Pharmaceutical Patents and Adversarial Examination

*Dmitry Karshtedt**

Abstract

Proposals to improve the work quality of the U.S. Patent and Trademark Office ("PTO" or "USPTO") continue to generate vigorous debate. On one hand, several scholars maintain that the short times allotted to the examination of patent applications and the agency's other operational constraints yield numerous patents of questionable validity and conclude that the PTO must be fixed. On the other hand, a noteworthy dissenting view defending the PTO's "ignorance" as "rational" holds that examination should function chiefly as a coarse filter because most patents are never enforced or licensed and that devoting substantial resources to ascertaining validity is sensible only after an issued patent proved to be valuable. This Article does not take a side in this debate, but instead uncovers a point of potential agreement between these two positions. It argues that there is a class of patent applications—those intended to support the marketing of branded small-molecule pharmaceutical products—that one can predict with some degree of confidence will turn into commercially important exclusive rights. Specifically, the economic and social impacts of so-called "secondary" drug patents, which cover incremental innovations, can be readily anticipated in many cases. Thus, it stands to reason that interested third parties, such as generic manufacturers, should be allowed to participate in the process of pharmaceutical patent examination as early as possible. This Article proposes such an adversarial proceeding. This reform should result in better performance by the PTO in a critical technological area, help prevent the issuance of questionable patents that can lead to unnecessarily high drug prices, and cut down on the waste of resources, errors, and other destabilizing effects caused by repetitive adjudication of patent validity.

Table of Contents

* Associate Professor at The George Washington University Law School. J.D., Stanford Law School. Ph.D., Chemistry, U.C. Berkeley. Professor Karshtedt tragically passed away on October 30, 2022, before this article could be published. Professor Karshtedt is widely regarded as a leading patent scholar of his generation. Issues explored in this article—pharmaceutical patents, patent quality, and patent examination reform—were close to his heart. Professor Karshtedt will be remembered for his generosity, intellect, collegiality, and many and varied contributions to patent law. Many thanks to Sean B. Seymore, Centennial Professor of Law at Vanderbilt Law School, for his final review of this Article on behalf of Professor Karshtedt.

October 2023 Vol. 91 No. 5

Introduction

The U.S. Patent and Trademark Office ("PTO" or "USPTO") is no stranger to controversy. The agency's job is to examine patent applications for compliance with statutory requirements of

validity[1]—a significant responsibility because patent rights can be quite powerful. Patents can incentivize innovative activity, but they do so at a cost because patent owners can use courts—or at least threaten legal action—to limit the conduct of other participants in the economy.[2] Activities that could otherwise be undertaken freely may draw a civil lawsuit as soon as the patent issues, potentially resulting in substantial monetary damages and an injunction.[3] As a result, when the patentee is unwilling to forbear or when the parties are unable to reach an agreement to license the patented technology, research and manufacturing activity could be impeded.[4] Related, based on the economics of supply and demand, patent-covered products usually end up more expensive than they would have been in the absence of patents—a phenomenon known as "deadweight loss."[5] When patents are granted improvidently, they generate these costs without the corresponding benefit of encouraging socially valuable innovation.[6] At least on first approach, these intuitions indicate that it is very important for the PTO to get patent allowances right. Empirical work, however, shows that the rate of erroneous patent grants is in fact quite high.[7] This observation has led to a vigorous policy debate.

On one side are the scholars who say that the PTO must be fixed. For example, in an article titled *Irrational Ignorance at the Patent Office*, Michael Frakes and Melissa Wasserman argue that the agency woefully lacks the resources needed for adequate examination of patent applications.[8] They explain that examiners have only eighteen hours on average per application to perform the challenging tasks of reviewing an applicant's proposed claims, searching for information that might render them unpatentable, and writing up "Office Actions" that justify their decisions to reject or allow the claims.[9] Frakes and Wasserman maintain that such short examination times and other operational constrains on the agency

---

1 *See* 35 U.S.C. § 2 (2018).

2 *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 990 (1997).

3 *See* 35 U.S.C. § 271; *see also* John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 Berkeley Tech. L.J. 727, 739–40 (2002).

4 *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1026–28 (1989).

5 Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 Mich. L. Rev. 985, 987 (1999).

6 *See* Thomas, *supra* note 3, at 739–40.

7 *See* Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 Vand. L. Rev. 975, 978 (2019); *see also infra* notes 88–93.

8 *See* Frakes & Wasserman, *supra* note 7, at 981.

9 *See id.* at 978.

are responsible for many incorrectly granted patents, and they document how these errors generate social costs alluded to above—including needlessly high product prices, foregone opportunities for research and development, and excessive litigation expenses.[10] Accordingly, they propose various PTO reforms that include hiring more examiners and changing incentive structures within the agency to create an environment in which patent applications are vetted more thoroughly.[11]

The Frakes and Wasserman *Irrational Ignorance* formulation is a direct response to *Rational Ignorance at the Patent Office*, a well-known article Mark Lemley authored.[12] Challenging an earlier line of scholarship proposing PTO reforms, Lemley contends that the future value of patent claims is generally difficult to assess at the time of examination, and that evidence shows that very few issued patents ever end up mattering.[13] He thus maintains that the expenditure of significant public and private resources during examination is simply not worthwhile.[14] As for those patents that do become commercially valuable, Lemley posits that litigation and other forms of post-issuance patent review can sort the valid wheat from the unpatentable chaff.[15] The key difference between these routes and examination is, of course, the presence of private parties who may be threatened by an infringement suit or otherwise affected by a patent. These entities should thus be highly motivated to make arguments for invalidity that could help them avoid liability or at least the payment of supracompetitive prices caused by patent exclusivity,[16] which results in a vetting of validity at the level of rigor that the PTO simply cannot match.[17]

These two positions seem difficult to reconcile. Still, this Article aims to do so anyway—in one specific technological area. To be sure, this Article will not attempt to show that the PTO's ignorance during patent examination (often referred to as "patent prosecution") is both

---

10 *See id.* at 1013–14; *see also* Adam B. Jaffe & Josh Lerner, Innovation and Its Discontents 4 (2004); Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & Econ. 463, 465 (1995).

11 *See* Frakes & Wasserman, *supra* note 7, at 1029–30.

12 *Id.* at 980; Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495 (2001).

13 *See* Lemley, *supra* note 12, at 1479, 1511, 1514; *see also* Kimberly A. Moore, *Worthless Patents*, 20 Berkeley Tech. L.J. 1521, 1526 (2005).

14 *See* Lemley, *supra* note 12, at 1497.

15 *See id.* at 1518; *see also* John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 Geo. L.J. 435 (2004).

16 *See* Lemley, *supra* note 12, at 1518; *see also* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 953 (2011).

17 *See* Janet Freilich, *Ignoring Information Quality*, 89 Fordham L. Rev. 2113 (2021) (discussing inadequacies of the PTO review process).

rational and irrational, for that is a logical impossibility. This Article will argue, however, that for this class of patents, both sides can perhaps agree that a more thorough examination is both warranted and worthwhile because the patents' future value can be readily anticipated at the application stage, and because regulatory mechanisms make them easy to identify.[18] In addition, certain features of the prosecution of these patents make the likelihood of an improvident grant particularly high, with the errors in turn generating significant social costs because of the patents' particular economic significance.[19]

The patent applications subject to this Article's proposal are those that brand drug firms plan to use, if the PTO grants them, to protect pharmaceutical products the Food and Drug Administration ("FDA") approved. Such patents are typically listed in the so-called "Orange Book,"[20] which the FDA administers.[21] This publication notifies the brand sponsor firm's generic competitors, and the public, which patents support its exclusive rights to market the drug—and which the generics must normally try to invalidate if they wish to market their copies of the product prior to the patents' expiration.[22] In addition, Orange Book listings confer significant advantages on the brand firms in litigation.[23] In the last several years, policymakers have focused a great deal of attention on the impact of Orange Book patents on drug prices, with both executive and legislative branch actors training their focus on the PTO.[24] For example, pursuant to an executive order titled "Promoting Competition in the American Economy," which issued less than six months

---

18 *See* Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination* 4–9 (Nat'l Bureau of Econ. Rsch., Working Paper No. 27579, 2020) (arguing that "increasing time allocations [at the PTO] by 50% over just one year of reviews of secondary drug patents will result in an aggregate acceleration of generic entry of 16.9 years among the set of FDA-approved drugs").

19 *See infra* Section II.B.

20 U.S. FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (43d ed. 2023), https://www.fda.gov/media/71474/download [https://perma.cc/R2U5-F64G]; *see also* 21 C.F.R. § 314.53 (2018) (governing Orange Book requirements).

21 *See generally* U.S. FDA, *supra* note 20. The agency, however, does not police Orange Book listings. *See* Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 Mich. Telecomm. & Tech. L. Rev. 197, 207 (2015); *see also* Jacob S. Sherkow, *Administrating Patent Litigation*, 90 Wash. L. Rev. 205, 214–15, 250–53 (2015) (stating that the FDA has "long abdicated any substantive authority over policing Orange Book listings" and calling for a greater role for the FDA to police certain conduct by owners of pharmaceutical patents).

22 *See generally infra* Section II.B. *See* 21 U.S.C. § 355(j) (2018).

23 *See* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 710–11 (2009).

24 The judiciary has been involved, too—in, among other things, deciding antitrust claims. *See, e.g.*, New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).

after the start of the Biden presidency, the Acting Commissioner of Food and Drugs sent a letter to the PTO noting, among other things, that "[c]oncerns . . . have been raised about patent 'evergreening,' or the practice of patenting 'post-approval' or 'secondary' changes to previously approved drug products."[25] The Acting Commissioner went on to opine that these patents can "unduly extend market monopolies and keep drug prices high without any meaningful benefits for patients."[26]

As should be apparent based on these comments, the patents that the Acting Commissioner had in mind are generally not subject to Lemley's fundamental assumption of inadequate information about commercial value at the application stage, which he used to largely justify the PTO's "ignorance."[27] In contrast to the average patent, whose worth at the time of filing might be completely unknown, one can predict with some confidence that many patent applications slated for the Orange Book will turn into commercially significant patents—particularly, so-called "secondary" patents alluded to by the Acting Commissioner.[28] In addition, the classes of private entities that would be motivated to prevent those patents from issuing—most obviously, generic manufacturers—are also known.[29] Finally, it is well established that pharma is different from many other technology fields because of the FDA regulatory connection. Policymakers have acknowledged that drug patents require special treatment since at least the Hatch-Waxman Act, adopted in 1984.[30] This legislation sets up a mechanism for linking brand companies' patent rights with the corresponding FDA-approved drugs via the Orange Book, governs the conduct of litigation over the listed patents, and includes provisions unique to these lawsuits.[31]

This Article argues that, when it comes to small-molecule pharmaceuticals, a rigorous adversarial process for determining the validity

---

25 Letter from Dr. Janet Woodcock to Mr. Andrew Hirshfeld, Performing the Functions and Duties of the Under Sec'y of Com. for Intell. Prop. and Dir. of the U.S. Pat. and Trademark Off. 3 (Sept. 10, 2021), https://www.fda.gov/media/152086/download [https://perma.cc/TC8F-A3NT].

26 *Id.* at 5.

27 *See* Lemley, *supra* note 12, at 1531.

28 *See* Letter from Dr. Janet Woodcock to Mr. Andrew Hirshfeld, *supra* note 25, at 3; Amy Kapczynski, Chan Park & Bhaven N. Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1–2 (Dec. 5, 2012).

29 *See* Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1727, 1727 n.62 (2016) (citing Benjamin P. Liu, *Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage*, 11 J. MARSHALL REV. INTELL. PROP. L. 623, 665–68 (2012)).

30 *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 357 (2007).

31 *See id.* at 358; *see also* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 460 (1986).

of the underlying patent applications at the PTO is likely to provide significant payoffs. Indeed, adversarial patent examination is something of a compromise between the two contrasting views on patent quality. Nevertheless, the literature has largely overlooked this solution[32]—perhaps because preissuance third-party participation in prosecution has generally been viewed with disfavor.[33] As this Article will show, however, this approach is well worth a fresh look at least in this one technological and regulatory context. Besides their anticipated value and the unique Orange Book connection, drug patent applications tend to differ from others in another significant way that justifies an early adversarial process. In this field, applicants frequently rely on expert affidavits and other technical information that can end up decisively moving the needle toward validity, but whose quality and reliability are sometimes questionable. These patents often fall in litigation, which demonstrates that the examiner's reliance on such evidence was in error.[34] As this Article explains, scientific assertions can instead be more effectively tested through a private adversary's challenge at the PTO and the challenger's own technical experts, which is a resource that the PTO lacks.[35] This process should, among other things, reduce rates of erroneous grants of secondary pharmaceutical patents, which often present close questions of patentability.

To be sure, other circumstances and fields of technology to which this proposal could apply are conceivable, though implementing it in these other contexts can run into barriers that are more significant than in small-molecule pharma.[36] The barriers include identification problems and other confounding factors. For example, trade secrecy and nonpatent exclusivity in the context of so-called "biologics" (i.e., large-molecule drug products) can serve as powerful nonpatent mechanisms for keeping competitors out of the market,[37] which calls into

---

32 *See, e.g.*, Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 Berkeley Tech. L.J. 763, 776–83 (2002) (discussing an example of a study entertaining this possibility).

33 *See infra* notes 59–63 and accompanying text.

34 *See infra* Section II.B.1.b; *see also* Harris A. Pitlick, *Some Thoughts About Unexpected Results Jurisprudence*, 86 J. Pat. & Trademark Off. Soc'y 169, 177 (2004).

35 *See* Thomas, *supra* note 3, at 728; *see also* Jeremy W. Bock, *Expanding the Patent Office's Regulatory Footprint: A Proposal for Reimbursing Invalidity Challenges*, 96 Denv. L. Rev. 441, 441 (2019).

36 *Cf.* John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. Chi. L. Rev. 1073 (2015) (exploring how different industries experience the patent system). One general scenario for using an adversarial process could be the prosecution of continuation applications that include claims drafted to cover existing products.

37 *See* Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 Hastings Sci. & Tech. L.J. 109, 135–36 (2011).

question the primacy of patents as exclusivity drivers in this area.[38] In this vein, it is worth noting that the Patent Offices of Israel and India, two of the major international jurisdictions that allow pre-grant oppositions, mostly see challenges to small-molecule pharmaceutical patent applications rather than those in other fields.[39] Nevertheless, the proposal's focus on these patents can be seen as a kind of a policy pilot,[40] and if the proposal is adopted and works well in this space, it could be extended to other contexts.

In sum, after highlighting the special nature of pharmaceutical products and the patents that cover them, this Article proposes a unique procedure for examining the applications that can lead to those patents. It argues that, instead of having a system that starts with *ex parte* prosecution and is then followed by Hatch-Waxman litigation and other forms of post-issuance reviews, we should aim to get validity right the first time. Accordingly, after making the case that the current approach to drug patent validity is flawed, this Article proposes a pre-grant third-party opposition system for applications intended to mature into Orange Book patents. Under this scheme, generic challengers would have the power to participate fully in the prosecution of such applications as soon as they publish.[41]

Making use of the adversarial process, this scheme would improve patent examination quality in a crucial technological area. Furthermore, it would reduce repetitive and wasteful validity determinations, and more quickly lead to clarity and stability of the respective rights of both brand and generic firms by operation of estoppels and other limits on arguments against validity if the patent does get through the enhanced prosecution.[42] These benefits, in turn, would help reduce unnecessary costs to the public from erroneous decisions on patentability,[43] whether in favor of patentees or against. Notably, the proposal brings with it

---

38 *See* Yaniv Heled, *Regulatory Competitive Shelters*, 76 Ohio St. L.J. 299, 338 n.155 (2015).

39 *See* Eran Bareket & Chen Ben Dori-Alkan, *New Empirical Study of ILPO Relating to Pre-Grant Oppositions in Israel*, mondaq (April 28, 2017), https://www.mondaq.com/patent/589860/recently-published-new-empirical-study-of-ilpo-relating-to-pre-grant-oppositions-in-israel [https://perma.cc/6QVR-5HCN]; Veena Johari, K. M. Gopakumar & Arundhati Abhyankar, *Policy Brief on Patents and Pre-Grant Opposition in India*, Third World Network: Briefing Paper 100, 1 (June 2019).

40 *Cf.* Sofia Ranchordás, *Innovation Experimentalism in the Age of the Sharing Economy*, 19 Lewis & Clark L. Rev. 871, 918–19 (2015) (discussing policy pilots in a specific technological area).

41 *See infra* Section II.B.2.

42 *Cf.* Mark A. Lemley, Doug Lichtman & Bhaven N. Sampat, *What to Do About Bad Patents?*, 28 Regul. 10, 12–13 (2005).

43 *See infra* note 54 (noting the assumption that patents can be a good proxy for social value).

additional advantages. For example, adversarial examination may make it more difficult for brands and generics to enter into potentially anticompetitive settlements that one now sees in Hatch-Waxman litigation,[44] and it may also pave the way for more accurate Orange Book listings.[45]

The rest of this Article proceeds as follows. Part I lays out the opposing sides in the patent quality debate. Part II discusses small-molecule pharmaceutical patents subject to the Hatch-Waxman Act to argue that the current approach to determining their validity is ineffective and wasteful and shows why it is well worth investing in the initial examination of these patents. Part III proposes the adversarial prosecution solution and sets forth its mechanics, which would enable increased rigor in the examination process and confer significant benefits on patents eligible to be challenged by third parties. The Article then concludes.

I. The Patent System's Processes and the Patent Quality Debate

A. Establishing and Challenging Patent Rights

1. Patent Theory Basics and Prosecution Mechanics

One of the theories justifying the patent system is that exclusive rights that come with patents can provide incentives for the creation of socially valuable innovation by enabling inventors (or their assignees or exclusive licensees) to charge supracompetitive prices for patent-covered products.[46] The flip side of patent exclusivity is that someone has to pay those higher prices—the patentee's competitors, consumers, and other participants in the economy.[47] If the invention is truly deserving of a patent, however, we are generally willing to

---

44 *See generally* Impax Lab'ys, Inc. v. Fed. Trade Comm'n, 994 F.3d 484 (5th Cir. 2021).

45 *See, e.g.*, United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co., 11 F.4th 118 (2d Cir. 2021); *see also* Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399 (2012). This is important because the Orange Book can provide significant benefits for the New Drug Application holder. *See* Dogan & Lemley, *supra* note 24; Ashley M. Winkler, M. David Weingarten & Shana K. Cyr, *Requirements, Benefits, and Possible Consequences of Listing Patents in FDA's Orange Book*, *in* BNA Pharm. L. & Indus. Rep. 4–5 (July 3, 2018), https://www.finnegan.com/print/content/65249/Requirements-Benefits-and-Possible-Consequences-of-Listing-Patents-in-FDAs-Orange-Book.pdf [https://perma.cc/T3P6-AA84].

46 *See generally* Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. Chi. L. Rev. 999 (2014). *See* Michael Abramowicz, *Perfecting Patent Prizes*, 56 Vand. L. Rev. 115, 172–77 (2003); *see also infra* notes 136–40 and accompanying text.

47 *See infra* note 138.

tolerate these and other costs because of the countervailing benefits of inventions. But if not, and the inventor manages to obtain a patent anyway, the costs generally represent a loss to society without an offsetting gain.[48]

While patentability does not always perfectly track desirable innovation,[49] theorists typically see it as a superior alternative to prizes and other forms of incentivizing research and development efforts that are appropriable by copyists.[50] The pharmaceutical industry, as will be further discussed below, is viewed as particularly dependent on the patent system as an incentive and sorting mechanism for the creation of valuable inventions and products.[51] In practice, the grant of any given patent, even if correct, may not actually correspond to properly calibrated economic incentives in any given case, and this observation can hold true in the drug space as in any other.[52] Said another way, it might sometimes make sense as a matter of innovation economics to grant a firm a patent that is invalid under the strictures of the Patent Act (or to forbid a patent even if valid).[53] Nevertheless, the Article proceeds on the assumption that patentability is generally a good proxy for socially valuable inventions—which is the *raison d'etre* of the patent system.[54] Accordingly, at least on first approach, it seems important to get patents right,[55] which leads us to the antecedent question of who is responsible for this weighty task.

Even those who are generally unfamiliar with patent law know the answer—it is the PTO. Indeed, patent rights are not automatic and do not arise at common law. Instead, inventors must convince this federal

---

48 *See* Roin, *supra* note 46, at 1023–25.

49 *See generally* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503 (2009) (tracking shortcomings of the drug patent system). *See also* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 Yale. L.J. 544, 563–66 (2019).

50 *See generally* Roin, *supra* note 46; Timothy Chen Saulsbury, *Pioneers Versus Improvers: Enabling Optimal Patent Claim Scope*, 16 Mich. Telecomm. & Tech. L. Rev. 439, 443, 463 (2010) (discussing the nonrivarlousness and nonexcludability justifications for patent rights). *Cf.* Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, 3 Brookings Papers on Econ. Activity 783, 783 (1987) ("To have the incentive to undertake research and development, a firm must be able to appropriate returns sufficient to make the investment worthwhile.").

51 *See infra* notes 131–85 and accompanying text; *cf.* Mark A. Lemley, *Ignoring Patents*, 2008 Mich. St. L. Rev. 19, 29–30.

52 *See* Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 Geo. L.J. 269, 328 (2007).

53 *See* Roin, *supra* note 49, at 515; *see also* Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 Wash. L. Rev. 1317, 1353 (2020).

54 *See* Anup Malani & Jonathan S. Masur, *Raising the Stakes in Patent Cases*, 101 Geo. L.J. 637, 639 n.7 (2013). And especially so in the pharmaceutical field. *See* Lemley, *supra* note 51.

