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EVERGREENING AT RISK

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I. INTRODUCTION

Suboxone, a drug manufactured by Indivior, could be the salvation of the nation's 2.5 million victims of the growing opioid epidemic.¹ However, only 30% of people who suffer from an opioid use disorder can afford the high cost of the medication, which has yearly sales of \$1.86 billion.² On June 15, 2018, armed with a newly obtained approval from the Food and Drug Administration ("FDA"), Dr. Reddy's Laboratories Ltd. announced its decision to launch a generic version of Suboxone while the drug was still under patent protection, which is not due to expire until 2023.³ Dr. Reddy's anticipated that its actions would trigger a patent infringement lawsuit by Indivior.

The decision to launch a competing version of Suboxone was firmly founded in Dr. Reddy's Laboratories Ltd.'s theory that Indivior's patent is invalid, or not infringed, and thus cannot serve to block generic entry. The decision by Dr. Reddy's to market a generic version for a branded product while still under patent protection is a chancy business bargain commonly known as an "at-risk launch."⁴ The success of such a bargain depends on the probabilistic nature of patent protection, which can only be settled by a final court decision.⁵ If, in the subsequent infringement litigation, the court sides with Dr. Reddy's to find the challenged patents invalid or not infringed, then the at-risk launch strategy would prove highly profitable: facing no competition from other generic entrants, Dr. Reddy's would be able to capture a significant market share and earn duopoly profits alongside Indivior.⁶

1. See *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, No. 17-7111 (KM) (CLW), 2018 WL 3496643 (D.N.J. July 20, 2018), *vacated and remanded*, 752 F. App'x 1024 (Fed. Cir. 2018).

2. *Id.*; see Dr. Reddy's Labs. Inc., *Dr. Reddy's Laboratories Announces USFDA Final Approval and Launch of Buprenorphine and Naloxone Sublingual Film in the U.S. Market*, PR NEWSWIRE (June 15, 2018, 12:00 PM), <https://www.prnewswire.com/news-releases/dr-reddys-laboratories-announces-usfda-final-approval-and-launch-of-buprenorphine-and-naloxone-sublingual-film-in-the-us-market-300667109.html> [https://perma.cc/8ZYN-R7EN]; *Dr. Reddy's Re-launches Generic Version of Suboxone in US Market*, THE PIONEER (Feb. 21, 2019), <https://www.dailypioneer.com/2019/business/dr-reddy-s-re-launches-generic-version-of-suboxone-in-us---market.html> [https://perma.cc/XR9B-2K8J] ("Suboxone had sales of around USD 1.86 billion in the US for the 12 months ended April 2018.").

3. See Dr. Reddy's Labs. Inc., *supra* note 2; see also Darshan Mehta, *Nomura Sees This as a Catalyst for Dr. Reddy's Despite the Risk*, BLOOMBERG QUINT (June 13, 2018, 2:44 PM), <https://www.bloomberquint.com/markets/nomura-sees-this-as-a-catalyst-for-dr-reddys-despite-the-risk> [https://perma.cc/Y6VU-9UZT].

4. See, e.g., Mehta, *supra* note 3; Viswanath Pilla, *Dr. Reddy's Gets USFDA Nod to Launch Generic Suboxone, Opts for "At-Risk" Launch*, MONEYCONTROL (June 15, 2018, 10:28 AM), <https://www.moneycontrol.com/news/business/companies/dr-reddys-gets-usfda-nod-to-launch-generic-suboxone-opts-for-at-risk-launch-2591861.html> [https://perma.cc/A2TT-HXWY].

5. See *infra* Section II.A.1.

6. See Andrew Dunn, *Court Opens Path for Dr. Reddy's to Launch Generic Suboxone*, BIOPHARMA DIVE (Nov. 21, 2018), <https://www.biopharmadive.com/news/court-opens-path-for-dr-reddys-to-launch-generic-suboxone/542775> [https://perma.cc/8ARW-Y75H].

However, if the litigation ends unfavorably for Dr. Reddy's and the patent is deemed valid and infringed, then Dr. Reddy's will lose all of its profits from the venturesome market entry along with additional significant losses.⁷ The outcome of the bargain by Dr. Reddy's has yet to be determined, but past experiences provide a cautionary tale. In 2013, for example, Teva Pharmaceutical Industries Ltd. lost their gamble with respect to the 2007 at-risk launch of the gastric acid disorder treatment Protonix.⁸ After a New Jersey federal judge affirmed a jury decision in 2010 finding Protonix's patent valid and enforceable, Teva agreed to pay Pfizer Inc. \$1.6 billion to settle the patent infringement lawsuit.⁹

It is not surprising, therefore, that generic manufacturers usually think long and hard before risking entry into the market to compete with a branded product that presumably has strong patent protection.¹⁰ Unlike the generic at-risk launchers, however, when brand-name manufacturers strategically aggregate and enforce multiple patents to burden generic entry — a practice commonly known as “evergreening” — they expect substantial value while facing no apparent risk.¹¹

As explained below, by leveraging the legal, regulatory, and economic idiosyncrasies of the prescription drug market, follow-on “improvement” patents — patents claiming features of a drug that was already subject to legal protection — allow brand-name manufacturers to strengthen and effectively prolong their drug monopolies. At the same time, brand-name manufacturers are not required to disgorge these monopoly profits if their patents are later found invalid.¹² Brand-

7. If found liable, Dr. Reddy's would have to compensate Indivior for the latter's lost profits, which are likely to exceed the former's own revenues. See *infra* text accompanying note 276. Moreover, Dr. Reddy's could face treble damages if the infringement is deemed willful. See 35 U.S.C. § 284 (2018).

8. See Tova Cohen, *Teva Launches Generic Protonix, Ups '07 EPS Forecast*, REUTERS (Dec. 24, 2007, 6:23 AM), <https://www.reuters.com/article/us-teva-protonix-idUSL2461155520071224> [<https://perma.cc/2LHY-UURP>]; Bill Donahue, *Pfizer Lands \$2.15B Settlement from Teva, Sun over Protonix*, LAW360 (June 12, 2013, 12:14 PM), <https://www.law360.com/articles/449432/pfizer-lands-2-15b-settlement-from-teva-sun-over-protonix> [<https://perma.cc/49FR-68P8>].

9. See Donahue, *supra* note 8; Carly Helfand, *Teva Loses \$2B Gamble on Generic of Pfizer's Protonix*, FIERCEPHARMA (June 12, 2013, 9:06 AM), <https://www.fiercepharma.com/legal/teva-loses-2b-gamble-on-generic-of-pfizer-s-protonix> [<https://perma.cc/GW97-3Y5H>].

10. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1609 (2006); Thomas Gryta, *Generic-Drug Firms Get Bolder*, WALL ST. J. (Feb. 6, 2008, 11:59 PM), <https://www.wsj.com/articles/SB120227504432347199> [<https://perma.cc/JF49-TDBB>]; Natasha Singer, *That Pill You Took? It May Well Be Theirs*, N.Y. TIMES (May 8, 2010), <https://www.nytimes.com/2010/05/09/business/09teva.html> [<https://perma.cc/LWL4-HU82>].

11. The value should be expected unless these evergreening practices include unlawful acts such as fraudulent procurement of patents or sham litigation. Even then, the benefits of evergreening may outweigh the costs of liability. See *infra* Section III.A.2.

12. See Tun-Jen Chiang, *The Upside-Down Inequitable Conduct Defense*, 107 NW. U. L. REV. 1243, 1284 (2013) (“[E]x post judicial invalidation does not place a patentee who obtained an invalid patent in the same position as if the patent never issued because the patentee

name manufacturers retain their profits even if they should have known or could have known (and sometimes even if they did know) that their follow-on improvement patents are invalid.¹³ Thus, brand-name manufacturers are incentivized to pursue and enforce such patents not based on their perceived (low) value, but based on the established (high) value of existing branded products. Unsurprisingly, the more profitable branded drugs are, the thicker the web of patents — many of them clearly dubious — that surrounds them.¹⁴

It is somewhat counterintuitive that private parties retain the value of a grant given by the government even after the mistake is revealed.¹⁵ Imagine, for example, that a mistaken grant of social security payments or an erroneously granted tax refund would not have to be disgorged to the government once the mistake has been discovered.¹⁶ After all, an invalidated patent is deemed *void ab initio* and thus, should never have been granted; therefore, the value obtained by its protection potentially constitutes unjust enrichment.¹⁷

is not required to disgorge monopoly profits”); Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 28 (“[T]he owners of invalid patents can capture supracompetitive profits . . . that they will never have to disgorge.”).

13. Without specific knowledge, there is no liability. See Chiang, *supra* note 12, at 1284; *infra* note 274 and accompanying text. Even with actual knowledge, bad faith may be cost-effective. See *infra* Section III.A.2.

14. Pharmaceutical overpatenting has grown in popularity with time. See Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 617–18 (2018). Compare Lisa L. Ouellette, *How Many Patents Does It Take to Make a Drug: Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 300 (2010) (“The average was nearly 3.5 patents per drug in 2005, with over five patents per drug for the best-selling pharmaceuticals”), and Julie Appleby & Jayne O’Donnell, *Consumers Pay as Drug Firms Fight over Generics*, USA TODAY (June 5, 2002, 11:32 PM), <https://usatoday30.usatoday.com/money/health/2002-06-06-generic-drugs.htm> [<https://perma.cc/ZFT7-SGGR>] (“The average number of patents on a drug has gone from two to 10 in the past two decades”), with I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 2 (2018) [hereinafter I-MAK REPORT], <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> [<https://perma.cc/9FH8-6VBS>] (finding that, across the twelve highest-grossing pharmaceuticals, “[t]here are 125 patent applications filed and 71 granted patents per drug”).

15. See Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 164 (2006) (“The government has a long-standing right to recover funds that have been erroneously granted to a private party.” (citing *United States v. Wurts*, 303 U.S. 414, 415 (1938))).

16. Cf. 26 U.S.C. § 6532(b) (2018) (allowing recovery of an erroneous tax refund); 42 U.S.C. § 404(a) (2018) (allowing recovery of mistaken overpayments).

17. Cf. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964) (emphasizing public governance of unpatented subject matter); *Virgin Atl. Airways Ltd. v. Zodiac Seats UK Ltd.* [2013] UKSC 46, [2014] AC 160 (appeal taken from Eng.) (“The revocation of the patent deprived the patentee of the rights, which the patent had bestowed on him as against the world; furthermore, it did so retrospectively. . . . [E]veryone was entitled to conduct their affairs as if the patent had never existed.”); Chiang, *supra* note 12, at 1285 n.163 (2013) (“Another way of thinking about this is that a patentee who obtained an invalid patent has breached his contract with society Society should then be entitled to rescission, including a disgorgement of interim payments.”).

While patent policy rejects imposing disgorgement in the usual case of patent invalidity for fear of undermining precious innovation incentives,¹⁸ this Article suggests that, in the unique context of follow-on pharmaceutical innovation, such enrichment may nevertheless be unjust. In the course of developing this fundamental insight, this article makes two major contributions to the existing literature.

First, Part II defines evergreening — an enigmatic concept that is often criticized as pejorative — as a problem of skewed overpatenting incentives. Because follow-on improvement patents can artificially strengthen and prolong market exclusivity for existing drugs, brand-name manufacturers' incentives to pursue such patents greatly exceed the social value and economic significance of such patents. This Part further develops an analytical model that expresses the evergreening phenomenon as a multilayered theory of patent leverage in a unique legal,¹⁹ regulatory,²⁰ and economic²¹ environment.

Drawing on this analysis, Section III.A critically evaluates and exposes the inadequacies of existing remedial policies under the regulatory, antitrust, and patent regimes. Then, Section III.B offers a novel evergreening at-risk approach to combat the evergreening epidemic. Under the suggested approach, the monopoly proceeds secured by invalid follow-on patents would be disgorged and vested as a bounty in favor of the first successful patent invalidator.²²

This approach has two appealing properties. First, the suggested approach would discourage brand-name manufacturers from enforcing follow-on patents but only if such patents are likely to be invalidated once challenged. Because a disgorgement-based regime is not punitive, incentives to enforce follow-on patents that are capable of withstanding an invalidation challenge, would remain.²³ Second, the suggested approach would mitigate the problem of “pay-for-delay” settlement agreements, where brand-name manufacturers pay generic manufacturers in return for dropping their challenges and staying out of the market.²⁴ Under the suggested regime, generic challengers would often benefit more from pursuing a validity challenge all the way to judgment

18. See *Troxel Mfg. Co. v. Schwinn Bicycle Co.*, 465 F.2d 1253, 1258 (1972) (“An even more serious consequence of requiring royalty refunds with respect to patents held to be invalid is that it would deter inventors from resorting to the patent system in the first instance.”).

19. See *infra* Section II.A.

20. See *infra* Section II.B.

21. See *infra* Section II.C.

22. See *infra* Section III.B.

23. See *infra* Section III.B.

24. See *infra* Section III.A.2; see also C. Scott Hemphill, *An Aggregate Approach to Anti-trust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 639 n.40 (2009) [hereinafter Hemphill, *An Aggregate Approach*]; Hemphill, *supra* note 10, at 1557.

rather than accepting a payment offered by the brand-name manufacturer in return for dropping that challenge.²⁵ After a comprehensive legal, economic, and institutional analysis of the suggested approach, this Article offers two policy prescriptions that would advance the main idea of the suggested proposal with no need for legislative reform. One approach would require courts to broaden patent owners' responsibilities concerning their patent validity and to enforce these heightened duties by imposing a disgorgement remedy directly or by accommodating third-party enforcement.²⁶ Another approach would require the courts either to condition the issuance of a preliminary injunction on a disgorgement of profits instead of confiscation of a damage-based bond or to accommodate restitutionary claims by third parties.²⁷ Both options are thoroughly and critically evaluated and are informed by comparative legal analysis.

II. DEFINING EVERGREENING: SKEWED OVERPATENTING INCENTIVES IN THE PHARMACEUTICAL INDUSTRY

Patent incentives are invaluable in the pharmaceutical industry to encourage investment in the risky and resource-intensive venture of discovering new drugs.²⁸ However, patent incentives are far less justified when they encourage the development of marginal improvements to existing drugs, a process that is less risky and less costly than the

25. See *infra* Section III.B.

26. See *infra* Section III.B.2.a.

27. See *infra* Section III.B.2.b.

28. See, e.g., JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 88–89 (Princeton Univ. Press 2008) (noting that patents are especially important in the pharmaceutical industry); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 40–41 (Princeton Univ. Press 2004); Jay P. Kesan, *Transferring Innovation*, 77 *FORDHAM L. REV.* 2169, 2195 (2009) (noting that patents are not important for technology transfer in most fields other than pharmaceuticals and biotechnology); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 *BROOKINGS PAPERS ON ECON. ACTIVITY* 783, 796–97, 824 (“In only one industry, drugs, were product patents regarded by a majority of respondents as strictly more effective than other means of appropriation.”); Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 23, 32 tbl.1 (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000), <https://www.nber.org/papers/w7552.pdf> [<https://perma.cc/6HSS-AJZU>] (finding that pharmaceutical industry was one of the few places “where patents are effective”).

search for new pharmaceuticals.²⁹ Some of these improvements, or follow-on patents, cover trivial innovative advances of negligible therapeutic value to patients.³⁰

In a well-functioning patent system, such patents would not be pursued. Profit-maximizing entities value patents for inventions that have a strong market demand and that are not easily substitutable.³¹ Easily circumvented patents would not provide their owners with substantial market power, let alone monopoly power, and thus would be economically insignificant.³² Profit-maximizing entities would not pursue economically insignificant patents because the expected gains from market exclusivity in such cases would likely be dwarfed by the expected costs of patent procurement, maintenance, and most significantly, assertion.³³ In this manner, patent policy directs corporate resources toward economically significant inventions and away from negligible improvements.³⁴

29. See C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 337 (2012) (suggesting without taking a stand that “[i]f ‘low quality’ patents are on innovations that do not require costly R&D (e.g., obvious changes to the drug) their elimination may not meaningfully affect R&D incentives”); Sandeep K. Rathod, *Ever-greening: A Status Check in Selected Countries*, 7 J. GENERIC MED. 227, 228 (2010) (“Although creating a successful new product from the scratch is a lot of effort, adding minor variations on an existing successful product is less resource intensive and a much more certain way to protect revenues.”).

30. See *infra* Section II.C.2. This is not to say that all follow-on patents are necessarily unjustified. Just like in any other field of innovation, follow-on patents can cover meaningful improvements and improve patient’s welfare. It is not always easy to tell whether improvement pharmaceutical patents have true innovative merit or whether they are strategically procured as part of a nefarious strategy to impair generic competition. One useful indication, however, is timing — improvement patents are far more likely to impose substantial anticompetitive concerns when they are obtained right before generic competition is expected to ensue and direct sales away from the branded product.

31. While the market value of an invention is not necessarily indicative of its social value, see Robert D. Cooter & Uri Y. Hacothen, *Progress in the Useful Arts: Foundations of Patent Law in Growth Economics*, 23 YALE J.L. & TECH. 191 (2020), the patent system was nevertheless founded upon the premise that “competition is a better spur to new ideas than government mandate,” Mark A. Lemley, *Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 995 n.24 (1997).

32. Indeed, patents do not automatically confer market power. See, e.g., HERBERT HOVENKAMP, *ECONOMICS AND FEDERAL ANTITRUST LAW* § 8.3, at 219 (West, 1985); Mark A. Lemley, Comment, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CALIF. L. REV. 1599, 1626 (1990); Russell Lombardy, Comment, *The Myth of Market Power: Why Market Power Should Not Be Presumed when Applying Antitrust Principles to the Analysis of Tying Agreements Involving Intellectual Property*, 8 ST. THOMAS L. REV. 449, 453 (1996); William Montgomery, Note, *The Presumption of Economic Power for Patented and Copyrighted Products in Tying Arrangements*, 85 COLUM. L. REV. 1140, 1156 (1985).

33. See, e.g., Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1526 (2005) (finding that more than 50% of the patents that are issued are abandoned for failure to pay maintenance fees).

34. See Cooter & Hacothen, *supra* note 31, at 4 n.2 (explaining that the rules and doctrines of patent policy are designed to encourage economically significant inventions).

This logic is turned on its head in the pharmaceutical industry. In this industry, patents of negligible market value are sometimes disproportionately rewarded by allowing brand-name manufacturers to artificially extend their monopolies over existing drugs when their current legal protections are about to expire. This phenomenon, known pejoratively as evergreening (also called stockpiling, layering, clustering, lifecycle management, or line extension), has severely skewed the patenting incentives for follow-on pharmaceutical inventions.³⁵ In the pharmaceutical industry, incentives to pursue new patents are dictated not by the expected value of the *new* inventions, but by the well-established market value of *old* inventions that should no longer be legally protected.³⁶ Unsurprisingly, the most profitable drugs are also the most patented ones.³⁷ The market value for the anti-inflammatory biologic drug Humira, for example, is worth close to \$40 million a day to AbbVie, its brand-name manufacturer.³⁸ As of 2017, AbbVie filed 247 patent applications related to Humira;³⁹ over 100 of which have already been issued.⁴⁰ If unchallenged, the combined legal protection provided by these patents would reach until 2034, over three decades since the

35. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348–49 (2007); Thomas Alured Faunce, *Global Intellectual Property Protection of “Innovative” Pharmaceuticals*, in GLOBALIZATION AND HEALTH: CHALLENGES FOR HEALTH LAW AND BIOETHICS 87, 91 (Belinda Bennett & George F. Tomossy eds., 2006); Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 30 (2005); Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J.L. & MED. 125, 136 (2008); Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law’s Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106 (2008); Rathod, *supra* note 29, at 227.

36. Brand-name manufacturers’ motivation to sustain market exclusivity carries beyond evergreening to other strategies such as launching “authorized generics” to siphon profits from competing generic manufactures, limiting competitors’ access to drug samples, and filing sham citizen petitions to the FDA. See, e.g., ROBIN FELDMAN & EVAN FRONDORF, *DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET* 113–36 (2017); *The Law on Damages in Generic Drug Launches Remains Vague*, AM. CONF. INST. (Apr. 10, 2014), <https://www.americanconference.com/blog/the-law-on-damages-in-generic-drug-launches-remains-vague> [<https://perma.cc/DAG2-WL6V>] (“Branded companies sometimes respond to an at-risk launch by selling an ‘authorized generic’ version of the drug, competing with the infringing generic product on somewhat even grounds, and mitigating loss to some degree.”).

37. See, e.g., *supra* note 10.

38. In 2016, Humira’s manufacturer, AbbVie, generated more than \$13.6 billion in Humira sales. See Marcia Frellick, *Humira Again Top-Selling Drug in U.S.*, WEBMD (Oct. 3, 2017), <https://www.webmd.com/drug-medication/news/20171003/humira-again-top-selling-drug-in-us> [<https://perma.cc/98AV-28ZN>]. While innovation policy in the biologic drug sphere suffers from similar pathologies as those introduced in this article, the analysis and policy prescriptions discussed here would focus on chemical pharmaceuticals.

