent that makes it more difficult and costly for generic firms to invalidate. This would be a partial step towards Robin Feldman's "one and done" proposal: patent owners wouldn't be entitled to multiple patents that are obvious variants of each other, but would be able to add claims to the existing patent if those claims are permissible under current law.[141]

Cutting down on the number of patents that firms have to challenge to get their generic drugs to market could lower costs of the proceeding, encourage patent challenges, and reduce the number of litigations by reducing barriers to entry. This could help lower drug costs by allowing generic firms to enter the market faster.

3. Allow Firms to File One IPR that Targets Claims from Related Patent Families

Another solution to prevent firms from creating large patent thickets to prevent IPRs is to simply change the rules for the scope of IPRs to permit

application with twenty claims and a child application with an additional twenty claims, then the child application would be given the same patent number, and the additional twenty claims would be listed as claims 21–40. The PTO would collect additional fees for the claims in the second application as if it were filed with forty claims.

The PTO could also create a tiered system where the fees increase by a significant amount for the maintenance as well as the fees charged for any claim over 100. If each claim over 100 would cost $10,000 to file as well as an additional large-patent maintenance fee, brand firms may be less inclined to create large patent thickets on weak patents that only serve to increase litigation costs and delay generic entry. That said, given the immense value to pharmaceutical companies in even short delays in generic entry, we are skeptical that higher filing fees will do much to deter abusive filing practices. *See* Erik Hovenkamp & Stephen C. Salop, *Asymmetric Stakes in Antitrust Litigation* (USC Legal Stud. Rsch. Paper Series No. 20-1, 2020) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3563843 [https://perma.cc/6NNE-HNEK].

141. *See* FELDMAN, *supra* note 136; *see also* Charu Gupta, One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry (Oct. 22, 2021) (unpublished manuscript) (on file with author).

IPR challenges to include claims from related patent family members. This would allow generic firms to avoid the patent thickets created by brand firms. Congress could give real teeth to this solution by allowing IPR invalidation to trigger the 180-day exclusivity given to the first ANDA filer.[142] The PTO would likely also have to change its page limits to allow multi-patent IPRs in the specific context of Orange Book-listed patents. This proposal wouldn't be necessary if our previous suggestion of consolidating the claims into a single patent were adopted, but without that change it would be a partial step making it easier to challenge patent thickets.[143]

D. Use of Competitors to Stop Invalid Patents

If applicants fail to disclose the fact that the application is an Orange Book patent application or if the claims in the application were initially not appropriate for the Orange Book, we could give incentives to challengers to invalidate these patents. This would be justified since these patents did not undergo the "gold plating" review completed by the new Orange Book art unit.[144] Alternatively, we could eliminate the presumption of validity for patents that do not comply with the rule.

One incentive could be to give competitors 210 days of exclusivity for invalidating these patents rather than the customary 180 days of exclusivity. The extra month of exclusivity would represent the additional time it takes to invalidate a whole family of patents designed to increase costs for competitors and consumers. And it would increase the incentives for generics to challenge patents, since generics make most of their money in the 180-day exclusivity period.[145] But it would raise the costs to consumers in cases where multiple generics were already lining up to challenge a patent.

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142. *See* Brian T. Apel, *An Administrative Meter Maid: Using Inter Partes Review and Post-Grant Review to Curb Exclusivity Parking via the "Failure to Market" Provision of the Hatch-Waxman Act*, 114 MICH. L. Rev. 107 (2015).

143. For other proposals to strengthen IPRs in the pharmaceutical context, see Sturiale, *supra* note 39, at 87; Karshtedt, *supra* note 124.

144. *See* Lemley, Lichtman & Sampat, *supra* note 4.

145. *See* MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 61 (2005) (stating that generic drug companies often make a majority of their profit in the 180-day exclusivity period); Michael A. Carrier, *Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment*, 67 RUTGERS U. L. REV. 697, 710 (2015) (stating that "[g]enerics have estimated that they make '60% to 80% of their potential profit' in the exclusivity period" and that the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period"); Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First*, 25 BIOTECH. L. REP. 525, 525–26 (2006); FTC v. Actavis, Inc, 570 U.S. 136, 144 (2013).