55 *See generally* Stephen Yelderman, *The Value of Accuracy in the Patent System*, 84 U. Chi. L. Rev. 1217 (2017) (discussing consequences of erroneous patent grants and the value in correcting them).

agency to award them a patent—a process that begins with the filing of a patent application and the payment of a fee.[56] The application, usually prepared and filed by a patent attorney or agent, must include a description of the invention and a proposed set of claims, which are numbered sentences at the end of the patent that define the boundaries of the inventor's rights.[57]

The application then undergoes prosecution, during which an examiner decides if the claims meet the statutory requirements of patentability. For example, the examiner must search for relevant pre-application disclosures such as prior patents and journal publications (collectively known as "the prior art") and analyze them to determine if the claims are novel, 35 U.S.C. § 102, and nonobvious, § 103, in view of these references.[58] If the examiner concludes that they are not, the claims will be rejected. In a typical case, the applicant (again, usually through a patent attorney or agent) will end up amending the claims several times during prosecution—often by narrowing their scope and sometimes by canceling the original claims and introducing new ones—to overcome the rejections.[59] The applicant may also obtain claim allowance by continuing to press arguments for patentability before the examiner or by challenging the examiner's adverse decisions within the PTO and, further, in a federal court.[60]

Patent examination is an *ex parte* process. Private entities other than the applicant are allowed to make pre-issuance submissions to the PTO "of a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination" to explain their relevance to the patent being prosecuted.[61] The statutory scheme, however, precludes the submitter's further participation.[62] From the perspective of would-be challengers, this mechanism

---

56 *See* 37 C.F.R. § 1.16(a) (2020).

57 *See* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. 63, 66–67 n.5 (2004). Note that each claim of an issued patent is, technically, a separate right—i.e., the examiner may allow some claims but not others, and invalidation of some claims in litigation does not doom all the claims in the patent unless the litigated claims are treated by the parties as representative.

58 *See* 35 U.S.C. §§ 102–103 (2018); *see also* Yelderman, *supra* note 55, at 1233–34, 1268 (discussing how the system of presenting prior art may lead to inaccuracies).

59 *See* Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261, 281–83 (2016); *cf.* Lemley & Moore, *supra* note 57, at 66–67.

60 *See* 35 U.S.C. §§ 6, 141, 145 (2018).

61 35 U.S.C. § 122(e)(1); *see also* 37 C.F.R. §§ 1.291–.292 (1998) (repealed) (setting forth rules for so-called "public use proceedings").

62 *See* Thomas, *supra* note 3, at 742; *see also* Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 Berkeley Tech. L.J. 577, 611 (1999).

is plainly inadequate because the third party is not involved in characterizing the references, and the applicant and the examiner remain the masters of the prosecution record. In addition, no one can appeal or otherwise block patent allowance—the only Article III court challenges of PTO examination outcomes available under the Patent Act are those by the applicants contesting patent *denials*.[63] Although some commentators have argued strenuously that the Administrative Procedure Act ("APA") should allow for third-party court challenges of patent grants,[64] the United States Court of Appeals for the Federal Circuit ("Federal Circuit") has definitively closed the door on such suits when it concluded that the Patent Act preempts them.[65] This precedent seems safe—and even if the Supreme Court reversed it to allow APA challenges to block patents from issuing, third parties would still lack the ability to participate meaningfully in the examination process—and thus, in the all-important exercise of building a record during examination.

2. Post-Issuance Patent Challenges

Prosecution, however, is not the final word on validity, and issued patents are by no means guaranteed to survive for their entire remaining terms. Private parties, and sometimes even the PTO itself, can take many cracks at patentability after a grant. In fact, patents can be challenged repeatedly and in multiple tribunals.

First, patents can be invalidated in court. Under 35 U.S.C. § 282(b), a party sued for patent infringement can assert invalidity on any statutory ground in pleadings styled as both counterclaims and affirmative defenses.[66] In addition, an entity can bring a claim of invalidity against a patentee in a declaratory judgment action—assuming the potential of an infringement suit is high enough that the Article III case or controversy requirement is met.[67] To get the patent knocked out, the challenger

---

63 *See* Jonathan Masur, *Patent Inflation*, 121 YALE. L.J. 470, 470 (2011); John C. Stedman, *The U.S. Patent System and its Current Problems*, 42 TEX. L. REV. 450, 463 (1964); Melissa F. Wasserman, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 401 (2011).

64 *See, e.g.*, John F. Duffy, *Reasoned Decisionmaking vs. Rational Ignorance at the Patent Office*, 104 IOWA L. REV. 2351, 2357 (2019).

65 *See* Pregis Corp. v. Kappos, 700 F.3d 1348, 1357 (Fed. Cir. 2012); s*ee also* Melissa F. Wasserman, *Deference Asymmetries: Distortions in the Evolution of Regulatory Law*, 93 TEX. L. REV. 625, 628 (2015).

66 35 U.S.C. § 282(b). In addition, invalidity can be raised by the United States as a defense against a claim of infringement in the Court of Federal Claims, or by a private party at the International Trade Commission ("ITC")—though the ITC's decisions lack preclusive effect.

67 *See, e.g.*, MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 139–140 (2007).

must overcome the statutory presumption of validity, which requires proof of invalidity by clear and convincing evidence.[68] But that is the extent of deference to the PTO.[69] In contrast to an appeal or a (hypothetical) direct APA challenge to the examiner's decision, which would be conducted under the highly deferential standard of "substantial evidence" supporting the agency's fact findings,[70] the PTO prosecution record is basically irrelevant during litigation over patentability.[71] Furthermore, once a patent claim is invalidated—even if it had previously been upheld by another court—it is effectively dead. This is because, under the rule from the Supreme Court's decision in *Blonder-Tongue Laboratories v. University of Illinois Foundation*,[72] the patentee is collaterally estopped from asserting the invalidated claims against anyone again.[73] The overall kill rate of litigated patents over the years, which ranges roughly from forty percent to sixty percent in the various eras of the modern patent system, shows that the examination outcomes are far from conclusive on validity.[74]

Second, in a route that has become one of the dominant stories in patent law in the past decade, patents can be challenged back at the PTO via post-issuance reviews created by the Leahy-Smith America Invents Act ("AIA").[75] Alluded to in the Introduction, these *inter partes* review ("IPR") and post grant review ("PGR") mechanisms are trial-like proceedings that private parties can petition the PTO

---

68 *See* Microsoft Corp v. i4i Ltd. P'ship, 546 U.S. 91, 97 (2011).

69 On whether presumption of validity matters, see generally Etan S. Chatlynne, Stephen Kenny & Lucas Watkins, *Investigating Patent Law's Presumption of Validity, Part II: An Empirical Analysis of How Unconsidered Evidence and Evidentiary Standards Affect Jury Verdicts*, 2011 Cardozo L. Rev. de novo 46 (providing an empirical study that suggests that a presumption of validity and its implementation of the clear and convincing evidence standard might not matter that much in practice). *But see* David L. Schwartz & Christopher B. Seaman, *Standards of Proof in Civil Litigation: An Experiment from Patent Law*, 26 Harv. J.L. & Tech. 429, 432 (2013) (questioning the result of this study and concluding otherwise). Perhaps the real question, though, is how the clear and convincing standard compares to the substantial evidence standard.

70 Dickinson v. Zurko, 527 U.S. 150, 162–63 (1999).

71 *See* Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1329 (Fed. Cir. 2000) ("The Administrative Procedure Act standard of review adopted in *Zurko* . . . has no application here."); *see also* Joshua L. Sohn, *Can't the PTO Get a Little Respect?*, 26 Berkeley Tech. L.J. 1603, 1605 (2011) (arguing for more deference to the PTO's findings in district courts). *But cf.* Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 Minn. L. Rev. 101, 117 (2006) (documenting difficulties with proving invalidity in litigation).

72 402 U.S. 313 (1971).

73 *See id.* at 329.

74 *See, e.g.*, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 209 tbl.2 (1998).

75 Pub. L. No. 112-29, 125 Stat. 284.

to initiate.[76] Often, these proceedings essentially become collateral attacks on patentability by defendants in infringement suits, which these entities pursue in addition to invalidity counterclaims against the same patentees.[77] IPRs and PGRs are conducted in the Patent Trial and Appeal Board ("PTAB"), the adjudicatory arm of the PTO.[78] Because the presumption of validity does not apply at the PTAB, the standard for canceling the claims is preponderance of the evidence[79]—a characteristic that, along with the lower cost of these proceedings relative to federal court lawsuits, and other factors, makes these challenges attractive to potential infringers.[80]

There are, to be sure, some limitations on IPRs and PGRs. One, challengers opting for IPRs can only seek to strike down the claims as non-novel or obvious (and only based on documentary evidence—i.e., prior patents or printed publications) and cannot invoke other patentability requirements,[81] such as enablement or written description under 35 U.S.C. § 112(a). Two, while PGRs allow for an attack on any ground the Patent Act requires for validity, these proceedings must be initiated within nine months of the patent's issuance.[82] Three, it may be possible to invoke statutory and common law estoppels against a patent challenger who had failed to invalidate a patent in a prior PTAB or court proceeding, though the contours of these provisions are still being worked out.[83] Four, the PTO has the discretion to deny institution of post-issuance review and has sometimes exercised it when the prior art referenced and arguments advanced in a petition for IPR or PGR mirror those the examiner or prior PTAB panel considered, or when they are being used to argue invalidity in a parallel district court proceeding.[84] In spite

---

76 *See* Regents of the Univ. of Minn. v. LSI Corp., 926 F.3d 1327, 1339 (Fed. Cir. 2019) (discussing the history of this and related legislation); *see also* Colleen Chien, Christian Helmers & Alfred Spigarelli, Inter Partes *Review and the Design of Post-Grant Patent Reviews*, 33 Berkeley Tech. L.J. 817, 819–20 (2018).

77 *See* Saurabh Vishnubhakat, Arti K. Rai & Jay P. Kesan, *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 Berkeley Tech. L.J. 45, 70 (2016).

78 *See* 35 U.S.C. § 6.

79 *See id.* § 316(e).

80 *See* Vishnubhakat et al., *supra* note 77, at 51–52, 54.

81 *See* 35 U.S.C. § 311(b).

82 *See* 35 U.S.C. § 321(b)–(c).

83 *See* Christa J. Laser, *The Scope of IPR Estoppel: A Statutory, Historical, and Normative Analysis*, 70 Fla. L. Rev. 1127, 1127 (2018).

84 *See* Apple Inc. v. Fintiv, Inc., No. IPR2020-00019, 2020 WL 2126495, at *1–3 (P.T.A.B. Mar. 20, 2020) (precedential); Robert Colletti, Christopher Gosselin & Brian Murphy, *The Recent Rise of Discretionary Denials at the Patent Trial and Appeal Board*, JDSupra (Nov. 19, 2020), https://www.jdsupra.com/legalnews/the-recent-rise-of-discretionary-97285 [https://perma.cc/78QQ-JDND]; *see also* Apple Inc. v. Iancu, No. 20-cv-06128, 2021 WL 5232241, at *2–3 (N.D. Cal. Nov. 10, 2021).

of these various constraints, these mechanisms are often successful—institution and invalidation rates in IPRs in the first few years of the PTAB's existence were as high as eighty percent[85]—and the litigation battlefield is littered with infringement suits extinguished by the PTO's determinations of unpatentability.[86]

B. The Validity Churn: Critiques, Reform Proposals, and Counterarguments

1. The Critics

This validity churn makes one wonder if there is something wrong with PTO examination. Sure enough, the current setup for judging patent validity, which relies ever so greatly on post-issuance proceedings, has come under significant criticism. One common thread of commentary maintains that high rates of patent invalidation indicate that the PTO is doing a poor job of vetting patent applications[87] and that something must be done to reduce examiner error. For example, the empirical work of Michael Frakes and Melissa Wasserman documents in detail the assertedly dire situation at the PTO. It concludes that examiners simply do not have enough time to perform the necessary work of generating the information needed for building an adequate prosecution record and conducting a proper analysis of the applications before them:

> On average, a U.S. patent examiner spends only eighteen hours reviewing an application, which includes reading the application, searching for prior art, comparing the prior art with the application, writing a rejection, responding to the patent applicant's arguments, and often conducting an interview with the applicant's attorney. If examiners are not given enough time to evaluate applications, they may not be able to reject applications by identifying and articulating justifications with appropriate underlying legal validity.[88]

Frakes and Wasserman contend that the PTO's resource shortages have caused the agency to issue numerous patents mistakenly, as evidenced

---

85 *See* Vishnubhakat et al., *supra* note 77, at 78.

86 *See id.* at 69–73; Chien et al., *supra* note 76, at 844–46.

87 *See, e.g.*, Frakes & Wasserman, *supra* note 7; Freilich, *supra* note 17, at 2154–55 (discussing mechanisms for improving searching at the PTO); Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent & Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 Stan. L. Rev. 613 (2015).

88 Frakes & Wasserman, *supra* note 7, at 978.

by the high rates of patent invalidation mentioned above,[89] and that these errors have led to significant social costs.[90] Building on earlier work making the general claim that the PTO's ignorance is hardly rational,[91] they document these costs—including expenses incurred in defending against infringement claims, forgone follow-on innovation, and deadweight losses in the form of higher product prices.[92] In addition, they show that the PTO's errors in prosecution impose significant burdens on the agency itself in the form of complex, resource-intensive PTAB trials, like PGRs, over the validity of issued patents.[93] To remedy these problems, Frakes, Wasserman, and other commentators have proposed bolstering the PTO's resources, such as by increasing the agency's funding so that the director could hire more patent examiners and by improving agency quality controls in various ways.[94] One of the overarching goals of these proposals is to facilitate examiners' ability to find and analyze relevant prior art. This reform could, the argument continues, lead to a greater incidence of justified—but presently missed—§ 102 and § 103 rejections and, ultimately, help forestall grants of patents that do not comply with these provisions.[95]

Other critics focus on the agency's struggles with § 112(a), which requires that patent claims be enabled and adequately described.[96] As to these conditions of patentability, several recent articles have maintained that the PTO is particularly poorly equipped to perform the necessary fact findings in prosecution, leading once again to improvident patent grants and associated unnecessary social costs.[97] Specifically, the enablement requirement asks whether a person of ordinary skill

---

89 *See id.*

90 *See id.*; *see also* Leslie, *supra* note 71, at 103–04 (discussing these costs in the context of the pre-AIA regime).

91 *See, e.g.*, Kesan, *supra* note 32, at 763; Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 689–90 (2004); Thomas, *supra* note 3, at 728.

92 *See, e.g.*, Malani & Masur, *supra* note 54, at 639; Frakes & Wasserman, *supra* note 7; *see also* Lerner, *supra* note 10, at 463; *supra* notes 5–7 and accompanying text (discussing drug prices and drug access).

93 Frakes & Wasserman, *supra* note 7, at 994–95.

94 *See id.*; *see also, e.g.*, Kesan, *supra* note 32, at 765; Beth Simone Noveck, *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123, 132 (2006).

95 *See supra* notes 11, 18, and accompanying text.

96 35 U.S.C. § 112(a); *see also* Freilich, *supra* note 17, at 2119; Lisa Larrimore Ouellette, Pierson, *Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1826–27 (2016); Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 848 (2017).

97 *See* Freilich, *supra* note 17, at 2137; Ouellette, *supra* note 96, at 1828; Sherkow, *supra* note 96, at 898–902.

in the art could practice the claims without undue experimentation.[98] While experimentation can accordingly help with determining whether claims are enabled, examiners have no access to a laboratory, and are therefore often left guessing at the factors necessary for a full analysis.[99]

Moreover, because the PTO has no "inquisitorial powers"[100] or an ability to cross-examine experts, examiners "lack[] the means or resources to gather evidence which supports or refutes the applicant's assertion[s]"[101] relating to validity in affidavits submitted to the PTO. Such means or resources to gather evidence are especially important for enablement and nonobviousness and often for the novelty and written description requirements too. This structural deficiency, combined with the fact that the burden to prove unpatentability of the applicant's desired claims is on the PTO,[102] is thought to lead to lax examination generally and underenforcement of § 112(a) in particular.[103] To remedy this problem, some commentators have again advocated bolstering resources available to the agency, including mechanisms for peer reviews of patent claim enablement and written description analyses.[104] Others have argued for various legal reforms that would correct the information asymmetry between applicants and examiners by removing the applicants' procedural advantages (e.g., shifting the burden to prove validity onto the applicant) or otherwise inducing or even forcing inventors to reveal information that would help examiners make more accurate validity decisions.[105]

Leaving aside the PTO's well-documented difficulties with enforcement of particular statutory validity provisions and the proposed solutions tailored to improve examiners' job performance, the overarching critiques in this line of literature are unified by one consistent insight: the PTO's error rate is unacceptable, and the agency must receive additional resources or novel legal advantages so it could do a better job of sifting good patent applications from bad. While the critics acknowledge that some of the proposals might come with significant

98 *See In re* Wands, 858 F.2d 731, 736–77 (Fed. Cir. 1988).

99 *See* Freilich, *supra* note 17, at 2124.

100 *See* John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. Ill. L. Rev. 305, 314.

101 *In re* Huang, 100 F.3d 135, 139 (Fed. Cir. 1996).

102 *See* 35 U.S.C. § 282(a) (2018); *see also* Sean B. Seymore, *The Presumption of Patentability*, 97 Minn. L. Rev. 990, 997 (2013).

103 *See* Seymore, *supra* note 102, at 992–93.

104 *See* Ouellette, *supra* note 96, at 1838–93.

105 *See* Seymore, *supra* note 102, at 1023 (proposing a reversal of the rule that places the burden on the examiner to show why the proposed claims are unpatentable); *see also* Kesan, *supra* note 32, at 769 (proposing various mechanisms for inducing the applicants to reveal information).

costs, they argue that the additional expenditures would be worth it given the problematic effects of improvidently granted patents.[106]

2. *Rationalizing PTO Ignorance*

In *Rational Ignorance at the Patent Office*, which went against the grain of much of patent quality literature, Mark Lemley fundamentally questioned the very project of investing significant public and private resources into initial patent examination.[107] Lemley's thesis rested on two related empirical insights: first, we usually lack information with respect to the future commercial value of patents while they are at the application stage, and second, we also know that many patents end up being worthless.[108] Indeed, most patents are never asserted or licensed, and many even become affirmatively unenforceable due to nonpayment of relatively modest maintenance fees—a telltale sign that the patent has no value to its owner.[109] Given this state of affairs, Lemley concluded that a thorough *ex parte* examination was not worth the requisite public and private expenditures and that the validity of patents that do end up having commercial significance is best sorted out in litigation.[110]

Further, Lemley suggested that, no matter how much one tries to support the agency with added funding or otherwise bolster its resources, the PTO's traditional *ex parte* examination process simply cannot replicate the crucible of an adversarial third-party challenge to an issued patent.[111] He contended that litigation is intrinsically more effective at revealing the facts that are relevant to patentability, such as the existence of certain types of prior art, and at facilitating stronger arguments for and against validity.[112] Accordingly, Lemley's proposal

---

106 *See* Seymore, *supra* note 102, at 1037; Kesan, *supra* note 32, at 774.

107 Lemley, *supra* note 12.

108 *See id.* at 1503–06.

109 *See id.*; *see also* Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 Fla. St. U. L. Rev. 119, 125, 125 n.21 (2005). To be sure, patents might be accumulated for reasons other than litigation, and these other roles of patents might be more difficult to track. *See* Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. Small & Emerging Bus. L. 137, 140–41 (2000); Moore, *supra* note 13, at 1522–23; *see also* Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 4 (Nat'l Bureau of Econ. Rsch., Working Paper No. 7552, 2000) ("Other reasons for patenting—found to vary by industry—include blocking rivals from patenting related inventions, protection against infringement suits, and using patents in negotiations over technology rights.").

110 *See* Lemley, *supra* note 12, at 1508.

111 *See id.* at 1499; *see also* Freilich, *supra* note 17, at 2150.

112 *See* Lemley, *supra* note 12, at 1528.

in *Rational Ignorance* was not to improve the PTO, but to eliminate the presumption of validity accorded to issued patents in litigation and replace it with a preponderance standard.[113] Lemley explained

> My argument in this article is based on the idea that it is more efficient to decide validity after in-depth consideration in those few cases in which it matters than to decide it upon a cursory review of all patent applications. My argument is undermined if validity litigation does not in fact involve a searching investigation of validity, but instead defers to the cursory review already conducted. Based on what we know of patent examinations, deference is not appropriate. If there is to be deference to PTO decisions in litigation, it should be coupled with some form of real third-party opposition system, and only patents that have been through that system should be entitled to deference.[114]

In sum, Lemley's contention was that highly accurate *ex parte* examination is unnecessary and perhaps even impossible and that an adversarial post-issuance process involving patents that end up mattering is the best way to get validity right.[115] In this frame, repetitive and ongoing re-evaluation of patent validity is unavoidable and even reasonable. Lemley maintained that, unless some form of meaningful third-party opposition becomes a part of the prosecution process, examination should function as no more than a coarse filter, and a more thorough patentability analysis should be deferred until ex post proceedings, if and when they need to be initiated.[116] Notably, Lemley suggested that the logic of his proposal might even support patent registration, a system under which substantive examination would be dispensed with altogether, though in the end he refused to endorse a pure registration system.[117] Nor did Lemley ultimately endorse adversarial examination based on his insight that, at the time of application, it is generally too early to know if the resulting patent would matter.[118]

Lemley acknowledged the social costs of improvidently granted patents, such as the potential for holdup and *in terrorem* effects, which could be felt especially strongly by entities lacking the resources to

---

113 *Id.*

114 *Id.* at 1529.

115 *See id.*

116 *See id.*

117 *See id.* at 1526; *see also* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 61 (2007).