39. See I-MAK REPORT, *supra* note 14, at 3.

40. See Class Action Complaint at 4, UFCW Local 1500 Welfare Fund v. AbbVie Inc., No. 1:19-cv-01873 (N.D. Ill. Mar. 18, 2019).

drug was launched and nearly two decades after the lead patent for the drug has expired.⁴¹

Proponents of the existing system assert that even if follow-on patents do prolong exclusivity for existing drugs, there is little reason to complain. In their view, any additional exclusivity provided by the new patents rightfully complements preexisting legal protections for the old drug, which is grossly insufficient to account for the costly and uncertain process of pharmaceutical development.⁴² While it may be true that in some cases legal protections for drugs should be stronger,⁴³ the practice of evergreening is nevertheless extremely difficult to justify. Evergreening is an outrageously wasteful method for strengthening legal protections for drugs. It redirects corporate funds away from socially desirable research and development and toward excessive advertising and pointless legal crusades.⁴⁴ It also misleads consumers and unnecessarily complicates the already chaotic health market.⁴⁵ Most importantly, evergreening allows the government to grant an arbitrary extension of a monopoly without sufficient oversight or control.⁴⁶

While evergreening has recently grown in popularity, the phenomenon is grossly undertheorized and poorly understood.⁴⁷ Some critics argue that the term is inappropriate and misleading overall because new patents cannot simply extend the legal protections that were provided by expired patents.⁴⁸ Other critics accept that overpatenting may have

41. *See id.* at 3.

42. *See* Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275, 300 (2008) (“[I]nnovators argue that effective patent life-cycle management is critical to maintaining the innovation industry.”); Hemphill & Sampat, *supra* note 29, at 337.

43. *See, e.g.*, Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2045 (2015) (showing insufficient incentives for long-term research).

44. *See infra* notes 150, 206–210 and accompanying text.

45. *See infra* notes 206–210 and accompanying text.

46. A better approach to providing stronger legal protection for valuable drugs is through designated regulatory exclusivities. *See* Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 64 (2016). Another approach is to provide longer terms of protection for pharmaceutical patents. *See* Cooter & Hacothen, *supra* note 31, at 214 (discussing optimal patent duration).

47. *See, e.g.*, CPIP Scholars Examine the Flaws in the Term “Evergreening,” CTR. FOR PROT. INTELL. PROP. (May 1, 2018), <https://cpip.gmu.edu/2018/05/01/cpip-scholars-examine-the-flaws-in-the-term-evergreening> [<https://perma.cc/CL7L-SEVE>] (“[A] consistent and coherent definition of ‘evergreening’ does not appear to exist.”).

48. *See, e.g.*, JOHN R. THOMAS, CONG. RES. SERV., R40917, PATENT “EVERGREENING”: ISSUES IN INNOVATION AND COMPETITION 9 (2009) (“Industry experts further observe that patents on improvement inventions may not block competitors from marketing competing products that were covered by patents that have expired.”); GLAXOSMITHKLINE, GSK PUBLIC POLICY POSITIONS: EVERGREENING (2019), <https://www.gsk.com/media/2949/evergreening-policy.pdf> [<https://perma.cc/29R6-YZVN>]; Kevin Madigan & Sean O’Connor, “No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain, CTR. FOR PROT. INTELL. PROP. (June 27, 2019), <https://cpip.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain> [<https://perma.cc/MAY6-4BX5>].

an undesirable social impact but refuse to accept that such practices are in any way confined to the pharmaceutical industry.⁴⁹ These commentators often assert that the discussion over evergreening has targeted pharmaceuticals solely for political reasons, some of which are related to the continuing public debate over the cost of health care.⁵⁰

Finally, even commentators that accept that evergreening as endemic to the pharmaceutical industry often have different types of abusive practices and different theories of patent leverage in mind when they apply the term.⁵¹ This portion of the article eschews these confused conceptions by offering a unified theory of evergreening. Specifically, this Part elucidates three practices that empower brand-name manufacturers to extend monopolies for their drugs: patent thickening, patent listing, and product hopping. While analytically distinct, all three practices have been defined by various authors as synonymous with the term evergreening. This Part explores these practices and identifies the complex relationships and mutual dependencies between them.

Section II.A discusses patent thickening (also known as “clustering” or “flooding”),⁵² the most basic practice of pharmaceutical evergreening. By constructing a dense thicket of multiple patents (some of

49. See, e.g., Robin Jacob, *Patents and Pharmaceuticals: A Paper Given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-Sector Inquiry*, in 12 INTELLECTUAL PROPERTY LAW AND POLICY 233, 235 (Hugh C Hansen ed., 2013) (“[A]ny experienced patent lawyer will tell you that clusters of improvement patents are a feature of nearly all industries.”).

50. See THOMAS, *supra* note 48, at 4.

51. See, e.g., Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping*, 62 FLA. L. REV. 1009, 1016 (“The new dimension revealed in this Article is ‘product hopping.’ This activity (also known as ‘evergreening’ or ‘line extension’) refers to a drug company’s reformulation of its product.”); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug, Incentives, and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 948, 959 (2011) (also discussing the sequential thirty-month stay practice as evergreening); Aaron S. Kesselheim, *Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System*, 9 AAPS J., E306, E308 (2007) (patenting of nonessential features of products); Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 82 (2004) (“[A] pharmaceutical company could obtain not one, but many sequential thirty-month stays. This practice is known as ‘evergreening.’”); Mueller & Chisum, *supra* note 35, at 1106 (defining “evergreening” as “obtaining related patents on modified forms of the same drug”). The term is also confused in the empirical literature. Compare Feldman, *supra* note 14 (measuring the impact of evergreening by investigating Orange Book listings), and Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE, Dec. 2012, at 1, 2 (2012) (same), with I-MAK REPORT, *supra* note 14, at 5 (not considering Orange Book listing as a limiting measurement factor), and Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 HEALTH AFF. 2286, 2291 (2012) (mentioning that “[o]f the 108 patents we identified relating to ritonavir, lopinavir, and lopinavir/ritonavir, only 20 are currently listed in the Orange Book.”).

52. See European Comm’n Directorate-General for Competition, *Pharmaceutical Sector Inquiry: Final Report*, at 184 (July 8, 2009), <http://ec.europa.eu/competition/sectors/>

them weak or even dubious) around a single drug, brand-name manufacturers increase the costs and risks associated with generic entry. For example, when the FDA first approved Thalomid for treating leprosy in 1998, Celgene could not patent the active ingredient, thalidomide, because the substance had already been known for decades.⁵³ Instead, Celgene secured multiple patents related to Thalomid's risk evaluation and mitigation system ("REMS").⁵⁴ REMS are distribution plans required by the FDA for potentially dangerous drugs.⁵⁵ While the validity of Celgene's REMS patents was heavily disputed,⁵⁶ their existence alone provided the manufacturer with a viable threat to initiate costly, lengthy, and uncertain multipatent infringement lawsuits against generic entrants.⁵⁷

Section II.B discusses the practice of patent listing. This practice builds on the existence of patent thickets, but an additional element is added — patents are also listed in the FDA's database, commonly known as the Orange Book. The act of regulatory listing carries with it a bundle of privileges and obligations that might be leveraged by brand-name manufacturers to prolong their market exclusivity beyond the

pharmaceuticals/inquiry/staff_working_paper_part1.pdf [https://perma.cc/98A3-XV9P] (discussing "patent clusters"); Mattias Ganslandt, *Intellectual Property Rights and Competition Policy* 12 (IFN Working Paper No. 726, 2008) (discussing "patent floods").

53. The active ingredient in Thalomid, thalidomide, was originally marketed in Europe in the late 1950s to treat various maladies but was later abandoned for being extremely dangerous for fetuses. For the horrific story of the thalidomide babies, see, for example, Scott Hensley, *Thalidomide Maker Apologizes After More Than 50 Years*, NPR (Aug. 31, 2012, 4:27 PM), <https://www.npr.org/sections/health-shots/2012/08/31/160391482/maker-of-thalidomide-apologizes-after-more-than-50-years> [https://perma.cc/NNN8-4LMG].

54. See Class Plaintiff's Memorandum in Support of Motion for Class Certification and Appointment of Class Counsel at 8, *In re Thalomid & Revlimid Litig.*, No. 14-6997 (MCA) (MAH) (D.N.J. Oct. 3, 2017) [hereinafter Class Action Support] ("Celgene filed for and obtained . . . fourteen patents on its REMS program.").

55. See generally FDA, THALOMID (THALIDOMIDE) NDA # 020785: RISK EVALUATION AND MITIGATION STRATEGY (REMS) (2014), <https://www.fda.gov/media/79047/download> [https://perma.cc/M9F5-3Y4Q].

56. See, e.g., Class Action Complaint at 44–46, *Int'l Union of Bricklayers v. Celgene Corp.*, No. 2:14-cv-06997-KSH-CLW (D.N.J. Nov. 7, 2014).

57. See, e.g., Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018, 5:00 AM), <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away> [https://perma.cc/GZ4B-WBE4] ("Under FDA rules, if a generic drugmaker wants to market thalidomide, it has to use the same REMS system as Celgene's. That means it would have to negotiate a deal with Celgene, sue to invalidate those patents or wait for them to expire."). In this case, the exclusionary power of Celgene's REMS went beyond the usual thicket leveraging theory because it allowed Celgene to deny access to drug samples and thus to frustrate generic manufacturers' efforts to prove bioequivalence, which is required to obtain regulatory approval. See Andrew Dunn, *CREATES Act Looks Likely to Pass in Congress, Policy Analyst Predicts*, BIOPHARMA DIVE (Nov. 28, 2018), <https://www.biopharmadive.com/news/congress-creates-act-generic-branded-samples/543147> [https://perma.cc/L8ED-D97Q]; see also Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661 (2017) (explaining the heightened exclusionary power that REM patents provide brand-name manufacturers and proposing various solutions to the REM patent problem).

thicket leverage theory. For example, by listing its Thalomid-related patents in the Orange Book, Celgene was able to enjoy two and a half years of market exclusivity by operation of the regulatory regime when the generic manufacturer Barr challenged its listed patents in 2006.⁵⁸

Finally, Section II.C discusses the practice of product hopping. This practice builds on the previous two practices in the sense that patents are both procured from the U.S. Patent and Trademark Office (“USPTO”) and listed in the Orange Book, but an additional third element is required — these patents relate not to the original marketed drug but to a newer, reformulated version of the drug that is now marketed separately. With strategic reformulation and boosted advertising, brand-name manufacturers leverage the dysfunctional health care market to switch consumers between similarly effective drugs. These manufacturers then are given a renewed opportunity to enjoy the strategic benefits of patent thickening and listing.⁵⁹ For example, in the case of Thalomid, Celgene enjoyed two and one half years of uninterrupted market exclusivity provided by the listing regime to switch patients from Thalomid to a newly introduced product — Revlimid.⁶⁰ With Revlimid in hand, Celgene followed its standard playbook discussed above. It constructed an impenetrable patent thicket around Revlimid by filing well over one hundred patent applications for the drug.⁶¹ It also listed twenty-seven of the Revlimid patents in the Orange Book to reap further strategic advantages such as more years of uninterrupted

58. There are at least two theories of regulatory abuse through patent listing at work here. First, to the extent that Celgene’s REMS patents are exceptionally weak (and/or fraudulently obtained), it follows that it listed solely to facilitate sham litigation and delays. See Class Action Complaint, *supra* note 56, ¶ 215; *infra* notes 150–152 and accompanying text. Second, Celgene listed its REMS patents as “product” patents instead of “method-of-use” patents particularly to deny generic manufacturers of the opportunity to file for a “skinny label” application. See Class Action Complaint, *supra* note 56, ¶¶ 34–37, 218; *infra* note 175 and accompanying text.

59. See *infra* text accompanying notes 240–242 (discussing the role of patents in the product hopping operation).

60. See Class Action Support, *supra* note 54, at 23; *infra* Section II.C. The market switch from Thalomid to Revlimid is not a classic product hop because the new formulation is allegedly therapeutically superior. See, e.g., Francesca Gay et al., *Lenalidomide plus Dexamethasone Versus Thalidomide plus Dexamethasone in Newly Diagnosed Multiple Myeloma: A Comparative Analysis of 411 Patients*, 115 BLOOD 1343, 1343–50 (2010). But see, e.g., Class Action Support, *supra* note 54, at 11–12 (claiming that Revlimid is “a virtual Clone of Thalomid” and citing Celgene’s own description of Revlimid as a “thalidomide analogue” with “structural similarity” to thalidomide).

61. I-MAK, AMERICA’S OVERSPEND: HOW THE PHARMACEUTICAL PATENT PROBLEM IS FUELING HIGH DRUG PRICES 3 (2017), http://www.i-mak.org/wp-content/uploads/2017/10/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf [https://perma.cc/AE5L-8NGK] (“[T]he combined patent protection for these drugs is potentially set to expire at the end of 2036, giving Celgene’s Revlimid® patent portfolio a lifespan of at least 40 years.”).

exclusivity⁶² and a significant clout when negotiating with generic manufactures over delaying market entry.⁶³

Figure 1 visualizes the relationship between the three evergreening practices as a three-level pyramidal staircase. Patent thickening is located at the base of the pyramid, as it is the most basic practice. Patent listing appears above it, as it adds the element of Orange Book registration. Finally, product hopping is located at the top, as it requires an additional layer of product reformulation and market switching. While the practices work best in combination, as in the case of Thalomid/Revlimid, they are analytically distinct and brand-name manufacturers can utilize them independently.

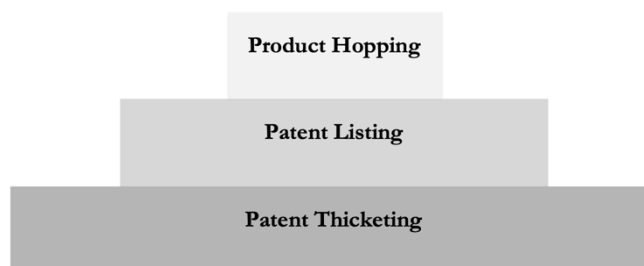


Figure 1: Hierarchy Among the Three Evergreening Practices

The three Sections below describe these practices. The first part of each Section explores the fundamental pathologies of the legal, regulatory, or economic environment that are then leveraged through patent protection. Building on this background, a separate part in each Section emphasizes the role of patents and their capacity to strengthen or prolong market exclusivity for branded drugs.

A. Patent Thickening

Under the most simplified definition, evergreening means a strategic accumulation of patents to create a thicket capable of burdening and potentially blocking generic competition.⁶⁴ Because patents are of

62. See, e.g., *Celgene Corp. v. Dr. Reddy's Labs., Inc.* No. 2:16-cv-07704 (D.N.J. Oct. 20, 2016) (holding that Celgene secured a 30-month statutory stay as part of its infringement lawsuit against Dr. Reddy's).

63. See Class Action Complaint, *supra* note 56, at 11 (stating that Celgene's position is weak, and would likely lose an infringement claim brought against generic manufacturer Natco).

64. Cf. ROBIN JACOB, *IP AND OTHER THINGS: A COLLECTION OF ESSAYS AND SPEECHES* 263–64 (2015) (describing follow-on patents as monopolies that are “kept alive after the patent has come to an end . . . by patenting large numbers of minor improvements to the original

questionable validity and uncertain scope, it is impossible to know for sure the extent of their permissible exclusion without investing in costly and lengthy litigation. Thus, by accumulating multiple probabilistic patents, brand-name manufacturers strategically raise the costs and risks associated with generic entry and maintain monopoly power.

Section II.A.1 explores the legal environment that gives rise to probabilistic patents generally. Section II.A.2 argues that because patent owners gain a strategic advantage by imposing uncertainty costs on patent users, they are encouraged to increase these costs by securing multiple patents. The discussion begins by distinguishing patent thickening in the pharmaceutical industry from the more rigorously explored patent thickening pathology that takes place in the information technology (IT) sector. The discussion then explores specific types of pharmaceutical patenting practices that are often criticized as opportunistic thickening.

1. Legal Environment

The patent examination process at the USPTO is notoriously insufficient. The office spends, on average, only eighteen hours across a two-to three-year period examining each patent application they receive.⁶⁵ This time frame is hardly sufficient to review complex patent applications, especially in the pharmaceutical field where patents may contain hundreds of claims. Additional resources that were invested in the USPTO in recent years were offset by the increasing workload and did little to alleviate the situation. Indeed, although the number of patent examiners has doubled since 2005, the number of patents approved in a year has doubled as well, rising to over 300,000 new patents in the fiscal year ending August of 2017.⁶⁶

More substantially, examiners' motivations to reject overbroad patent claims are greatly undermined by zealous prosecution by brand-name manufacturers and pro-applicant procedural rules. For example, patent applicants are not required to justify their broad claims, nor are they limited in the number of claims or claim adjustments they can make.⁶⁷ Instead, it is the examiner's duty to detect unjustifiably broad claims based on the available information and to strike them down as

invention," deterring competition until a courageous competitor skillfully "design[s] around" the patent).

65. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 (2001).

66. See Feldman, *supra* note 14, at 600.

67. See *infra* Section II.A.2 (discussing the continuations practice).

overbroad.⁶⁸ In a similar vein, patent applicants have no duty to uncover information material to the patentability of their claims, even if readily accessible to them.⁶⁹ As suggested below (see Section II.A.2), these rules may be abused by brand-name manufacturers.

For these reasons, many patents issued by the USPTO are of questionable validity and uncertain scope, or probabilistic — they confer a right *to try to exclude* rather than a right to exclude.⁷⁰ The inadequacy of ex ante examination by the USPTO could potentially be remedied by ex post scrutiny by the courts.⁷¹ Unfortunately, the incentives to challenge and litigate patents are severely skewed.⁷² First, pharmaceutical patent litigation is notoriously risky, lengthy, and resource-intensive.⁷³ These costs and risks alone are sometimes sufficient to deter generic manufacturers from pursuing patent challenges.⁷⁴ Second, the payoffs associated with a favorable court decision diverge substantially between the two litigating parties.⁷⁵ Because brand-name manufacturers' expected monopoly profits dwarf generic manufacturers' expected competitive profits, the former has substantially more to lose than the

68. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 848–49 (1990) (“The rule puts the burden of *disproving* enablement on the examiner.”); see also Tun-Jen Chiang, *Forcing Patent Claims*, 113 MICH. L. REV. 513, 557–58 (2015) (arguing that self-drafting forces patentees to disclose part of the value of their claims, while contesting overbroad claims); Lemley & Moore, *supra* note 51, at 74–75.

69. Suggestions to impose affirmative duties on patent applicants to recover prior art or to submit to the USPTO relevancy statements were considered before but rejected for the fear that such obligations would make the prosecution process too costly. See, e.g., FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 11–12 (2003), <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> [<https://perma.cc/U98X-F9RF>] (recommending against an affirmative duty); Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 780–81 (2009) (against imposing a general duty).

70. See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 75 (2005); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 667–68 (2002) (“[E]valuation of a patent may be so poor or hurried as to be near meaningless.”); see also Peter S. Menell & Michael J. Meurer, *Notice Failure and Notice Externalities*, 5 J. LEGAL ANALYSIS 1, 3–4 (2013).

71. See Lemley, *supra* note 65, at 1500 (“[I]n litigated cases that actually resulted in a final judgement on validity, issued patents are held invalid forty-six percent of the time.”).

72. See generally Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won’t Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 946, 948–50 (2004).

73. A Paragraph IV challenge can easily reach \$10 million or more. See, e.g., Annie Gowen, Comment, *Saving Federal Settlement Privilege After Actavis*, 83 U. CHI. L. REV. 1505, 1510 (2016); Hemphill & Lemley, *supra* note 51, at 952.

74. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073–74 (11th Cir. 2005) (“It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation.”); see also Lemley, *supra* note 65, at 1501; Lemley & Shapiro, *supra* note 70, at 75 (“[O]nly 1.5 percent of patents are ever litigated.”).

75. See Farrell & Merges, *supra* note 72, at 951 (“In many cases where each party’s respective incentive is expressed by the difference in its profits between winning and losing, a patentee’s incentive to defend its patent grossly exceeds an alleged infringer’s incentive to challenge it.”).

latter has to gain. For example, the brand name of Simvastatin, which treats high cholesterol, can cost \$150 for 30 tablets, while the generic version of the drug can cost as little as \$7 for the same quantity.⁷⁶ This environment nurtures collusive pay-for-delay settlement agreements wherein brand-name manufacturers pay generic manufacturers to drop their challenges, leaving the patent's status unresolved.⁷⁷ Such pay-for-delay arrangements are most likely to be made for patents of the most questionable validity — the same patents that, from society's perspective, should be most closely scrutinized.⁷⁸

Finally, even for patents that are litigated to judgment, the incentives of generic challengers to invalidate dubious patents diverge from the social interest. While society would benefit from invalidation of unwarranted patents, generic challengers are incentivized to pursue non-infringement defenses rather than invalidity defenses.⁷⁹ Invalidity defenses are disfavored because they generate substantial positive externalities.⁸⁰ As Professor Scott Hemphill explains:

If a favorable judgment [finding invalidity] is the only impediment to entry, then potential challengers will face a serious free-rider problem. Not only will a firm fail to internalize the full benefits of its challenge, since others can use the judgment as well, but in addition, the gains will tend to be rapidly dissipated, as

76. See Hemphill & Lemley, *supra* note 51, at 952. This substantial price difference is the result of multiparty competition. Competition between a brand-name manufacturer and a single generic manufacturer in the presence of the statutory bounty would result only in a slight price reduction (about 10%). See Hemphill & Lemley, *supra* note 51, at 954 (“The FDA has estimated an average price discount of just 6 percent when there is only one generic manufacturer competing with the brand-name firm. In the case of Zocor, the difference in retail prices between the brand-name drug and the exclusive generic was about 10 percent.” (footnote omitted)); *infra* Section II.B.1.