Another, more promising, possibility would be to allow generics to enter the market if they invalidate the primary patent or (if no primary patent is listed or it has expired) if they invalidate *any one* of the listed secondary patents. Patentees could still sue on the remaining patents, but the existence of those other patents would not prevent the FDA from approving the ANDA or prevent the generic from entering the market. A generic who did enter after invalidating a listed patent would face limited liability—a cap on damages less than the amount the generic made on the market.[146] This would encourage companies who invalidated a key patent in a thicket to enter "at risk" even if other patents remained.[147] And it would encourage patent owners not to divide their applications just to create a thicket or impose regulatory delay.

CONCLUSION

Orange Book listed patents are certainly one of the most valuable classes of patents. They are litigated at much higher rates than ordinary patents. And they are overwhelmingly secondary patents used as part of a patent thicket rather than patents on new chemical entities. We find evidence that the owners of Orange Book patents know from the outset that they are valuable, and they prosecute those patents very differently than other patents in the same field. While the PTO has the opportunity to devote more attention to this important subset of patents, we find that it is squandering that opportunity, cutting and pasting standard rejections rather than delving more deeply into their validity.

We suggest ways to improve the examination of pharmaceutical patents, changing the procedure to ensure that bad patents don't make it to court while also enhancing certainty for patentees. And we suggest ways to combat the problems of patent thickets and evergreening, allowing generic firms and consumers to benefit from lower prices once the central patent on a drug has expired.

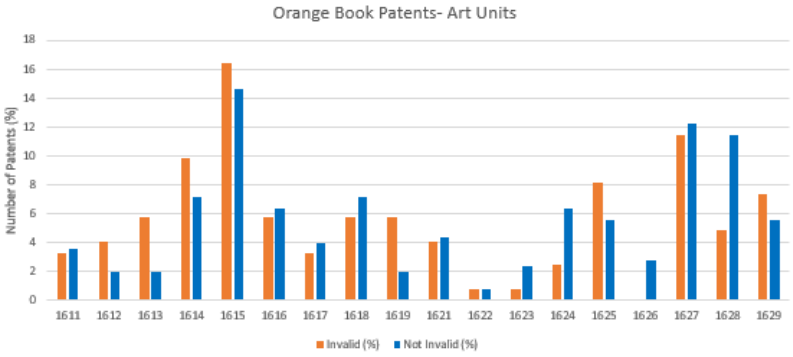
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146. One possibility is to award only reasonable royalty damages in that situation. A reasonable royalty is theoretically negotiated between a willing buyer and a willing seller, so it should leave some profit for the infringer. *See* Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655, 661–69 (2009). But the Federal Circuit has not always been so careful with its reasonable royalty calculations, and there is a risk that courts would set a royalty rate that made generic entry at risk uneconomic. *Id.*

Another possibility would be to keep the generic exclusivity at 180 days but preclude the patentee from obtaining damages based on a secondary patent during that period. That would reduce patentee damages somewhat, but would give generics much more comfort that they would not end up paying more in damages than they stood to make by entering after having invalidated the first patent.

147. Generics are presently often unwilling to enter at risk. *See* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation*, 10 NW. J. TECH. & INTELL. PROP. 19, 29 (2011) (noting the rarity of an at-risk launch and positing reasons why).

APPENDIX 1


Orange Book Patents- Art Units
Number of Patents (%)
18
16
14
12
10
8
6
4
2
0
1611
1612
1613
1614
1615
1616
1617
1618
1619
1621
1622
1623
1624
1625
1626
1627
1628
1629
Invalid (%)
Not Invalid (%)

APPENDIX 2 - PATENT FAMILY SIZE: PRIORITY DOCUMENTS

	Total Priority Documents	US Priority	Foreign Priority
Not Invalid	3.17	2.72	0.44
Invalid	3.16	2.99	0.18
Average 1610	2.02	1.50	0.51

APPENDIX 3 - PATENT FAMILY SIZE: CHILDREN

	Total Child Documents	Child Patented	Child Pending	Child Published	Child Abandoned
Not Invalid	4.03	2.02	0.21	0.07	1.74
Invalid	5.61	3.72	1.53	1.27	5.06
Average 1610	0.58	1.71	1.35	1.10	1.38

APPENDIX 4 - NUMBER OF UNIQUE ASSIGNEES

Invalid Patents	Counts
Total Unique Assignees	47
Total Unique Secondary Patent Assignees	46
Total Unique Primary Patent Assignees	3
Total Number of Assignees	125

Not Invalid Patents	Counts
Total Unique Assignees	80
Total Unique Secondary Patent Assignees	77
Total Unique Primary Patent Assignees	8
Total Number of Assignees	266