118 *See* Lemley, *supra* note 12, at 1524–25; Lichtman & Lemley, *supra* note 117, at 45, 56 n.31.

pursue invalidity challenges.[119] He concluded, however, that these concerns simply do not justify the added investment into prosecution.[120] Lemley's thesis has remained controversial since he published *Rational Ignorance* in 2001, with Frakes and Wasserman among the latest in a long line of critics who argued that the costs of bad patents outweigh the expenditures necessary for improving examination.[121] Nevertheless, Lemley's points that the value of patents is generally difficult to predict at the time of application and that most patents do not end up mattering remain largely uncontested,[122] and the *Rational Ignorance* thesis has proven influential. For example, in an important 2019 opinion involving the power of the PTO to cancel issued patents, the Federal Circuit cited Lemley's article (and other academic works) in generally justifying procedures for "reevaluating those patents of particular concern to the public."[123]

There is even an argument to be made that rational ignorance has triumphed (so to speak). As noted earlier, among the most significant developments in patent law in the past decade has been the rise of new routes for post-issuance review of validity.[124] Once little used, proceedings against issued patents back at the PTO have grown tremendously after the AIA, which created the PTAB and introduced the concept of the adversarial patentability trial.[125] Although adjudication of validity of issued patents has not fully migrated from trial courts to the PTO, the incursion of PTO claims has been significant, and PTAB judges continue to invalidate the work of their colleagues

---

119 *See* Lemley, *supra* note 12, at 1516–19 ; *see also* Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 Cornell L. Rev. 71, 71 (2013) (arguing that a plaintiff's incentives to challenge a patent on noninfringement grounds instead of invalidity grounds "exacerbates the problem of invalid patents"); Leslie, *supra* note 71, at 103 (arguing that "antitrust law's current treatment of invalid patents remains inadequate" and that knowingly holding an invalid patent should be considered a violation the Sherman Anti-Trust Act). *But see* Paul R. Gugliuzza, *The Procedure of Patent Eligibility*, 97 Tex. L. Rev. 571, 574 (2019) (arguing that the Supreme Court's recent decisions to lower a plaintiff's burden when challenging invalid patents has been "bad for patentees").

120 *See* Lemley, *supra* note 12, at 1512–13.

121 *See* Frakes & Wasserman, *supra* note 7; *see also* Shubha Ghosh & Jay Kesan, *What Do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*, 40 Hous. L. Rev. 1219, 1226 (2004); Thomas, *supra* note 3.

122 *See, e.g.*, Ghosh & Kesan, *supra* note 121, at 1242 (conceding that there are significant limitations on what the PTO can do).

123 Regents of the Univ. of Minn. v. LSI Corp., 926 F.3d 1327, 1334 (Fed. Cir. 2019) (citing Lemley, *supra* note 12, at 1497, 1501–08).

124 *See supra* Section I.A.

125 Leahy-Smith America Invests Act, Pub. L. 112–29, 125 Stat. 284. *See generally* Vishnubhakat et al., *supra* note 77 (analyzing how litigants use PTAB review proceedings relative to Article III proceedings).

in the examination corps at a relatively high clip.[126] While, as further discussed below, this setup brings with it some significant inefficiencies, it must be acknowledged that the patents that come to the PTAB's attention are usually the ones that proved to be valuable after issuance. Specifically, a study by Saurabh Vishnubhakat, Arti Rai, and Jay Kesan showed that a large majority of patents under review by the PTAB were also involved in litigation.[127] These are the patents that ended up mattering, and they are accordingly getting a second (and often a third and a fourth) look.

The patent quality debates are not going away, and the salience of the PTAB's rise should not be overstated in resolving the debate over the importance of investing resources into initial prosecution. Indeed, one must be careful not to derive the "ought" from the "is" of patent law's PTAB revolution, and Congress's determination that issued patents must be subject to more rigorous post-issuance review does not mean that prosecution is completely fine as it now is. Frakes and Wasserman have argued as much,[128] and they could well be right in that further investments into *both ex parte* prosecution and the PTAB's post-issuance proceedings are economically justified. These are difficult empirical questions, and we should expect more work and new data that will help answer them as the patent system enters the PTAB's second decade. As Part II argues, however, a significant class of patents can be identified now for which the two sides of the patent quality debate might already agree that the PTO's "ignorance" during prosecution is "irrational."[129] As we will see, pharmaceutical patents are generally outside the ambit of Lemley's fundamental assumption of inadequate information about commercial value of the covered product at the application stage.[130] This insight suggests that even adherents of the *Rational Ignorance* thesis might well concur that, at least as to those patents, close attention at the prosecution stage is economically justified. The Article now turns to pharmaceutical patent applications (and patents), discussing their generally predictable value and the odd ways in which we adjudicate their validity.

---

126 *See* Vishnubhakat et al., *supra* note 77, at 65. *But see, e.g.*, Paul D. Ackerman, Michael S. Turner, Clifford A. Ulrich & Christopher Gresalfi, *Recent Changes at the PTAB Appear to Benefit Patent Owners*, Hunton Andrews Kurth (Dec. 23, 2018), https://www.lexology.com/library/detail.aspx?g=d73a4005-a459-4ec4-8d3e-b54f1942de16 [https://perma.cc/H9HZ-55N9] (documenting a change in the trend).

127 *See* Vishnubhakat et al., *supra* note 77.

128 *See* Frakes & Wasserman, *supra* note 7.

129 *See infra* Part II.

130 *See infra* Part II.

II. The Unusual Case of Pharmaceutical Patents

A. *Brands, Generics, and the Orange Book: The Power, Value, and Costs of Hatch-Waxman Patents*

The patents that are the focus of this Article are drug products, and thus, implicate the competencies of both the FDA and the PTO.[131] On the FDA side, the relevant statutory scheme is the Federal Food, Drug, and Cosmetic Act ("FDCA"), which sets forth the parameters of the FDA's jurisdiction over the regulation of pharmaceuticals (and other products beyond the scope of this Article).[132] On the PTO side, it is, of course, the Patent Act, which contains the requirements of patentability.[133] Linking the two is the Drug Price Competition and Patent Term Restoration Act, an amendment to the FDCA (and the Patent Act) often referred to simply as the Hatch-Waxman Act.[134] This legislation was passed to "balance incentives for the discovery and development of drugs against the goal of making those medicines available to consumers at reasonable prices," and it "contemplates two types of actors: brand and generic manufacturers."[135] As I explained in prior work, the Hatch-Waxman Act leverages both the FDCA and the Patent Act to "provide[] for exclusive rights for brand companies to market new drugs that they develop, while also facilitating the entry of generic equivalents of the branded drugs."[136]

The stakes of obtaining pharmaceutical patents can be very high. While a successful drug is on-patent, it can command a high revenue stream for the brand firm—which becomes severely curtailed once the relevant patent expires or is proved invalid.[137] For example, Merck experienced over ninety percent drop in domestic sales for its asthma drug Singulair after its patent expired and ten generics were launched into the market following the expiration.[138] From the public health perspective,

---

131 *See* Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 Iowa L. Rev. 1129, 1146 (2019) (describing the Hatch-Waxman Act as "a statutory scheme for regulating small-molecule drugs under which the FDA and the PTO play distinct but interrelated roles").

132 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–392 (Supp. 5 1934); *see also* Karshtedt, *supra* note 131, at 1146.

133 Patent Act, 35 U.S.C. §§ 1–39.

134 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, 21 U.S.C. § 355.

135 *Id.*

136 *Id.*

137 *See* Chie Hoon Song & Jeung-Whan Han, *Patent Cliff and Strategic Switch: Exploring Strategic Design Possibilities in the Pharmaceutical Industry*, 5 SpringerPlus 692 (2016).

138 *See* Brandy Betz, *Merck's Crash of a Titan*, The Motley Fool (Feb. 12, 2013, 11:03 PM), https://www.fool.com/investing/general/2013/02/12/mercks-crash-of-a-titan.aspx [https://perma.cc/V5B6-38ZJ].

however, the existence of relevant patents could mean a period of unaffordable prices and limited drug access, and generic entry could thus represent financial relief and a wider availability of cures.[139] Though it is difficult to extrapolate from what (one hopes to be) a once-in-a-generation pandemic, and the products involved are not small-molecule drugs, patents and other forms of intellectual property have been at the center stage in the discussion regarding access to COVID-19 vaccines.[140]

It is helpful to first address the FDA side of pharmaceutical regulation because the drug approval process undergirds the frequently high value of pharmaceutical patents relative to the average patent that comes out of the PTO. Under the FDCA, the FDA must evaluate a pharmaceutical firm's submissions, which center on clinical trial data, in order to decide whether the drug is safe and effective for a particular therapeutic indication.[141] Though not completely unique to drugs, the premarketing approval requirement that makes it illegal to sell these products without a government agency's imprimatur is certainly unusual.[142] The FDA's involvement should foster analytical rigor in the science behind the drug, in turn promoting innovation and careful product development, and it creates significant barriers to competitor entry.[143] Although the agency's decision that a pharmaceutical is safe and effective does not guarantee success in the market,[144] it surely sets these products apart from others—most of them—for which no government preclearance is needed. In addition, based on further FDCA requirements, most drugs marketed under New Drug Applications ("NDA") cannot be obtained without a physician's prescription for a period of time after FDA approval, which, at least in theory, reflects considered professional judgment that a particular remedy is needed to deal with a patient's condition.[145] When insurance coverage is added to the mix, pharmaceutical companies can claim powerful scientific, professional, and financial backing for their products, and these factors can in turn bolster the drugs' commercial value.[146]

---

139 *See* Kapczynski et al., *supra* note 28, at 2.

140 *See, e.g.*, Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 Conn. L. Rev., 57, 59 (2022).

141 *See* Karshtedt, *supra* note 131, at 1175.

142 *See* Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 Wis. L. Rev. 331, 381–82. Pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act includes a provision for generic entry that is similar to the ANDA process for pharmaceutical drugs. *See* 7 U.S.C. § 136a(c)(3)(B).

143 *See* Eisenberg, *supra* note 30, at 371; Swanson, *supra* note 142, at 367.

144 *See* Lietzan & Lybecker, *supra* note 53, at 1322.

145 *See* Karshtedt, *supra* note 131, at 1150.

146 *Cf. id.* at 1179–82 (discussing the impact of insurance companies on a consumers' economic incentives).

In all, aided by the FDA approval process, many drug products represent breakthroughs in human health and command significant revenue that is supported by various exclusivities the brand firm enjoys.[147] Moreover, even if the innovation is an incremental one, the underlying therapies may nonetheless still carry high-revenue potential. First, pharmaceutical products such as new dosage forms, extended-release versions of drugs previously approved only as immediate-release therapies, and "combination" drugs—which are examples of drug innovations that are considered incremental—can offer significant added health benefits and, thus, end up selling well for that reason.[148] Second, as prior work has amply demonstrated,[149] even when the therapeutic value of improvement drug products is only marginal, regulatory barriers and other distinctive features of pharmaceutical markets might still result in a handsome payoff to the brand when these follow-on products are supported by the secondary patents that cover them.[150]

On the flip side of the FDA's apparent stamp of quality for approved drugs are the inputs needed to get that approval, which are considerable. Estimates of the average cost of drug development, which of course includes the sometimes-extremely expensive clinical trials, run into hundreds of millions of dollars.[151] Implicit in this number is the relatively high rate of failure of early-stage pharmaceutical research,[152] which can run into dead ends for reasons including inadequate efficacy, unpredictable side effects, and many others.[153] Significantly, however, once a small-molecule drug has been proven safe and effective and a method for producing it has been worked out, competitors can, in theory, readily copy and market it themselves without having to undertake the pioneer's research efforts.[154] Without any intervention, such as some type of an exclusivity, pioneering efforts might become so unprofitable as to be unworthy of taking on. Thus, the pharmaceutical field

147 To be sure, many are so-called "me-too" drugs that may not add much in terms of therapeutic utility. *See* Aidan Hollis, Me-Too Drugs: Is There a Problem? 1–2 (Dec. 13, 2004) (unpublished manuscript), https://www.researchgate.net/publication/228919661 [https://perma.cc/2YJ5-Y7W5]. In addition, so-called orphan drugs by definition command smaller markets, and policymakers have devised incentives other than patents for those drugs. *Id.*

148 *See supra* notes 137–40 and accompanying text.

149 *See, e.g.*, Karshtedt, *supra* note 131, at 1217.

150 *See id.* (collecting references).

151 *See* Mark Terry, *The Median Drug Development Cost is $985 Million, According to New Study*, BioSpace (Mar. 4, 2020), https://www.biospace.com/article/median-cost-of-bringing-a-new-drug-to-market-985-million [https://perma.cc/BL6X-C4A8].

152 *See* Lietzan & Lybecker, *supra* note 53, at 1328–29, 1328 n.54.

153 *See id.*

154 *See* Wheaton, *supra* note 31, at 463–64.

presents a paradigmatic case for some form of government-promoted incentives for innovation.

The principal legal mechanism through which brand pharmaceutical firms seek to recoup their investments into drug research and development is patents, which vest their owners with exclusive rights to make, use, and sell the patented inventions.[155] In accordance with the predictions of economic theory sketched out above, exclusivity that patents create allows their owners to charge supracompetitive prices for patent-covered products.[156] As noted, the resulting deadweight loss entails substantial social costs, which is particularly significant in this field of technology relative to others because—as the COVID-19 pandemic has underscored—drug prices can lead to reduced access to health care.[157] Still, these costs are generally thought to be worthwhile because the promise of patent-aided return on investment encourages socially valuable innovation. While patents are not perfect as incentive mechanisms go,[158] they indisputably play a crucial role in supporting drug research and development—likely more so in pharma than in most other technological fields.[159] Indeed, among various areas of technology, patent-based incentive mechanisms are viewed as particularly effective and justifiable in the drug industry because of the significance of the underlying products to public health,[160] the great complexity and expense of the research involved,[161] and, as noted above, the high rate of failure in the various phases of the approval process.[162]

The power of pharmaceutical patents is further boosted by the Hatch-Waxman Act, the connective tissue between the FDCA and the

155 *See* 35 U.S.C. § 154(a)(1). To be sure, nonpatent exclusivities have come to play an important role as incentive mechanisms in this space. *See generally* John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 Food & Drug L.J. 39 (2015).

156 *See supra* notes 137–54 and accompanying text; *see also* Roin, *supra* note 46.

157 *See* Kapczynski et al., *supra* note 28, at 1.

158 *See* Roin, *supra* note 49, at 545; *see also supra* notes 49–52 and accompanying text.

159 *See* Dan L. Burk & Mark A. Lemley, The Patent Crisis and How the Courts Can Solve It 4 (2009). In addition, pharmaceutical patent claims present fewer concerns with vagueness. *See id.* at 27 (stating that pharmaceutical patent claims more precisely determine the scope of the invention as compared to information technology patent claims).

160 *See id.*

161 *See generally* Levin et al., *supra* note 50 (demonstrating, empirically, the extent to which patent protection incentivizes research and development, and suggesting that patent protection is most important in the pharmaceutical industry); Cohen et al., *supra* note 109 (building on Levin's work and finding in part that, since the 1980s, large firms have increased reliance on patents to protect an innovation's profits). *See also* Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 66–70 (2021).

162 *See supra* notes 143–44 and accompanying text.

Patent Act.[163] Under that legislation, brand owners list the patents covering their FDA-approved products in the Orange Book, which helps preclude generics from marketing their equivalents of the approved drug under a so-called Abbreviated New Drug Application ("ANDA") until the patents expire, are invalidated, or determined to be not infringed.[164] Should the generic firm choose to go the route of challenging validity as opposed to waiting for expiration, it must file a so-called Paragraph IV certification with the FDA.[165] The certification constitutes an artificial act of patent infringement that gives rise to a cause of action by the brand firm under a special provision of the Patent Act that Hatch-Waxman created.[166]

The Hatch-Waxman Act includes several additional sections that set brand-generic litigation apart from other patent cases. For example, if a suit is brought within forty-five days of a Paragraph IV filing, the brand receives an automatic thirty-month stay of the ANDA approval unless all of the relevant Orange Book patents are invalidated before the end of that period.[167] Because the stay can significantly "slow down the generics' path to market,"[168] it is considered to be a key advantage of Orange Book listings for brands. A generic firm, to be sure, might attempt to obtain a quicker invalidation by pursuing a parallel proceeding to cancel the patent at the PTAB or perhaps even convince a court to take expedited action.[169] However, an inevitable appeal to the Federal Circuit and other potential complications could slow things down, so even an ultimately invalidated patent could keep generics out for a time.[170] If the brand ultimately ends up prevailing, not only is the generic usually enjoined against marketing its competing product under the Patent Act, but it is also prevented from obtaining FDA approval for the ANDA until the expiration of the infringed patent—a dual ban that is effectively impossible to get around.[171] In all, as we will further see in

---

163 *See* 35 U.S.C. § 271(e)(2)(A). To some extent, though, the Act also lowered the power of brand firms by allowing ANDAs.

164 *See id.*

165 *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

166 *See* 35 U.S.C. § 271(e)(2)(A); *see also* John R. Thomas, *Hatch-Waxman's Renegades*, 2023 U. Ill. L. Rev. 101, 108 (manuscript in preparation); Winkler et al., *supra* note 45, at 3.

167 *See* 21 U.S.C. § 355(j)(5)(B)(iii).

168 Karshtedt, *supra* note 131, at 1145. *But cf.* Sunand Kannappan, Jonathan 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*, 14 Clinical & Translational Sci. 1917, 1921 (2021).

169 *See* Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and* Inter Partes *Review*, 6 N.Y.U. J. Intell. Prop. & Ent. L. 14, 37 (2016).

170 *See infra* Section II.B.

171 *See* Braintree Lab'ys, Inc. v. Novel Lab'ys, Inc., 749 F.3d 1349, 1367 (Fed. Cir. 2014) (Moore, J., dissenting).

the next Section, drug patent applications tend to be prosecuted, and then litigated, with great intensity precisely because Orange Book patents can be so valuable.[172]

The regulatory process helps the brand in other ways. Because the ANDA product must have the same active ingredient as the pioneering drug, it is typically quite difficult for a generic to "design around" a brand's patent.[173] As a result, generics rarely succeed based on noninfringement—even though the plaintiff has the burden of proof in that aspect of a patent case—and often have no choice but to establish invalidity if they wish to enter the market under an ANDA if there is an unexpired patent.[174] This is yet another dimension in which the field of small-molecule pharmaceutical patents differs dramatically from other, less regulated fields, where design-arounds are often more possible (and defendants are thereby relieved from relying mainly on proving invalidity to avoid liability).[175] This aspect of drug patenting creates a very strong incentive for the brand to get the application through the PTO, and this pressure might in turn explain the borderline patents one sometimes sees in the field. Furthermore, as I and others have shown in prior work, this incentive is multiplied for incremental innovations.[176] As the Acting Commissioner of Food and Drugs stated in her letter to the PTO, mentioned in the Introduction,[177] "[b]rand sponsors often seek approval for these changes just as earlier patents on the drug product are expiring, effectively extending protection against competition."[178]

---

172 *See infra* Section II.B.1; *see also* Cynthia M. Ho, Access to Medicine in the Global Economy: International Agreements About Patents and Related Rights 273–74, 277–78 (2011); Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 Fordham Intell. Prop., Media & Ent. L.J. 245, 272 (2012).

173 *See* Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law's Doctrine of Equivalents with the FDA's Bioequivalence Requirement*, 66 SMU L. Rev. 59, 78–87 (2013); Karshtedt et al., *supra* note 161, at 68; *cf.* Cohen et al., *supra* note 109, at 14 (arguing that the risks of others' liability avoidance by inventing around may be a reason to avoid patenting).

174 *Cf.* Jonathan J. Darrow, Mengdong He & Kristina Stefanini, *The 505(b)(2) Drug Approval Pathway*, 74 Food & Drug L.J. 403, 432 (2019) (stating that secondary patents under the 505(b)(2) approval process are more likely to be invalidated since they do not cover the active ingredient).

175 *See* Cohen et al., *supra* note 109, at 14–15; Lerner, *supra* note 10.

176 Karshtedt, *supra* note 37, at 113; Karshtedt, *supra* note 131, at 1157 n.162 (collecting references). For another approach for dealing with this problem in the context of so-called biologic drugs rather than those slated for the Orange Book, see Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 Nature Biotechnology 20, 21 (2021).

177 *See supra* Introduction.

178 Letter from Dr. Janet Woodcock to Mr. Andrew Hirshfeld, *supra* note 25, at 3. These changes can allow brands to sidestep the effects of state generic substitution laws upon expiration of patents that cover original versions of drug product. *See supra* note 175.

To be sure, a prediction of a drug patent application's high value is not guaranteed to be foolproof.[179] Particularly in the life sciences, patent application filings often take place early in the research process, when success in clinical trials required for a drug's approval is uncertain.[180] At first glance, this scenario appears to fall under the umbrella of rational ignorance because it could still result in examinations destined to produce worthless patents. Nevertheless, pharmaceutical applications—especially those seeking secondary patents—unquestionably beat the average patent filing in terms of anticipated commercial and social significance.[181] As a result, competitors and other entities that could be affected by the issuance of a patent covering a small-molecule drug may well seek to know whether a potentially problematic examination is under way and be motivated to prevent the application's allowance.[182]

To summarize, pharma is unique. First, while the vast majority of patentees do not end up making any product at all, drug patent applicants are actively trying to develop one that might well have a significant market given the inexhaustible demand for health care.[183] Second, and related, drugs are different from most other products in that they bear a government agency's official stamp of approval, frequently require a prescription by a learned professional (i.e., a physician) before purchase,[184] and are normally covered by insurance rather than by ultimate consumers' out-of-pocket payments. All these factors can help the manufacturer cash in, and there are plenty of examples of high-revenue drugs. Third, some pharmaceutical products embody incremental innovations and, thus, stand a very high chance of garnering FDA approval, making the significance of the underlying patent applications particularly straightforward to predict.[185] While these drugs may not be "blockbusters" in

---

179 *Cf.* Moore, *supra* note 13, at 1522–23 (discussing various sources of patent value in small-molecule pharmaceuticals and other fields).

180 *See* Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. Rev. 1171, 1179 (2016).

181 Kevin T. Richards, Kevin J. Hickey & Erin H. Ward, Cong. Rsch. Serv., R46221, Drug Pricing and Pharmaceutical Patenting Practices 17 (2020).

182 A recent article authored by Mark A. Lemley and Sean Tu provides some empirical evidence for the claim that brands act in ways that reveal the competitive significance of the secondary patent applications that they are prosecuting. *See generally* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 Wash. L. Rev. 1673, 1673–74 (2022).