77. See *infra* Section III.A.2.

78. See Gregory H. Jones et al., *Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1398 (2016) (summarizing the critical role of patent challengers “at the center of pay-for-delay settlements, with 1 study finding that (1) 89% of patents in settled litigation are ‘secondary patents’ . . . and (2) the brand firm is far less likely to win on these secondary patents (32%) than it is on active ingredient patents (92%).”).

79. See Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 71 (2013) (“The net effect of these trade-offs and asymmetries is that patent defendants often have an incentive to argue noninfringement instead of invalidity . . .”).

80. This is the result of the Supreme Court's decision in *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971), which established a defensive, nonmutual issue preclusion for patent invalidity. *Id.* at 349–50; see also Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 685 (2004).

other firms enter and compete away the benefits of the favorable judgment.⁸¹

The noninfringement defense gives generic challengers the same benefits (prompt market entry, for example) without needing to share this value with their competitors.⁸²

Recently, the introduction of the post-grant opposition proceedings under the Leahy-Smith America Invents Act, notably inter partes review (“IPR”),⁸³ had a mixed impact on these issues. On the one hand, IPRs substantially mitigated the first problem noted, namely, that litigation costs deter challenges.⁸⁴ On the other hand, IPRs potentially aggravate the second problem, namely, that the stark differences in payoffs between adversaries motivate parties to collude. A new “reverse-trolling” trend has emerged, fueled by relaxed standing and evidentiary requirements, in which unconventional patent challengers are fishing for lucrative settlement payments from brand-name manufacturers in exchange for dropping frivolous IPR charges.⁸⁵ Pending legislation is attempting to fix this.⁸⁶

To summarize, patent examination, reexamination, and litigation are all imperfect tools to cleanse invalid and overbroad patents, and the problem of probabilistic patents subsists. As discussed next, this legal environment empowers brand-name manufacturers to depress and prolong generic competition by securing multiple patents.

81. Hemphill, *supra* note 10, at 1605; *see also* Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 258 (2007); Miller, *supra* note 80, at 685; Gideon Parchomovsky & Alex Stein, *Intellectual Property Defenses*, 113 COLUM. L. REV. 1483, 1513 (2013); Ariel Porat, *Private Production of Public Goods: Liability for Unrequested Benefits*, 108 MICH. L. REV. 189 (2009).

82. *See* Hemphill, *supra* note 10, at 1606 (“[T]he noninfringement route pursued by the generic firm is not readily available to other firms . . .”); Miller, *supra* note 80, at 729.

83. Pub. L. No. 112-29, § 5, 125 Stat. 284, 299 (2011) (codified at 35 U.S.C. § 311 (2018)).

84. *Cf.* Sapna Kumar, *Standing Against Bad Patents*, 32 BERKELEY TECH. L.J. 87, 94 (2017) (comparing costs).

85. *See* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016); Kumar, *supra* note 84, at 119; *see, e.g.*, Adam L. Perlman & Kathryn S. Kayali, ‘Reverse’ Patent Trolling: Nontraditional Participants in the Inter Partes Review Process, WESTLAW J. PHARMACEUTICAL, Feb. 2017, at 1, 2, <https://www.wc.com/portalresource/lookup/poid/Z1tOI9NPluKPtDNlqLMRVPMQILsSwOZDmG3!/document> [<https://perma.cc/3UMT-Q2TM>]; *see also* Jacob Schindler, “Reverse Patent Trolls” Plague Big Pharma in China, IAM (Apr. 9, 2019), <https://www.iam-media.com/law-policy/reverse-patent-trolls-plague-big-pharma-in-china> [<https://perma.cc/546R-8V5N>].

86. *See, e.g.*, Hatch-Waxman Integrity Act of 2018, H.R. 7251, 115th Cong. (2018); *see also* Phillip S. Johnson, *Hatch Amendment Would Preserve Balanced Incentives for Pharmaceutical Innovation and Drug Affordability*, HEALTH AFF. (Nov. 9, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181106.217086/full> [<https://perma.cc/6W6D-HWP6>] (arguing in favor of the new legislation proposal).

2. Patent Leverage

Probabilistic patents impose uncertainty costs on the users of patented technology, which gives patent owners a strategic advantage. This strategic advantage plays out differently in different innovation industries. In the IT sector, for example, innovation is famously cumulative, and it advances incrementally by multiple entities.⁸⁷ In such industries, patent uncertainty provides patent owners with a strategic advantage by leveraging downstream companies' sunk costs in developing patented technology without knowing that such technology is, in fact, patented.⁸⁸

Because patents confer a right on the patent owner to seek an injunction that could shut down an entire business operation, patent owners can threaten greater harm when negotiating for a patent license after companies have invested resources in project development. At that point, patent owners could leverage developers' sunk costs to extract better licensing deals than are justified based on the contribution of their patented input to the overall project.⁸⁹ In 2001, for example, NTP Inc. sued Research in Motion ("RIM") alleging that RIM's BlackBerry device infringed its wireless email communications patents.⁹⁰ After prevailing in court and with an injunction threatening to shut down BlackBerry's business, NTP was able to force RIM into a \$612.5 million settlement agreement.⁹¹

Patent owners' chances of reaping greater rewards by leveraging the sunk costs of downstream developers increase the denser the patent

87. See, e.g., Peter S. Menell, *Tailoring Legal Protection for Computer Software*, 39 STAN. L. REV. 1329, 1338 (1986) (noting, with respect to software development, that "'secondary inventions' — including essential design improvements, refinements, and adaptations to a variety of uses — are often as crucial to the generation of social benefits as the initial discovery"); Carl Shapiro, *Navigating the Patent Thicket: Cross Licensing, Patent Pools, and Standard Setting*, 1 INNOVATION POL'Y & ECON. 119, 119 (2001).

88. This problem, known as holdup, was heavily investigated. See, e.g., Shapiro, *supra* note 87, at 124–26.

89. See Menell & Meurer, *supra* note 70, at 39; Shapiro, *supra* note 87, at 125 ("[The] most important [reason] is timing . . . if the manufacturer has already designed its product and placed it into large scale production . . . the manufacturer is in a far weaker negotiating position.").

90. For a concise overview of the NTP v. RIM controversy, see Menell & Meurer, *supra* note 70, at 2–4.

91. See Menell & Meurer, *supra* note 70, at 4.

thicket becomes, and the more uncertain the scope and validity of individual patents are.⁹² Thus, patent owners are often incentivized to strategically aggregate patents and to intentionally obscure their scope.⁹³ The degree to which sunk costs can be leveraged in the IT sector (also known as “holdup” or pejoratively as “trolling”) can be substantial at times and might impede rather than promote cumulative technological progress.⁹⁴

The pharmaceutical industry presents a fundamentally different pathology.⁹⁵ Unlike what occurs in the IT sector, innovation in the pharmaceutical industry is usually discrete (not cumulative),⁹⁶ the number of patents per product is comparatively low,⁹⁷ and licensing and cross-

92. Patent owners’ perverse incentives to remove legal certainty are often complemented by the fact that patents are already uncertain for reasons that are outside the control of a single rent-seeker patentee. For example: (1) the economic necessity to keep the patent scope flexible, *see* Cooter & Hacothen, *supra* note 31, at 27; (2) Cryptic USPTO records and outdated secrecy rule, *see* Menell & Meurer, *supra* note 70, at 1–6; (3) The inferential quality of language, *see, e.g.*, John M. Golden, *Construing Patent Claims According to Their Interpretive Community: A Call for an Attorney-Plus-Artisan Perspective*, 21 HARV. J.L. & TECH. 321, 329–31 (2008); Kristen Jakobsen Osenga, *Linguistics and Patent Claim Construction*, 38 RUTGERS L.J. 61, 62 (2006); (4) The related problem of economic complements (also known as holdouts or anticommons) as applied to patents, *see, e.g.*, Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 660, 667–73 (1998); Michael A. Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698–99 (1998); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2010 (2007); Cooter & Hacothen, *supra* note 31, at 244–48; Shapiro, *supra* note 87, at 123–26.

93. *See* Menell & Meurer, *supra* note 70, at 9; *see also* Michael Risch, *The Failure of Public Notice in Patent Prosecution*, 21 HARV. J.L. & TECH. 179, 188 (2007) (“Patent applicants have an incentive to allow claims to remain vague.”).

94. *See* James Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 CORNELL L. REV. 387, 417 (2014); Menell & Meurer, *supra* note 70, at 39; Shapiro, *supra* note 87, at 121 (labeling “holdup” as a tax on innovation).

95. *See, e.g.*, European Commission, Commission Decision AT. 39612 — Perindopril (Servier), C(2014) 4955 ¶ 116 [hereinafter *The Perindopril Case*] (noting that given the time it takes the patent office to publish applications, the brand-name manufacturer must “do everything possible to try to draft as quickly as possible new patent applications on these alternative routes . . . so that third parties are informed thereof”); *cf.* Menell & Meurer, *supra* note 70, at 49 (“[T]here is reason to believe that notice externalities are relatively small in [the pharmaceutical] technology neighborhood.”). Conversely, brand-name manufacturers also degrade notice information through an extensive use of continuations. *See* Olga Gurgula, *Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies — Two Different Concepts Sharing Similar Features*, 48 INT’L REV. INTELL. PROP. & COMPETITION L. 385–404 (2017) (distinguishing between patent thickets in the IT and the pharmaceutical sectors). *But see* notes 122–124 and accompanying text. In practice, notice plays a complicated role in the formation of pharmaceutical thickets. When securing new patents, brand-name manufacturers often have a strong incentive to provide timely notice to scare off competitors.

96. *See* DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 81 (2011); Gurgula, *supra* note 95, at 9 (stating that the “lack of attention to the pharmaceutical industry is due to the nature of the technology — most often, it is discrete”); Merges & Nelson, *supra* note 68, at 880 (defining discrete innovation and arguing that “many new pharmaceuticals may also fit this model.”).

97. While the number of patents per drug has increased over time, pharmaceutical innovation is still characterized by relatively low numbers of patented features per product compared

licensing are rare to nonexistent.⁹⁸ Patent uncertainty in the pharmaceutical industry provides patent owners with a strategic advantage not by leveraging the sunk costs of downstream developers, but by leveraging patent owners' own *sunk benefits* from commercializing their patented technology exclusively for longer periods of time.⁹⁹

Indeed, patent owners are not usually required to disgorge the supra-competitive profits made by threatening patent enforcement and deterring competition, even if these patents are later found to be invalid or overbroad.¹⁰⁰ For these reasons, patent owners are incentivized to magnify these threats by securing multiple patents of probabilistic validity and scope.¹⁰¹ Confronted with a dense portfolio of patents, prospective generic entrants must carefully map out the legal landscape; speculate about the strength of each patent; waste substantial resources in an attempt to invent around the dense minefield of patents; and risk facing costly, lengthy, and uncertain patent litigation.¹⁰²

The denser the patent thicket, the more likely it is that generic manufacturers will be discouraged from assuming the risk of market entry while allowing brand-name manufacturers to reap monopoly profits. As one generic pharmaceutical manufacturer states:

The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible in all areas of the drug and create a 'minefield' for the generic to navigate. All generics know that very few patents in that larger group will be valid and infringed

to other industries. In 2005, for example, the average number of patents per drug was 3.5, with over 5 patents per drug for the best-selling pharmaceuticals. *See* Ouellette, *supra* note 14, at 300. The average smartphone in comparison is thought to be protected by more than 250,000 active patents. *See* RPX Corporation, Registration Statement (Form S-1) (Sept. 2, 2011), <https://www.sec.gov/Archives/edgar/data/1509432/000119312511240287/ds1.htm> [<https://perma.cc/352X-JFJV>]; *Too Many Patents*, PATENT PROGRESS, <https://www.patentprogress.org/systemic-problems/too-many-patents> [<https://perma.cc/DS2U-Q4QR>]; *see also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1590 (2003) ("In some industries, such as chemistry and pharmaceuticals, a single patent normally covers a single product."); Mark A. Lemley, *Ten Things to Do About Patent Holdup of Standards (and One Not to)*, 48 B.C. L. REV. 149, 150 (2007).

98. *See* Gurgula, *supra* note 95, at 393 ("[T]he most frequent number of licenses is zero."). Also, as opposed to the IT sector, legal uncertainty in the pharmaceutical field is "nearly always about the validity of patents rather than their scope." *See* Jacob, *supra* note 49, at 238.

99. *See* JACOB, *supra* note 64, at 263.

100. *See supra* notes 12–18 and accompanying text.

101. *See* JACOB, *supra* note 64, at 263–64; *see also* Chiang, *supra* note 12, at 1284 (stating that "applicants have a strong incentive to apply for patents regardless of the underlying merits of their inventions"); Farrell & Merges, *supra* note 72, at 961 ("[T]he rules are set up in such a way that the applicant has an incentive to conceal as much as it can get away with concealing."); Lemley, *supra* note 12, at 28 ("That extra profit, in turn, would create significant incentives to obtain and enforce dubious patents.").

102. *See, e.g.,* Amin & Kesselheim, *supra* note 51, at 2291.

by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.¹⁰³

Furthermore, by extending the reach of this patent minefield beyond the initial term of protection afforded for each drug, brand-name manufacturers prolong the temporal risk associated with generic entry since “new patents become active as old patent[s] expire.”¹⁰⁴ To the extent that this risk actually deters market entry, multiple patents can effectively extend the legal protection of a drug. According to a 2017 study, multiple patents have the potential to extend the legal protection of the twelve top-grossing drugs to thirty-eight years, on average.¹⁰⁵

This form of patent thickening is in no way confined to the pharmaceutical industry and may appear in many areas to prevent profitable inventions from being easily imitated.¹⁰⁶ Nevertheless, this phenomenon is especially common in the pharmaceutical industry because the inelasticity of consumer demand in certain drug markets makes sustained exclusivity in these markets unprecedentedly profitable.¹⁰⁷ In addition, it occurs because a variety of doctrinal levers make it particularly easy for brand-name manufacturers to patent and re-patent various features in a single drug.

One of these levers is the nonobviousness requirement for patentability.¹⁰⁸ Some critics contend that the nonobviousness requirement fails to screen unworthy follow-on improvement patents that claim ancillary features of the drug, including: metabolites (products of the drug’s transformation in a patient’s body),¹⁰⁹ features of the product (such as a tablet’s coating),¹¹⁰ and methods of use (such as a method of

103. European Comm’n Directorate-General for Competition, *supra* note 52, ¶ 525.

104. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has The Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 234 (2001); *see also* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 621 (2011) (“A patent that expires later than the strong patent potentially provides a substantial temporal extension in a brand-name drug maker’s effective exclusivity.”). Unsurprisingly, many brand-name manufacturers apply for patents later into the life of the branded product. *See* European Comm’n Directorate-General for Competition, *supra* note 52, ¶ 451; Kapczynski et al., *supra* note 51, at 4.

105. *See* I-MAK REPORT, *supra* note 14, at 6.

106. *See* JACOB, *supra* note 64, at 263–64; Jacob, *supra* note 49, at 240.

107. *See* FELDMAN & FRONDORF, *supra* note 36, at 14 (explaining that the demand for some drugs is inelastic).

108. *See infra* Section III.A.3.

109. *See, e.g.,* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003).

110. *See, e.g.,* Astra Aktiebolag v. Andrx Pharmaceuticals, 222 F. Supp. 2d 423, 510 (S.D.N.Y. 2002) (stating the product’s subcoating was not infringed upon by its generic equivalent).

treating disease).¹¹¹ These patents are often called “secondary patents” and contrasted with primary patents that cover the active pharmaceutical ingredient of the drug.¹¹² For example, to protect ritonavir and lopinavir, two protease inhibitors widely used to treat HIV infection, Abbott Laboratories secured two primary patents that cover the drug compound as well as an additional 106 secondary patents that claim ancillary features of the drug.¹¹³ Taken together, these secondary patents extend legal protection for the drugs to 2028, thirty-nine years after the first patents on Ritonavir were filed.¹¹⁴

Another questionable policy is the legal standard that prohibits “double patenting.”¹¹⁵ Patent applicants are generally not allowed to claim the same invention (or obvious variations thereof) more than once.¹¹⁶ Nevertheless, this rule does not prevent patent applicants from patenting a broad genus of components, and then patenting a specific nonobvious species within that genus.¹¹⁷ UCB Inc., for example, secured three separate patents all covering the same antiepileptic drug compound lacosamide. In January 1995, UCB received its first patent directed to a broad genus of functionalized amino acids, with lacosamide falling within that genus’ scope.¹¹⁸ Then in August 1995, UCB

111. See, e.g., Aaron S. Kesselheim & Michelle M. Mello, *Medical-Process Patents—Monopolizing the Delivery of Health Care*, 355 (19) NEW ENG. J. MED. 2036–41 (2006) (criticizing such patents).

112. See Hemphill & Sampat, *supra* note 104, at 621; Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1789, 1799 (2011); Kapczynski et al., *supra* note 51, at 3; see also Amin & Kesselheim, *supra* note 51, at 2291.

113. See Amin & Kesselheim *supra* note 51, at 2288. Because most patents have multiple claims, patents that claim the pharmaceutical compound usually also claim “secondary” elements. See Kapczynski et al., *supra* note 51, at 3.

114. Amin & Kesselheim, *supra* note 51, at 2291.

115. See Matthew Bultman, *Mylan Asks Supreme Court to Rein in “Tactical” Drug Patenting*, LAW360 (Nov. 28, 2018, 9:12 PM), <https://www.law360.com/articles/1105771/mylan-asks-supreme-court-to-rein-in-tactical-drug-patenting> [<https://perma.cc/RQ3X-AT6B>]; see also Douglas L. Rogers, *Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition*, 14 NW. J. TECH. & INTELL. PROP. 317, 375 (2017) (offering robust prohibition against double patenting in pharmaceuticals).

116. See *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279 (Fed. Cir. 1992); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (discussing the judicially made restriction of “obviousness-type double patenting”).

117. See, e.g., Cooter & Hacoen, *supra* note 31, at 27; Merges & Nelson, *supra* note 68, at 848. This practice is made possible because at the time of filing, the patent applicant is not required to enable all the existing variations of his invention — only those available or expected at the time the application is filed. See Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1084, 1098 (2009) (calling it “the foreseeability rule”); Robert P. Merges, *Rent Control in the Patent District: Observations on the Grady-Alexander Thesis*, 78 VA. L. REV. 359, 379 n.73 (1992) (labeling it “temporal disparity”). The purpose of this rule is to foster a “blocking patents regime” which encourages competition over improvements.

118. *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1319 (Fed. Cir. 2018); Petition for Writ of Certiorari at 8–10, *Mylan Pharm. Inc. v. UCB, Inc.*, No. 18-692 (U.S. Nov. 21, 2018) [hereinafter “Mylan Petition”].

secured another patent, this time for a slightly different genus of functionalized amino acids, and lacosamide again fell within the scope of that genus.¹¹⁹ Finally, in 2004, UCB received a third patent, claiming lacosamide directly.¹²⁰ The combined term of legal protection afforded by this serial patenting extended UCB's monopoly over lacosamide for more than a quarter of a century.¹²¹

A third controversial policy lever is the continuation application process.¹²² Continuations allow brand-name manufacturers to initially secure patents of limited scope while keeping the option to strategically broaden that scope later.¹²³ Continuation patents cannot extend the temporal protection of drugs (because they do not provide a later expiration date), but they may nevertheless extend the effective scope of legal protection by providing a broader range of exclusion. Specifically, brand-name manufacturers can use continuations to capture generic manufacturers' attempts to design or litigate around the language of previously issued claims, and thus to defeat their attempts to enter the market.¹²⁴

Consider the case of Suboxone, the drug for treating opioid use disorder discussed in the introduction. In that case, the road to generic market competition was cleared after the generic manufacturer Dr. Reddy's Laboratories Ltd. was successful in proving that its generic product did not infringe Indivior Ltd.'s patent on Suboxone.¹²⁵ To prevent Dr. Reddy's from entering the market then and there, Indivior went back to the USPTO and obtained a continuation patent with a broader scope, essentially claiming what was un infringed upon.¹²⁶ Armed with a broader patent, Indivior sued Dr. Reddy's for patent infringement again, and this time was able to secure a preliminary injunction in its favor that blocked market entry for Dr. Reddy's.¹²⁷

119. Mylan Petition, *supra* note 118, at 8–9.

120. *Id.* at 9.