APPENDIX 5 - NUMBER OF UNIQUE EXAMINERS

Invalid Patents	Counts
Total Unique Examiners	62
Total Unique Secondary Patent Examiners	57
Total Unique Primary Patent Examiners	8
Total Number of Examiners	142

Not Invalid Patents	Counts
Total Unique Examiners	112
Total Unique Secondary Patent Examiners	108
Total Unique Primary Patent Examiners	12
Total Number of Examiners	295

APPENDIX 6- FREQUENCY OF RESTRICTION REQUIREMENTS, SPECIES ELECTION AND TRAVERSALS TO RESTRICTION REQUIREMENTS

	Invalid	Not Invalid	1610 Average Patents
Restriction Requirements	0.24	0.27	0.29
Species Elections	0.056	0.070	0.14
Restriction / Election Traversals	0.095	0.13	0.11

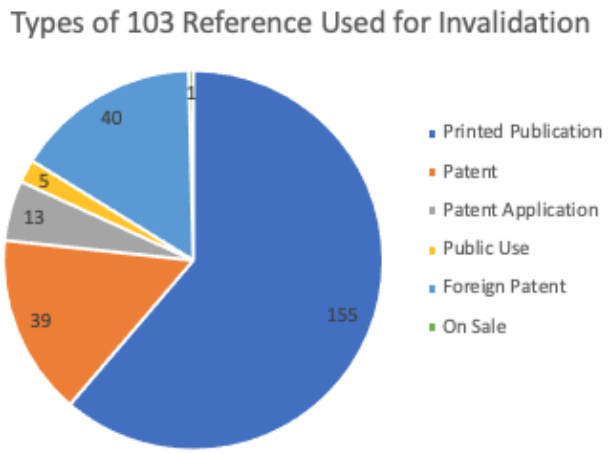
APPENDIX 7 - FREQUENCY OF REJECTION TYPE PER OFFICE ACTION

	Invalid	Not Invalid	1610 Average Patents
§112(b) Indefiniteness	0.16	0.17	0.17
§112(a) Written Description	0.079	0.049	0.068
§112(a) Enablement	0.075	0.053	0.11
§101 Statutory Double Patenting	0.021	0.0074	0.011
§101Utility	N/A	N/A	0.0049
§101 Patentable Subject Matter	0.012	0.0044	0.0083

APPENDIX 8 - APPLICANT RESPONSES TO EXAMINER REJECTIONS

Traversal Strategy	Invalid Patents	Not Invalid Patents	1610 Average Patents
§112(b) Indefiniteness-Claim Amendments	0.13	0.14	0.16
§112(b) Indefiniteness-Arguments	0.023	0.017	0.019
§112(a) Written Description- Claim Amendments	0.056	0.036	0.046
§112(a) Written Description- Arguments	0.033	0.016	0.029
§112(a) Enablement-Claim Amendments	0.060	0.043	0.076
§112(a) Enablement-Arguments	0.028	0.017	0.034
§101 Statutory Double Patenting- Claim Amendments	0.017	0.0068	0.011
§101 Statutory Double Patenting- Arguments	0.0053	N/A	N/A
§101Utility- Claim Amendments	N/A	N/A	0.0050
§101Utility- Arguments	N/A	N/A	N/A
§101 Patentable Subject Matter- Claim Amendments	0.012	0.0040	0.0083
§101 Patentable Subject Matter- Arguments	0.0016	0.00041	0.0033

APPENDIX 9


Types of 103 Reference Used for Invalidation
40
1
5
13
39
155
Printed Publication
Patent
Patent Application
Public Use
Foreign Patent
On Sale

APPENDIX 10

	1610 Control	Invalid	Not Invalid
Original Filing	0.426	0.205	0.268
Average Number of Restriction Requirements	0.297	0.231	0.272
Average Number of Office Actions	2.02	1.86	1.76
Average Number of Non-Final Office Actions	1.48	1.32	1.28
Average Number of Final Office Actions	0.545	0.538	0.482
Average Number of RCEs	0.456	0.393	0.562
Examiner- Average Allowance Rate	60.1%	58.7%	51.7%
Earliest Filing Date	2/25/2002	3/6/2001	1/24/2001
Median Filing Date	4/30/2007	11/30/2011	08/29/2008
Latest Filing Date	10/21/2013	5/8/2017	6/16/2006
Earliest Issue Date	3/8/2005	3/2/2004	8/27/2002
Median Issue Date	8/10/2010	1/22/2013	6/5/2012
Latest Issue Date	2/7/2017	12/5/2017	12/5/2017
Average Number of Independent Claims at Grant	2.57	2.55	2.69
Average # Words / Each Independent Claim	101.99	98.68	93.85
Assignees Citizenship (United States)	54.0%	53.8%	46.5%
First Named Inventor (United States)	75.0%	71.8%	66.5%