183 Moreover, the demand can be somewhat inelastic. *See* Uri Y. Hacohen, *Evergreening at Risk*, 33 Harv. J.L. & Tech. 479, 499 (2020) (citing Robin Feldman & Evan Frondorf, Drug Wars: How Big Pharma Raises Prices And Keeps Generics Off the Market 14 (2017)). To be sure, not all drugs face such a demand—for example, so-called orphan drugs for treating rare diseases.

184 Even if a drug ends up getting to the "over the counter" status, that switch usually takes place years after the initial FDA approval.

185 *See* Karshtedt, *supra* note 131, at 1154.

the sense that a new chemical entity drug might be,[186] such products often still represent a commercially valuable prospect—and the patents covering them can cause a significant competitive impact thanks in part to the unique financial and regulatory dynamics of the pharmaceutical marketplace.[187] In sum, the *Rational Ignorance* thesis does not readily apply to these patents, and the Section that follows explores the consequences of this conclusion.

B. Lopsided Examination and Repetitive Adjudication

1. Lopsided Examination

a. Technical Evidence in Pharmaceutical Patent Prosecutions

As earlier discussion makes clear, drug patent applications can frequently ripen into commercially significant patents. Moreover, inventors often have a good sense that this is going to be the case—and they approach examination accordingly.[188] Sometimes, getting the patent is a bet-the-company proposition for the sponsor firm, or at least a major revenue driver, leading to significant outlays into the prosecution process that simply cannot compare to those for an average patent in most other technology fields.[189] Nevertheless, there is no special track for these filings at the PTO,[190] and they formally receive no additional scrutiny from the agency relative to a run-of-the-mill application.[191]

In particular, prosecution of patent applications that are headed for the Orange Book often feature the use of affidavits and declarations by the inventors or by experts retained by the applicant.[192] As further

---

186 In addition, stakes for the patenting of such second-generation drugs might be high because these products might not be entitled to any FDA exclusivity. The FDA provides for what is effectively four-year exclusivity for drugs that embody new chemical entities, but such exclusivity is not available for improvement products—though they may be eligible for another type of exclusivity if developed pursuant to a so-called Supplemental New Drug Application (SNDA). *See generally* Kannappan et al., *supra* note 168.

187 *See* Karshtedt, *supra* note 131, at 1146–52 (discussing the state law generic substitution framework and the role of payers).

188 *See* Tu & Lemley, *supra* note 182, at 1673–74.

189 *See* Lietzan & Lybecker, *supra* note 53, at 1321–22.

190 As explained below, even if such a track was created, it might not be sufficient. *See infra* notes 312–451 and accompanying text.

191 For an argument that scrutiny without adversarial examination might not be enough, see *infra* notes 326–28 and accompanying text.

192 *See* 37 C.F.R. §§ 1.131–.132 (2020); *see also* Pitlick, *supra* note 34, at 182; Eric M. Brusca, *IP: These Claims Are Not Obvious, Just Ask My Expert!*, InsideCounsel (Feb. 4, 2014), https://www.marshallip.com/content/uploads/2014/10/These-claims-are-not-obvious-just-ask-my-expert_EB.pdf [https://perma.cc/JEU9-CU6Z].

explained below and elaborated through illustrative examples in the next Section, this evidence can play a crucial role in close cases, tipping the scales toward patentability.[193] However, given the *ex parte* nature of prosecution, such proffers do not get challenged by mechanisms that are traditionally thought useful for revealing weaknesses in testimonial evidence,[194] including cross-examination, testimony of opposing experts, or any means other than the examiner's assessment of the data.[195] This lack of pushback results in something of a credibility free pass for the applicants and their experts.[196] As a result, it is not surprising that post-issuance proceedings often reveal weaknesses in this evidence, making clear that a full accounting of all the relevant information actually points to the conclusion that the patent was improvidently granted. This outcome may eventuate even with well-resourced and conscientious examiners because these officials may have no opportunity to question the testifying scientists about their declarations or other technical evidence—let alone independently verify the experts' work.[197]

To help understand why affidavits, declarations, and even scientific information in the patent's specification might matter in close prosecutions,[198] some background on substantive patent law and recurring issues in pharmaceutical patenting is useful. By far the most vigorously contested requirement of patentability is nonobviousness.[199] Section 103, which codifies it, asks decision makers to answer the highly judgment-laden question: whether the claimed subject matter is different enough from what is already disclosed in a particular reference or a combination of references, such as earlier patents or journal publications, to justify a patent.[200] Modern case law breaks this requirement down into two elements: the entity challenging the patent must show whether the person having ordinary skill in the art ("PHOSITA"), the field's hypothetical average scientist, would have been motivated to come up with the claimed invention based on the prior art and whether

193 *Cf.* Dmitry Karshtedt, *Nonobviousness: Before and After*, 106 Iowa L. Rev. 1609, 1618 (2021).

194 *See* Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 Yale L.J. 1535, 1595–96 (1998).

195 Frederick G. Michaud & David Schlitz, *The Use of Experts to Prove Obviousness*, Practising L. Inst. 21–22, https://legacy.pli.edu/emktg/toolbox/ExpProve_Obvious44.doc [https://perma.cc/8PQA-VAPF]; Freilich, *supra* note 17, at 2116.

196 *See* Michaud & Schlitz, *supra* note 195, at 10–11; Freilich, *supra* note 17, at 2116.

197 *See* Freilich, *supra* note 17, at 2116.

198 *See In re* Soni, 54 F.3d 746, 750 (Fed. Cir. 1995).

199 *See* Karshtedt, *supra* note 193, at 1611.

200 35 U.S.C. § 103; *see also* Karshtedt, *supra* note 193, at 1624.

a PHOSITA would have had a reasonable expectation of doing so at the time of patent filing.[201]

The inventor can disprove these elements with a variety of evidence. Possible proffers include documentary information, such as prior art disclosures suggesting that the invention could not be achieved successfully (described in patent jargon as "teaching away"), and scientific facts, such as evidence that the claimed material embodies unexpected properties or results.[202] This latter type of evidence can be particularly significant for drug patenting. Harris Pitlick, a veteran patent attorney who spent twenty-four years as a PTO solicitor before moving to private practice,[203] noted that unexpected results are "the most prevalent form of evidence of nonobviousness . . . during patent examination,"[204] and, as I have noted in prior work, "many of the cases featuring this evidence involve properties of pharmaceuticals or materials (such as therapeutic utility and shelf stability)."[205]

How is this evidence useful to the applicant? As I have explained, "if a compound exhibits unexpectedly beneficial properties for the purpose that the invention seeks to achieve, an inventor can argue that he or she should get the patent for bucking conventional wisdom, which would have instead predicted inferior or pedestrian outcomes and thus discouraged the pursuit of the invention."[206] In this way, unexpected results can help patent applicants establish both the absence of motivation and of reasonable expectation of success, giving them a chance to overcome what is sometimes called the "prima facie case" for unpatentability that an examiner might make based on prior art disclosures.[207]

---

201 *See* WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1326, 1334 (Fed. Cir. 2016); *see also* Karshtedt, *supra* note 193, at 1613 n.16.

202 *See* Karshtedt, *supra* note 193, at 1633 n.179.

203 *Harris A. Pitlick, Of Counsel*, OLIFF, https://www.oliff.com/professional/harris-a-pitlick [https://perma.cc/WKE7-YBB3].

204 Pitlick, *supra* note 34, at 169 (discussing also that unexpected results evidence frequently comes up during litigation as well); *see also* Ryan T. Holte & Ted Sichelman, *Cycles of Obviousness*, 105 Iowa L. Rev. 107, 158 tbl.4 (2019).

205 Karshtedt, *supra* note 193, at 1647; *see also* R. Scott Roe, Note, *Nanotechnology: When Making Something Smaller is Nonobvious*, 12 B.U. J. Sci. & Tech. L. 127, 134 (2006) (discussing "less predictable fields" in the obviousness context); Shine Sean Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Nonprior Art Rejections*, 2021 Mich. St. L. Rev. 411, 416–28 (discussing the relevant PTO processes).

206 Karshtedt, *supra* note 193, at 1648 (citations omitted); Mark A. Lemley, *Expecting the Unexpected*, 92 Notre Dame L. Rev. 1369, 1388 (2017) ("Truly unexpected results may cause us to question whether the PHOSITA really had a reasonable expectation of success . . . .").

207 Unexpected results are representative of the problem, and one sees technical evidence in other forms. Often, such evidence is used to rebut the "prima facie" case of obviousness. *See* Karshtedt, *supra* note 193, at 1679; Andrew C. Michaels, *Benefits of the Invention and Social Value in Patent Law*, 29 Geo. Mason L. Rev. 827, 848 (2022).

Experienced patent prosecutors know that arguments based on real-world data can turn into wins, especially after the examiner remains unpersuaded by the back-and-forth over the prior art.[208] But because unexpected results can critically boost the odds of allowance of patent claims, it is troubling that this evidence embodies an aspect of prosecution in which applicants hold a particularly great advantage over examiners.[209] Given enough time for search and analysis, examiners can perhaps hold their own against even highly motivated and well-represented applicants when it comes to making arguments against patentability based on documentary prior art. In contrast, the PTO is not in a good position to take on the technical evidence of unexpected results during prosecution.

I am not the first to make the general observation that scientific evidence is hard for the PTO. In a recent article, Janet Freilich nicely captured the agency's institutional strengths and weaknesses by positing a distinction between "matching"—which refers to activities like searching for prior art, evaluating it, and then comparing it to the patent claims—and "digging"—which refers to tasks such as assessing the quality of the proffered technical evidence.[210] One of Freilich's bottom-line conclusions is that the PTO is particularly weak on enablement, a patentability requirement that demands some critical digging that examiners simply cannot readily do.[211] However, nonobviousness arguments based on evidence outside the prior art, which includes unexpected results and other industry information (such as expert skepticism that the claimed invention could be achieved), can also unduly stick for lack of digging.[212] This is a crucial flaw for pharmaceutical patent prosecution because § 103 nonobviousness, unlike § 112 enablement, comes up in basically every drug patent case.[213] While examiners sometimes get a chance to, for lack of a better phrase, dig in—such as through applicant interviews[214]—it is unlikely that they can ultimately gauge the reliability

208 *See* Chris P. Miller & Mark J. Evans, The Chemist's Companion Guide to Patent Law 225–34 (2010); *In re* Merck & Co., 800 F.2d 1091, 1099 (Fed. Cir. 1986).

209 *Cf.* Seymore, *supra* note 102, at 995 (exploring other ways in which an applicant may have advantages over an examiner, such as the presumption of patentability, especially given an examiner limited resources).

210 Freilich, *supra* note 17, at 2115.

211 *See id.* at 2127; *supra* notes 97–102 and accompanying text; *see also* Karshtedt et al., *supra* note 161, at 8.

212 *See infra* Section II.B.1.b.

213 *See* Allison & Lemley, *supra* note 74, at 209.

214 To be sure, examiners can interview inventors, but generally this is done at the applicant's request. *See* S. Sean Tu, *Patent Examination and Examiner Interviews*, 49 Fla. St. U. L. Rev. Online 1 (2021).

and persuasiveness of applicant-proffered data allegedly supporting validity in a rigorous way.[215]

There are other reasons to believe that technical information provided by experts can play an outsized role in the prosecution of pharmaceutical patents. Particularly for secondary or "improvement" patents on incremental innovations, such as extended-release versions or new dosage forms of drugs for which the active pharmaceutical ingredient ("API") has been previously approved (e.g., as an immediate-release drug), or of "combination" products involving two or more known APIs previously used separately to treat the same or similar conditions,[216] finding the prior art and matching it to the claims is not the difficult part of the prosecution. In a recurring pattern, the key prior art might be a well-known publication (perhaps even the inventors' own prior patent) disclosing the API itself and something like a desk reference or a manual that describes various formulation techniques.[217] With this undisputed documentary information in hand, nonobviousness of the new formulation can come down to the highly technical details of its biological action or other properties relative to the original drug,[218] which the applicant would naturally assert to be probative of validity.[219] For some types of incremental innovations, the law of § 103 all but invites data submissions by mandating a presumption of obviousness that evidence of unexpected results must rebut in order for the inventor to obtain a patent.[220]

---

215 *See* Daralyn J. Durie & Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 Wm. & Mary L. Rev. 989, 1010 (2008) ("Under the time and evidentiary constraints the PTO faces, examiners may have no choice but to accept . . . affidavits uncritically. This is unfortunate. Because these affidavits will not be subject to cross-examination or to rebuttal by an expert proffered by an opponent, they will frequently prove to be unreliable evidence, and if they are unrebuttable they will make it fairly easy for applicants to establish nonobviousness.") (footnotes omitted); *see also* Vandana Prajapati & Harish Dureja, *Product Lifecycle Management in Pharmaceuticals*, 12 J. Med. Marketing 150, 150 (2012).

216 *See* Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 Vand. J. Ent. & Tech. L. 295, 314 (2015); Karshtedt, *supra* note 131, at 1132. Other improvements could include characteristics such as better shelf stability relative to the original product. A particularly interesting scenario involves the purification of a so-called enantiomeric mixture of organic compounds, though in this scenario there sometimes is not a prior approved product. *See* Lemley, *supra* note 206, at 1372.

217 *See* Karshtedt, *supra* note 131.

218 *See, e.g.*, Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293, 1307 (Fed. Cir. 2015) (finding an improvement from 0.3% active ingredient in eye drops to 0.1% as nonobvious).

219 To be clear, this sort of technical information can come from printed publications, not just applicant-generated data. *See, e.g.*, AstraZeneca Pharms. LP v. Anchen Pharms., Inc., No. 10-cv-1835 (JAP)(TJB), 2012 WL 1065458, at *4, *55 (D.N.J. Mar. 29, 2012) (additional docket numbers omitted), *aff'd per curiam*, 498 F. App'x 999 (Fed. Cir. 2013).

220 *See* E.I. Dupont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1006 (Fed. Cir. 2018); *In re* Malagari, 499 F.2d 1297, 1303 (C.C.P.A. 1974).

All this is a problem for patent quality. Even assuming the PTO does a perfect job of applying the law and adjudicating obviousness given the facts before it, those underlying facts must be pressure-tested before they can be accurately established. Unfortunately, although technical evidence in the form of unexpected results can challenge the agency's fact-finding function much more severely than the prior art, this evidence is where much of the critical action is in many improvement patent prosecutions. In this context, the PTO's structural disadvantage becomes particularly apparent. What makes this problem especially acute is that—to no one's surprise—patent applications on incremental pharmaceutical innovations tend to present extremely close obviousness cases in which evidence outside the prior art can play a decisive role.[221] Worse yet is that, as noted before, the underlying products stand a particularly good chance of FDA approval in these circumstances, sometimes with potentially anticompetitive effects.[222] This regulatory background, thus, boosts the likelihood that such patents will be valuable and encourages a vigorous effort to obtain these patents that examiners may not be able to match.[223]

b. Examples of Erroneous Allowances Based on Bad Technical Evidence

Consistent with the intuition that close pharmaceutical cases can present difficulties for the PTO, secondary drug patents are often invalidated in litigation and during post-issuance PTAB review. Moreover, case law is rife with examples of unexpected results and similar evidence that, after playing an outsized role during prosecution and helping chart the path to allowance, turns out to be exposed as weak during litigation.[224] Again, the PTO's shortcomings can manifest themselves in scenarios other than patent applications on follow-on products and can involve errors that have nothing to do with misconceived evidence outside the prior art. For example, in a high-profile opinion, the Federal Circuit invalidated a new chemical entity patent based on a reference that the applicant did not submit to the PTO and the examiner did not find.[225]

---

221 *See* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327, 337 (2012); Pitlick, *supra* note 34, at 171.

222 *See* Karshtedt, *supra* note 37, at 132.

223 *See* Tu & Lemley, *supra* note 182, at 1677.

224 *See, e.g.*, Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc., 752 F.3d 967 (Fed. Cir 2014).

225 *See id.* at 972, 976. This case involved some evidence of unexpected results as well, and it was not enough to get the claims upheld.

In the view of many critics of the patent system, this kind of error represents the paradigmatic failure mode at the PTO and should be fixed by boosting the agency's resources.[226] To be clear, this Article's proposal should be able to handle it: a motivated generic-firm adversary may well have found that piece of prior art (and, in the litigation mentioned above, the defendant in fact did).[227] The scenario I focus on in this Section, however, arguably creates even greater difficulties for the PTO and occurs with particular frequency in the pharmaceutical prosecution context. Significantly, and in contrast with prior art searching, the examiner might require resources, such as access to experts who could conduct laboratory experiments or at least tools that would enable him or her to engage in rigorous data analysis. A caveat is that the PTO currently lacks the infrastructure that would support this kind of work, and the agency has generally been described as lacking capacity to examine the science behind the inventions that come before it.[228]

The case of *McNeil-PPC, Inc. v. L. Perrigo Co*.[229] is illustrative and memorable given the subject matter involved. The patent at issue stemmed from the research undertaken when McNeil, faced with the expiration of an earlier patent covering its "best-selling antidiarrheal product Imodium® A-D . . . sought patentable improvements that would allow it to extend its position as market leader."[230] The claims were drawn to a combination of compounds for treating diarrhea and flatulence. As the district court recounted, the examiner was erroneously led to believe during prosecution that the inventor "discovered the concurrence of diarrhea and flatulence" (one wonders how) and that he was the first to combine medicaments for treating these two assertedly unrelated conditions.[231] The claims were still rejected twice as obvious, however, prompting the applicant to respond with evidence of unexpected results.[232] The studies provided to the PTO purported to demonstrate "unexpectedly enhanced diarrhea relief, including faster

226 *See, e.g.*, Frakes & Wasserman, *supra* note 7, at 1029–30.

227 *See Bristol-Myers Squibb*, 752 F.3d at 972.

228 *See* Durie & Lemley, *supra* note 215, at 1009; *see also* Lawrence Schlam, *Compulsory Royalty-Free Licensing as an Antitrust Remedy for Patent Fraud: Law, Policy and the Patent-Antitrust Interface Revisited*, 7 Cornell J.L. & Pub. Pol'y 467, 516 n.277 (1998) ("[T]he prosecution of the patent is accomplished *ex parte*, and the Patent Office typically takes the applicants' representations at face value."); *cf.* Sean B. Seymore, *Patently Impossible*, 64 Vand. L. Rev. 1491, 1494 (2011) (suggesting that "a more robust enforcement of the enablement requirement . . . can perform the gatekeeping role by weighing objective, technical factors").

229 337 F.3d 1362 (Fed. Cir. 2003).

230 *Id.* at 1364.

231 McNeil-PPC, Inc. v. L. Perrigo Co., 207 F. Supp. 2d 356, 361 (E.D. Pa. 2002).

232 *See id.* at 365.

relief in the critical first twelve hours, and . . . unexpectedly enhanced gas relief."[233] The claims were then allowed.[234]

Once challenged in litigation, however, this evidence fell apart—and so did the patent. As one of the defendant's experts demonstrated after reviewing the studies on which the PTO relied, "the results . . . were inconsistent and not readily reproducible," used the wrong comparators, and were based on subjective criteria.[235] The studies apparently also ignored the fact, proffered by another of defendant's experts, that diarrhea sometimes mercifully "go[es] away on its own."[236] The district court found this testimony persuasive and concluded that the alleged unexpected results were "doubtful."[237] The court, furthermore, called out the patentee's behavior in prosecution:

> [B]y concocting multiple patent applications and litigating their validity, this period of exclusivity [previously granted to the plaintiff] has been extended by two years and, with an appeal, will extend even further, effectively doubling the initial period of exclusivity. The business-driven decision that it is worth the investment to "invent an invention" will continue unabated unless a vigorous PTO or a Court sees this transparent attempt to subvert the patent laws for what it is. . . . [W]hile this patent litigation continues, competition in the marketplace is foreclosed and the public is forced to pay higher prices.[238]

On appeal, the Federal Circuit "agree[d] . . . that the district court properly discounted the probative value of McNeil's asserted evidence," including unexpected results, and affirmed the judgment of invalidity.[239] Nevertheless, a weak patent propped up by faulty evidence did survive for a time and kept out the competition from the moment it issued from the PTO and until invalidation.[240] Unnerved by this dynamic, the district court awarded attorney fees to the defendant under the section of the Patent Act authorizing this course of action in "exceptional cases."[241] The Federal Circuit, however, reversed that part of the judgment due to the high standard for awarding this remedy. As the Federal Circuit

---

233 *Id.*

234 *Id.* at 361–62.

235 *Id.* at 365–66.

236 *Id.* at 366 (alterations in original) (citations omitted).

237 *Id.* at 372.

238 *Id.* at 375.