121. *Id.* at 3.

122. See 35 U.S.C. § 120 (2018); THOMAS, *supra* note 48, at 5 (naming continuations as a driver for evergreening); Lemley & Moore, *supra* note 51, at 69 (“[Continuations] are especially important in . . . pharmaceuticals.”).

123. See Lemley & Moore, *supra* note 51, at 76 (“Inventors can keep an application pending in the PTO for years, all the while monitoring developments in the marketplace. They can then draft claims that they can be sure will cover those developments.”); Harold Wegner, *The End of Equivalents? Examining the Fallout from Festo*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 727, 742 (2003).

124. Cf. Lemley & Moore, *supra* note 51, at 77.

125. See *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs., S.A.*, Nos. 14-1451, 14-1573, 14-1574, 2017 WL 3837312, at *20 (D. Del. Aug. 31, 2017), *appeal docketed*, No. 18-1115 (Fed. Cir. Oct. 27, 2017).

126. See *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, No. 17-7111 (KM) (CLW), 2018 WL 3496643, at *4 (D.N.J. July 20, 2018), *vacated and remanded*, 752 F. App'x 1024 (Fed. Cir. 2018) (“Indivior obtained [a] continuation . . . patent, in which it sought to claim around the ‘drying’ problem.”).

127. The preliminary injunction has since been lifted. See *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024, 1025 (Fed. Cir. 2018).

Lastly, as discussed in greater detail later, while patent applicants do have some duties with respect to their patents' quality and breadth, these duties are fairly limited.¹²⁸ For these reasons, patent applicants can opportunistically procure and assert overbroad or unwarranted patents and intentionally delay, or prevent timely scrutiny of such patents, all with a limited risk of liability.¹²⁹ With these doctrinal tools in hand, brand-name manufacturers labor to enrich their drugs' patent portfolios and frustrate timely generic competition.

B. Patent Listing

The preceding discussion explained how brand-name manufacturers strategically accumulate patents and patent applications to raise the risks and costs associated with generic market entry. This practice, dubbed patent thicketing, is located at the base of the pyramid in Figure 1. The practice of patent listing is located at the second level of that diagram, as it includes one additional ingredient above and beyond the basic patent thicket scenario: listing the patents in the Orange Book.¹³⁰

Unlike the basic patent thicket paradigm, the practice of patent listing is a product of the special regulatory regime and is thus endemic to the pharmaceutical industry.¹³¹ As long as all the patents in a pharmaceutical thicket are also listed in the Orange Book, the distinction between the two practices becomes moot. But this was not always the case — for example, out of the 108 patents in the thicket that Abbott Laboratories has built around ritonavir and lopinavir, only twenty patents were also listed in the Orange Book.¹³²

The act of Orange Book listing carries with it a bundle of privileges and obligations that can be leveraged by brand-name manufacturers to further prolong market exclusivity for their products. It is unsurprising, therefore, that many pharmaceutical patents that are procured are also listed. Orange Book listings provide a mirror for the growing practice of overpatenting in recent years. A study by Professor Robin Feldman reveals that more than one third of all drugs marketed between 2005

128. See *infra* Sections III.A.2, III.B.2.a. See generally Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J.L. BUS. & FIN. 250 (2013).

129. See *infra* Sections III.A.2, III.B.2.a.

130. The official name of the Orange Book is the Approved Drug Products with Therapeutic Equivalence Evaluations. Other than patents, the Orange Book also includes unexpired regulatory exclusivities and approved therapeutically equivalent generic drugs. For an overview of patent listing, see generally Ashley M. Winkler, M. David Weingarten & Shana K. Cyr, *Requirements, Benefits, and Possible Consequences of Listing Patents in FDA's Orange Book*, FINNEGAN (July 3, 2018), <https://www.finnegan.com/en/insights/requirements-benefits-and-possible-consequences-of-listing-patents-in-fdas-orange-book.html> [https://perma.cc/WTk7-DJ2G].

131. See *supra* notes 105–106 and accompanying text.

132. See Amin & Kesselheim, *supra* note 51, at 2291.

and 2015 had multiple patents listed in the Orange Book and that the overall growth in patent listings almost doubled within a decade.¹³³

To clarify the strategic advantage of listing patents in the Orange Book, Section II.B.1 explores the federal regulatory scheme for approving prescription drugs, with an emphasis on its core policy objectives. Then, building on this discussion, Section II.B.2 explains how by listing patents, brand-name manufacturers can leverage the regulatory environment to further strengthen and prolong legal protections for their drugs.

1. Regulatory Environment

Without safety and efficacy regulation by the FDA, patent policy would ideally balance innovation incentives with consumer (or patient) welfare. Patents provide innovators with limited legal protection against competition, which then empowers innovators to raise prices and profit from venturing into innovation.¹³⁴ Legal protection is required because information — the subject matter of all patented inventions — is a unique economic resource that is not easily appropriable. Economics refers to information (as well as other notable examples such as lighthouses and national security) as “public goods” — resources that are both non-excludable (others cannot be denied from accessing them) and non-rivalrous (they are not depleted once consumed by others).¹³⁵ In the absence of legal protection, the private market will under supply these goods because producers cannot reap the marginal value of their investment in providing them.¹³⁶

Once expired, however, the previously protected information returns to its pre-patent public good status — nondepletable and widely accessible — and thus the welfare of all consumers (and patients) increases. Easy to imitate and cheap to reproduce (though massively expensive to develop), pharmaceutical drugs were always the poster child

133. See Feldman, *supra* note 14, at 618.

134. See F. SCOTT KIEFF ET AL., *PRINCIPLES OF PATENT LAW, CASES AND MATERIALS* 66 (4th ed. 2008) (discussing the incentive function); Cooter & Hacoen, *supra* note 31 at 5, 11 (same).

135. Cf. Letter to Isaac McPherson (Aug. 13, 1813), *reprinted in* JEFFERSON WRITINGS 1291–92 (M. Peterson ed., 1984) (“He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.”). See generally Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* at 609 (1962); KIEFF ET AL., *supra* note 134, at 62.

136. See PAUL A. SAMUELSON & WILLIAM D. NORDHAUS, *ECONOMICS*, at 48–49, 713–15 (12th ed. 1985); RICHARD W. TRESCH, *PUBLIC FINANCE: A NORMATIVE THEORY* 107–29 (1981). See generally Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36 *REV. ECON. & STAT.* 387, 389 (1954). Patents are not the only regulatory tool for solving the public good problem. Other means include subsidies and prizes.

of the public good story.¹³⁷ Accordingly, once patent protection over drugs expires, quick imitation and fierce competition should drive down the prices of drugs to the marginal costs of production.¹³⁸

When first introduced in the late 1930s, federal regulation of prescription drugs shattered the realization of that economic ideal. Once patent protection for branded drugs expired, imitation and competition did not drive down prices, and the drugs remained monopolized because generic competitors feared undertaking the lengthy and expensive road of regulatory approval.¹³⁹ This regulatory environment led to longer terms of market exclusivity for branded drugs.

Then, in 1984, the legislature passed the Hatch-Waxman Act, an ambitious legislative scheme enacted to reach an ideal balance between patents and patients — innovation incentives on one hand and access to medicine on the other.¹⁴⁰ The approach of the Hatch-Waxman Act was to strengthen legal protection for branded drugs for a limited period¹⁴¹ and then facilitate immediate generic entry once that legal protection expired.¹⁴² As part of the comprehensive regulatory regime, the Act requires brand-name manufacturers to list in the Orange Book all of their patents that are deemed relevant to the authorized drug.¹⁴³ The

137. See *infra* Section III.B.2.b. Although for some biological compounds the price of production may be relatively high. See, e.g., Anders Kelto, *Why Is Insulin So Expensive in the U.S.?*, NPR (Mar. 19, 2015 3:06 AM), <https://www.npr.org/sections/health-shots/2015/03/19/393856788/why-is-u-s-insulin-so-expensive> [<https://perma.cc/T3AN-LS72>].

138. In the case of Simvastatin, for example, within a few months of generic entry, one month's worth of the medication had dropped from \$150 to \$7 and the prescription rate increased more than 70%. See *supra* note 76 and accompanying text.

139. See Feldman, *supra* note 46, at 68 (“[G]eneric companies would have no incentive to enter into costly [clinical] trials, given that there would be no opportunity to recoup those costs.”); Feldman, *supra* note 14, at 598 n.40 (discussing the massive costs of clinical testing).

140. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in 15 U.S.C. § 68b–68c, 70b (2012); 21 U.S.C. § 301, 355, 360cc (2018); 28 U.S.C. § 2201 (2018); and 35 U.S.C. § 156, 271, 282 (2018)).

141. The Hatch-Waxman Act has strengthened legal protection for branded drugs by: (1) providing up to five years of patent term “restoration” for half of the period devoted to clinical trials, and for all the period consumed by the FDA approval process, 35 U.S.C. § 155A (2006); (2) providing a five-year data exclusivity for new chemical entities, 21 C.F.R. § 314.108(b)(2) (2016), and three years data exclusivity for modifications of existing drugs significant enough to require new clinical trials, 21 C.F.R. § 314.108(b)(5)(ii) (2016). Since then, various other regulatory protections were added. See Feldman, *supra* note 46, at 80–87.

142. The Act facilitates cheaper and prompter generic entry in two ways. First, it created the Abbreviated New Drug Application (ANDA) process, 21 U.S.C. § 355(j) (2018), allowing generic manufacturers to piggyback on clinical data already generated by brand manufacturers. See, e.g., *infra* notes 208–211 and accompanying text. Second, it has amended the Patent Act to exclude from patent infringement uses related to regulatory compliance. See 35 U.S.C. § 271 (e)(1) (2018). Before these statutory amendments, courts refused to expand the common-law experimental use defense to accommodate generic manufacturers’ experimentation. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984). This amounted to a de facto extension of market exclusivity. See Erik K. Steffe & Timothy J. Shea, Jr., *Drug Discovery Tools and the Clinical Research Exemption from Patent Infringement*, 22 BIOTECHNOLOGY L. REP. 369, 370 (2003).

143. 21 U.S.C. § 355(b)(1) (2018).

FDA then refers to this list and withholds approval for generic versions of an authorized branded drug for as long as there is an unchallenged and unexpired patent listed. Recognizing the risk that dubious patents may be listed to prevent generic entry, the Act has created a designated procedure for generic manufacturers to challenge listed patents. This procedure can be summarized as follows: A generic applicant who wishes to challenge a listed patent files with the FDA an Abbreviated New Drug Application (“ANDA”) containing a “Paragraph IV” certification asserting that certain patents are invalid or are not infringed by the proposed generic product.¹⁴⁴ The filing of such an ANDA is considered an act of patent infringement.¹⁴⁵ In response to the ANDA, the brand-name manufacturer has a window of forty-five days to file a patent infringement lawsuit and to establish the validity and infringement of the patent in suit.

This procedure provides both the brand-name manufacturer and the generic manufacturer with lucrative privileges. If a brand-name manufacturer sues for patent infringement in a timely manner, it receives an automatic stay of thirty months (equivalent to an automatic preliminary injunction) in its favor.¹⁴⁶ During the statutory stay, the FDA is prevented from authorizing the pending generic application for up to thirty months while giving the parties time to resolve their litigation. This lengthy stay is valuable for brand-name manufacturers as it gives them an extended period to market their products exclusively without fearing competition.

The generic challenger is also granted a valuable privilege. The first generic applicant to file an ANDA with a Paragraph IV certification receives a 180-day period of market exclusivity.¹⁴⁷ Once the first generic applicant commences with commercial marketing for its product, it has 180 days to market its product in competition only with the brand-name manufacturer. All other generic manufacturers are prohibited from entering the market during this time.

144. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2018). Prospective generic filers would need to certify to all listed patents (even if listed later into the market life of a product) for as long as these patents are listed before the ANDA is submitted. See Kurt R. Karst, *One Sponsor's Failure is Another Sponsor's Fortune: The Importance of Timely Listing (and Challenging) Orange Book Patents*, FDA L. BLOG (Nov. 25, 2013), <http://www.fdalawblog.net/2013/11/one-sponsors-failure-is-another-sponsors-fortune-the-importance-of-timely-listing-and-challenging-or> [https://perma.cc/RQ6D-BJR7]; Winkler et al., *supra* note 130.

145. 35 U.S.C. § 271(e)(2)(A) (2018). This is sometimes called “artificial infringement,” because at this point in time a generic manufacturer has done nothing more than request FDA approval to market the drug.

146. 21 U.S.C. § 355(j)(5)(B)(iii) (2018). See also JOHN R. THOMAS, *PHARMACEUTICAL PATENT LAW* 17 (2d ed. 2005); M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV. 359, 382–83 (2002).

147. 21 U.S.C. § 355(j)(5)(B)(iv) (2018).

Thus, the aim of the Orange Book challenging procedure was to advance the underlying goal of the Hatch-Waxman Act by encouraging early patent challenges, thereby accelerating generic competition.¹⁴⁸ However, instead of incentivizing zealous patent challenges, the regulatory scheme has nurtured collusion and sustained monopolization of branded products. The next Section explores the gap between the idealized vision of the Hatch-Waxman Act and its realized abuse.¹⁴⁹

2. Patent Leverage

This Section discusses three strategic advantages that the regulatory framework confers on brand-name manufacturers who list their patents in the Orange Book. The first advantage is the privilege of the thirty-month automatic stay.¹⁵⁰ Assume, for example, that the initial term of drug protection is about to end naturally in the absence of generic challengers attempting to hasten its expiration. At this point, a brand-name manufacturer may want to list another patent (even if meritless) in the Orange Book to benefit from the thirty-month stay privilege.¹⁵¹ In the past, a brand-name manufacturer would secure multiple

148. See 149 CONG. REC. S16,104, S16,104 (2003) (statement of Sen. Hatch) (noting that the intention behind the 180-day marketing exclusivity was to encourage “vigorous patent challenges”); Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 318–19 (2011).

149. This is not to say that the regulatory scheme is considered a failure. The Hatch-Waxman regime was notably successful in encouraging generic competition overall, but at the same time, it also introduced various complications that opened the gate for abuse by brand-name manufacturers. For an overview, see Garth Boehm et al., *Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013) (“There is no doubt that the US generic industry has been successful beyond the wildest dreams of those who formulated the Hatch-Waxman Act. Even though successful, the development of the generic drug industry has been anything but smooth.”)

150. See Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 327 (2002) (noting that the 30-month stay creates “an opportunity for ‘sham’ or delaying litigation,” which has “little to do with the underlying value of the patent(s) at issue, and [may amount] to a stipulated preliminary injunction without judicial review”); Glasgow, *supra* note 104, at 235.

151. Note that the FDA does not limit brand-name manufacturers in the number of patents that can be listed per drug, nor does the agency scrutinize listed patents to determine whether they support the drug as claimed. The only feasible way to remove added patents is through a generic challenge that would then trigger the automatic thirty-month stay and provide the brand-name manufacturer with an artificial extension of its monopoly. See Analysis to Aid Public Comment: In the Matter of Bristol-Myers Squibb Company, 68 Fed. Reg. 12,080, 12,081 (Mar. 13, 2003). The Canadian practice is different. Health Canada’s Office of Patented Medicines and Liaison accepts third-party information on the eligibility and validity of a listed patents, and “[i]f a patent is alleged to be improperly listed, the office will undertake a review of the patent and may delist it.” Amin & Kesselheim, *supra* note 51, at 2292.

thirty-month stays by repeatedly adding patents to the Orange Book.¹⁵² In 2003, Congress closed this loophole.¹⁵³

A second feature of the regulatory scheme that brand-name manufacturers leverage to prolong drug protection is the 180-day exclusivity bounty in favor of the first generic filer.¹⁵⁴ The bounty was originally designed to reward generic manufacturers for challenging patents early in an attempt to open up the market for competition.¹⁵⁵ Instead, the bounty system was manipulated by brand-name manufacturers to further a sustained monopoly.¹⁵⁶ In what has become a systematic industry practice, brand-name manufacturers and first generic filers often settle their patent infringement case instead of litigating the case to judgment while agreeing on delaying generic market entry.¹⁵⁷

Settlements for a delayed market entry may be socially acceptable from the perspective of consumer welfare if the date of agreed-upon entry is set to occur before the expiration date of the challenged patent, and for as long as the period of delayed entry reflects the probabilistic strength of the challenged patent.¹⁵⁸ If, for example, a challenged patent has a 50% probability of being invalidated in litigation, the parties might agree to settle the case and divide the patent's remaining term in half. Thus, if ten years of effective patent term remains, the parties may agree to allow generic entry after five years. Such an agreement is not objectionable from a consumer welfare perspective. Full-blown litigation with a 50% chance of generic entry is economically identical to a

152. In the case of Paxil, multiple listings delayed generic entry for 65 months. See Hemphill & Lemley, *supra* note 51, at 959.

153. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2066, 2449–52. For review, see Hemphill & Lemley, *supra* note 51, at 959–60.

154. See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 425 (1999) (suggesting eliminating the bounty); Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck,"* 78 FORDHAM L. REV. 1075, 1113–14 (2009) (same).

155. See *supra* notes 71–81 and accompanying text (discussing the skewed patent challenging incentives in the absence of a bounty); see also Hemphill, *supra* note 10, at 1560–61.

156. Cf. Jon Leibowitz, Commissioner, Fed. Trade Comm'n, Statement Concurring in Part and Dissenting in Part in the Matter of Cephalon, Inc. 2 (Feb. 13, 2008), https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commissioner-jon-leibowitz-concurring-part-and-dissenting-part-matter-cephalon-inc./080213comment.pdf [<https://perma.cc/B2WU-RUTS>] (arguing that the bounty “does precisely the opposite” of what Congress intended: “it extends the brand’s monopoly”); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 340–42 (similar).

157. See Hemphill, *An Aggregate Approach*, *supra* note 24, at 634–36; *infra* Section III.A.2.

158. See FELDMAN & FRONDORF, *supra* note 36, at 41 (distinguishing between socially acceptable settlements and settlements for excessive delay); Hemphill, *supra* note 10, at 1588–94 (same).

settlement for delayed market entry with a 50/50 divide of the remaining patent term; in both scenarios, consumers get the same expected value from the competition.¹⁵⁹

As many commenters warned, however, there is a strong reason to suspect that the settling parties would stipulate to delayed market entry that far exceeds the term that is socially tolerable. While it is true that it is in the first generic filer's best interest to pursue an early date of market entry (to start profiting early), first generic filers have much greater interest in assuring that their 180-day exclusivity bounty is secured, not lost.¹⁶⁰ Because first generic filers secure their bounty by settling with brand-name manufacturers while they risk losing their bounty by pressing on with litigation and losing the case, first generic filers are likely to trade an earlier date of market entry in return for having their bounty secured.¹⁶¹

Putting it differently, by making the bounty a certainty rather than a probability for first generic filers, brand-name manufacturers are likely to convince first generic filers to delay their market entry far beyond the reasonable period that reflects the patent's strength.¹⁶² In the previous example, the first generic filer would be likely to favor entering the market eight years into the patent term (instead of five) with a guaranteed bounty, over litigating the case with a 50% chance of success and a 50% chance of losing its bounty.¹⁶³ Sometimes, brand-name manufacturers offer additional benefits above and beyond retaining the generic exclusivity, in return for even longer delays.¹⁶⁴

Settlement agreements for delayed generic entry are socially disturbing for another reason. By agreeing to settle the case with the first generic filer, brand-name manufacturers not only remove an imminent threat to their patent protection, but they also substantially discourage subsequent challenges by other generic filers. Knowing that the bounty was already "wasted" on the first generic filer who settled, other generic

159. Hemphill, *supra* note 10, at 1588–89.

160. *See* Hemphill, *supra* note 10, at 1593 ("Enjoying the exclusivity period with certainty is more important to a generic firm than its timing."); Hemphill & Lemley, *supra* note 51, at 965 (describing the incentive for generic firms to settle). In fact, if future demand for the drug is expected to increase rather than to dwindle, the first generic filer may even prefer a delayed market entry over an expedited one. *See* Hemphill, *supra* note 10, at 1593.

161. The first generic filer has secured its right to the bounty by filing first. This privilege is not generally forfeited absent a court judgement finding the challenged patents valid. *See* Hemphill, *supra* note 10, at 1590; Hemphill, *supra* note 157, at 658–60 (discussing the forfeiture conditions).

162. *See* Hemphill, *supra* note 10, at 1590; Hemphill & Lemley, *supra* note 51, at 965 ("Elimination of the risk of losing by the generic company is not just a payment in and of itself, but the primary form of payment in Hatch-Waxman settlements." (internal quotation marks omitted)).

163. Such settlements become a common industry practice. *See* Hemphill & Lemley, *supra* note 51, at 963; *infra* Section III.A.2; *see also* Hemphill, *supra* note 157, at 645–56.