STATISTICAL APPENDIX

For each variable, the variables are grouped (indicated by letters) by whether they are different from each other. The letter "A" represents a higher score than the letter "B," and "B" represents a higher score than "C." For example, our data show that when it comes to the time in prosecution, the control group spend significantly longer in prosecution than the valid group, which in turn spend significantly longer in prosecution than the invalid group. Thus, in that example we designate the control group A, the valid group B, and the invalid group C. Where two groups are not significantly different they receive the same letter. For example, both valid and invalid litigated patents have significantly more examiner interviews than the control group, but there is no significant difference between the two litigated groups, so in that example they are both designated A. An "A/B" designation indicates that a group that is not significantly different from either those above or below them. For example, the control group has significantly longer applicant responses top examiner rejections (measured in pages) than valid litigated patents, but invalid litigated patents, which sit in between, are not significantly different than either the group above them or the group below them.

Several variables were not consistent across the 1610 data and the valid/invalid data, precluding analysis. Specifically, the 1610 data lacked a breakdown of parent priority US vs. foreign, as well as the child data about applications, patenting, publishing, and abandonment. The invalid/valid data lacked data on examiner/applicant error and same examiner priority. As such, we could not conduct a full statistical analysis on those variables.

Table 1- General Statistics / Examiner Rejections

	Invalid	Not Invalid	1610 Control
Prosecution Duration	C	B	A
Pages in Response	A/B	B	A
Examiner Interviews	A	A	B

	Control/Invalid		Control/Not Invalid		Invalid/Not Invalid	
	Odds Ratio	p-Value	Odds Ratio	p-Value	Odds Ratio	p-Value
Prosecution Duration	4.617	<0.0001	3.010	0.00783	-2.504	0.0368
Pages in Response	1.136	0.564	2.571	0.0304	1.090	0.827
Examiner Interviews	-4.250	<0.0001	-4.728	<0.0001	0.248	1

Table 2- Examiner Rejections

	Invalid	Not Invalid	1610 Control
Enablement/OA	A/B	B	A
ODP/OA	A	A	B
103/OA	A	A	B

	Control/Invalid		Control/Not Invalid		Invalid/Not Invalid	
	Odds Ratio	p-Value	Odds Ratio	p-Value	Odds Ratio	p-Value
Enablement/OA	1.303	0.577	2.838	0.0136	1.388	0.496
ODP/OA	-3.502	0.00163	-2.674	0.0176	1.353	0.528
103/OA	-2.373	0.0530	-3.394	0.000688	-0.6568	1

Table 3- Applicant Responses

	Invalid	Not Invalid	1610 Control
ODP- Terminal Disclaimer/OA	A	A	B
102(b)- Claim Amendments/OA	B	B	A
103- No Motivation to Modify/OA	A	B	A
103- No Expectation of Success/OA	B	A/B	A
103- Missing Elements/OA	A	A	B
103- Unexpected Results/OA	A	A	B
103- Use of 132 declaration/OA	A	A	B

	Control/Invalid		Control/Not Invalid		Invalid/Not Invalid	
	Odds Ratio	p-Value	Odds Ratio	p-Value	Odds Ratio	p-Value
ODP- Terminal Disclaimer/OA	-3.842	0.0003667	-3.171	0.00456	1.387	0.496
102(b)- Claim Amendments/OA	3.601	0.000952	3.556	0.00111	-0.680	1

103- No Motivation to Modify/OA	-2.226	0.0260	-2.806	0.0150	-0.216	1
103- No Expectation of Success/OA	-2.541	0.0332	-2.190	0.0855	0.8193	1
103- Missing Elements/OA	-3.684	0.00142	-4.107	0.000120	-0.0272	1
103- Unexpected Results/OA	-3.715	0.000608	-4.083	0.000134	0.271	1
103- Use of 132 declaration/OA	-4.488	<0.001	-4.040	0.000160	1.138	0.766