239 McNeil-PPC, Inc. v. L. Perrigo Co., 337 F.3d 1362, 1370 (Fed. Cir. 2003).

240 The patentee arguably engaged in a "product hop" behavior here, as well. *See infra* note 271 and accompanying text.

241 *McNeil*, 207 F. Supp. at 373–74 (citing 35 U.S.C. § 285 (2000)).

explained, "[g]iven the existence of patents issued by the PTO with a presumption of validity, the present lawsuit was not found to have been brought in bad faith."[242]

In *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*,[243] another Hatch-Waxman case, the claimed invention was also directed to a combination therapy—treatment of Type II diabetes with a combination of drugs called repaglinide and metformin.[244] Each of these drugs was independently indicated for treatment of Type II diabetes, and "it was apparently well-known in the art that two drugs having different mechanisms for attacking diabetes may be more effective than one, and so drugs were often tested in combination therapy after demonstrating effectiveness in monotherapy."[245] In an attempt to overcome initial obviousness rejections made on this general basis, Novo argued to the PTO that the claimed drug combination "yielded synergistic results" based on a clinical trial that it conducted and included in the patent's specification.[246] After reaching an impasse with the examiner, Novo "present[ed] via declaration the results of an additional study conducted by [a] Novo scientist."[247] This study purported to show a reduction of blood glucose levels in rat models that was greater "than the 'hypothetical additive effect'" of the two drugs, suggesting an unexpected result, and the claims were therefore allowed.[248]

In litigation, however, Caraco introduced "new prior art and evidence which the examiner had never considered, such as testimony from expert witnesses and Novo scientists."[249] This information suggested that "additive or synergistic action [of the two drugs] to control hyperglycemia should be anticipated,"[250] weakening the unexpected results argument. Worse yet, the Novo researcher behind the study—who was critical for getting the repaglinide/metformin claims to allowance—admitted that there were serious problems with his statistical analysis.[251] This problem was confirmed with Novo's internal documents that "were not provided to the examiner" but were revealed in discovery.[252] Based on the full scientific record, the trial court concluded flatly that the study

242 *McNeil*, 337 F.3d at 1372–73.
243 719 F.3d 1346 (Fed. Cir. 2013).
244 *Id.*
245 *Id.* at 1351.
246 *Id.* at 1350.
247 *Id.*
248 *Id.*; *see also* Lemley, *supra* note 206, at 1380.
249 *Novo*, 719 F.3d at 1352.
250 Novo Nordisk A/S v. Caraco Pharm. Lab'ys, Ltd., 775 F. Supp. 2d 985, 1009 (E.D. Mich. 2011).
251 *See id.* at 1013.
252 *Id.* at 1013–14.

that went to the PTO "is not probative on the question of whether the claimed combination produces unexpected results in Type II diabetes patients" and, ultimately, invalidated the claims.[253] In addition, the court went so far as to also render the patent unenforceable based on inequitable conduct, a doctrine that polices particularly egregious breaches of patent attorneys' and inventors' duty of candor and good faith in their dealings with the PTO.[254]

The Federal Circuit upheld the invalidity judgment based on the various evidence—including expert testimony introduced in litigation—that revealed there was nothing unexpected about the activity of the claimed therapy, but the court rejected the inequitable conduct finding.[255] The latter conclusion reflects the court's stringent requirements for establishing this affirmative defense[256]: the opinion reasoned that the study and the patent attorney arguments accompanying it were couched in careful-enough language—use of the word "'evidence' rather than 'proof,'" for example—that they could not have been "but for" material to getting the claim allowed.[257] Indeed, courts are careful to resort to inequitable conduct—once called "the 'atomic bomb' of patent law"[258]—given the severe reputational and substantive effects of that determination.[259] Nevertheless, because the declaration purporting to show "synergy" was followed by allowance after repeated rejections, it is reasonable to infer that the examiner was at least somewhat influenced by this kind of testimony and advocacy and that only through litigation was the weakness of this evidence fully exposed.[260]

McNeil and *Novo* are not unusual in pharmaceutical patent litigation, and the litigation process frequently reveals holes in the evidence that the PTO sees (and believes) during prosecution. In still another, particularly egregious case (which did not draw an appellate decision at the Federal Circuit due to settlement), an applicant overcame § 103 rejections based on data shown in litigation to be "not only incorrect, but scientifically impossible."[261] The trial court invalidated the patent

253 *Id.*

254 *See id.* at 1018–25.

255 Novo Nordisk A/S v. Caraco Pharm. Laby's, Ltd., 719 F.3d 1346, 1357–59. (Fed. Cir. 2013).

256 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1276 (Fed. Cir. 2011) (en banc).

257 *Novo*, 719 F.3d at 1359.

258 *Therasense*, 649 F.3d at 1288; *see also* Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).

259 *See* Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723, 725, 774 (2009).

260 *Novo*, 719 F.3d at 1350–51.

261 Hospira, Inc. v. Sandoz Inc., No. 09-4591, 2012 WL 1587688, at *31 (D.N.J. May 4, 2012), *vacated*, 2014 WL 794589 (D.N.J. Feb. 27, 2014); *see also id.* at *15 n.9. *But cf.* Janssen Pharms., Inc. v.

once the full truth came out but refused to find inequitable conduct due to lack of specific intent to deceive the PTO.[262] Moreover, even post-issuance review in the PTAB, an adversarial agency process in which both the challenger and the patentee can introduce the testimony of their own respective experts, can take apart declarations and affidavits that an examiner thought critical to allowance after also repeating some of the work the examiner had done.[263] In these circumstances, PTAB judges sometimes reach the opposite conclusion from the examiner and find the challenged claims unpatentable—sometimes, surely, thanks in part to better record development and a sharper presentation of the issues than in prosecution.[264]

None of this is to say that the use of experts is somehow a bad thing in general in patent cases.[265] Patents involve subject matter that is technologically complex, making expert input critical for a tribunal attempting to understand the field of the invention and determine issues relevant to validity.[266] However, when expert testimony plays a decisive role in a setting in which it cannot be effectively debiased,[267] there is a cause for concern—especially when the underlying right is as powerful and valuable as a patent often is in the pharmaceutical context. Unfortunately, the standard debiasing or at least checking mechanisms, such as opposing expert testimony or a brief taking apart arguments based on weak testimonial evidence, are simply unavailable in prosecution.[268] Nor, as mentioned, is there a full opportunity for the examiner to

---

Watson Lab'ys, Inc., No. 08-5103, 2012 WL 3990221, at *20 (D.N.J. Sept. 11, 2012), *appeal dismissed*, No. 12-1693 (Fed. Cir. Mar. 28, 2013) (providing an example of a district court's failure to require scientific rigor).

262 *Hospira*, 2012 WL 1587688, at *33. For a successful inequitable conduct claim, see Apotex Inc. v. UCB, Inc., 763 F.3d 1354, 1360–62 (Fed. Cir. 2014).

263 *See, e.g.*, K-40 Elecs., LLC v. Escort, Inc., No. IPR2013-00203, 2014 WL 4273883, at *16–17 (P.T.A.B. Aug. 27, 2014); *In re* Entresto (Sacubitril/Valsartan) Patent Litig., No. 20-md-2930-LPS, 2021 WL 2856683, slip op. at *1 (D. Del. July 8, 2021).

264 *See K-40 Elecs.*, 2014 WL 4273883, at *16–17; *see also* Patrick E. Brennan, *Lessons Learned from IPR Live Testimony: An Eye-Witness Account of the Patent Trial and Appeal Board's (PTAB) Recent Witness Questioning*, Nat'l L. Rev. (June 19, 2014), https://www.natlawreview.com/article/lessons-learned-ipr-live-testimony-eye-witness-account-patent-trial-and-appeal-board [https://perma.cc/5V52-MXFG] (discussing another important credibility issue).

265 *But cf.* Sapna Kumar, *Judging Patents*, 62 Wm. & Mary L. Rev. 871, 891 (2021) ("The U.S. system of district judges relying almost exclusively on partisan experts is, overall, deeply troubling.").

266 *See id.* at 888–89. To be sure, the examiner has the relevant expertise as well, but he or she still lacks the ability to conduct experiments. *See supra* notes 227–28 and accompanying text.

267 *Cf.* Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 Ohio St. L.J. 1391, 1447 (2006) (examining hindsight bias empirically).

268 *See* Michael O'Brien & Idonah Molina, *Using Signal Theory to Determine Non-Obviousness of Inventions*, 23 J. Intell. Prop. L. 241, 249 (2016). Expert praise and some

evaluate an expert or an inventor's credibility because the PTO cannot compel those individuals to appear to "take the stand," which is something that is simply not a part of prosecution.

Worse yet, some cases implicating Orange Book patents granted thanks in part to questionable evidence have generated satellite antitrust litigation. One set of cases challenges allegedly anticompetitive settlements of Hatch-Waxman suits involving patents of dubious validity.[269] Another targets monopolization through so-called "product hopping," which involves replacing a pharmaceutical product covered by an expiring patent with a similar, newly patented product.[270] These types of cases frequently involve patents on secondary drug innovations: in the settlement cases, improvement patents are in particular danger of invalidation if adjudicated on the merits,[271] and in the product-hopping cases, the technology is incremental by assumption.[272] To decide these claims (if they advance to trial), judges and juries must engage in the mental gymnastics of (among other things) figuring out how strong the brand's case really was, including assessing the likelihood that the patent would have been invalidated if the case went to final judgment.[273] These cases further consume judicial resources without apparently leading to any notable deterrence of questionable patent prosecutions,[274] while prices of certain drugs might remain unjustifiably high due to weak patents. It is a system that only lawyers can love.

In sum, examples in which patents appear to have been improvidently granted based on bad unexpected results and other questionable evidence outside the many existing prior art. Absent extreme circumstances, however, there is no penalty other than the loss of the patent

---

other secondary considerations embody other forms of similarly problematic evidence that can come in during prosecution.

269 *See generally* Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281 (2011). Such settlements can keep drug prices unnecessarily high. *See* Ian Lopez, *Lawmakers Face Push to Limit Drugmaker Deals as Prices Skyrocket*, BLOOMBERG (July 13, 2021, 4:58 PM), https://www.bloomberg.com/news/articles/2021-07-13/lawmakers-face-push-to-limit-drugmaker-deals-as-prices-skyrocket#xj4y7vzkg [https://perma.cc/KE7T-R3WT].

270 Karshtedt, *supra* note 131, at 1132.

271 *Cf. In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 161 (3d Cir. 2017) (patent antitrust settlement dispute).

272 *See* Karshtedt, *supra* note 131, at 1154.

273 *See, e.g.*, *Wellbutrin*, 868 F.3d at 168–69; Impax Labs., Inc. v. Fed. Trade Comm'n, 994 F.3d 484, 493 (5th Cir. 2021).

274 In addition to a "reverse payment" antitrust claim, often asserted by the FTC, private parties can pursue another type of an antitrust claim—under a "sham litigation" theory. But this kind of a claim, like inequitable conduct, is difficult to prove. *See* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1072 (Fed. Cir. 1998).

that the brand firm should not have obtained in the first place.[275] Given the value that even an eventually invalidated patent can bring thanks to the Orange Book linkage, there is little incentive not to engage in prosecution brinksmanship, and the ex post measures discussed in this Section do little to deter it.[276] One bad consequence involves the social costs of improvidently granted patents that manifest themselves in high drug prices (potentially limiting access to health care), and the next Section explores others.

2. Repetitive Adjudication

So far, this Article has focused on the effects of the flawed patent prosecution process on generic competitors who are kept out of the market and on members of the public who end up paying unnecessarily high drug prices due to improvidently granted patents. Surprisingly, however, the current setup also harms brand companies and could lead to negative downstream effects on investment and research and development—an insight that reveals that weak pharmaceutical patent examination might be bad for everyone involved. As noted above, issued patents can be challenged repeatedly and without real deference to the initial examination.[277] This Section will further explain why this state of affairs is problematic.

This Article is not the first to observe that *ex parte* prosecution deserves a share of the blame for endless litigation over patents. For example, chronicling the growth and multiplicity of routes for challenging issued patents, the Federal Circuit noted that "in light of the USPTO's constrained resources and the absence of material outside input during the initial examination, it is inevitable that there are patents granted in error."[278] This Article maintains that things do not have to stay this way.

Before addressing how repeated validity challenges may impact innovation, let us consider how the general patent adjudication scheme sketched out above plays out in the pharma context. The commercial significance of Orange Book listings leads to attacks on brand patents from various generic firms (and occasionally from other types of challengers) in district courts and, sometimes, through additional and usually

---

275 *See supra* notes 255–60 and accompanying text.

276 *See* Paul R. Gugliuzza, *Patent Law's Deference Paradox*, 106 Minn. L. Rev. 1397, 1398 (2022); Leslie, *supra* note 71, at 152–53 (discussing "cost-beneficial" remedies).

277 *See supra* Section I.A.2.

278 Regents of the Univ. of Minn. v. LSI Corp., 926 F.3d 1327, 1332 (Fed. Cir. 2019).

concurrent post-issuance proceedings, in the PTAB.[279] Significantly, as with other patents, such attacks can advance and succeed even when the entity contesting patentability offers no evidence or arguments that are materially different from those that appeared in prosecution.[280] For example, even when the defendant adduces the same prior art and associated theories of invalidity that the examiner considered and rejected, and does not offer any testimony or some other attempt to call into doubt declarations and other scientific evidence the PTO considered, the invalidity claim may still proceed in court in a pharma case as in any other.[281] Moreover, even if one defendant, "A," fails in such a challenge, another defendant, "B," may bring forth exactly the same evidence and arguments in a different case because the first noninvalidity adjudication against A is not binding on B.[282]

The only protection for the patentee in these circumstances is 35 U.S.C. § 282(a)'s clear and convincing standard.[283] However, if the PTAB grants an IPR petition against the patent, even that safeguard falls off because, as discussed above, the standard for the PTAB's Administrative Patent Judges ("APJ") to unwind the work of their examiner colleagues is a mere preponderance of the evidence.[284] Again, this standard does not change even if the PTAB trial basically rehashes the same issues that were already considered in detail during examination.[285] Although the PTO Director has sometimes exercised the discretion given to the agency by statute to deny IPR or PGR petitions in these circumstances, there are plenty of examples of petitions that have been granted (and of claims that have been invalidated) on the same prior art and evidence that was before the examiner in prosecution.[286]

---

279 *See* Vishnubhakat et al., *supra* note 77, at 65; Wayne Winegarden, *Fostering Innovation Requires Fixing the Patent System*, Forbes (Nov. 1, 2017), https://www.forbes.com/sites/econostats/2017/11/01/fostering-innovation-requires-fixing-the-patent-system/?sh=306f76aa2332 [https://perma.cc/8CVH-G556] (calling this a "double jeopardy" problem).

280 *See, e.g.*, *In re* Baxter Int'l, Inc., 678 F.3d 1357, 1360 (Fed. Cir. 2012); *see also* Peggy P. Ni, *Rethinking Finality in the PTAB Age*, 31 Berkeley Tech. L.J. 557 (2016). *See generally* Paul R. Gugliuzza, *(In)valid Patents*, 92 Notre Dame L. Rev. 271 (2016).

281 *See, e.g.*, Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330 (Fed. Cir. 2013).

282 *See* Ben Picozzi, *Reimagining Finality in Parallel Patent Proceedings*, 125 Yale L.J. 2519, 2521 (2016).

283 35 U.S.C. § 282(a). In some cases, the deference appears to be fairly weak. *Cf.* Sohn, *supra* note 71, at 1613.

284 *See* 35 U.S.C. § 316(e); *see supra* note 79 and accompanying text.

285 *See* Vishnubhakat et al., *supra* note 77, at 70.

286 *But cf.* Mark D. Janis, *Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law*, 11 Harv. J.L. & Tech. 1, 82 n.355 (1997) (explaining that perhaps there should be an elevated presumption of validity after a rigorous reexamination).

An example helps illustrate the general problem. In 2001, the PTO allowed certain patents covering an FDA-approved formulation of a chemical called rivastigmine, a drug for the treatment of dementia. The same district judge twice concluded that the claims of these patents would not have been obvious, and the Federal Circuit affirmed one of these decisions.[287] Nonetheless, in 2015—about 14 years after the patents issued!—the PTAB in *Noven Pharmaceuticals, Inc. v. Novartis AG* invalidated the rivastigmine formulation claims as obvious in view of the same prior art that the inventors had overcome in prosecution and in prior district court litigation.[288] Worse yet, no testimony that would somehow undermine the patentee's previously successful theory of validity was adduced in the PTAB. The agency simply decided to reach a different conclusion from the district court (or itself, in prosecution) on essentially the same facts.[289]

The Federal Circuit, faced with a second appeal involving the same subject matter, but this time from the PTAB and with the patentee as the appellant, affirmed the decision holding the claims unpatentable.[290] Leaning heavily on the difference in the burdens of proving invalidity in court versus the PTO, the court held that there was no contradiction with its earlier decision under a telling (though jarring) heading titled "Prior Judicial Opinions Did Not Bind the PTAB."[291] To be sure, the Federal Circuit's decision was also driven by the APA-mandated deference to the factual aspects underlying the PTAB's final written decision of unpatentability.[292] However, it is notable, once again, that the agency reached factual determinations that were the opposite of those a district court made in prior litigation over the same patents and on basically the same technical evidence.

The Federal Circuit was unmoved by this discrepancy, accepting the PTAB's assertion that it was entitled to find its own facts. Nor did the court explain how the difference in the burdens of proving invalidity between courts and the PTAB has enabled the latter to come to the opposite conclusion on nonobviousness, which after all is an ultimate question of law. As Paul Janicke noted, there is surprisingly

---

287 *See* Novartis Pharms. Corp. v. Noven Pharms., Inc., 125 F. Supp. 3d 474, 477 n.2 (D. Del. 2015); Novartis Pharms. Corp. v. Par Pharm., Inc., 48 F. Supp. 3d 733 (D. Del. 2014), *aff'd sub nom.* Novartis Pharms. Corp. v. Watson Lab'ys, Inc., 611 F. App'x 988 (Fed. Cir. 2015) (nonprecedential).

288 No. IPR2014-00549, 2015 WL 5782080, at *2 (P.T.A.B. Sept. 28, 2015).

289 *See id.* at *3–4.

290 *See* Novartis AG v. Noven Pharms. Inc., 853 F.3d 1289, 1294 (Fed. Cir. 2017).

291 *Id.* at 1293.

292 *See* 5 U.S.C. § 706; *see also* Greg Reilly, *The Justiciability of Cancelled Patents*, 79 Wash. & Lee L. Rev. 253 (2022) (discussing concurrent powers of Article III courts and the PTAB).

little substance behind the Federal Circuit's burden of proof "mantra" because the court has rarely tried to explain how the burdens have made a material difference in any particular case, including *Noven*.[293] This is a problem. Because they have the flavor of "let's keep throwing the same thing at the patent until it finally sticks," such exercises in *volte-face* have caused no small amount of frustration within the patent bar.[294] Even the Federal Circuit once said that "the PTO ideally should not arrive at a different conclusion" if it faces the same evidence and argument as a district court,[295] but the Federal Circuit has allowed this very result anyway. Besides being objectionable to a reasonable sense of fair adjudication,[296] this outcome is rife with the possibility of error.[297] Under *Blonder-Tongue*, an invalidated patent stays invalidated—even if the patent has been challenged twenty times and on the twentieth try the tribunal wrongly concluded for the first (but now final) time that it is invalid.[298] This approach invites error.

Concurrent PTAB and court challenges to issued patents create additional complications.[299] For example, if the trial court decides not to stay the suit, the race as to which tribunal reaches a validity decision first is on. This forces adjudicators to confront what it means for a decision to be final and decide whether a prior judgment in favor of the patentee should be wiped out by a later determination of invalidity.[300] Although, for various reasons, this particular problem has not been encountered as frequently in pharmaceutical patent litigation as in other fields, the possibility of concurrent challenges in the pharma space can further destabilize investment-backed expectations by

---

293 *See* Paul M. Janicke, *An Interim Proposal for Fixing* Ex Parte *Patent Reexamination's Messy Side*, 4 HLRe: Off Rec. 43, 54 (2013).

294 *See*, *e.g.*, *id.*

295 *In re* Baxter Int'l, Inc., 678 F.3d 1357, 1360 (Fed. Cir. 2012).

296 *See* Michael S. Greve, *Exceptional, After All and After* Oil States*: Judicial Review and the Patent System*, 26 B.U. J. Sci. & Tech. L. 101, 139 (2020) (describing the *Fresenius* rule as "doubly problematic"); Ni, *supra* note 280, at 575.

297 *See* Malani & Masur, *supra* note 54, at 650 (discussing errant patent invalidations).

298 Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971). *See generally*, Matteo Sabattini, *PTAB Challenges and Innovation: A Probabilistic Approach* (Aug. 6, 2020) (unpublished manuscript), https://papers.ssrn.com/abstract=3668216 [https://perma.cc/Q88X-9ZQW] (arguing, probabilistically, that "[e]ndless challenges to the same patent . . . will eventually lead to the denial of that patent right").

299 *See* Shashank Upadhye & Adam Sussman, *A Real Separation of Powers or Separation of Law: Can an Article I Administrative Agency Nullify an Article III Federal Court Judgment?*, 25 Fordham Intell. Prop. Media & Ent. L.J. 1, 39 (2014) (explaining that stays are of limited value).

300 *See* Versata Comput. Indus. Sols., Inc. v. SAP AG, 564 F. App'x 600 (Fed. Cir. 2014) (nonprecedential); Gugliuzza, *supra* note 280, at 299–302 (describing the situation in *Versata* case as a "procedural free-for-all"); *see also* Picozzi, *supra* note 282, at 2519. In many circumstances, a patent may be invalidated in a later decision, but the first one is not wiped out if it was final.

threatening even well-prosecuted patents with erroneous adjudications of invalidity. Of course, one might contemplate an amendment to the Patent Act that mandates stays of litigation in cases of a granted PGR or IPR petitions, limiting the number of cracks at a patent and reducing wasted effort by Article III judges.[301] Still, the problem that initial PTO examination—even if thorough and free of questionable evidence—might be completely ignored by the time the PTAB got hold of the case, would remain.

Repeated or concurrent validity attacks on the same factual record are deeply troubling because, besides using up precious adjudicatory resources, the current setup creates nontrivial legitimacy costs and can undermine confidence in the patent system, affecting investment into research and development. The PTAB's questionable cancellations of seemingly well-prosecuted patents—sometimes involving subjective-seeming obviousness determinations[302]—should be a source of worry to anyone who cares about the innovation economy. While the focus of legitimacy-cost critiques in patent law scholarship has been on incoherency in legal doctrine,[303] the incoherency of the same agency's reaching the opposite conclusion from a court (or from itself) on the same or similar facts, and without an articulation of what precisely the prior adjudicator did incorrectly, arguably presents a bigger legitimacy problem (and, one might add, an anomaly in administrative law). If the PTO and courts give off the impression that it is acting on a whim, the patent system could lose its standing as an important economic driver.[304] This problem is accentuated in the pharmaceutical space, in which patent rights are particularly important, and this can lead to significant social costs in the form of forgone innovation.

---

301 I thank Professor Arti Rai for suggesting that I make this point; *see also infra* notes 306–21 and accompanying text (further discussing this possibility).

302 *See* 3 R. Carl Moy, Moy's Walker on Patents § 9:7 (4th ed. 2012) (discussing subjectivity of § 103 determinations); Gregory N. Mandel, *A Nonobvious Comparison: Nonobviousness Decisions at the PTAB and in the Federal Courts*, 24 Tex. Intell. Prop. L.J. 403, 404 (2016).