164. Such agreements may attract antitrust scrutiny. *See* Hemphill, *An Aggregate Approach*, *supra* note 24, at 661–63; *infra* Section III.A.2.

manufacturers have a considerably reduced incentive to initiate a challenge.¹⁶⁵ As explained above, in the absence of a bounty, the incentives to challenge patents are severely skewed.¹⁶⁶ To make matters worse, some settlement agreements provide that the first generic filer is allowed to enter the market immediately upon FDA approval or market launch by a subsequent generic filer.¹⁶⁷ This tweak further reduces the incentives of subsequent filers to initiate patent challenges.¹⁶⁸

Finally, and perhaps most troublingly, settlements for delayed generic entry may block entry by subsequent generic filers altogether. Based on current law, the approval of a subsequent generic filer's ANDA is delayed for 180 days from the date of "first commercial marketing" by the first filer.¹⁶⁹ Because the settlement prevents commercial marketing from occurring, it has the potential to block subsequent generics from obtaining FDA approval.¹⁷⁰

Subsequent filers can force the first filer to either use its bounty (i.e., enter with exclusivity) or lose it, but not without filing their own ANDA with a Paragraph IV certification, waiting to be sued, winning the resulting lawsuit, and then winning again on appeal.¹⁷¹ As Professors Hemphill and Lemley have stated, "[t]he resulting delay from this process — file the ANDA, conduct the district court suit, win the appeal, wait until just before the end of seventy-five days, then wait another 180 days — can easily stretch to several years."¹⁷² Furthermore,

165. See 21 U.S.C. § 355(j)(5)(D)(iii)(II) (2018) (stating that upon first applicant's forfeiture, no applicants are eligible for the exclusivity period); see also Hemphill, *supra* note 10, at 1583.

166. See *supra* notes 71–81 and accompanying text.

167. See Hemphill & Lemley, *supra* note 51, at 964.

168. See Hemphill, *supra* note 10, at 1586; see, e.g., Complaint for Injunctive Relief at 15, FTC v. Cephalon, No. 2:08-cv-02141 (E.D. Pa. April 15, 2015).

169. See 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2018). For the pre-Medicare Modernization Act regime, see Hemphill, *An Aggregate Approach*, *supra* note 24, at 658–59.

170. Under the current legal regime, the exclusivity bounty is forfeited for failure to market if the applicant fails to market the drug by the later of: (1) 75 days after the first generic applicant's ANDA is approved or 30 months after that ANDA was submitted, or (2) 75 days after a final court determination that the patents in question are invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I) (2018). A final court determination includes a court-approved settlement. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) (2018). Thus, if the brand-name manufacturer and the first generic filer craft their agreement in a way that does not assign a determination of blame or reach a judgement of invalidity, the latter of the two conditions never occurs and the parties can settle without triggering the forfeiture. See Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgement for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1, 11 (2013); FELDMAN & FRONDORF, *supra* note 36, at 40; Hemphill, *An Aggregate Approach*, *supra* note 24, at 659.

171. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2018) (setting up the failure to market trigger).

172. Hemphill & Lemley, *supra* note 51, at 964. This description applies to drugs with new ANDAs. For old ANDAs, the result of a later filer's appellate win is not a forfeiture but a triggering of the first filer's exclusivity. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (2003) (codified at 21 U.S.C. § 355 note (2018)).

if a brand-name manufacturer chooses not to sue the subsequent generic filer, the latter would have to win a declaratory judgment lawsuit to get out of the emerging bottleneck. This venture is even chancier because it is unclear whether the subsequent generic filer has the standing to sue.¹⁷³

The third and final benefit that brand-name manufacturers get from listing a patent in the Orange Book is the potential to leverage the so-called “use code” procedure. When brand-name manufacturers list patents, they provide the FDA with a brief statement describing which of the approved uses of the drug are claimed by these patents.¹⁷⁴ These statements are then translated into use codes that are listed in the Orange Book, and they help the FDA make determinations on “skinny label” applications — applications to market a generic product for limited uses that are no longer under patent protection.¹⁷⁵ For example, when the patent covering the FDA-approved use of gabapentin to treat partial seizures expired, Apotex sought a skinny label approval for this specific use.¹⁷⁶

Alas, the use code procedure is ripe for abuse.¹⁷⁷ The FDA does not scrutinize brand-name manufacturers’ statements before translating them into use codes,¹⁷⁸ nor does the FDA prevent brand-name manufacturers from amending listed use codes or adding additional codes as time passes.¹⁷⁹ Thus, by providing the FDA with overbroad statements regarding the range of protected uses or by adding new use codes over time, brand-name manufacturers can keep skinny label generics off the market.¹⁸⁰

173. Hemphill & Lemley, *supra* note 51, at 964 n.65; *see also* Avery & Nguyen, *supra* note 170, at 31.

174. *See* Feldman, *supra* note 14, at 603; *see also* Terry G. Mahn, *The Patent Use Code Conundrum — or Why FDA Can’t Read (Patents)*, PHARMACEUTICAL COMPLIANCE MONITOR (Oct. 17, 2014), <https://www.fr.com/files/Uploads/attachments/MahnPharmaComplianceMonitor-ThePatentUseCodeConundrum20141017.pdf> [<https://perma.cc/4KAZ-H3L3>].

175. Applying for a “skinny label” application would require a generic applicant to submit a Section VIII statement, asserting that the generic product is not marketed for protected uses. *See* 21 U.S.C. § 355(j)(2)(A)(viii) (2018); Mahn, *supra* note 174 (explaining this procedure and its rationale). *See also* Arti Rai, *Use Patents, Carve-Outs and Incentives in the Drug-Patent Wars*, 367 NEW ENG. J. MED. 491, 491 (2012) (same).

176. *See* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1352 (Fed. Cir. 2003).

177. To be fair, the use code procedure is also leveraged by generic manufacturers who sometimes benefit from having their products prescribed for off-label uses. *See id.* at 1363–64 (noting that Warner-Lambert argued that over three-quarters of prescriptions for gabapentin were made for off-label (protected) uses).

178. *See* Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 403 (2012) (explaining that “[t]he FDA does not attempt to determine if [use codes are] accurate”); Feldman, *supra* note 14, at 603 (“FDA does not read or construe patent claims.”); Mahn, *supra* note 174 (same).

179. *See* Feldman, *supra* note 14, at 603.

180. *See id.* at 604; *see also* Rai, *supra* note 175, at 491–92.

For example, in 2005, Novo Nordisk had only one unexpired patent listed in the Orange Book for its branded drug Prandin (repaglinide). Novo's method of use patent was relatively narrow and covered only treatment of non-insulin-dependent diabetes by combining repaglinide with another drug, metformin.¹⁸¹ When the generic manufacturer Caraco attempted to get FDA approval for its skinny label application that carved out the repaglinide-metformin combination therapy, Novo Nordisk listed a much broader use code in the Orange Book that covered all methods for "improving glycemic control in adults with type 2 diabetes mellitus."¹⁸² Based on the amended use code, the FDA rejected Caraco's skinny label application.

In 2012, the Supreme Court ruled in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S* that generic manufacturers can file statutory counterclaims to seek correction of inaccurate use codes.¹⁸³ Nevertheless, this approach still requires entering into the lengthy and expensive legal campaign of submitting a Paragraph IV certification, getting sued by a brand-name company for infringement, and successfully defending against that infringement lawsuit.¹⁸⁴ Overall, the various procedural complexities of the Hatch-Waxman Act greatly enhance brand-name manufacturers' ability to delay generic competition.

C. Product Hopping

Section II.A explored how brand-name manufacturers can raise the risks and costs associated with generic market entry by strategically accumulating patents. Section II.B explained that by listing accumulated patents in the Orange Book, brand-name manufacturers gain additional strategic advantages. This Section discusses the practice of product hopping, which adds a third and final layer of exclusion to the evergreening model depicted in Figure 1 — product reformulation and aggressive marketing.

In a typical product-hopping case, to prolong exclusivity for a drug that reaches the end of its legal protection, a brand-name manufacturer would marginally modify the drug, shift its market from the original

181. For a concise overview of the *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S* controversy, see generally Frederick H. Rein & Joseph B. Crystal, *Novo Nordisk v. Caraco: Beware the Perils of an Overbroad Use Code*, 7 J. GENERIC MED. 371 (2010); Michael Vincent Ruocco, *Brand Name or Generic? A Case Note on Caraco Pharmaceutical Laboratories v. Novo Nordisk*, 33 J. NAT'L ASS'N ADMIN. L. JUDICIARY 341 (2013).

182. See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1363 (Fed. Cir. 2010) (all approved methods were not claimed), *rev'd*, 566 U.S. 399 (2012).

183. 566 U.S. 399 (2012).

184. *Id.* at 428 (Sotomayor, J., concurring) (stating that, at the very best, the statutory scheme allows the generic manufacturer to "file an ANDA with a section viii statement — but only after expensive and time-consuming litigation"); see also Feldman, *supra* note 14, at 603; Rai, *supra* note 175, at 491.

drug to the modified drug, and then secure additional patents (or other legal protections) to block competition over the modified drug. A product-hopping strategy would not have worked in a well-functioning market in which consumers make rational quality/price decisions. Assuming that the modified branded drug does not offer a substantial advantage to justify its high price, consumers in a well-functioning market would simply opt for the generic version of the original branded drug that is no longer protected and thus is subject to price-reducing competition. The idiosyncrasies of the pharmaceutical market, however, make a product-hopping strategy scandalously effective.¹⁸⁵

Unlike the previous two practices discussed, product hopping is independent of patent protection (or other legal protections) and may also occur in its absence.¹⁸⁶ Nevertheless, the economic significance of product hopping without patent protection is drastically impaired. Hopping between products is a risky and costly operation, and without patents protecting the new formulation, the short term of effective exclusion — i.e., until generic manufacturers “follow the hop” and get their reformulated product approved as well — may not justify the costs.¹⁸⁷ Unsurprisingly, most product-hopping cases involve patents (or other legal exclusivities).¹⁸⁸

Consider again the Suboxone case. In that case, Indivior began by making Suboxone in a tablet form.¹⁸⁹ When the legal protection for the tablet formulation of Suboxone was about to expire in October 2009, Indivior undertook a product hop. Indivior reformulated Suboxone from a tablet to a film, obtained a new patent for the film formulation, listed it in the Orange Book, and moved its market to the new product.¹⁹⁰ Even though there was no therapeutic difference between the

185. See, e.g., Kodjak, *supra* note 57 (noting that, with product hopping, “[t]he clock for [blocking] generic competition started again”).

186. See Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 712 (2009) (“[E]ven without new patent claims, product hopping delays generic substitution for the new branded product because the generic firm must file a second ANDA, which faces the same lengthy FDA review as the first one.”).

187. See *infra* note 198 and accompanying text.

188. See FELDMAN & FRONDORF, *supra* note 36, at 69.

189. See *Indivior Inc. v. Dr. Reddy’s Labs., S.A.*, No. 17-7111 (KM) (CLW), 2018 WL 3496643, at *2–3 (D.N.J. July 20, 2018), *vacated and remanded*, 752 F. App’x 1024 (Fed. Cir. 2018).

190. See *id.*

tablet and the film versions of Suboxone,¹⁹¹ Indivior was nevertheless able to switch 85% of its consumers to the new product.¹⁹²

Section II.C.1 explores the distorted market economics of prescription pharmaceutical drugs. Building on that discussion, Section II.C.2 explains how brand-name manufacturers leverage this unique economic environment through product hopping and the role of patents within this operation.

1. Economic Environment

In typical markets, consumers are equipped to make rational quality/price determinations, and product reformulation is unlikely to undermine consumer welfare.¹⁹³ Faced with a reformulated product, consumers compare the value added from the reformulation with the value of the original product and adjust their demand accordingly. Assume, for example, that McDonald's has a monopoly in the milkshake market, and it charges a monopoly price of \$8 per cup. Assume further that Burger King and Wendy's are about to enter the milkshake market, which would reduce the price of a milkshake from \$8 to \$2 per cup. Then, to get a competitive advantage over its competitors, McDonald's decides to reformulate its product and produce its milkshakes using only organic milk.

In this scenario, when competition between the fast-food vendors ensues, consumers would only benefit from the reformulation made by McDonald's. Consumers who do not care about the origin of the milk would buy milkshakes at Burger King or Wendy's for \$2 a cup. Alternatively, consumers who value the origin of the milk and can afford the price difference would opt to get the more expensive organic milkshake at McDonald's for, say, \$2.50 a cup.

191. See *id.*; Rebecca L. Graham, *Buprenorphine for Opioid Dependence: Are There Really Differences Between the Formulations?*, 4 MENTAL HEALTH CLINICIAN 20 (2014) (finding "no clear advantages" to the new formulation). Indeed, the declared reason for the switch was that the box of pills was unsafe for children. See Pat Anson, *Drug Maker to Stop Selling Suboxone Tablets*, NAT'L PAIN REP. (Sept. 25, 2012), <http://nationalpainreport.com/drug-maker-to-stop-selling-suboxone-tablets-8815934.html> [<https://perma.cc/5T5F-JJ2K>]. Paradoxically, the film version might be even worse. See Nate Raymond, *U.S. Joins Lawsuits Against Indivior, Reckitt over Drug Suboxone*, POPULATION HEALTH LEARNING NETWORK (Aug. 9, 2018), <https://www.managedhealthcareconnect.com/content/us-joins-lawsuits-against-indivior-reckitt-over-drug-suboxone> [<https://perma.cc/WM76-CKME>] ("[T]he lawsuit alleges that the film version was inferior to the tablets . . . and posed an increased risk to children.").

192. See *Indivior*, 2018 WL 3496643, at *2.

193. See, e.g., SAMUELSON & NORDHAUS, *supra* note 136, at 80 (emphasizing consumer sovereignty); see also W.H. Hutt, *The Concept of Consumers' Sovereignty*, 50 ECON. J. 66, 66–77 (1940).

When consumers are incapable of making a quality/price comparison, however, this simplified analysis fails miserably.¹⁹⁴ In such an environment, consumer demand does not reflect consumer welfare, and product reformulations may prove anticompetitive. Imagine that by introducing the organic milk formulation, McDonald's could have eliminated the competition from Burger King and Wendy's over the nonorganic milkshake formulation. In this scenario, McDonald's could continue charging monopoly pricing for its reformulated product irrespective of its social value. McDonald's would be able to charge \$8 for organic milkshakes even if consumers place a value of only five cents on the added benefit. Worse yet, McDonald's could introduce a reformulation that has no added value to consumers whatsoever — e.g., changing the color of the plastic cup from blue to yellow — and nevertheless, charge a monopoly price of \$8 for its reformulated product.¹⁹⁵

Incapable of appreciating the value added by the reformulation and of distinguishing it from the value attributed to the original product, consumers would fail to opt for the cheaper, though satisfactory, alternative. To rephrase Daniel Day-Lewis in Paul Thomas Anderson's masterpiece *There Will Be Blood*, McDonald's would be drinking their competitors' milkshake!¹⁹⁶

As evident by the Suboxone example mentioned above, this alarming description aptly depicts the realities of the market for prescription drugs.¹⁹⁷ Consider another example: When patent protection for Prilosec — the nation's number one best-selling drug, with \$6 billion

194. JOHN STUART MILL, PRINCIPLES OF POLITICAL ECONOMY 957 (1848) (Oxford Univ. Press 1998) (noting that if consumers cannot judge their own interests, “the foundation of the *laissez-faire* principle breaks down entirely”); cf. George A. Akerlof, *The Market for “Lemons”: Quality Uncertainty and the Market Mechanism*, 84 Q. J. ECON. 488–500 (1970) (explaining that in the presence of information deficiency, suppliers cannot attract a premium for higher-quality products).

195. Arguably, this was the case with Suboxone. See *supra* notes 191–192 and accompanying text (indicating that Suboxone's film formulation had no added value, and was potentially even more dangerous).

196. *There Will Be Blood*, IMDb, <http://www.imdb.com/title/tt0469494/> [<https://perma.cc/2VCE-5N4N>]. The catchphrase — “I drink your milkshake!” — originates from the well-known final scene of the film. See Gabriel Affonso, *I Drink Your Milkshake!*, KNOW YOUR MEME, <https://knowyourmeme.com/memes/i-drink-your-milkshake> [<https://perma.cc/8CYW-JP6H>].

197. See, e.g., M. Joseph Sirgy, Dong-Jin Lee & Grace B. Yu, *Consumer Sovereignty in Healthcare: Fact or Fiction?*, 101 J. BUS. ETHICS 459–74 (2011). This is not to say that all pharmaceutical product reformulations are inherently useless. See, e.g., *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 646–47 (2d Cir. 2015) (noting that the newer Namenda formulation had an improved extended-release mechanism that simplified the drug's use); Ernest R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24 PHARMACOECONOMICS 69, 71 (2006) (discussing how reformulated products can increase compliance, improve pharmacokinetics, and reduce side effects). Instead, the concern with product hopping is that, in many cases, the overwhelming market shift to the improved formulation cannot rationally be justified by the incremental addition in value.

in yearly sales — was nearing expiration in 2001, AstraZeneca reformulated Prilosec to Nexium.¹⁹⁸ Though many prominent physicians warned that Nexium is a “no value-added drug”¹⁹⁹ and irrespective of the fact that Nexium cost some patients more than four times as much as Prilosec,²⁰⁰ when generic competition finally ensued, Generics were able to capture only 25% of the market (rather than the 85% that they were allegedly expected to capture in the absence of the product hop).²⁰¹ By 2013, the market for Nexium was just below \$6 billion in yearly sales.²⁰² The profitability of Nexium and the film version of Suboxone are striking evidence of the economic impact of product hopping in drug markets.

This economic impact is attributed to problems of information asymmetry and a “price disconnect” that characterizes these markets.²⁰³ A price disconnect occurs when the entity that chooses the product and the entity that pays for the product are different. Because physicians do not bear the costs of the drugs they prescribe to patients and because insurance-paying patients also do not pay the full costs of their treatment, both physicians and some patients are grossly price insensitive, i.e., they are unresponsive to price when conducting their decisions.²⁰⁴

198. See Steve D. Shadowen, Keith B. Leffler & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 65–66 (2009); see also First Amended Complaint and Demand for Jury Trial at 26, *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) [hereinafter *Walgreen’s Complaint*] (contesting Nexium’s therapeutic superiority over Prilosec).

199. Stuart Elliott & Nat Ives, *Questions on the \$3.8 Billion Drug Ad Business*, N.Y. TIMES (Oct. 12, 2004), <https://www.nytimes.com/2004/10/12/business/media/questions-on-the-38-billion-drug-ad-business.html> [<https://perma.cc/PY25-YFR3>]; Gardiner Harris, *Prilosec’s Maker Switches Users to Nexium, Thwarting Generics*, WALL ST. J. (June 6, 2002, 5:22 PM), <https://www.wsj.com/articles/SB1023326369679910840> [<https://perma.cc/4T57-NDBB>] (“Nexium clearly is [a] no-value added drug”); Robert Pear, *U.S. Limiting Costs of Drugs for Medicare*, N.Y. TIMES (Apr. 21, 2003), <https://www.nytimes.com/2003/04/21/us/us-limiting-costs-of-drugs-for-medicare.html> [<https://perma.cc/HM6U-6WQN>] (similar).

200. See FELDMAN & FRONDORF, *supra* note 36, at 73 (“As early as 2004, doctors noted that a monthly Nexium prescription could cost \$200 versus \$45 for a monthly supply of over-the-counter Prilosec.”).

201. See *Walgreen’s Complaint*, *supra* note 198, at 38–39 (arguing that generics had captured only 25% of the market rather than the 85% that they were expected to capture in the absence of the product hop).

202. See FELDMAN & FRONDORF, *supra* note 36, at 73–74.

203. BUREAU OF CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 2 (1979) (“[T]he forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay.”); Shadowen, Leffler & Lukens, *supra* note 198, at 9.

204. Shadowen, Leffler & Lukens, *supra* note 198, at 11 n.33 (citing studies showing that doctors are unfamiliar with or underestimate costs). Doctors and patients are in a classic principal-agent predicament.

Moreover, patients and many doctors do not have the necessary information or skill required to make informed quality determinations between competing drug products.²⁰⁵

Brand-name manufacturers leverage these vulnerabilities of price insensitivity and information deficit with advertising. Funded campaigns, institutional lectures, office visits, and distribution of free samples and instructive booklets are all part of the substantial footprint that brand-name manufacturers have on physicians' drug-related education.²⁰⁶ Worse yet, many brand-name manufacturers are infamous for offering various kickbacks, such as consulting fees, research funding, expense-paid vacations, and lucrative advisory board memberships, to physicians in return for touting their products. Most physicians refuse to believe they can be swayed by these marketing techniques, yet empirical evidence suggests otherwise. One study, for example, has demonstrated that the mere availability of advertised drug samples to doctors during treatment would serve to increase the prescription rates of the advertised product.²⁰⁷

Brand-name manufacturers also educate patients through direct-to-consumer advertising and celebrity endorsements.²⁰⁸ From 1997 through 2016, medical marketing expanded substantially, and spending on it increased from \$17.7 to \$29.9 billion, with direct-to-consumer advertising for prescription drugs and health services accounting for the most rapid growth.²⁰⁹ Commercials featuring Jane Lynch and "Larry the Cable Guy," for example, were widely aired as part of Astra-Zeneca's market-switching campaign.²¹⁰ Studies have shown a strong

205. See FELDMAN & FRONDORF, *supra* note 36, at 15 ("[Doctors] are not experts on drug prices, product hopping, and shifts in the pharmaceutical market — they have exquisitely imperfect information themselves.").