303 *Cf.* Tun-Jen Chiang, *Defining Patent Scope by the Novelty of the Idea*, 89 Wash. U. L. Rev. 1211, 1235–36 (2012); *see also* Saurabh Vishnubhakat, *Patent Inconsistency*, 97 Ind. L.J. 59, 64 (2022).

304 It is no answer to argue that the sometimes-poor examination quality justifies complete abandonment of finality principles and lack of deference to the first-instance decisionmaker within the agency. Besides the distinctive "two wrongs make a right" flavor underlying that argument, basic administrative law principles support some form of deference when the initial examination was conducted well (and indeed the gold-plating proposals build on this intuition). *See infra* Section III.B.iii.a and accompanying text.

The problem of repetitive adjudication has become sufficiently worrisome to the innovators in this space that legislative proposals to exclude Hatch-Waxman patents from PTAB attacks have gained some traction.[305] While recently gathered empirical evidence shows that the popularity and effectiveness of PTAB challenges against pharmaceutical patents have somewhat abated, even leading to some counterproposals to make PTAB review essentially mandatory,[306] the problem is not going away.[307] One reason for the pharma-friendly spell is that the previous PTO Director aggressively relied on the aforementioned agency power of discretionary petition denial so as to quell repeated and concurrent validity attacks,[308] which is an approach that is not guaranteed to hold under the new Director. Although I do not support the specific legislative proposals advanced by brand firms because I believe that a rigorous PTO prosecution process is the superior solution, I am generally sympathetic to the various stakeholders' discontent with the validity churn in this area. This is to say nothing of the fact that a patent system that appears to be at the mercy of political winds—at the expense of technical expertise and impartial adjudication[309]—does not inspire long-term confidence in that system.[310]

---

305 *See* Bryan Koenig, *New Bill Would Bar Quick Generics Approval for PTAB Users*, Law360 (June 14, 2018, 3:54 PM), https://www.law360.com/articles/1053604/new-bill-would-bar-quick-generics-approval-for-ptab-users [https://perma.cc/9U6Z-S3ET]; 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, 341 (2017); Nora Xu, *AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs*, 66 Emory L.J. 1007 (2017).

306 *See* Arti K. Rai, Saurabh Vishnubhakat, Jorge Lemus & Erik Hovenkamp, *Post-Grant Adjudication of Drug Patents: Agency and/or Court?*, 37 Berkeley Tech. L.J. 139, 142–43 (2022); *cf.* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284.

307 *See, e.g.*, Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc., No. 2:16-cv-7721, 2020 WL 3428078 (D.N.J. June 22, 2020), *aff'd*, Nalox-1 Pharms., LLC v. Adapt Pharma Operations Ltd., No. IPR2019-00688, 2020 WL 4920198 (P.T.A.B. Aug. 21, 2020) (recent examples of repetitive adjudication).

308 *See* Apple Inc. v. Fintiv, Inc., No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. March 20, 2020); *see also* Britain Eakin, *PTAB Won't Review Solar Energy Patent, Citing ITC Case*, Law360 (May 27, 2021, 5:52 PM), https://www.law360.com/articles/1388805/ptab-won-t-review-solar-energy-patent-citing-itc-case [https://perma.cc/RE9B-V75U].

309 *See* United States v. Arthrex, Inc., 141 S. Ct. 1970, 1996 (2021) (Breyer, J., concurring in part and dissenting in part) ("Given the technical nature of patents, the need for expertise, and the importance of avoiding political interference, Congress chose to grant the APJs a degree of independence."); *see also* Tejas N. Narechania, Arthrex *and the Politics of Patents*, 12 Calif. L. Rev. Online 65, 71 (2022).

310 *See* Saurabh Vishnubhakat, *Constitutional Structure in the Patent Office* (manuscript in preparation); *cf.* Jonathan J. Darrow, Ameet Sarpatwari & Gregory Curfman, *Battling Over Patents: The Impact of* Oil States *on the Generic Drug Industry*, 19 Yale J. Health Pol'y L. & Ethics 250, 252 (2019) (discussing benefits of *inter partes* review).

To be clear, repetitive adjudication of validity is not without limits, and it would be unusual to see the aforementioned twenty challenges to the same patent. For example, an important provision of the AIA states that "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously *were presented* to the Office."[311] In addition, the AIA includes an estoppel provision with respect to unpatentability grounds that a petitioner "raised or reasonably could have raised" at the PTAB.[312] As a result, a court (or the PTO itself, in a subsequent proceeding) may not be allowed to duplicate the earlier work of the agency *in a post-issuance review*, at least when the patent challenger and the prior art references are the same as before.[313] The precise contours of these provisions, however, are still getting hashed out, and in some cases, the operation of estoppel has been evaded even though it sure looked like someone was taking multiple bites at the same apple.[314] And, besides the clear and convincing standard in litigation, there is no formal deference to an examination.[315]

Overall, repeated validity challenges continue to be part and parcel of the patent system—particularly of pharmaceutical patent litigation.[316] Moreover, it is no great surprise that such continual adjudication is particularly likely to involve hard-fought secondary patents that tend to come close to the (in)validity line and tend to support commercially significant products. The system involves the worst of both worlds—a sometimes nonrigorous prosecution process followed by endless validity attacks that sometimes also sweep in and unfairly punish owners of well-prosecuted patents. Indeed, it is almost as if the absence of meaningful third-party participation at the PTO is made up by unlimited and expensive ex post challenges and an amorphous, if not nonexistent,

311 *In re* Vivint, Inc., 14 F.4th 1342, 1349 (Fed. Cir. 2021) (quoting 35 U.S.C. § 325(d)) (emphasis added by the court).

312 35 U.S.C. § 315(e).

313 *See* Olaplex, Inc. v. L'Oréal USA, Inc., 855 F. App'x 701, 715 (Fed. Cir. 2021) (applying the estoppel provision to an obviousness challenge) (nonprecedential); *cf.* NuVasive, Inc. v. Alphatec Holdings, Inc., No. 18-CV-00347, 2021 U.S. Dist. LEXIS 71338 (S.D. Cal. Apr. 13, 2021) (denying motion to strike invalidity contentions); *see also* Laser, *supra* note 83, at 1132.

314 *See, e.g.*, Clearlamp, LLC v. LKQ Corp., No. 12 C 2533, 2016 WL 4734389, at *9 (N.D. Ill. Mar. 18, 2016). In addition, traditional court-to-court issue preclusion can prevent repeated validity challenges in some circumstances. *See* Stephen C. DeSalvo, Comment, *Invalidating Issue Preclusion: Rethinking Preclusion in the Patent Context*, 165 U. Pa. L. Rev. 707, 714 (2017).

315 *See supra* Section I.A.ii and accompanying text.

316 *See* Fish & Richardson, *IPR and Hatch-Waxman Strategy: A Look at the Data*, JDSupra (Apr. 10, 2019), https://www.jdsupra.com/legalnews/ipr-and-hatch-waxman-strategy-a-look-at-23342 [https://perma.cc/2HAR-Z5BA].

conception of finality.[317] The perceived general weakness of the examination process has created an environment in which patent rights are never secure, even if the examiner actually did a good job on a particular application.

The important pharmaceutical sector deserves better. Both types of dynamics discussed in this Section lead to reduced confidence in the patent system and create problems for the pharmaceutical field,[318] in which getting patentability right is often critical.[319] This setup destabilizes the expectations of both brands and generics in the clarity of patent rights (with extensive post-issuance fights over validity as the one thing that all may expect), creates a great deal of work for courts and the PTO, and—given the significance of pharmaceutical products to human health—it imposes significant costs on the public. The status quo is thus less than ideal: as the Supreme Court said nearly 60 years ago, "it must be remembered that the primary responsibility for sifting out unpatentable material lies in the Patent Office. To await litigation is—for all practical purposes—to debilitate the patent system."[320] Part III, to which the Article now turns, explores a different approach based on third-party involvement in the PTO's prosecution process that would help avoid this debilitation.

III. Toward Adversarial Examination of Pharmaceutical Patents

This Part of the Article translates the insights about the special nature of pharmaceutical patents into a proposal for the unique treatment of the underlying applications during prosecution. The scheme harnesses efforts of nongovernmental actors to improve the quality of examination of these patents,[321] with the ultimate aim of enlisting the adversarial process to help the PTO build a strong prosecution record and, thus, increase the odds of getting patentability right the first

317 *Cf.* Greg Reilly, *The Complicated Relationship of Patent Examination and Invalidation*, 69 Am. U. L. Rev. 1095, 1142–52 (2020) (discussing some features of the patent system that cut against finality, such as different approaches to claim construction in prosecution and litigation). *But cf.* Burk & Lemley, *supra* note 159, at 33 (noting that this problem is less acute in pharma, where claim scope is clearer than in other fields).

318 *See* Vishnubhakat, *supra* note 310.

319 *See*, *e.g.*, Burk & Lemley, *supra* note 159, at 4.

320 Graham v. John Deere Co., 383 U.S. 1, 18 (1966).

321 For adjacent proposals, see Kesan, *supra* note 32, at 776; Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. Rev. 1341, 1391 (2009); Thomas, *supra* note 3, at 756.

time.[322] The solution marries the PTO's specialized technical and legal expertise with the resources of motivated private entities who can help facilitate the thorough and balanced factual development needed for a high-quality validity analysis.[323]

Although there are some costs to moving the center of gravity for judging patentability from the courts to the agency, such as potential for undue political influence,[324] it should be noted that the ship of PTO primacy over courts on validity questions has, to some extent, already sailed. In an important decision, the Supreme Court observed that at least as a matter of constitutional structure, "granting patents is one of 'the constitutional functions' that can be carried out by 'the executive or legislative departments' without 'judicial determination'"[325]—in a case in which a court was actually involved in adjudicating a parallel patentability claim! Of course, under the proposal, Article III courts would still deal with appeals and APA-style challenges to PTO decisions as they traditionally have done—but post-issuance validity challenges will be very limited.

While the adversarial examination framework could be viewed as a logical extension of the already specialized Hatch-Waxman approach, the proposal does represent a significant break with past PTO practice, which the *ex parte* examination model has historically dominated.[326] In addition, while active third-party participation in prosecution is not unknown in patent systems around the world,[327] such schemes—which tend to be generally applicable to all patent applications—have sometimes been viewed as controversial.[328] Given the possible criticisms and

---

322 *Cf.* H.R. 1617, 116th Cong. § 2 (2019). One might argue that this scheme might be in tension with the TRIPs agreement, but such a challenge is likely to fail because the "discrimination" involved is procedural, not substantive.

323 *See generally* Michael Goodman, *What's So Special About Patent Law?*, 26 Fordham Intel. Prop. Media & Ent. L.J. 797 (2016); Jonathan S. Masur, *Regulating Patents*, 2010 Sup. Ct. Rev. 275 (discussing the heightened technical expertise required of patent adjudicators); *cf.* Kumar, *supra* note 265, at 923 (proposing "increasing the technical expertise" within Article III courts). *See* Thomas, *supra* note 100, at 307.

324 *See* Oil States Energy Servs., LLC v. Greene's Energy Grp. LLC, 138 S. Ct. 1365, 1381 (2018) (citation omitted).

325 *Id.* at 1374.

326 For example, under regulations promulgated by PTO Commissioner Marshall Dann in the 1970s, private parties could fully participate in a so-called patent reissue (which is very similar to initial examination). *See* Janis, *supra* note 286, at 17.

327 *See id.* at 744–56 (discussing pre-grant oppositions in Japan, which were abolished in the 1990s). India and Israel currently have pre-grant oppositions, though those jurisdictions do not have patent linkage. *See supra* note 39 and accompanying text.

328 *See, e.g.*, Org. Econ. Coop. & Dev., Enhancing Market Openness, Intellectual Property Rights, and Compliance Through Regulatory Reform in Israel 10–11, 48–49 (2011), https://www.oecd.org/israel/48262991.pdf [https://perma.cc/NR6M-8K2D]; *see also* Muhammad

relative lack of precedent, this Part of the Article lays out in detail the mechanics of the proposed system and outlines what role remains for courts after an enhanced examination.

A. Basic Mechanics of the Proposed Scheme

1. Certification

Identification of patents eligible for adversarial prosecution is a key element of the scheme. To accomplish this aim of notice, every patent applicant will be required to certify at the time of filing the intent for the application to ripen into a patent that would support the marketing of a small-molecule drug product. While many pharmaceutical patent applications are filed early in the research process, when FDA approval of the underlying therapy is far from guaranteed,[329] the brand firm's *intent* to use the patent system to obtain exclusivity for a small-molecule drug should typically be knowable at filing date (and especially so for patent applications on incremental innovations). A side benefit here is that initial PTO certification might create a useful record and serve something of a disciplining function for the brands. Improper Orange Book listings currently occur with some frequency,[330] and they can be rather difficult to correct.[331] While ex post solutions to this problem have been attempted, they have their own weaknesses.[332] To this end, representations about listing plans at the PTO might deter later shenanigans at the FDA in the first place.[333]

Moreover, in keeping with the focus of this proposal on secondary pharmaceutical products, certain applications on patents that can potentially be listed in the Orange Book will be exempt from the ambit of this proposal. Specifically, patents that would support products the FDA classified as "Type 1—New Molecular Entity" would not be exposed to

---

Zaheer Abbas, *An Evaluation of the Indian Legislative Framework for Patent Opposition Mechanism: Merits and Demerits of the Procedural Safeguard*, 5 J. Intell. Prop. Stud. 62, 77–79 (2021).

329 *See* Lemley & Moore, *supra* note 57, at 82, 85.

330 *See* FDA, Orange Book Patent Listing Dispute List (Feb. 10, 2023), https://www.fda.gov/media/105080/download [https://perma.cc/ZBX6-3AM2]; *see also* 21 C.F.R. § 314.53(f)(1) (2018).

331 The FDA disclaims any policing role due to its purported lack of patent expertise. *See* Eisenberg & Crane, *supra* note 21, at 213–14; Sherkow, *supra* note 21, at 251–52.

332 *See, e.g.*, Joseph Fielding, *From Pay-for-Delay to Product Hopping: The Limited Utility of Antitrust Law in the Pharmaceutical Industry*, 38 Cardozo L. Rev. 1915, 1918 (2017).

333 *Cf.* United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co., 11 F.4th 118 (2d Cir. 2021) (evaluating a situation where brand manufacturer filed applications with the FDA and described the combination patents as "claiming" the drug ACTOS).

the adversarial process (and sponsor firms can point to the carve-out in their certification statements). This carveout is included for several reasons. First, patents on new APIs tend to be filed particularly early in terms of the drug approval timeline, resulting in uncertainty in intent and consequent identification difficulties.[334] Second, new molecular entity patents are not invalidated nearly as frequently as secondary patents, suggesting that the prosecution process works reasonably well for primary patent applications and tends to result in correct grants and stable rights.[335] Third, primary patents are generally not implicated in the potentially anticompetitive scenarios described as "evergreening" and "product hopping," which were flagged by the Acting Commissioner for Food and Drugs in her letter to the PTO.[336]

With the scope of the certification requirement now set, the Article addresses penalties for noncompliance. To help discourage brand firms from skirting the requirement, the failure to timely certify an application that ripens into an Orange Book patent should be remedied by statutorily mandated patent unenforceability, and—in contrast to inequitable conduct[337] —the standard of negligence, rather than intent to defraud, should be adopted. In addition, if noncompliance is pled in litigation, that issue would be resolved in a bench trial before validity and infringement and without the benefit of the thirty-month stay (to limit the delay of generic entry if unenforceability is found), and a generic firm's win on this ground could be followed by penalties such as antitrust counterclaims of attorney fees. However, brands should be allowed to add a certification in cases of an innocent mistake or a change of plans if those contingencies come to light early in prosecution. Likewise, brands could decertify applications if the patent is no longer intended to support the marketing of an FDA-approved product.

The primary purpose, however, of the certification requirement, of course, is to put generic firms and the public on notice that patents that may be problematic for them are potentially in the works, thus inviting third-party participation in the prosecution process. In furtherance of this goal, a certifying brand would be prohibited from opting out of the standard path of the application's publication at eighteen months from the priority date (which is what most drug companies appear to choose anyway) or expediting examination such that substantive PTO action

334 *See* Hemphill & Sampat, *supra* note 221, at 332–36.

335 *See id.*

336 *See* Letter from Dr. Janet Woodcock to Mr. Andrew Hirshfeld, *supra* note 25, at 5.

337 *See supra* notes 255–60.

occurs before publication.[338] An applicant can of course always decide to withdraw a patent filing from publication at any time before eighteen months pass and abandon prosecution—and if a "certified" application is pulled, the world would likely never learn that this particular drug patent was being contemplated. In the normal course, however, an application would publish and, at that point, the PTO would list it—along with the best possible description of the underlying proposed product—in the Official Gazette, much as is now done for trademark registration applications up for oppositions.[339] Again by loose analogy with trademark oppositions,[340] any entity wishing to challenge the claims during prosecution would have a sixty-day period in which to file a notice of intent to do so. If multiple parties decide to take this path, the proceeding would be consolidated, a practice that is generally observed in Hatch-Waxman suits.[341]

2. Claim Construction

After the procedural preliminaries, examination of the applicant's proposed claims would begin. A key first step in determining patentability is to ascertain the scope of the claims,[342] which is a process that does not always get the attention it deserves in traditional *ex parte* prosecution.[343] To be sure, one generally tends to see fewer disagreements over claim scope in the small-molecule pharmaceutical field relative to others,[344] but they do occur and must be resolved before validity can be coherently evaluated. So too under the proposed framework, though—as in traditional prosecution—inventors should be given an opportunity to amend and clarify the claims if that action would moot the claim construction dispute. In addition, a preliminary claim scope determination could be made if the challenger explains that, depending on the

338 *See* 35 U.S.C. § 122(b). To be sure, the examiner (or International Search Authority) could search for prior art before the prosecution begins and make it available to the applicant, perhaps leading to abandonment before publication. *See infra* note 375 and accompanying text.

339 *See* 15 U.S.C. § 1063(b)(1). Currently, the Patent Gazette publishes only issued patents.

340 *See id.* § 1071(b).

341 *See* 35 U.S.C. § 299; *see also* Thomas, *supra* note 166, at 115 ("Over the past decade, Hatch-Waxman cases have been among the most heavily consolidated patent lawsuits in the nation."). *But see* Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1382–83 (Fed. Cir. 2020) (declining to join claims due to venue concerns, based on the plain meaning of § 1400(b) of the Hatch-Waxman Act).

342 *See* Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc).

343 *See generally* John F. Duffy, *On Improving the Legal Process of Claim Interpretation: Administrative Alternatives*, 2 WASH. U. J.L. & POL'Y 109 (2000).

344 *See* BURK & LEMLEY, *supra* note 159, at 127–28; Levin et al., *supra* note 50, at 818.

construction, it would be using materially different prior art.[345] Otherwise, claim construction can be consolidated with validity evaluations in a single hearing in most cases.[346]

A further antecedent, but significant, issue is the standard of claim construction for the PTO to apply. Here, there are two potential options: courts and the PTAB in its post-issuance determinations use the predominant *Phillips* standard, named after a key Federal Circuit opinion setting the methodology for this determination.[347] In *ex parte* prosecution, however, the PTO adopts the broadest reasonable interpretation ("BRI") approach, which forces examiners to construe the claims in an artificially broad manner.[348] Although the inventor's ability to amend claims under the proposed scheme, to be discussed below, potentially counsels toward BRI, the *Phillips* standard is preferable.

First, a part of the reason for BRI is to "compensate for the lack of other incentives to produce precise patent claims,"[349] but this is less of a concern in an adversarial process.[350] During a pre-grant opposition, the freedom to operate could be implicated in a concrete way for the potential infringers, who would be concerned with getting the scope exactly right. Indeed, third-party participation provides an opportunity for what Matthew Sag and Kurt Rohde called "negative claim construction"—an inventor-adverse determination that places the intended product outside the scope of the claims, or creates an opportunity to design around them, resulting in no infringement.[351] Here, the description of the proposed product lodged along with the certification should prove useful for making targeted claim construction arguments with the patentee, of course,

---

345 *See* Qualcomm Inc. v. Intel Corp., 6 F.4th 1256, 1262–63 (Fed. Cir. 2021).

346 District courts already consolidate claim construction hearings with dispositive validity motions under the decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), and the PTAB does as well. *See, e.g.*, Virentem Ventures, LLC v. Google LLC, No. 2021-1805, 2022 WL 17087139 (Fed. Cir. Nov. 21, 2022).

347 *See Phillips*, 415 F.3d at 1315.

348 *See* Timothy R. Holbrook, *The Patent Trial and Appeal Board's Evolving Impact on Claim Construction*, 24 Tex. Intell. Prop. L.J. 301, 302 (2016); *cf.* Laura E. Dolbow, Note, *A Distinction Without a Difference: Convergence in Claim Construction Standards*, 70 Vand. L. Rev. 1071, 1073 (2017).

349 Michael Risch, *The Failure of Public Notice in Patent Prosecution*, 21 Harv. J.L. & Tech. 179, 181 (2007) (citations omitted).

350 A related reason for BRI is that the applicant has an opportunity to amend claims to the point that there is essentially no ambiguity. *See id.* In this sense, BRI is a kind of a *contra proferentem* rule that resolves doubt in favor of broader claims. But in an adversary process, with both the examiner and the private parties challenging the claims and testing their scope, this rationale for BRI appears to be less salient.

351 Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 Minn. J.L. Sci. & Tech. 1, 83, 85–86 (2007).

pursuing a scope that would cover the desired product formulation and, if possible, end up even broader so as to prevent a ready avoidance of the patent by a design-around.[352] At the same time, the patentee may not want claims so broad that their validity could be readily challenged,[353] so the incentives are there for both sides to set the correct scope.

While this process naturally involves some degree of uncertainty because the patent application usually precedes the product,[354] applicants usually must decide what claims to pursue in regular *ex parte* prosecution prior to ultimate FDA approval, and with that, brand companies still routinely obtain claims that provide effective protection in Hatch-Waxman suits. From the challenger's perspective, however, a favorable claim construction could be all it needs to avoid liability after examination.[355] Of course, if there are multiple challengers, they could be contemplating somewhat different products and, thus, potentially pursue different claim construction arguments (or even wish to challenge different claims in the applicant's filing). Nevertheless, as with consolidated judicial proceedings, the challengers would normally have to agree upon a unified litigation strategy, inevitably limiting the number of proposed claim constructions—and the examining official would ultimately pick the one he or she believes to be correct.