206. See, e.g., Julia Lurie, *Doctors Receive Opioid Training. Big Pharma Funds It. What Could Go Wrong?*, MOTHER JONES (Apr. 27, 2018), <https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong> [<https://perma.cc/H6YX-BEZR>]; Shadowen, Leffler & Lukens, *supra* note 198, at 11–12 nn.36–37.

207. Richard F. Adair & Leah R. Holmgren, *Do Drug Samples Influence Resident Prescribing Behavior? A Randomized Trial*, 118 AM. J. MED. 881, 883 (2005); see also John M. Boltri et al., *Effect of Antihypertensive Samples on Physician Prescribing Patterns*, 34 J. FAM. MED. 729, 731 (2002) (finding that "there is an association between drug sample availability and physician prescription behavior for patients with hypertension").

208. See, e.g., Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1481 (2008); FELDMAN & FRONDORF, *supra* note 36, at 15.

209. Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997–2016*, 321 JAMA 80, 82 (2019).

210. FYI, *Jane Lynch Commercial for Nexium*, YOUTUBE (May 15, 2018), <https://www.youtube.com/watch?v=dQG2hOoixAo> [<https://perma.cc/H8TB-82DP>]; *wwe24seven, Troy Hobza- Prilosec OTC Picnic Commercial 2013 Larry the Cable Guy*, YOUTUBE (June 20, 2013), <https://www.youtube.com/watch?v=-mYP7eiz5Co> [<https://perma.cc/B8GK-D26G>].

linkage between such advertising and the growth in patients' interest in branded drugs.²¹¹

In theory, generic manufacturers could also advertise to doctors and patients to counter the persuasive impact of brand-name advertising. However, the nature of drug markets makes this option highly infeasible.²¹² Unlike brand-name manufacturers, generic manufacturers do not enjoy legal protection for their products. As explained, drugs have the characteristics of a public good: They are easy to imitate and cheap to reproduce. Without legal protection, other generic manufacturers are expected to swiftly enter the market, compete, and drive down drug prices toward the marginal costs of production.²¹³ In this environment, generic manufacturers cannot be expected to invest in marketing, let alone compete with the massive marketing expenditure already undertaken by brand-name manufacturers.²¹⁴

In a market reality in which patients cannot make welfare-enhancing decisions and doctors are ill-equipped to do so on their behalf, policymakers have found other agents more fitted to assume this paternalistic role — pharmacists.²¹⁵ Unlike doctors, pharmacists have the expertise and the economic incentive to make prescription decisions that are price sensitive. Pharmacists respond to drug prices because they

211. See Marjorie Kauffman Sherr & Donna Cutrone Hoffman, *Physicians — Gatekeepers to DTC Success*, PHARMACEUTICAL EXECUTIVE, Oct. 1997, at 56, 56; Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-To-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 1995 (2005); Cheng, *supra* note 208, at 1483. See generally KATHRYN J. AIKEN, JOHN L. SWASY & AMIE C. BRAMAN, FDA CTR. FOR DRUG EVALUATION & RESEARCH, PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS — SUMMARY OF FDA SURVEY RESEARCH RESULTS (2004), <https://www.fda.gov/media/112016/download> [<https://perma.cc/69XY-KTYC>] (indicating that DTC advertising has both positive and negative effects, including evidence that some physicians experience pressure to prescribe requested drugs from patients who have seen DTC advertisements).

212. Promotion expenditures can be analogized to the safety and efficacy data that brand-name manufacturers produce in clinical trials to obtain FDA approval. Both data and promotion are costly resources that brand-name manufacturers are incentivized to generate by the promise of market exclusivity. In both cases, the regulatory scheme (the ANDA process and automatic substitution) specifically allows the generic entrants to free ride on the brand-name manufacturer's investment to encourage early access. See *supra* note 140 and accompanying text; *infra* note 216 and accompanying text.

213. See ROBIN FELDMAN, RETHINKING PATENT LAW 159 (2012); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 J.L. & ECON. 331, 335–36 (1992); Cheng, *supra* note 208, at 1476 n.30.

214. Once automatic substitution by the state laws is triggered, advertising by generic manufacturers becomes even less probable because of the free riding phenomenon. See *infra* notes 216–217 and accompanying text.

215. Other potential candidates for encouraging cost-sensitive prescriptions are pharmacy benefit managers (PBMs) who manage drug purchases for insurance companies. Alas, accused of dealing with brand-name manufacturers. PBMs are ineffective in buffering the price disconnect problem at best, or even aggravate the problem at worst. See FELDMAN & FRONDORF, *supra* note 36, at 16; Shadowen, Leffler & Lukens, *supra* note 198, at 18–21.

make greater margins on generics than on branded drugs, and competition between pharmacy retailers drives some of these savings to consumers.²¹⁶

Based on this rationale, starting in the mid-1970s, all fifty states and the District of Columbia enacted Drug Product Selection (“DPS”) laws.²¹⁷ These laws permit and sometimes even require pharmacists to dispense a generic drug in place of a branded drug if there is consumer consent and the absence of contrary instructions by the doctor.²¹⁸ Therefore, by their operation, the DPS laws “shift the choice of [product] for most prescriptions from the physician to the pharmacist.”²¹⁹

The DPS laws essentially counteract the persuasive influence of brand-name advertising. Conditioned by years of promotion, doctors may continue prescribing the branded drug, but in most cases, the pharmacist will substitute it with the cheaper generic product.²²⁰ Once the impact of brand-name advertising is removed, generic entrants can compete effectively. Because promotions in the presence of functioning DPS laws are no longer cost effective when there is competition, all economic players (brand and generic manufacturers) are unlikely to invest in advertising.²²¹ Without advertising and with the aid of the pharmacists’ discretion, rational price/quality choice is restored and consumer welfare enhanced.

216. See Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, in BROOKINGS PAPERS ON ECON. ACTIVITY, MICROECONOMICS 1, 6 (1991) (noting that generics generally yield higher gross margins to pharmacists relative to brands); Shadowen, Leffler & Lukens, *supra* note 198, at 15.

217. See Norman V. Carroll et al., *The Effects of Differences in State Drug Product Selection Laws on Pharmacists’ Substitution Behavior*, 25 MED. CARE 1069, 1069 (1987); Cheng, *supra* note 208, at 1479.

218. See Shadowen, Leffler & Lukens, *supra* note 198, at 13 n.41 (“Approximately 28% of states require the pharmacist to substitute a generic when one is available; about 78% of states require the pharmacist to obtain the patient’s consent before substituting a generic.”).

219. See ALLISON MASSON & ROBERT L. STEINER, FED. TRADE COMM’N, *GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 1–7* (1985), <https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf> [<https://perma.cc/8LH4-SC4B>].

220. Substitution is only the default. Consumers and doctors may still insist on having the branded product prescribed if they prefer. Indeed, to sustain control over deep-pocket, brand-loyal consumers, brand-name manufacturers often keep prices high even after generic entry. See, e.g., Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 242 (1999); Jayanta Bhattacharya & William B. Vogt, *A Simple Model of Pharmaceutical Price Dynamics*, 46 J.L. & ECON. 599, 602 (2003).

221. See Shadowen, Leffler & Lukens, *supra* note 198, at 15; see also Caves et al., *supra* note 216, at 39.

2. Patent Leverage

Unlike what occurs in the two evergreening practices discussed in Sections II.A and II.B, the role of patents in product hopping is complementary, not obligatory. Patents improve the attractiveness of the product-hop venture, but the venture itself is independent of patent protection. This Section explores the product-hopping operation first and then discusses the complementary role of patent protection.

Product hopping in the pharmaceutical industry is a two-phase marketing strategy designed to evade automatic substitution by the DPS laws.²²² The first phase involves product reformulation, namely, redesigning the branded drug in a way that defeats automatic substitution by pharmacists under the DPS laws.²²³ The second phase aspires to switch the market and redirect doctors' prescriptions from the old drug formulation toward the new.

The product reformulation phase is vital to getting around the regulatory regime. Under the laws of most states, pharmacists are authorized to substitute a branded drug with a generic drug only if the latter is designated as "AB" rated in the Orange Book, which means that it is therapeutically equivalent to a brand-name drug.²²⁴ To obtain the AB rating, the generic product must be both (1) pharmaceutically equivalent

222. See Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016) (defining product hopping "to include only those instances in which the brand manufacturer: (1) reformulates the product in a way that makes the generic non-substitutable; and (2) encourages doctors to write prescriptions for the reformulated product rather than the original").

223. Not all (not even most) product reformulations are pursued solely for the nefarious objective of frustrating generic competition. The timing of the reformulation serves as a valuable indicator as to whether the product reformulation imposes anticompetitive concerns. The most suspicious product reformulations are those that are made during the so-called "Generic Window," namely these that are strategically timed to frustrate immediate or expected generic entry. See, e.g., Shadowen, Leffler & Lukens, *supra* note 198, at 25 (hypothesizing that reformulations that made within the Generic Window — which they define as product reformulations that took place in the period of time from three years before FDA approval of the first competing generic product to the original formulation until one year after the approval of that generic — were potentially part of a manufacturer's strategy to impair generic competition. And finding that "of the total 425 product changes within the study period [1995-2009], only 81 occurred within the Generic Window"); see also *id.* at 206 (proposing safe harbors that would immune brand-name manufacturers from antitrust scrutiny for product hopping if (1) the contested reformulation was made long enough before generic approval, or (2) the contested reformulation was introduced after the generic version of the original drug already entered the market).

224. See JOHN R. THOMAS, CONG. RESEARCH SERV., R44222, PHARMACEUTICAL PATENT-ANTITRUST: REVERSE PAYMENT SETTLEMENTS AND PRODUCT HOPPING 13 (Oct. 7, 2015); Jaymes V. Fairfax-Colombo & David DeMatteo, *Are Bioequivalents Really Equal? Generic Substitution in the Context of Mental Illness*, 12 IND. HEALTH L. REV. 281, 287-90 (2015).

lent: having the same active ingredient, dosage, form, and route of administration as the branded drug;²²⁵ and (2) bioequivalent: being absorbed in the patient's body at approximately the same rate and speed as the branded drug.²²⁶ By reformulating a drug in a way that defeats either of these conditions, brand-name manufacturers create a new drug formulation that is not therapeutically equivalent to the old formulation. Accordingly, a generic version of the latter would also not be therapeutically equivalent to the former and could not be automatically substituted by a pharmacist.²²⁷ Equivalency-defeating reformulations include, but are not limited to, changing the drug's form (i.e., from a tablet to a film as in the case of Suboxone), marginally altering the chemical composition of the drug (as in the case of Prilosec), and combining several pharmaceutical compositions into a single drug meant to be marketed separately.²²⁸

When the reformulation phase is completed, the market-switching phase begins. As mentioned, the purpose of this phase is to switch doctors' prescriptions from the old drug formulation to the new. Brand-name manufacturers pursue this goal with the aid of the most powerful tool at their disposal — advertising.²²⁹ Soft market-switching strategies involve redirecting vast marketing resources — customer lists, marketing know-how, and product expertise — from the old formulation and toward the new formulation. These techniques are sometimes called “cannibalizing” because brand-name manufacturers are diverting sales away from their own products.²³⁰ In July 2013, for example, to switch the market of Alzheimer's patients from Namenda IR to the newer drug formulation Namenda XR, Forest Laboratories redirected marketing efforts to doctors, caregivers, pharmacists, and patients from the old formulation to the new. Forest also priced the new formulation lower than the old one and issued rebates to health plans for the new formulation to assure that consumers' co-pays for the new formulation would not exceed the old.²³¹

225. FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2020), <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface> [<https://perma.cc/9CAL-UZZU>].

226. *Id.* But cf. European Comm'n Directorate-General for Competition, *supra* note 52, at 341 (stating that the European regulatory system considers a generic drug equivalent and substitutes as not significantly different in safety and efficacy, regardless of its different chemical formulation).

227. See Shadowen, Leffler & Lukens, *supra* note 198, at 7.

228. See Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 HOUS. J. HEALTH. L. & POL'Y 379, 398 (2007).

229. Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry*, 18 INT'L J. INDUS. ORG. 1085, 1088 (2000); Shadowen, Leffler & Lukens, *supra* note 198, at 44–46.

230. Shadowen, Leffler & Lukens, *supra* note 198, at 44.

231. See *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 648 (2d Cir. 2015).

The most aggressive cannibalizing measures, also known as hard-switching techniques (in contrast to soft switching), include discontinuing production lines and distribution channels of the old formulation, buying back all remaining inventories of the old formulation, and removing the original formulation from insurance formularies or from national databases for determining generic equivalency.²³² For example, in the second wave of Namenda cannibalization, Forest Laboratories discontinued marketing of the IR formulation altogether, removed the product from the Medicare drug formulary list, and reached out to health-care providers and caregivers to urge them to switch patients to the XR reformulation.²³³

Cannibalizing or market switching is most effective before generic competition over the original drug formulation begins.²³⁴ In the absence of price competition from generic manufacturers, doctors, as well as patients who are already susceptible to advertising's persuasive force given their information deficit and price insensitivity, are becoming sitting ducks.²³⁵ As Shadowen, Leffler, and Lukens explains:

Doctors are presented a choice between two branded products, usually offered at the same price (sometimes even with a slightly lower price for the new product), often with an uncontested message that the new product is better. The generic version of the original product being unavailable, consumers have no choices at all.²³⁶

Once generic competition over the original product finally ensues, a significant portion of the market has already switched to the new formulation.²³⁷ Consumers who did not switch by this point may still be persuaded to do so going forward by the continuous promotional efforts undertaken by brand-name manufacturers. Generic manufacturers, on the other hand, cannot cost-effectively advertise the original formulation to counter the persuasive impact of brand-name advertising. Free

232. See FELDMAN, *supra* note 213, at 175; FELDMAN & FRONDORF, *supra* note 36, at 71; Carrier, *supra* note 51, at 1019–20.

233. Hard-switching cases are likely to attract antitrust scrutiny. See *Actavis*, 787 F.3d at 643, 647–48; *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 415–18 (D. Del. 2006); *infra* notes 264–265 and accompanying text.

234. See European Comm'n Directorate-General for Competition, *supra* note 52, at 356; Sven Gallasch, *A New Dimension to EU Pharma Antitrust Product Hopping and Unilateral Pay for Delay*, 12 EUR. COMPETITION J. 137, 145 (2016); Shadowen, Leffler & Lukens, *supra* note 198, at 45.

235. Shadowen, Leffler & Lukens, *supra* note 198, at 45.

236. *Id.* at 51.

237. In theory, once the generic version of the original product enters the market, doctors can prescribe the original product. In practice, this rarely happens. See *id.* at 52–53.

riding by other generic manufacturers, which is fostered by the operation of DPS laws, eliminates the incentive to advertise the old formulation even if generic manufacturers are well positioned to engage in advertising (which they are not).²³⁸ With no advertising on behalf of the old formulation, doctors and patients get a one-sided perspective that favors the product switch.²³⁹

Because they cannot advertise, generic manufacturers wishing to compete with the new branded formulation have no choice but to follow the hop themselves in order to also reformulate their generic product and get regulatory approval for the new reformulation.²⁴⁰ This is where the complementary role of patents fits into the greater product-hopping scheme. By obtaining additional patents to cover the new reformulation, brand-name manufacturers prevent generic manufacturers from following the hop in this way and essentially reset the term of legal protection for their drug.²⁴¹

Without added patent protection, product hopping is technically probable, but its economic attractiveness is substantially impaired. Product hopping is a very costly venture, at least in the short run, and potentially even a losing one. Engaging in a product hop requires brand-name manufacturers to invest in product reformulation, legal advice, and, most substantially, advertising. By cannibalizing the sales of their old pricy formulation in favor of the new and usually cheaper formulation (at least in the beginning), brand-name manufacturers are also expected to lose profits in sales. Without patents to prevent generic manufacturers from quickly following the hop, the costs of the whole product-hopping operation may not justify its benefits.²⁴²

Patents, on the other hand, protect the new reformulation for an additional twenty-year period and provide brand-name manufacturers with the host of strategic advantages previously discussed in Section II.A and — if the patents are listed — the advantages discussed in

238. Promoting the original formulation to doctors is no longer a profitable investment because the pharmacist could simply substitute one version of the drug with another. *See id.* at 15.

239. Carrier, *supra* note 51, at 1019; *see also* Shadowen, Leffler & Lukens, *supra* note 198, at 46–47.

240. Cheng, *supra* note 208, at 1488; *see also* Shadowen, Leffler & Lukens, *supra* note 198, at 5.

241. *See supra* text accompanying note 185.

242. However, this is not always true. Even with no patent protection to cover the new branded formulation, product hopping may prove cost-efficient for at least three reasons. First, it might take time for a generic manufacturer to follow the hop, especially because brand-name manufacturers are not required to provide notice to generic competitors of the reformulation. *See* Carrier, *supra* note 51, at 1018; Shadowen, Leffler & Lukens, *supra* note 198, at 5. Second, the generic reformulator must wait for the FDA to approve the reformulation, which typically takes at least eighteen months. *See* Shadowen, Leffler & Lukens, *supra* note 198, at 5 n.18. Finally, once a generic manufacturer successfully follows the hop, the brand-name manufacturer can hop again to yet another reformulation, thereby repeating the whole process. *See* Cheng, *supra* note 208, at 1491–93.

Section II.B as well. Unsurprisingly, most successful product-hopping cases involve patents.²⁴³

To summarize, the three-tier pyramid model helps visualize the central exclusionary role of patent protection in brand-name manufacturers' overall efforts to prolong market exclusivity for drugs. This model also helps contextualize and evaluate competing legal and regulatory approaches and appreciate their capacity to curtail strategic behavior based on their location in the pyramidal model.

For example, tinkering with state DPS laws to broaden pharmacists' substitution authority²⁴⁴ or limiting brand-name manufacturers' ability to advertise directly to consumers²⁴⁵ would curb the abusive practice of product hopping but would not stem the abuses of the patent-listing procedure. Similarly, correcting the various loopholes in the regulatory regime would serve to curtail patent-listing abuses but would not eliminate basic social concerns related to patent thickets.²⁴⁶

Only by hacking at the base of the pyramid, namely, by targeting pharmaceutical patents themselves, can one expect to have the broadest impact on the evergreening problem. The next Part critically examines existing remedial approaches to evergreening and then offers a new approach.

III. REMEDYING EVERGREENING: INTERNALIZING THE COSTS OF PHARMACEUTICAL OVERREACH

As Part II reveals, follow-on patenting incentives in the pharmaceutical industry are severely skewed. Though the social value of many follow-on patents is negligible, the private benefit they generate for brand-name manufacturers is massive.²⁴⁷ Thus, when it comes to the improvements of existing drugs, as opposed to the creation of new drugs, the patent system generates too much innovation incentive — i.e., brand-name manufacturers are likely to gain more from making improvements to drugs than society gains by encouraging such improvements. Unsurprisingly, “[o]n average, 78% of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.”²⁴⁸

243. See FELDMAN & FRONDORF, *supra* note 36, at 69.

244. Cf. European Comm’n Directorate-General for Competition, *supra* note 52, at 44 (describing the European practice).

245. See, e.g., John Commins, *Final Rule Requires Drug Price Disclosures in TV Ads*, HEALTH LEADERS MEDIA (May 8, 2019), <https://www.healthleadersmedia.com/final-rule-requires-drug-price-disclosures-tv-ads> [<https://perma.cc/2FBA-SKSN>].

246. Cf. *supra* Section II.B.2 (mapping contemporary concerns with the Hatch-Waxman regime).

247. See, e.g., Glasgow, *supra* note 104, at 232 (finding that “[t]he incentive to extend the patent life of brand name drugs is overwhelming”).

248. Feldman, *supra* note 14, at 597.

Various policy approaches have been adopted or considered in an attempt to force brand-name manufacturers to “internalize” the social costs associated with overpatenting. These approaches include rewarding generic manufacturers for challenging weak patents under the Hatch-Waxman regime, penalizing patent owners for “misusing” their patent rights under antitrust laws, and making patents harder to obtain under patent laws. Section III.A critically examines these approaches. Then, building on this discussion, Section III.B offers a novel evergreening at risk remedial approach.