3. Patentability Analysis

Claim construction precedes application of the requirements of patentable subject matter, novelty, nonobviousness, and disclosure.[356] While the examining official would perform the standard prior art

---

352 *See* Ashish Arora, *Patents, Licensing, and Market Structure in the Chemical Industry*, 26 RES. POL'Y 391, 392 (1997) (discussing the importance of patents for preventing design-arounds in the chemical industry); Levin et al., *supra* note 50, at 818 (discussing appropriability mechanisms through claim breadth). Of course, in the small molecule pharmaceutical context, design-arounds are made particularly difficult by regulatory lock-in.

353 *See* Giles S. Rich, *The Proposed Patent Legislation: Some Comments*, 35 GEO. WASH. L. REV. 641, 644 (1967).

354 *See* Moore, *supra* note 13, at 1544. *But cf.* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 72 (2009) (noting that U.S. patent law "creat[es] a strong presumption that the filing date is the date of invention"). This is less of a problem for secondary patents. *See* Tu & Lemley, *supra* note 182, at 168.

355 The negative claim construction theories might necessarily be based on some guesswork by the generic given the information asymmetries between it and the patentee. In spite of the required description of the proposed product, it still might not be clear what final form the product will take, and the patentee will pursue different claims to hedge its bets. *Cf.* Bruce L. Hay, *Effort, Information, Settlement, Trial*, 24 J. LEGAL STUD. 29, 31, 56 (1995). Still, the generic's expertise in designing around formulation-type patents in particular could also inform its claim construction strategy to some extent.

356 *See* 35 U.S.C. §§ 101–103, 112.

searching and validity analysis, the challengers could introduce their own references and make arguments against patentability of the applicants' proposed claims for the agency to weigh.[357] In addition, and in contrast to the "paper prior art" limitation on IPRs,[358] the PTO official could entertain challengers' motions for discovery with the aim of revealing nondocumentary references, i.e., invalidating public use and sale events, as well as with other information relevant to compliance with requirements like enablement.[359]

Crucially, should the applicant come forward with technical evidence in support of patentability, such as unexpected results allegedly probative of nonobviousness,[360] the challengers could offer their own expert affidavits and analysis countering those proffers.[361] In addition, they might submit their own technical evidence of nonenablement and lack of adequate written description, helping to fill what is now a significant gap in the PTO's ability to enforce these disclosure requirements.[362] As with current PTAB post-issuance trials, the parties may take depositions and request live cross-examination of the experts, and it would be up to the PTO to decide whether such a hearing is warranted in the context of a patentability trial.[363] While, as Arti Rai noted, a battle of the experts can sometimes "shed more heat than light" in court,[364] an expert adjudicator should have some ability to see through the rhetoric and grasp who has the better science.[365] This level of process and adversarial

---

357 *Cf. supra* notes 210–14 and accompanying text.

358 *See* Stephen Yelderman, *Prior Art in* Inter Partes *Review*, 104 Iowa L. Rev. 2705, 2708–09 (2019).

359 *See* Holly Grant, *The PTAB's Subpoena Power*, Foley Hoag LLP PTAB Blog (Nov. 25, 2015), https://www.ptab-blog.com/2015/11/25/the-ptabs-subpoena-power/ [https://perma.cc/HZ7Y-M5HN]; Freilich, *supra* note 17, at 2144 (discussing discovery at the PTAB); *see also* Sag & Rohde, *supra* note 351, at 86–87.

360 *See generally* Karshtedt, *supra* note 193.

361 For example, they could offer this evidence in reply if the patentee offers unexpected results in rebuttal of a prima facie case of obviousness. *See In re* Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976).

362 *See* Holbrook, *supra* note 348, at 324; Ouellette, *supra* note 96, at 1836; *supra* note 228 and accompanying text.

363 *See* McDermott Will & Emery, *PTAB Clarifies when Live Testimony at Oral Argument Is Permitted, and Motion to Amend Practice*, JDSupra (May 2, 2019), https://www.jdsupra.com/legalnews/ptab-clarifies-when-live-testimony-at-65905 [https://perma.cc/M7PH-AQRD]; 37 C.F.R. § 42.53 (2018).

364 Arti K. Rai, *Specialized Trial Courts: Concentrating Expertise on Fact*, 17 Berkeley Tech. L.J. 877, 892 (2002).

365 *See* Masur, *supra* note 323, at 279; *see also* Brewer, *supra* note 194, at 1539 (modelling the "reasoning process by which nonexpert legal reasoners defer to scientific experts"). *But cf.* Mandel, *supra* note 302 (discussing the varying levels of expertise among PTO examiners and PTAB administrative judges).

presentation should result in a more thorough examination record than in *ex parte* prosecution, helping reduce the number of errant patent grants.[366]

After the hearing, the PTO official would allow or reject some or all the claims, mirroring prosecution practice. In response, the applicant would have the standard options of amending or replacing the rejected claims, abandoning them (especially if satisfied with those claims that have been allowed), or appealing the decision.[367] As with an inventor-adverse claim construction, a narrowing amendment might well extinguish the threat of liability for the challenger.[368] If, on the other hand, the amended claims continue to present a problem, the challenger could maintain arguments against patentability. For the claims that are rejected again, the applicant would then be allowed to make one final set of amendments or replacements, and if an invalidity argument against them succeeds, then the proceeding would conclude. Abandonment or allowance that resolves the status of all the proposed claims one way or another would also end the matter at the PTO, setting the stage for the parties' appeals (including any cross-appeals).[369]

Notably, if the parties settle or if all challengers otherwise decide to drop out before the proceeding is complete,[370] the PTO would continue the examination and evaluate the claims as it would in the normal course.[371] At that point, the prosecution would follow, to some extent, the standard *ex parte* rules with respect to that application.[372] Thus, for the claims that are allowed, there would be no possibility of any third party to appeal, while the patentee could appeal a final rejection.[373]

---

366 *See supra* notes 321–28 and accompanying text. If further data needs to be developed during the FDA approval process to, for example, build a case for unexpected results, examining officials could be given the discretion to stay the proceedings. I thank Michael Furrow for suggesting that I make that point.

367 *See* Yelderman, *supra* note 55.

368 *See supra* note 110 and accompanying text.

369 Cross-appeals might take place if not all the claims are rejected.

370 *Cf.* Dolin, *supra* note 269, at 318–326 (discussing possible benefits of reverse settlements).

371 *Cf.* Christian Helmers & Brian J. Love, *Patent Validity and Litigation: Evidence from U.S.* Inter Partes *Review*, 66 J. L. Econ. 53 (2023) (demonstrating empirically that filing an IPR petition has a "large, positive effect on the settlement of parallel litigation"). In this context, it might be a good thing to discourage settlements, though, so that a final judgment on validity could be reached. *But see* Samsung Elecs. Co. v. Telefonaktiebolaget LM Ericsson, No. IPR2021-00446, 2021 WL 3410471 (P.T.A.B. Aug. 3, 2021) (terminating IPR through settlement) (additional docket numbers omitted).

372 In other words, it would just be the examiner who is involved in valuating patentability.

373 The first appeal would be to the PTAB. *See supra* notes 76–77. This is the asymmetric setup that has been criticized by several commentators. *See, e.g.*, Masur, *supra* note 63; Wasserman, *supra* note 63.

However, in contrast to traditional prosecution, the patentee would not be able to attempt so-called requests for continued examination or continuation applications with the intent to use them to obtain Orange Book patents—whether or not the challenger drops out.[374] This kind of strategy would have the effect of circumventing the proposed scheme, and a prior certification would serve as a bar to such filings.

4. Adjudicators and Review Within the PTO

Having the proper adjudicators for the novel examination process is critical. While patent examiners who are not required to have formal legal training conduct traditional *ex parte* prosecution, the trial-like process outlined in this Article is more suited for attorneys. This level of expertise, along with a background in chemistry or the life sciences, may be necessary to work through the relatively higher volume of evidence than in regular examination and to address the more involved legal arguments that the parties are likely to make.[375] The PTO, of course, already employs legally and technically trained adjudicators—the PTAB's APJs. They sit in panels of three or more to adjudicate applicant appeals of *ex parte* rejections,[376] decide whether to grant post-issuance review petitions under the power the Director delegated to them,[377] resolve IPR and PGR patentability trials, and even entertain claim amendments.[378] Based on this experience, APJs with the relevant technical background are prime candidates for the job of administering adversarial prosecution, which they can perform as solo adjudicators.

Alternatively, the PTO could develop a separate category of officials, perhaps called "patent examining attorneys" (by analogy with trademark examining attorneys), who could function as deciding officials in the manner of traditional administrative judges. Some PTO precedent for specialized decisionmakers outside the PTAB exists in the form of experienced examiners in the so-called Central Reexamination Unit, which deals with *ex parte* reexaminations, supplemental examinations, reissue proceedings, and any *inter partes* reexaminations

374 *See* Lemley & Moore, *supra* note 57, at 82.

375 *Cf.* H.R. Rep. No. 104-784, at 63 (1996) ("[I]t is intended that the Office, through rulemaking, will provide third-party requesters the right to participate in any examiner interview initiated by the patent owner or by the examiner, and that such interviews will be conducted under controlled conditions before the examiner and an additional, more senior, Office representative."); *see also* Merges, *supra* note 62, at 614 n.101.

376 *See* 35 U.S.C. § 6(b)(1)–(2).

377 *See* Ethicon Endo-Surgery, Inc. v. Covidien LP, 812 F.3d 1023, 1029 (Fed. Cir. 2016).

378 *See* 35 U.S.C. § 6(b)(4).

left over from the pre-AIA regime.[379] In sum, the new patent examining attorney corps, again with appropriate technical training, could be another specialized unit within the PTO.[380]

Next is the question of intra-agency challenges to the first-instance validity decision. As a matter of constitutional law, the PTO Director must be ultimately responsible for patentability decisions at the agency.[381]

However, Director review that is merely discretionary is constitutionally sufficient[382]—and is in fact preferable as a practical matter to avoid subjecting the Director to an overwhelming workload and creating a situation in which agency process would grind to a halt. Even so, there remains a question whether, as in traditional *ex parte* prosecution, a formal appeal as of right within the PTO should be allowed or whether the examining official's decision will be the final word for the agency subject to possible Director review.[383] The better route is for both the inventor and the challenger to be able to appeal the initial prosecution decision within the PTO to a PTAB panel,[384] though this step can be omitted without compromising the proposed scheme a great deal if it is determined that agency resources would be overly strained.

If practically possible, intra-agency review as of right can help with streamlining of the record and with further narrowing of issues before the claims head to the Federal Circuit after the Director's go-ahead. However, to maintain efficiency, the PTAB would have very limited remand authority.[385] Thus, rather than mandating that the examining attorney completely reopen prosecution, the PTAB's options would be to reverse the decision below in cases of factual or legal error that leaves the outcome in favor of the appellee in no doubt or to remand the case for the limited purpose of applying the correct legal standard

---

379 *See* 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, 322 (2011).

380 *Cf.* 35 U.S.C. § 6(a) (setting forth technical qualifications for PTAB judges).

381 *See* United States v. Arthrex, Inc., 141 S. Ct. 1970, 1986–88 (2021).

382 *See id.*

383 *See id.* at 1988 ("To be clear, the Director need not review every decision of the PTAB. What matters is that the Director have the discretion to review decisions rendered by APJs.").

384 Consistent with the scheme for IPRs and PGRs, the parties would not be able to challenge the PTO's determination via civil action under 35 U.S.C. § 145 under the proposed scheme—nor would it be necessary because the proposed proceeding is already intended to create a full factual record, thus obviating a part of the purpose for § 145. *See* Greve, *supra* note 296, at 113–16; Kappos v. Hyatt, 566 U.S. 431, 432 (2012).

385 Also, the PTAB could potentially use its fast-tracking program for these appeals to diminish cutting into patent term or use representative claims to expedite the process. *See* Karam J. Saab, *Patent Prosecution & USPTO Update*, LEXOLOGY (June 11, 2021), https://www.lexology.com/library/detail.aspx?g=4be09e85-f12e-4439-bc9e-dccc89f36604 [https://perma.cc/PTD5-RP7S].

at the point where the error first occurred. In cases of an incorrect claim construction, to be sure, a return to the starting point may be inevitable. Nevertheless, as noted earlier, such disputes are not particularly common in this area of technology and can sometimes be obviated early on with clarifying amendments.[386]

5. Standing and Appeals to the Federal Circuit

A traditional appeal to the Federal Circuit is the next stop after the PTO concludes its work.[387] Here, the threshold issue is standing. For the patentee, Article III's case or controversy requirement is readily met based on the adverse agency action of rejecting the claims. For the challenger, it is not so simple. In a series of opinions that could be described as, well, controversial, the Federal Circuit substantially restricted standing to appeal the PTAB's determinations upholding patentability in post-issuance proceedings.[388] The court held that to adequately demonstrate injury-in-fact in the absence of an infringement suit, the appellant must have concrete plans to develop a product that would infringe to be proven with particularized evidence.[389] Economic harm that is less direct would not suffice, and public interest organizations, such as patient advocacy groups, can forget about it.[390] At least until the Federal Circuit revisits the issue en banc or the Supreme Court gets to it, a mere "administrative injury" of losing at the PTO will not come close to establishing standing,[391] and a threat of an infringement action would need to be shown even by a for-profit corporate challenger.[392]

This is a potential problem. Although in the Hatch-Waxman context the filing of an ANDA represents an artificial act of patent infringement and would, thus, support standing by a losing generic firm,[393] the validity

386 *See supra* notes 334–36 and accompanying text.

387 *See* 35 U.S.C. § 141. *See generally* Dickinson v. Zurko, 527 U.S. 150 (1999).

388 *See* Richard J. Stark, *Standing to Appeal IPR Decisions of the PTAB: Article III and the Federal Circuit*, Landslide, Mar./Apr. 2020, https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2019-20/march-april/standing-appeal-ipr-decisions-ptab-article-iii-federal-circuit/ [https://perma.cc/C5G5-QVU7].

389 *See* Gen. Elec. Co. v. United Techs. Corp., 928 F.3d 1349, 1354–55 (Fed. Cir. 2019); Consumer Watchdog v. Wis. Alumni Res. Found., 753 F.3d 1258, 1261 (Fed. Cir. 2014).

390 *See* Michael J. Burstein, *Rethinking Standing in Patent Challenges*, 83 Geo. Wash. L. Rev. 498, 537 (2015); Sapna Kumar, *Standing Against Bad Patents*, 32 Berkeley Tech. L.J. 87, 113 (2017); Megan M. La Belle, *Public Enforcement of Patent Law*, 96 B.U. L. Rev. 1865, 1871–72 (2016).

391 *See Consumer Watchdog*, 753 F.3d at 1261.

392 *See, e.g.*, *Gen. Elec.*, 928 F.3d at 1357.

393 *See* Winkler et al., *supra* note 45, at 3. *But cf.* Momenta Pharms., Inc. v. Bristol-Myers Squibb Co., 915 F.3d 764, 768 (Fed. Cir. 2019) (finding no standing where the patent challenger had no concrete plans to market a biosimilar product).

dispute under the proposed scheme could long precede the filing of the ANDA and the approval of any product may, at that point, be far from guaranteed. Generics might, to be sure, be able to more readily allege competitive harm in cases of secondary innovation when the brand's attempts to obtain new patents might interfere with the intended marketing of an *off-patent* product for which an ANDA may be on the way to approval.[394] Under the muddled state of the law, however, even that kind of an injury is not guaranteed to support standing.[395]

How might the challenger, then, show injury under controlling precedent? One solution, borrowed from the work of Sapna Kumar, is to style the third party's role as similar to that of a qui tam relator,[396] with a bounty for a successful attack on patentability or perhaps even a token financial penalty for a failed one (either of which would create an injury-in-fact for an Article III appeal in case a patent is allowed under the "assignee" theory of qui tam standing).[397] An added benefit of this approach is that entities other than generics could maintain standing to appeal unsuccessful patent challenges.[398] As other scholars have discussed in extensive literature,[399] those who might reasonably seek to prevent a problematic patent from issuance include above-mentioned public interest organizations, payers, and industry groups.[400] Providing appeal rights to this set of challengers could help make up for collective action problems and otherwise inadequate challenges from generic firms, on which more will be said shortly. Qui tam standing deals with that problem, though it is of course no panacea; for example, nonmanufacturing patent challengers might be limited in their ability to push for effective narrowing amendments due to lack of expertise in making

394 *See* Karshtedt, *supra* note 131, at 1157–58.

395 *See* Ryan Fitzgerald, Note, *Standing Up to Bad Patents: Allowing Non-Infringing Competitors to Satisfy the Article III Standing Requirements Appealing an Adverse* Inter Partes *Review Decision to the Federal Circuit*, 105 Minn. L. Rev. 961, 989 (2020).

396 Kumar, *supra* note 390, at 132–33; *see also* Thomas R. Lee, Comment, *The Standing of Qui Tam Relators Under the False Claims Act*, 57 U. Chi. L. Rev. 543, 555–58 (1990) (explaining why qui tam relators have standing).

397 *See* Vt. Agency of Nat. Res. v. U.S. *ex rel.* Stevens, 529 U.S. 765, 772–73 (2000); Kumar, *supra* note 390, at 132–33.

398 As with IPRs and PGR, there will be no standing requirement to challenge patent applications under this proposal.

399 *See, e.g.*, Burstein, *supra* note 390, at 545; La Belle, *supra* note 390, at 1871.

400 *See supra* notes 389–90 and accompanying text. These sorts of entities already appear as plaintiffs in antitrust cases. *See, e.g.*, United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co., 11 F.4th 118 (2d Cir. 2021); *In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538 (1st Cir. 2016); James Y. Stern, *Indirect Purchaser Suits and Jurisdictional Competition*, Glob. Competition Rev. (2013), https://ssrn.com/abstract=2383490 [https://perma.cc/49B5-BAHG].

noninfringing products—or any intent to do so. Still, given that the name of the game in pharmaceutical patent disputes is usually invalidation, participation by public interest organizations and other such groups may make a large difference.

B. Other Significant Features of the Proposal

1. Exclusivity Incentives for Winning Challengers

One potential threat to the viability of the proposal is the free-rider phenomenon. Preventing a brand patent from issuance is a public good in that the benefits of a successful challenge are not fully appropriable by the winning generic.[401] The space that would have been limited by the patent is now free, and even those who sat out the proceeding can take advantage of the patent's absence. As a result, validity attacks might be undersupplied due to the collective action problem.[402] In other contexts, commentators have suggested bounties for entities that take the lead on attacking validity,[403] and the Hatch-Waxman Act essentially adopts this kind of a strategy.[404] A generic firm that is first to challenge a patent receives a 180-day period of FDA-administered exclusivity, during which that firm enjoys a duopoly privilege in marketing the now off-patent product along with the brand.[405]

A similar strategy should be adopted in the context of the Article's proposal—but with a twist.[406] First, if a generic convinces the PTO to quash the claims in a way that frees up the product space for everyone else, it should be entitled to a 180-day exclusivity period to market the now off-patent product along with the innovator after any brand nonpatent exclusivity has expired. To be sure, it is certainly possible that the sponsor, having failed to obtain the patent, will (in a manner of speaking) take its marbles and go home, abandoning the improvement product given the prospect that a patent would not support it. If that is the case, however, the story becomes more complicated. As

---

401 *See* Miller, *supra* note 91, at 680–82; Thomas, *supra* note 100, at 308–09; *see also* Margaret K. Kyle, *Competition Law, Intellectual Property, and the Pharmaceutical Sector*, 81 ANTITRUST L.J. 1, 7 (2016) ("[A] patent challenge is costly for the generic firm that attempts it, and successfully invalidating a patent creates a public good for all other generic firms.").

402 *See* Kyle, *supra* note 401, at 8–10.

403 *See, e.g.*, Miller, *supra* note 91, at 705; Thomas, *supra* note 100, at 342.

404 *See* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 953 (2011).

405 *See id.*

406 Another important difference from the Hatch-Waxman generic exclusivity is that reward will be given for a *successful* challenge—not merely the fact of a challenge.

an initial matter, a nonpatent exclusivity for the *sponsor*, addressed below, could provide some incentive for incremental innovation. The present discussion, however, is focused on access to drug versions that are cheaper—and older. One of the benefits of the proposal, which is somewhat paradoxical, but unsurprising given the unique dynamics of pharmaceutical markets, is that preventing the issuance of an improvement patent can actually facilitate generics' selling of a previously approved version of a product *covered by a previous patent that has now expired*.[407] If this is the practical outcome of blocking an improvement patent, then it stands to reason to give the winning generic a "bounty" in the type of nonpatent exclusivity for making the off-patent product instead.[408]

To elaborate, brands sometimes try to thwart post-expiration generic entry by taking the original product off the shelves or at least deemphasizing the marketing, shifting the demand to the new product and, thus, disabling the generics from selling the original one by taking advantage of state substitution laws.[409] The proposal, however, would help forestall this questionable practice by (1) reducing the odds that an improvidently granted follow-on patent will issue[410] and (2) granting the generic the exclusivity to market the *original* product, whereby the supracompetitive returns from this novel form of exclusivity should enable them to build up a marketing budget to promote the off-patent product if the brand decides to abandon it.

A few additional possibilities are to be noted here. First, if the proceeding includes multiple generic challengers, the exclusivity will be shared among those entities concurrently.[411] Second, if a particular generic firm wins on a "negative claim construction" or otherwise succeeds on blocking the patentee's claim that enables it to market a unique product that other generics are blocked from marketing by the claims that survive,[412] the exclusivity will not be granted. Third, if the successful challenger is not a generic firm but a public interest organization, there is no generic exclusivity to be awarded, but that is par for

---

407 *See* Karshtedt, *supra* note 131, at 1132–33. The reward here is for breaking up potentially anticompetitive product hopping and for preventing the creation of a so-called "patent thicket." *See* Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93, 109 (2019).

408 *Cf.* Thomas, *supra* note 100, at 342.

409 *See generally* Karshtedt, *supra* note 131.

410 To be sure, there might be a shorter period of nonpatent exclusivity for the brand's subpatentable invention. *See infra* note 439 and accompanying text.

411 This is perhaps a downside of joinder as far as generics are concerned, though the presence of multiple challengers also dilutes the impact of the free-rider problem.

412 *See* Sag & Rohde, *supra* note 351, at 83.

the course because the presence of such a group suggests that some incentive other than the wish to market a generic product already drove the patent challenge.[413] Finally, it is worth noting that this new form of exclusivity, combined with estoppel provisions, would ultimately make the Hatch-Waxman 180-day exclusivity obsolete—and the proposal would eliminate it for noninfringement defenses in litigation.[414]

2. Consolidation and Limits on Patent Aggregation

This Section addresses concerns relating to generics' ability to market their products after prevailing at the PTO. The first involves the possibility that the brand will attempt to obtain additional patents covering the intended product after losing out on one set of applications under the proposed proceedings. Indeed, brands often assert multiple patents in Hatch-Waxman suits and, in general, it is quite common for an Orange Book listing to include a number of patents against which the generic must make the Paragraph IV certification—and more of these patents are sometimes added to the Orange Book over time.[415] Here, a part of the answer is that such patents are often familially related and, under the proposal, the brand will be barred from seeking continuations for patent applications subject to the certification requirement.[416] But what about familially unrelated patents? Here, to the extent the underlying applications are filed close in time, the adversarial proceedings could either be consolidated to include multiple applications, as frequently done with multiple patents in Hatch-Waxman suits. In addition, if multiple entities are involved in the proceeding, they could try to pursue a divide-and-conquer strategy, and some can thereby focus on specific patents to the benefit of the entire "joint defense group."

If additional certified applications are filed significantly later in time than the first one, a more complicated situation arises. On one hand, the generic might feel justifiably frustrated in having to play the game of whack-a-mole after having already prevented a patent from issuance in pursuit of an ANDA. On the other, it is certainly not unusual or generally anticompetitive to protect different inventive aspects of a drug product

413 Here, the "bounty" consists of reduced drug prices for the constituent group. *Cf.* Miller, *supra* note 91, at 738.

414 *See infra* Section III.B.iii.b and accompanying text.

415 *See, e.g.*, Endo Pharms. Inc. v. Actavis, Inc., 746 F.3d 1371 (Fed. Cir. 2014).

416 *See supra* notes 329–41. If the PTO requires a so-called "divisional" application after the initial filing, the relevant patent applications can be consolidated into a single adversarial proceeding after certification—which, as noted below, can be done in the context beyond divisionals—to make the proceedings more efficient.

with multiple patents, and a patent "picket fence" can certainly play a positive innovation-encouraging function in some circumstances.[417] Still, if the goal is to clear the parties' rights and reduce litigation, continual attempted acquisition of patents might thwart that goal. To some extent, the brands' own published applications can serve as prior art against subsequent filings, but potential invalidity is of course not by itself enough to deter an application—and inventors can readily pursue novelty and nonobviousness arguments over their own publications.

Accordingly, to ensure the clarity and certainty of generics' rights to market their products, the brands should be subject to a time limit for follow-on certified filings. A reasonable restriction to prevent indefinite prolongation of the threat of exclusivity is a period of three years from the filing of the first application certified to cover a particular product with the proviso that any subsequent filings would be ineligible for the Orange Book. In addition, if the PTO decides that the patent filing was made in bad faith (based on the weakness of the claims) even within the three-year timeframe, it could strike the application and thus prevent it from going to prosecution. It must be added that it is currently unsettled whether patents obtained after ANDA approval are even listable in the Orange Book,[418] but the proposed time limit should curtail the attractiveness of the whack-a-mole strategy in any event.

3. Limits on Ex Post Validity Challenges and the Role of District Courts

a. Preclusion of Invalidity Litigation

This Section discusses limits on post-issuance challenges of the claims that make it through enhanced prosecution, which is a critical aspect of the proposed regime. These limits relate to concept of so-called gold-plated patents: certain patent applications would be subject to a rigorous form of prosecution, but the resulting patents would be

---

417 *See, e.g.*, Arora, *supra* note 352, at 400; Christian Sternitzke, *Shielding Innovative Products from Imitation: Patent Fencing, Dominance, and Firm Performance in Pharmaceuticals* (manuscript in preparation) (on file with author); *see also* Wu & Cheng, *supra* note 407, at 97.

418 *See* Endo Pharms. Inc. v. Amneal Pharms., LLC, No. 12 Civ. 8115 (TPG), 2016 WL 1732751, at *3–4 (S.D.N.Y. Apr. 29, 2016) (additional docket numbers omitted) (explaining the significance of the effective date of the ANDA relative to the patent issuance date for purposes of relief under 35 U.S.C. § 271(e)(4) in Hatch-Waxman cases), *aff'd on other grounds sub nom.* Endo Pharms. Inc. v. Teva Pharms. USA, Inc., 731 F. App'x 962, 967 n.4 (Fed. Cir. 2018) (nonprecedential), *vacated in part on other grounds*, 729 F. App'x 936, 937 (Fed. Cir. 2018) (nonprecedential); Strafford, Orange Book Listing Recent Developments: Impact on Prosecution of Pharmaceutical U.S. Patent Applications, Subsequent Orange Book Listings, Hatch Waxman Litigation (Nov. 16, 2021).

much more difficult to knock out after issuance than those without the bling. The general notion of gold-plating generated much discussion in the years leading up to the passage of the AIA,[419] but did not become embodied in any concrete legislation. Senator Thom Tillis, the ranking member of the Senate Subcommittee on Intellectual Property, recently expressed some interest in reviving this idea as part of his more general interest in patent quality, but his most recent proposal remains inchoate at the time of this writing.[420] We are not, however, without a good theoretical foundation here—Stuart Benjamin and Arti Rai usefully set forth the rationale for such a system and sketched out a mechanism for its implementation in an article published fifteen years ago:

> For those patentees who needed early certainty about their rights, Congress could provide for the same rigorous review of patents at the examination stage, rather than after the patent has been granted. That is, in addition to creating post-grant review, Congress could create an option for a patent applicant to have the initial consideration of its application undergo the same sort of rigorous evaluation that post-grant review would entail.[421]

Benjamin and Rai's suggested legislation differs from the adversarial examination scheme discussed in this Article in that the patentee opts into the rigorous review rather than being subjected to it by a third-party challenger. Indeed, third parties do not have to participate under Benjamin and Rai's proposal—though they may.[422] Consistent with this Article's focus on ex ante knowledge of value of pharmaceutical patents, however, Benjamin and Rai note in passing that a searching prosecution process might make the most sense "[f]or those types of invention for which firms might need early certainty about their patent rights (for example, drug inventions)."[423] Moreover, this Article agrees with Benjamin and Rai in that the result of an applicant's success in getting the claims to allowance should be a patent that is difficult to knock down afterwards, which is the essence of gold-plating. The very

---

419 *See, e.g.*, Lemley et al., *supra* note 42.

420 *See* Benjamin Din, *Lawmakers Set Sights on Boosting Patent Quality*, POLITICO (June 22, 2021, 10:00 AM), https://www.politico.com/newsletters/morning-tech/2021/06/22/lawmakers-set-sights-on-boosting-patent-quality-796068 [https://perma.cc/MXX8-YQDF]; Eileen McDermott, *Senate IP Subcommittee Mulls Ways to Improve Patent Quality (Again)*, IPWatchdog (June 23, 2021, 11:15 AM), https://ipwatchdog.com/2021/06/23/senate-ip-subcommittee-mulls-ways-to-improve-patent-quality-again/id=134887/ [https://perma.cc/7UVQ-5ND4].

421 Benjamin & Rai, *supra* note 52, at 328 (footnote omitted).

422 *See id.* at 328 & n.302.

423 *Id.* at 329. This observation logically applies to both brands and generics.

point of rigorous first-instance review is to create an environment in which issues are correctly decided in the first instance, thus reducing the need to rehash the same arguments later with little deference to the examiner. This intuition can be grounded in administrative law principles: a trial-type proceeding is a formal adjudication within the meaning of the APA, and it is a "more searching review that would be subject to more deference as a matter of administrative law."[424] In contrast, Benjamin and Rai note that those patents "that had not gone through formal adjudication ex ante would presumably be subject to such adjudication ex post throughout the life of the patent,"[425] which is precisely the scenario that this Article's proposal seeks to curtail.

The practical questions underlying gold-plating are what arguments should be precluded, who is to be precluded, and when. The Federal Circuit first grappled with issues underlying the first question in the 1990s, when it interpreted the "substantial new question of patentability" threshold for granting requests for *ex parte* reexaminations in the well-known *Recreative Technologies*[426] and *Portola Packaging*[427] cases. Observing that "unwarranted reexaminations can harass the patentee and waste the patent life,"[428] the court concluded that any reference cited during initial examination cannot serve as the basis for a substantial new question in a reexamination, even if the examiner allegedly "failed to appreciate" the reference.[429] These decisions were rightly criticized—because an examiner's citation to a reference might not always imply a well-developed novelty or nonobviousness challenge based on it[430]—and they were overruled by statute.[431] Under the current standard, the Director may order an *ex parte* examination "if the reference is presented in a new light or a different way that escaped review during earlier examination."[432] More recently, this framework

---

424 *Id.* at 328–29.

425 *Id.* at 329; *see also supra* Section I.B; Chatlynne et al., *supra* note 69, at 55.

426 *In re* Recreative Techs. Corp., 83 F.3d 1394, 1398–99 (Fed. Cir. 1996).

427 *In re* Portola Packaging, Inc., 110 F.3d 786, 789–92 (Fed. Cir. 1997).

428 *Portola*, 110 F.3d at 790 (quoting *Recreative*, 83 F.3d at 1397).

429 *Recreative*, 83 F.3d at 1398.

430 *See, e.g.*, Miller, *supra* note 91, at 734.

431 *See* 21st Century Department of Justice Appropriations Authorization Act, Pub. L. No. 107–273, § 13105, 116 Stat. 1758, 1905–06 (2002); *see also In re* NTP, Inc., 654 F.3d 1268, 1277 (Fed. Cir. 2011) (discussing the 21st Century Department of Justice Appropriations Authorization Act).

432 USPTO, R–10.2019, Manual of Patent Examining Procedure § 2216 (9th ed. 2014); *see also* 35 U.S.C. § 303(a) ("The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.").

was supplemented in a significant way—indeed, largely eclipsed—by the AIA's IPR and PGR regime, discussed above.[433]

Given these precedents, where does pre-grant opposition fit in? The scheme's adversarial nature places it relatively close to IPRs and PGRs, which are relatively rigorous trial-like proceedings, on the spectrum from informal to formal adjudication, suggesting that a relatively rigorous type of estoppel should be adopted.[434] In addition, and especially given the importance of certainty of patent rights in the pharmaceutical space, Congress should be cognizant of the indeterminacy and open-endedness of the AIA's "reasonably could have raised" standard and provide for a clearer threshold that would encourage early and thorough resolution of validity issues.[435] Accordingly, an attack on these gold-plated patents in ex post litigation should require either proof of patentee fraud or a showing that the invalidating art (or other evidence) was even theoretically unavailable to a PHOSITA.[436] This limitation would resemble (and flip around as a sword against defendants) the minimal public accessibility standard for novelty in patent law,[437] which admittedly makes such belated prior art a small set indeed, and generally puts the pressure on challengers to produce the best evidence of invalidity they can find during the opposition.[438] This standard allows post-issuance reliance on relatively unusual forms of after-discovered secret prior art as well as of post-filing evidence of § 112 failure[439]—possible, to be sure, though perhaps not particularly common.[440] Finally, given the rigor of the initial PTO review, validity could even in principle only be raised as a defense in litigation, and no IPR- or

433 *See supra* notes 72–82 and accompanying text.

434 *See* Benjamin & Rai, *supra* note 52, at 328.

435 *See generally* Laser, *supra* note 83.

436 *Cf.* Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628, 631 (2019).

437 *See id.*; *see also, e.g.*, *In re* Hall, 781 F.2d 897, 899–900 (Fed. Cir. 1986). Of course, the minimal or "theoretical" public accessibility standard of novelty works against the patentees, not defendants. The quiet title standard turns the tables by making defendants argue for near-impossibility of finding the relevant prior art the first time validity was adjudicated. While there is a paradox here—the proposal allows for litigation-stage invalidation by art that may not really be in possession of the public—the approach can be justified by the notion that the "secret" is often the patentee's own. *See generally* Karshtedt, *supra* note 193. In this sense, the approach halts the patentees' attempts to "extend" the patent term even in cases the nondisclosure of prior art was not fraudulent.

438 Under the proposed quiet title approach, prior art that is cumulative of that considered during the pre-grant opposition would also be prohibited in litigation even if shown to be inaccessible.

439 *See, e.g.*, Sprint Commc'ns Co. v. Charter Commc'ns, Inc., No. 17-cv-01734, 2019 WL 1082067, at *4 (D. Del. Mar. 7, 2019); *see also* Sean B. Seymore, *Patenting Around Failure*, 166 U. Pa. L. Rev. 1139, 1141–42 (2018) (similar); Sherkow, *supra* note 96, at 882.

440 *Cf.* Freilich, *supra* note 173, at 77; Yelderman, *supra* note 55, at 1275.

PGR-type proceedings will be available for the gold-plated pharmaceutical patents.[441]

The second question is who should be precluded, and the relevant categories here are those entities who were actually involved in the adversarial proceeding, those who could have joined the examination but did not, and those parties who were not even in existence at the time of examination. While the first two groups are easy targets for estoppel, which would provide a powerful stick for generics to participate in the system in addition to the exclusivity carrot,[442] the third often gives policymakers pause. Indeed, the strong forms of gold-plating run into pushback especially when it comes to applying it against entities who invented the patented subject matter after issuance and without any awareness of the patent.[443] In the small-molecule pharma context, though, this category is probably not significant. New generic firms often come into existence, to be sure, but the inventing is generally not independent in this field as far as generics are concerned. At best, follow-on innovators might modify the branded formulation somewhat in pursuit of a so-called "paper NDA" or other forms of design-around within the strictures of the FDA's requirements,[444] but usually, the competitor makes and sells a product under an ANDA, which essentially mandates copies of branded drugs.[445] Thus, estoppel of entities not in existence at the time of the opposition process would probably not chill follow-on innovation as a general matter, and the public interest in cheaper drugs can be vindicated through the challenges by existing generics. The estoppel will, accordingly, apply broadly to all parties.

One additional legal objection here is that preclusion of entities who were not parties to a prior judgment can generally raise due process concerns based on the apparent unfairness of binding those who did not have an opportunity to litigate the initial case.[446] Nevertheless, such an objection only lies because, as things stand now, invalidity is a statutory defense to a patent claim of which the accused infringer would be unfairly deprived by nonparty preclusion. If invalidity is no longer a full defense under the Patent Act, then there is no longer a due process complaint the defendant can make. Moreover, the proposed

441 For an early work proposing a quiet title-type approach, see Max L. Lieberman & George R. Nelson, *In Rem Validity—A Two-Sided Coin*, 53 J. Pat. Off. Soc'y 9, 36 (1971).

442 *See supra* notes 401–12 and accompanying text.

443 *See, e.g.*, Lichtman & Lemley, *supra* note 117, at 55.

444 *See* Darrow et al., *supra* note 174, at 403 (discussing follow-on "paper NDA" filings under § 505(b)(2)).

445 *See* Freilich, *supra* note 173, at 69–70.

446 *See* Parklane Hosiery Co. v. Shore, 439 U.S. 322, 327 n.7 (1979).

generous standing requirements allow for broad public participation in the process, thus increasing the potential for some vindication of rights of future entrants at the examination stage. To be sure, if *no one* chose to challenge the application even after it was exposed to adversarial examination, only those parties who could have challenged the patents, but did not , are to be precluded—and any truly new entities, as long as formed in good faith, could challenge the patents that have not undergone the rigorous process proposed here.

b. Infringement Litigation

After such a comprehensive PTO proceeding, the role that remains for trial courts when a gold-plated patent makes it out of the agency is limited. Of course, district judges would need to decide whether the proposed forms of estoppel apply to the defendant's validity challenge under the framework outlined above, but the focus of the litigation would be infringement. Allowing Article III tribunals to resolve this aspect of the patent case is arguably constitutionally mandated,[447] and regardless, the PTO has never been tasked with determining infringement or otherwise attempted to develop expertise in this aspect of patent law.[448] While resolution of liability issues at the PTO can perhaps be envisioned, taking charge of this aspect of patent cases would go significantly beyond the agency's core competence and historical role. Accordingly, assuming validity issues cannot be raised, a district court would conduct a trial based on the assertion of infringement of the patent against the generics' ANDAs. If the brand has nonpatent exclusivity in addition to the patent, the infringement case can begin sometime before the expiration of the period so that the generic can be ready to enter the market in case of a noninfringement judgment.[449]

During the case, the court's role will be simplified by the prior PTO process in a significant way. For example, the claim construction would be determined earlier and the *Markman* hearing would generally be unnecessary.[450] While courts must sometimes clarify or "construe" a

447 *Cf.* Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1379 (2018).

448 *But see* Goodman, *supra* note 323, at 842–43, 845–46.

449 *See* Darrow et al., *supra* note 310, at 254–56 (discussing nonpatent exclusivities in the pharmaceutical context).

450 Indeed, both sides would be estopped from rearguing claim construction under this Article's proposal. *But see* Panduit Corp. v. Corning Inc., No. 18-CV-229, 2021 U.S. Dist. LEXIS 124157, at *1–3 (E.D.N.C. July 2, 2021) (allowing reargument of a claim construction to contravene the PTAB's contrary construction).

construction,[451] such secondary proceedings are not expected to be frequent or particularly complex in this area of technology.[452] In addition, brand-generic cases often end up in bench trials,[453] thus obviating the need for jury instructions derived from the claim interpretation. Therefore, it remains for the court to decide whether the ANDA product infringes the claims literally or under the so-called doctrine of equivalents, which allows patents to reach products that are outside the claims' literal scope.[454] Given the close similarity between brand and generic products required under the FDA's regulatory framework,[455] the case for infringement is often easy for the plaintiff to win, and sometimes even stipulated, with validity taking up most resources in litigation under the current regime.[456] While I am not suggesting that a speedy resolution of infringement issues is always the case in Hatch-Waxman litigation, the nature of the issues does often lend itself to summary adjudication even if a stipulation is not on the table.[457]

4. Nonpatent Exclusivity

What about the applicant? What if the new invention has some social value such that it is worth having as an option for the consumers on the market, but the underlying patent cannot quite clear the nonobviousness hurdle? Here, too, there is some useful precedent within the Hatch-Waxman scheme. In addition to the patent exclusivity, the FDA provides for a five-year exclusivity for new chemical entity drugs, regardless of whether there is a patent,[458] and a three-year exclusivity for approved products that do not embody new chemical entities but nonetheless constitute a novel product either under a so-called Supplemental New Drug Application or even an NDA.[459] These regulatory incentives will remain undisturbed by this Article's proposal, and any novel drug would qualify for this type of exclusivity to preserve

---

451 *See* Colleen Murphy, *Judges Are Abusing Their Authority to Determine Obviousness by Applying* KSR *Without Changing the Legal Standard of Review*, 79 U. Cin. L. Rev. 349, 365 (2010).

452 *See supra* note 317 and accompanying text.

453 Many of these cases lack claims for past damages, and as a result, the Seventh Amendment does not attach (and indeed 35 U.S.C. § 271(e)(4)(C) bars damages if there has been on commercial manufacture of the accused product).

454 *See supra* notes 162–64 and accompanying text.

455 *See* Karshtedt et al., *supra* note 161, at 68–69.

456 *See* Freilich, *supra* note 173, at 78, 94; *see also* Cohen et al., *supra* note 109, at 25 & n.55.

457 *See* Karshtedt et al., *supra* note 161, at 67 n.460.

458 *See* Darrow et. al., *supra* note 174, at 406, 410.

459 *See* Robin Feldman, *Regulatory Property: The New IP*, 40 Colum. J.L. & Arts 53, 72 (2016) (discussing data and market exclusivities).

incentives for incremental, but subpatentable, innovation.[460] In sum, thanks to these FDA-based incentives, even if the brands are not able to obtain patents under the proposed scheme, they would still be encouraged to market follow-on products under a shorter exclusivity period.[461] Of course, even the nonpatent exclusivity might support product-hopping behavior, but the exclusivity given to the winning generic to market the off-patent product could somewhat limit the desirability and effectiveness of this strategy.[462]

Although this Proposal's details are significant, it is important not to lose sight of the central features of the new scheme. At the examination stage, the adversarial process offers advantages for improving patent quality that other proposals do not share, and the gold-plating likewise sets this proposal apart. In all, it is the expert agency designed for the job that would become the principal arbiter of pharmaceutical patent validity while courts would assume their traditional reviewing role. These measures would improve the quality of these patents and stabilize these important rights.

Conclusion

As the patent system evolves, the irrational versus rational ignorance debate will surely continue. When it comes to pharmaceutical patents, however, perhaps the debate is unnecessary. All the relevant economic and social considerations suggest that the quality of their prosecution should be improved—and adversarial examination can help get us there in a way that is well-tailored to the unique nature of these patents.

460 *See* Hemphill & Lemley, *supra* note 16, at 337. Such exclusivities have long played an important role in creating incentives for innovation in the pharmaceutical space. *See* Thomas, *supra* note 155, at 43.

461 *See* Thomas, *supra* note 155, at 44.

462 In other words, the incentives to engage in product hopping are perhaps not as great in these circumstances, where the right is not as powerful. *Cf.* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 Notre Dame L. Rev. 167, 181 (2016) (explaining the roles of patents, generic substitution laws, and generics' business models in facilitating product hopping).