A. Critical Analysis of Existing Remedial Approaches

1. Regulatory Policy

The fear that brand-name manufacturers would leverage patent rights to prolong market exclusivity did not escape the architects of the Hatch-Waxman Act. As mentioned above, the solution adopted by the legislators was to create a lucrative bounty regime to incentivize generic manufacturers to challenge unworthy and overbroad patents.²⁴⁹ As Senator Orrin Hatch explained, “[i]n order to give an incentive for vigorous patent challenges, the 1984 law granted a 180-day head start over other generic drug firms when the pioneer firm’s patents failed or were simply not infringed.”²⁵⁰ As described in Section II.B, however, instead of removing dubious patents and opening the market to competition, the bounty system achieves the opposite outcome of inviting collusion, nurturing unwarranted monopolies, and delaying generic entry.²⁵¹

Two major flaws prevent the statutory bounty from achieving its underlying policy objectives; one flaw relates to structure and the other relates to proportionality. The structural flaw in the bounty system is the fundamental mismatch between the condition for earning the bounty (i.e., filing first) and the action that needs to be incentivized from a public policy perspective (i.e., prevailing in litigation).²⁵² To address this concern, Professors Scott Hemphill and Mark Lemley offered to interpret (or amend) the statutory text so that only generic challengers that did something to “earn” the exclusivity would be entitled to get

249. See *supra* text accompanying note 142.

250. See 149 CONG. REC. S16,104, S16,104 (2003) (statement of Sen. Hatch).

251. See *supra* text accompanying notes 154–155.

252. Indeed, Senator Orrin Hatch, the prime mover behind the Hatch-Waxman Act, had openly criticized the “almost unbelievable advantage” given to first filers and had repeatedly urged limiting the bounty only to successful defenses. See *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 13 (2003) (statement of Sen. Orrin Hatch).

it.²⁵³ “For example, if the generic firm files a Paragraph IV certification, is sued, and wins the suit, it receives the bounty. If the generic firm instead loses the suit, it loses the exclusivity. Nor can it receive the bounty if it settles for delayed entry.”²⁵⁴

The other flaw in the current bounty regime is its disproportionate size. The bounty was meant to reward successful patent challenges that remove legal uncertainty and open the market to competition.²⁵⁵ When evaluating the proper size of such a bounty, one must bear in mind that both brand-name and generic manufacturers have misaligned incentives when it comes to patent challenges. As discussed in Section II.A.1, generic manufacturers do not fully internalize the social benefits of removing patent uncertainty and are thus under-incentivized to pursue patent challenges.²⁵⁶ In a similar vein, as discussed in Section II.A.2, brand-name manufacturers do not fully internalize the social costs of maintaining patent uncertainty and are thus over-incentivized to prevent patent challenges.²⁵⁷

While the problems are analytically identical, the reward that fuels them is not. Follow-on patents may provide brand-name manufacturers with years of extended monopoly, while the statutory bounty provides generic manufacturers with half a year of a duopoly.²⁵⁸ Thus, the profits expected by the generic manufacturer from securing the bounty, however substantial, are merely a fraction of the profits that can be expected by the brand-name manufacturers from delaying generic entry. Because brand-name manufacturers benefit more from retaining invalid or over-broad rights than generic manufacturers benefit from removing them, collusion is likely to endure. As Hemphill and Lemley themselves admitted, the parties could still settle for delay even under their suggested earning exclusivity regime; the “patentees may simply pay the generic more to compensate for the loss of exclusivity”²⁵⁹

253. Hemphill & Lemley, *supra* note 51, at 969–77. Others have also pointed out this fundamental problem, and various legislative solutions were made to address it. See, e.g., Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 99–103 (2009) (discussing the Senate Bill number 1315, from June 2009); Sabrina Malhi, *Solving the “Parking” Problem in the Drug Monopoly Game*, THE HILL (2019), <https://thehill.com/opinion/healthcare/476016-solving-the-parking-problem-in-the-drug-monopoly-game> [<https://perma.cc/3FAD-NYE7>] (discussing the more recent Senate Bill number 3092, from December 2019).

254. Hemphill & Lemley, *supra* note 51, at 969.

255. Cf. *supra* text accompanying notes 142–143, 250.

256. See *supra* text accompanying notes 79–80.

257. See *supra* text accompanying notes 99–101.

258. See 35 U.S.C. § 154(a)(2) (2018) (stating that the patent term is twenty years since filing); *supra* text accompanying notes 154–155 (discussing the 180-day exclusivity bounty).

259. Hemphill & Lemley, *supra* note 51, at 977.

To effectively curb collusion, a bounty system must offer generic manufacturers more in return for invalidating patents than they can reasonably expect to earn by not invalidating them. The proposal presented in Section III.B reflects this position.

2. Antitrust Policy

Antitrust laws are the primary tool for dealing with an unlawful extension of monopolies and thus are viewed as the natural way to curb patent abuses and misuses.²⁶⁰ Alas, the blunt antitrust remedy — treble damages based on the amount of competitive injury — simultaneously creates over- as well as under-deterrence concerns and thus fails to strike a proper balance between innovation and overreaching incentives.²⁶¹

The fear of over-deterrence is well founded in patent cases, given the risk of undermining precious innovation incentives.²⁶² As the Supreme Court stated in *Walker Process*:

[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble damage suits.²⁶³

Thus, in an attempt to avoid over-deterrence, the reach of antitrust scrutiny is slow to evolve, and the legal standards for imposing liability are notoriously demanding.²⁶⁴

The sluggish development in antitrust scrutiny leaves significant leeway for pharmaceutical manufacturers to adopt opportunistic practices with limited risk of attracting liability. For example, it took years of zealous advocacy by academics, practitioners, and regulatory authorities for the Supreme Court to finally expand the reach of antitrust scrutiny to the practice of pay-for-delay settlement agreements in its

260. See, e.g., Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 406 (2003).

261. 15 U.S.C. § 15(a) (2018); Spencer W. Waller, *The Incoherence of Punishment in Antitrust*, 78 CHI.-KENT L. REV. 207, 212 (2003) (“Treble damages are the *sole* damages for an antitrust violation”).

262. See Cooter & Hacoen, *supra* note 31, 17 n.18.

263. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179–80 (1965); see also Leslie, *supra* note 15, at 160.

264. See FELDMAN & FRONDORF, *supra* note 36, at 79 (“The weapons may differ . . . but the games remain the same”).

landmark 2013 *Actavis* decision.²⁶⁵ However, instead of ceasing to collude, many brand-name and generic manufacturers clung to the fact that the *Actavis* decision involved cash payments and moved to devise complex noncash side deals in the hope of evading antitrust scrutiny.²⁶⁶ The courts gradually came to realize that “the economic logic articulated by the Court applies regardless of the payment’s form,”²⁶⁷ and many more settlements became subject to antitrust scrutiny, but these legal developments took years to fashion.²⁶⁸

A similar development is seen with respect to the practice of product hopping. As courts expanded the reach of antitrust scrutiny to hard-switch product-hopping strategies (e.g., taking old formulation products off the market before generic entry), companies gradually moved toward soft-switching practices (e.g., cannibalization without product removal).²⁶⁹ Again commenters warned that “[t]he anticompetitive effect of both types of conduct is the same,” but courts have not yet taken heed.²⁷⁰

Sluggish development in the law is not the only undesirable side effect of avoiding over-deterrence; exceedingly stringent liability standards is another.²⁷¹ For example, patent owners who initiate sham patent infringement lawsuits that are “no more than an attempt to interfere with a competitor’s business relationship” could potentially curtail

265. *FTC v. Actavis, Inc.*, 570 U.S. 136, 154–58 (2013).

266. See Michael A. Carrier, *The Rule of Reason in the Post-Actavis World*, 2018 COLUM. BUS. L. REV. 25, 41 (“The primary issue that has been litigated since *Actavis* is whether payment is limited to cash or extends to noncash conveyances.”); FELDMAN & FRONDORF, *supra* note 36, at 49.

267. Aaron S. Edlin et al., *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585, 592 (2015).

268. Ed Silverman, *Cash Is Not King: FTC Sues Drug Maker over Pay-to-Delay Deal*, STAT (Mar. 31, 2016), <https://www.statnews.com/pharmalot/2016/03/31/patents-monopoly-antitrust> [<https://perma.cc/MY4Q-RJZL>]; Michael Carrier, *FTC v. Actavis: Where We Stand After 5 Years*, IPWATCHDOG (June 18, 2018), <https://www.ipwatchdog.com/2018/06/18/ftc-v-actavis-stand-5-years> [<https://perma.cc/RDX4-PRHE>]; FELDMAN & FRONDORF, *supra* note 36, at 63–65.

269. See *Pharmaceutical Antitrust Update: Courts Address how and when Product Hopping May Violate the Antitrust Laws*, HAUG PARTNERS (Mar. 29, 2017), <https://www.haugpartners.com/article/pharmaceutical-antitrust-update-courts-address-how-and-when-product-hopping-may-violate-the-antitrust-laws> [<https://perma.cc/ZX5J-7Q7J>]; *supra* notes 229–233 and accompanying text. Compare *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 660 (2d Cir. 2015) (finding liability for a hard switch), with *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 440–41 (3d Cir. 2016), *reh’g denied*, No. 15-2236 (Nov. 30, 2016) (declining to find liability for a soft switch).

270. Shadowen, Leffler & Lukens, *supra* note 198, at 71. See also Carrier & Shadowen, *supra* note 222, at 217 (criticizing the hard vs. soft distinction).

271. Cf. FELDMAN, *supra* note 213, at 167 (arguing that the sham litigation antitrust standard is too stringent); Leslie, *supra* note 15, at 166 (arguing that the *Walker Process* antitrust standard is too stringent).

many of the patent abuses discussed in Part II.²⁷² Nevertheless, the standard for proving sham litigation — showing by the heightened evidentiary standard of “clear and convincing” evidence that the legal action alleged to be a sham is both objectively baseless and was filed by the patent owner with subjective bad faith²⁷³ — is so demanding that this theory was proven successful only once, in 2018, two and a half decades after the legal theory was first established by the Supreme Court in 1993.²⁷⁴

Finally, and somewhat paradoxically, by emphasizing the damages to the plaintiff instead of the benefits to the patent owner, the antitrust remedy might sometimes lead to under-deterrence despite its punitive nature. For example, under the well-established Supreme Court precedent in the case of *Walker Process*, an assertion of a patent that is fraudulently procured in an attempt to monopolize a market is subject to antitrust liability.²⁷⁵ Nevertheless, because the most likely plaintiffs to prevail in a *Walker Process* action are generic competitors, not consumers, brand-name manufacturers could potentially silence *Walker Process* charges by paying prospective generic challengers to drop their charges. Because brand-name manufacturers’ profits dwarf generic manufacturers’ damages (even after trebling), such agreements are attractive and hardly detectable.²⁷⁶

272. See *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993). Sham litigation was established as an exception to *Noerr* immunity, which generally applies to antitrust liability activities directed toward influencing government action. See *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972).

273. *Prof'l Real Estate Inv'rs*, 508 U.S. at 57; *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368–69 (Fed. Cir. 1998); see FELDMAN, *supra* note 213, at 167.

274. Press Release, Fed. Trade Comm'n, FTC Testifies before House Subcommittee on Regulatory Reform, Commercial and Antitrust Law on Competition Enforcement Activities and Policy Priorities (Dec. 12, 2018), <https://www.ftc.gov/news-events/press-releases/2018/12/ftc-testifies-house-subcommittee-regulatory-reform-commercial> [<https://perma.cc/3HMM-QPUN>]; see *infra* notes 374–376 and accompanying text; see also FELDMAN, *supra* note 213, at 167.

275. See *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174 (1965); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998); see also *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 993–94 (9th Cir. 1979) (expanding *Walker Process* to bad-faith assertion of patents known to be invalid post-prosecution). Without antitrust liability, fraud on the USPTO would be incentivized. See Chiang, *supra* note 12, at 1284.

276. Cf. Feldman, *supra* note 128, at 305 (noting that “intellectual property rights holders are able to use the magnified power from their rights to bargain for invisibility and silence”). Unsurprisingly, consumers’ actions often follow upon successful challenges advanced by competitors in patent litigation. By colluding with such competitors, brand-name manufacturers can effectively evade future consumers’ lawsuits. See *infra* notes 421–423 and accompanying text. This problem was much worse when courts were hostile to the standing of consumers bringing *Walker Process* claims. See *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 505 (Fed. Cir. 2012) (endorsing consumer standing in *Walker Process* claims); Christopher R. Leslie, *The Role of Consumers in Walker Process Litigation*, 13 SW. J.L. & TRADE AM. 281, 290–91 (2007).

To effectively curtail overreaching practices without invoking fears of over-deterrence, policymakers should rethink the punishment that accompanies liability. A softer remedy would relax the existing stringent standards of liability and capture more opportunistic practices without having an impact on innovation incentives that is overly detrimental. Also, to curtail the fears of under-deterrence, the most suitable policy enforcers — generic manufacturers, not consumers — should be encouraged to move forward with their claims. The proposal advanced in Section III.B reflects both principles.

3. Patent Policy

The view advanced in this article is that patent policy, by improving the quality of pharmaceutical patents, should play a pivotal role in curbing the evergreening epidemic. The most natural approach to achieving this goal is to heighten patentability requirements for pharmaceutical inventions.²⁷⁷ Thus, more rigorous doctrines of utility or nonobviousness would potentially serve to weed out meritless patent applications on the front end.²⁷⁸ Many countries tinker with heightened patentability requirements;²⁷⁹ India, for example, forbids improvement patents to known pharmaceutical substances unless the applicant can show that the claimed improvement is therapeutically superior to the known substance.²⁸⁰ New legislation in this light has recently been proposed in the United States.²⁸¹

Nevertheless, a closer look at U.S. patent policy would suggest that the requirements of patentability for pharmaceutical inventions are already quite rigorous. Unlike in other industries in which innovators

277. See, e.g., Amin & Kesselheim, *supra* note 51, at 2292. Other patent policies can also be tailored. See, e.g., Lemley & Moore, *supra* note 51, at 65–66 (discussing tailoring the continuation practice); Rogers, *supra* note 115, at 334–35 (discussing strengthening double patenting doctrine).

278. Such approaches are usually subject to criticism. Cf. J. Bradley White, Vincent M. de Grandpré & Faylene Lunn, *Supreme Court Holds that Promises Are Not the Yardstick to Measure Patent Utility in Canada*, OSLER (July 4, 2017), <http://www.osler.com/en/resources/regulations/2017/supreme-court-holds-that-promises-are-not-the-yard> [<https://perma.cc/PFT2-F42U>].

279. *Id.*; see also Amin & Kesselheim, *supra* note 51, at 2292; Kapczynski et al., *supra* note 51, at 7.

280. See The Patents (Amendment) Act, No. 15 of 2005, § 3(d), INDIA CODE (2005). See, e.g., Novartis AG v. Union of India & Ors., AIR 2013 SC 1311, ¶¶ 9–10, 14 (India).

281. The “No Combination Drug Patents Act” would limit the issuance of pharmaceutical patents by providing that changes to dosing regimens or delivery mechanisms be considered obvious under U.S. patent law. See Steve Brachmann, *Congress Adds TERM Act and No Combination Drug Patents Act to List of Drug Patent Bills Being Considered*, IPWATCHDOG (June 20, 2019), <https://www.ipwatchdog.com/2019/06/20/congress-term-act-no-combination-drug-patents-act-added-list-drug-patent-bills-considered> [<https://perma.cc/VR3F-CU5W>].

need only to prove operability to satisfy the utility requirement,²⁸² inventors in the biotechnology and chemical fields must satisfy a heightened utility standard by proving a specific and concrete application for their inventions.²⁸³ The burden of proving non-obviousness is also heavier for pharmaceutical inventions.²⁸⁴ A chemical compound is presumed obvious if it is structurally similar to a molecule in the prior art and if a skilled artisan would have the motivation to tinker with that molecule to come up with the claimed compound.²⁸⁵ To defeat a presumption of obviousness, an inventor would have to demonstrate “surprising properties” of the claimed molecule not present in the prior art.²⁸⁶ This showing is difficult to make especially after the Supreme Court’s seminal decision in *KSR International Co. v. Teleflex Inc.*, which endorsed an expansive and flexible approach to obviousness and in effect made the claim of non-obviousness much harder to sustain.²⁸⁷

Indeed, the main cause for the proliferation of unwarranted or overbroad pharmaceutical patents is not the inadequacy of existing patentability standards but rather the insufficient scrutiny of these standards at the stage of issuance. During litigation, “with the benefit of a full evidentiary record, these [pharmaceutical] patents cannot withstand validity challenges.”²⁸⁸ Thus, a different policy approach would be to keep the standards of patentability unchanged but improve their scrutiny during and after the examination process.²⁸⁹ Professor Gregory Dolin, for example, offered to reexamine patents subject to an ANDA-triggered litigation if the parties settled the challenge in a way that was

282. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999).

283. See, e.g., Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1053 (2014); BURK & LEMLEY, *supra* note 96, at 110.

284. See generally Rebecca S. Eisenberg, *Pharma’s Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 375 (2008).

285. *In re Dillon*, 919 F.2d 688, 692–93 (Fed. Cir. 1990); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1377 (Fed. Cir. 2006); *Pfizer, Inc., v. Apotex, Inc.*, 480 F.3d 1348, 1361–62 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 941 (2007); see also Mark Metzke, *Targeting Enantiomer Product Hopping with a New “Obviousness” Standard*, 14 UCLA J.L. & TECH. 1, 10 (2010).

286. See, e.g., *In re Dillon*, 919 F.2d at 692–93. This showing is even harder to prove if courts classify the inquiry into the surprising properties as a “secondary consideration.” See *Pfizer*, 480 F.3d at 1372; Eric J. Marandett & Sophie F. Wang, *Secondary Considerations for Pharma Patents Get 2nd Look*, LAW360 (Nov. 6, 2014, 10:27 AM), <https://www.law360.com/articles/592128/secondary-considerations-for-pharma-patents-get-2nd-look> [https://perma.cc/9PPX-QSUQ]; see also Eisenberg, *supra* note 284, at 418.

287. 550 U.S. 398, 399–401 (2007). See, e.g., Yi-Chen Su, *What About Know-How: Heightened Obviousness and Lowered Disclosure Is Not a Panacea to the American Patent System for Biotechnology Medication and Pharmaceutical Inventions in the Post-KSR Era*, 14 MARQ. INTELL. PROP. L. REV. 321, 359 (2010); Eisenberg, *supra* note 284, at 376, 428; Furrow, *supra* note 42, at 276; Marandett & Wang, *supra* note 286.

288. Eisenberg, *supra* note 284, at 430.

289. The availability of IPRs ameliorated these concerns, but not without significant side effects. See *supra* text accompanying notes 84–86.

presumed anticompetitive.²⁹⁰ In a similar vein, Professor John Thomas offered payment on behalf of the USPTO to third parties for providing valuable information during the examination process.²⁹¹ Many countries allow outside experts to provide professional opinions to their agencies in hopes of improving the quality of the evaluation process.²⁹²

Policy prescriptions along these lines hit closer, but fail, to meet the target. A better approach would be to not rely on third parties (e.g., expert opinions) or objective signals (e.g., settlements above a certain amount) to trigger in-depth scrutiny of pharmaceutical patents of contestable merit. Instead, patent policy should bestow this task on the party the most qualified to assume it — patent owners themselves. The proposal in Section III.B takes this approach.

B. Evergreening At Risk

1. Theory and Benefits

As explained in Part II, follow-on improvement patents (unlike the “first-generation” patents that cover new pharmaceutical products) bestow upon brand-name manufacturers disproportionate value. Driven by that imbalance, brand-name manufacturers are over-incentivized to procure and enforce poor quality and even meritless patents.²⁹³ It is hardly surprising, therefore, that a 2002 report by the FTC found that brand-name manufacturers lose their patent infringement cases against generics 73% of the time, with nearly half of these losses on invalidity grounds.²⁹⁴ This number of successful invalidation cases could potentially be even higher in the absence of generic manufacturers’ perverse

290. See Dolin, *supra* note 148, at 322–23.

291. Thomas, *supra* note 156, at 305, 342.

292. Cf. Tahir Amin et al., *Expert Review of Drug Patent Applications: Improving Health in the Developing World*, HEALTH AFF. (Aug. 25, 2009), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.5.w948> [<https://perma.cc/C4RK-JB55>] (discussing pre-grant and post-grant proceedings in which third parties are invited to share relevant evidence); Amin & Kesselheim, *supra* note 51, at 2291–92 (discussing USPTO post-patent grant opposition proceedings, in which third parties can submit additional information bearing on the patentability of the claimed invention).

293. See, e.g., *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1379–82 (Fed. Cir. 2003); *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1389 (Fed. Cir. 2010); see also *The Perindopril Case*, *supra* note 95, ¶ 122 (noting that, of thirty-three process patents filed by Servier, twenty-one were described by Servier internally as “[b]locking” or “[p]aper patent[s],” of which three were further characterized as involving “[z]ero inventive step,” (emphasis omitted)); cf. Brian J. Love, *Patent Duration*, in 2 RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW 310, 317–19 (Peter S. Menell & David L. Schwartz eds., 2019); Eisenberg, *supra* note 284, at 429; Hemphill & Sampat, *supra* note 29, at 336 (observing that “[g]eneric challenges disproportionately target drugs with weak, late-expiring patents”); Kapczynski et al., *supra* note 51, at 7–8 (stating that “[s]econdary patents may be more vulnerable”).

294. See generally FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002).

incentives to prove noninfringement as opposed to invalidity.²⁹⁵ Another study from 2013, revealed that eighty-nine percent of the pharmaceutical patents at issue in settled litigation were “secondary” (covering an aspect other than the active ingredient), and that brand-name manufacturers prevailed in these cases only 32% of the time.²⁹⁶ In a similar vein, a report from 2016 indicated that “claimants had a win rate of 14.6% in ANDA cases, compared to a 4.4% win rate for other types of patent cases.”²⁹⁷

Since the private value of follow-on improvement patents is disproportionate compared to their social value, patent policy should aim to weaken the legal protection that is granted to such patents, at a minimum when such patents are invalid.²⁹⁸ Thus, under the proposed regime, follow-on improvement patents would no longer provide their owners with the available privilege to retain past monopoly profits made by enforcing such patents once they are invalidated.²⁹⁹ Instead, these wrongly gained profits would be vested as a bounty in favor of the first generic manufacturer who successfully invalidates the patent and opens the market to price-reducing competition.

In other words, a brand-name manufacturer who enforces an invalid follow-on patent to exclude generic competition would be required to pay the successful patent invalidator the monopoly premium earned

295. *Id.* at 20 (“This rate assumes that the patents underlying the non-infringement decisions and cases when the brand-name company abandoned the litigation are valid, even though the courts in these cases may not have addressed the validity question. Thus, the invalidity rate may be higher . . .”).

296. See Jones et al., *supra* note 78, at 1398–402.

297. See Sheila Swaroop & Kaitlin Heinen, *Recent Trends in ANDA Litigation*, PHARMAPHORUM (Dec. 19, 2016), <https://pharmaphorum.com/views-and-analysis/recent-trends-anda-litigation> [<https://perma.cc/49YR-LSGG>].

298. The analysis here, as well as the specific policy prescriptions that are presented in Sections III.B.2.a and III.B.2.b, is focused *at a minimum* on cases in which follow-on patents that serve to burden generic entry are subsequently proved invalid. The decision to limit the proposed bounty to invalidity cases (and not noninfringement cases) is not clear from doubt. *Cf.* Miller, *supra* note 80, at 728–30 (discussing “the uneasy case for rewarding a non-infringing defense”). Nevertheless, the proposed regime focuses on invalid patents for several reasons. First, as an empirical matter, many of the patents in the pharmaceutical thickets appear to be invalid. See *supra* notes 293–295. Second, because invalidity judgments generate stronger positive externalities than noninfringement judgments, see *supra* text accompanying notes 79–81, the former should be more zealously encouraged than the latter, see Miller, *supra* note 80, at 728–30. Third, sanctioning enforcement of invalid patents — as opposed to valid but irrelevant patents — is a more tailored approach that is less likely to upset established patent policies or to result in over-deterrence. See *infra* text accompanying notes 360–383. Nevertheless, a solution that does not address the problem of valid but opportunistically asserted patents is necessarily incomplete. *Cf.* FELDMAN, *supra* note 213, at 168 (“I could have a perfectly valid patent on Gummi Bears but choose to go after Microsoft with it. In other words, the validity of my patent does not necessarily relate to the validity of my choice of target.”). Future work could carefully expand the principles advanced in Sections III.B.2.a and III.B.2.b from invalidity to assertion.

299. Profits would be deemed attributed to these patents if the patents served to block generic competitors from entering the market. See *supra* text accompanying notes 13–18.

while generic competition was blocked. The monopoly premium would reflect the difference between the monopoly price charged while generic competition was blocked and the competitive price that would have been expected if generic entry had been allowed in a timely manner. To claim the bounty, the successful patent invalidator would have to show, at a minimum, that the enforcement of a follow-on patent served as the sine qua non for blocking a readily available generic entrant and that timely generic entry would have reduced the price of the drug. Other limitations could also be considered to further tailor the impact of the proposed regime.³⁰⁰

Consider again the case of Suboxone, a drug for the treatment of opioid use disorder discussed throughout the article. As explained in Section II.C, to stop Dr. Reddy's from entering the market with its approved generic version of Suboxone, Indivior obtained a follow-on continuation patent from the USPTO. Armed with its new patent, Indivior sued Dr. Reddy's for patent infringement and secured a preliminary injunction in July 2018, blocking Dr. Reddy's from entering the market.³⁰¹ In this case, the injunction did not last long because in November 2018, the Federal Circuit reversed the District Court decision and lifted the injunction.³⁰²

Under the proposed regime, if Indivior's follow-on patent is subsequently proved invalid in litigation and any other limiting factors are satisfied, Dr. Reddy's should be allowed to claim the monopoly premium that Indivior made in Suboxone sales between July and November 2018. If, in the absence of the Federal Circuit decision, the preliminary injunction would have endured until the end of the litigated conflict, Dr. Reddy's claim to Indivior's premium profits would have grown accordingly. Because Dr. Reddy's is the only approved generic competitor in the market at this point, Indivior's premium in selling

300. By targeting only invalid follow-on patents, the proposed scheme is already rather limited. See *supra* note 298. Nevertheless, a strict liability regime (imposing liability once invalidity is found) might still result in over-deterrence because patentees cannot always know of or prevent their patents' invalidity. For these reasons, it is better to limit the reach of liability to cases where the patentee could have reasonably avoided procurement or enforcement of the invalid patent. Cf. Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 796 (2002); Miller, *supra* note 80, at 709 ("The patentee's ability to have avoided prompting the grant of an invalid or unenforceable patent should be the key determinant in picking bounty-eligible grounds for voiding a patent."); Thomas, *supra* note 156, at 347. For concrete suggestions on how to tailor the reach of the proposed regime, see *infra* Sections III.B.2.a and III.B.2.b. Another limiting factor could be the ground for invalidation. Compare Miller, *supra* note 80 (favoring all grounds), with Kesan, *supra* (focusing on prior art concerns).

301. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, No. 17-7111 (KM) (CLW), 2018 WL 3496643, at *12 (D.N.J. July 20, 2018), *vacated and remanded*, 752 F. App'x 1024 (Fed. Cir. 2018).

302. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024, 1035 (Fed. Cir. 2018).

price will be calculated based on the expected competition between two competing manufacturers in that market.³⁰³

The period of blocked generic competition would usually be triggered either by a court-granted preliminary injunction or by implementation of the thirty-month automatic stay.³⁰⁴ In some cases, however, a successful invalidator would be able to prove that the period of blocked generic competition predated the litigated conflict. This showing will be possible if the brand-name manufacturer had sued an earlier generic entrant for infringing the same follow-on patent and the two parties settled the case and agreed on delayed market entry.³⁰⁵

Under these circumstances, a late-coming patent challenger who successfully invalidated the patent could argue, that in the absence of the patent just invalidated, the previous generic challenger would have entered the market in a timely manner as was originally intended. For example, if Indivior opts to settle the case with Dr. Reddy's without resolving the patent's validity, the bounty would then pass over to the next generic challenger to successfully invalidate the patent. In this scenario, the bounty would be greater, as it would reflect both the longer term of Indivior's unjustified monopoly and the greater reduction in price that would have been expected starting the minute the third market player obtained regulatory approval.³⁰⁶

The proposed regime is not the first to suggest that savvy patent policy should strive to discriminate between different layers of patents that cover the same pharmaceutical product. Notably, Professor Robin Feldman recently suggested that follow-on pharmaceutical improvements should be denied legal protection altogether.³⁰⁷ According to Feldman's "one-and-done" principle, brand-name manufacturers should be allowed to choose only one term of legal protection for each drug (e.g., a patent or a regulatory exclusivity).³⁰⁸ Once the choice was made, subsequent improvements would not be protected even if eligible

303. Assuming only two competitors, the price reduction is unlikely to be substantial. See Hemphill & Lemley, *supra* note 51, at 954 (10% retail price difference); cf. FELDMAN, *supra* note 213, at 159 (brand drug price drops 20–30% upon generic entry).

304. See *supra* text accompanying notes 89–91 (discussing the leverage of the injunction threat); *supra* notes 146–147 (discussing the leverage of the 30-month automatic stay).

305. Proving causality for noninfringement cases would be more difficult than for invalidity cases. Cf. Miller *supra* note 80, at 729 (discussing the limited impact of issue preclusion in noninfringement cases); *supra* note 294, at 7 (discussing extending the proposed regime to noninfringement).

306. In this scenario, the second generic invalidator could retroactively claim Indivior's premium profits from the day Dr. Reddy's generic product was first authorized.

307. See Feldman, *supra* note 14, at 640.

308. Feldman, *supra* note 14, at 640.

for a patent or a regulatory exclusivity because brand-name manufacturers would forever be estopped from enforcing these additional rights.³⁰⁹

Feldman's proposition is insightful but also quite radical. As Tom Wilbur, a spokesperson for Pharmaceutical Research and Manufacturers of America (PhRMA), recently said, "[a]s long as these new medical advances meet the statutory requirements for patentability, they rightfully deserve patent protection."³¹⁰ Many find Wilbur's pushback convincing, agreeing that denying patent owners the right to assert their patents goes against established patent policy and could potentially even run afoul of Constitutional principles.³¹¹ Wilbur's pushback is far less convincing, however, if these new medical advances do not meet the statutory requirements of patentability; namely, if the patents that cover them are proven *invalid*. Indeed, by limiting itself to cases of invalidity, the regime proposed in this article dodges the conventional "taking of property" criticism.³¹²

The regime proposed here has two appealing properties. First and foremost, the suggested bounty aligns the incentives of brand-name manufacturers with the social interest. Unlike existing punitive regimes, such as the antitrust laws or the False Claim Act,³¹³ a disgorgement-based approach nudges brand-name manufacturers away from pursuing and enforcing dubious patents but does not punish them for

309. Feldman, *supra* note 14, at 641 ("The election could be crafted so that it *mandates relinquishment of any other patent or exclusivity claims* as to the generic drug being approved." (emphasis added)).

310. Steve Brachmann, *Affordable Prescriptions for Patients Act Would Allow FTC to Prosecute Pharma Patent Thickets, Product Hopping*, IPWATCHDOG (May 20, 2019), <https://www.ipwatchdog.com/2019/05/20/affordable-prescriptions-patients-act-allow-ftc-prosecute-pharmaceutical-patent-thickets-product-hopping> [<https://perma.cc/92L2-487W>]. This argument is even stronger with respect to regulatory exclusivities. Unlike patents, regulatory exclusivities are not probabilistic because they cannot be challenged or invalidated. This makes their strategic accumulation *prima facie* justifiable. Regulatory exclusivities are also tailored in purpose, narrowed in duration (compared to patents), and limited in supply because they cannot be layered indefinitely. *But see* Feldman, *supra* note 14, at 619 (documenting accumulation of exclusivities).

311. 35 U.S.C. § 271(d) (2018) ("No patent owner . . . shall be denied relief or deemed guilty of misuse . . . by reason of his having . . . sought to enforce his patent rights against infringement."); *see* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 691 (2007). *But see* Feldman, *supra* note 14, at 641–42 (responding to Mossoff by distinguishing patent rights from full property rights).

312. *See* Mossoff, *supra* note 311, at 691. *See generally* John F. Duffy, Comment, *Intellectual Property Isolationism and the Average Cost Thesis*, 83 TEX. L. REV. 1077 (2005) (discussing the tension between "isolation" advocates that argue that intellectual property is *sui generis* and inherently different from traditional property such as land, and the "unification" advocates that argue that intellectual property is a species within of realm of private property).

313. *See* discussion *supra* Section III.A.2 (antitrust policy); *infra* text accompanying notes 371–373 (False Claims Act).

doing otherwise.³¹⁴ The obligation to disgorge past profits would not put brand-name manufacturers in a worse position by deciding to enforce their invalid rights than they would have been had they not done so.³¹⁵

While brand-name manufacturers do stand to lose the research and development costs associated with establishing the incremental patented improvement, these costs are not unusually high, and they are likely to be dwarfed by the outsized monopoly profits that can be expected if the patents would survive judicial scrutiny.³¹⁶ Let us assume, for example, that a blockbuster drug generates \$100 million per year under a monopoly and \$10 million once a generic competitor enters the market. By investing \$20 million, a brand-name manufacturer can secure a new improvement patent, assert the patent against the generic entrant, trigger the thirty-month stay, and profit an additional \$250 million by blocking competition. In this scenario, as long as the patent has more than an 8% chance of being held valid, an investment of \$20 million would be worthwhile.³¹⁷

314. Courts and commenters have often emphasized that restitution standing alone does not deter wrongdoing. *See, e.g.*, *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1158 (6th Cir. 1978) (noting that, with restitution standing alone, an “infringer would have nothing to lose, and everything to gain”); *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1563 (Fed. Cir. 1983); Robert D. Cooter, *Prices and Sanctions*, 84 COLUM. L. REV. 1523, 1547 n.51 (1984) (“Deterrence [from disgorgement of profits] is imperfect because disgorging profits eliminates the actual gain, but there is still an expected gain whenever there is a positive probability that the wrongdoing will go undetected.”); Robert D. Cooter, *Punitive Damages, Social Norms, and Economic Analysis*, LAW & CONTEMP. PROBS., Summer 1997, at 73, 77 (“‘Perfect disgorgement’ is a sum of money that leaves the injurer indifferent between the injury with liability for damages or no injury.”); Andrew Kull, *Restitution’s Outlaws*, 78 CHI.-KENT. L. REV. 17, 19 (2003) (noting that the facial result of “disgorgement-type restitution” is that “[t]he wrongdoer is left back where he started”); Bert I. Huang, *The Equipoise Effect*, 116 COLUM. L. REV. 1595, 1598 (2016) (“Someone who expects to disgorge her net gain knows that her act will be neither gainful nor costly; it will be a wash. . . . To fully persuade her not to act, then, other costs beyond disgorgement itself must finish the job.”); Chiang, *supra* note 12, at 1288 (“Even after applying a restitutionary remedy, there would be insufficient deterrence of fraud.”); Leslie, *supra* note 15, at 173 (“If the only punishment for bank robbing were to have to give the money back when caught, bank robbing would be highly rational — and popular.”). The same rationale works in reverse. When the goal is to discourage but not deter a social activity, disgorgement provides an optimal middle ground. *See* Withdrawal of the Commission Policy Statement on Monetary Equitable Remedies in Competition Cases, 77 Fed. Reg. 47,070, 47,071 (Aug. 7, 2012) (explaining that disgorgement is not “a punitive tool”); Ofer Grosskopf & Barak Medina, *Remedies for Wrongfully-Issued Preliminary Injunctions: The Case for Disgorgement of Profits*, 32 SEATTLE U. L. REV. 903, 906 (2009) (“[R]estitution can serve as a middle ground between the ideal, which drives us to confer rights and liberties, and reality, which forces us to be mindful of their misuse.”).

315. *See* RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 51(4) (AM. LAW INST. 2011) (“The object of restitution . . . is to eliminate profit from wrongdoing . . .”).

316. *See* discussion *supra* Part II (explaining the enhanced commercial value of follow-on pharmaceutical patents). But this need not be the case. An alternative calculation route would be to deduct the R&D investment costs that were required to come up with the follow-on improvements from the disgorgement bounty award.

317. When the investment is not made, the benefit per thirty-month (2.5-year) period is \$25M. When the investment is made, the expected benefit, excluding the \$20M cost, is given

Thus, in line with the social interest, brand name manufacturers' motivations to pursue and enforce follow-on patents under the proposed regime would increase in direct proportion to the perceived strength and potential social value of such patents. While it would be unattractive for brand-name manufacturers to pursue and enforce weak follow-on patents with substantial chances of being invalidated, pursuing potentially stronger follow-on patents at risk of disgorgement would remain attractive.

Second, the suggested approach also aligns the incentives of prospective generic invalidators with the social interest by promising them a greater reward for proving invalidity than what brand-name manufacturers are likely to offer them in return for dropping their invalidity challenges.³¹⁸ As such, the proposed bounty regime dramatically reduces the adverse incentive for brand-name and generic manufacturers to engage in anticompetitive settlements.

To make a collusive agreement attractive, a brand-name manufacturer would have to offer a prospective challenger at least as much for not challenging a patent as the challenger is expected to gain by successfully proving its challenge. Under the proposed regime, a prospective challenger's expected gain — as reflected by the brand-name manufacturer's past profits attributed to the contested patent discounted by the challenger's likelihood of success and the costs of litigation — grows as time passes. In the presence of a rolling bounty that grows over time, collective action between the parties would make any collusive agreement unattainable.

To illustrate, assume that a brand-name manufacturer considers procuring a completely meritless follow-on patent capable of extending the term of its drug's monopoly for several years. Yearly revenue of the drug is 100 under a monopoly and 10 under perfect competition among five manufacturers. In theory, it would make economic sense for all five parties — the brand-name manufacturer and four prospective generic challengers — to enter into a collusive deal. The generic manufacturers would agree not to challenge the patent, and all would share the future monopoly rent. In this scenario, each party could make 20 in yearly revenue instead of 10. In practice, however, each party has a growing incentive to betray the other parties. By opting to break the deal, initiate a patent challenge, and successfully invalidate the patent, each of the contracting generic manufacturers could seek disgorgement

by $p \times (2.5 \times \$100M) + (1 - p) \times (2.5 \times \$10M)$, where p is the chance that the patent is proved valid. Accounting for the additional cost of \$20M, the expected overall benefit is that result minus \$20M. Such an investment is cost-efficient when this difference is greater than \$25M, which is true when $p > 8\%$. In practice, multiple factors would impact this simplified analysis. See, e.g., Hemphill & Lemley, *supra* note 51, at 982; *supra* Part II (discussing various other advantages that follow-on patents generate). Regardless, the general point applies.

318. Cf. Miller, *supra* note 80, at 718 (explaining that a disgorgement-based bounty reduces collusion).

of 90 after the first year. Insuring against mutual betrayal would be costly for a few parties and unrealistic for many.³¹⁹ To sum up, prescribing a disgorgement-based bounty for challenging follow-on pharmaceutical patents would serve to align follow-on patenting incentives while mitigating the reverse-payment settlements epidemic.

2. Avenues for Implementation

Like the Hatch-Waxman Act, the proposed regime could be adopted through a complex legislative reform. Such a reform would do best to preserve the existing 180-day bounty as a mandatory minimum to be substituted by the disgorgement-based award only if the latter proves more substantial for the generic challenger than the former. Having a mandatory minimal bounty would serve to incentivize early challenges — i.e., before brand-name manufacturers make additional monopoly profits that would be subject to disgorgement.³²⁰

Any comprehensive legislation in this complex junction of law and regulation, however, is likely to be abused. A better approach would be to empower the courts with the discretion needed to prescribe this bounty.³²¹ Fortunately, the equitable nature of the disgorgement remedy presents a unique opportunity for courts to accommodate the gist of the proposed regime, even in the absence of legislative action. The remainder of this article explores two ways in which this could be done.

One option, explored in Section III.B.2.a, requires courts to alter the law of patent misuse by imposing on the owners of follow-on pharmaceutical patents more comprehensive duties of due diligence and good faith, and then to enforce these duties directly by prescribing a disgorgement remedy.³²² Alternatively, courts could enforce these heightened duties indirectly by facilitating legal actions by third parties, such as consumers or the Federal Trade Commission (“FTC”).³²³

Another option, explored in Section III.B.2.b, requires courts to condition the grant of preliminary injunctions with an undertaking by brand-name manufacturers to disgorge in favor of generic applicants

319. Cf. JEFFREY CHURCH & ROGER WARE, *INDUSTRIAL ORGANIZATION: A STRATEGIC APPROACH* 308 (2000) (explaining that cartels are often unstable).

320. Because the disgorged proceeds reflect the monopoly profits during the period when the contested follow-on patent prevented generics’ entry, if that patent is invalidated before, during, or soon after the expiration of the first patent (or regulatory exclusivity), the monopoly premium for this invalidated patent (i.e., the amount to be disgorged) is nonexistent or negligible. Preserving the existing 180-day bounty as a mandatory minimum encourages early challengers in such cases. See Miller, *supra* note 80, at 721 (calling for a mandatory minimum).

321. Feldman, *supra* note 128, at 311 (“The flexibility required for responding appropriately to inappropriate uses of intellectual property suggests that the courts or regulatory bodies would constitute more effective vehicles than legislatures.”).

322. See *infra* Section III.B.2.a.i.

323. See *infra* Section III.B.2.a.ii.

their interim monopoly profits in cases in which the preliminary injunctions are proved to be wrongly issued.³²⁴ Again, instead of imposing disgorgement directly, courts could accommodate restitutionary claims by third parties for recovery of losses suffered during the period the wrongfully issued preliminary injunctions were enforced.³²⁵

a. Altering the Law of Patent Misuse

Patent owners' equitable obligations with respect to their patents' validity, both before and after patent issuance, are very limited. At first blush, at least during patent prosecution, it seems that patent applicants have some obligation to aid the USPTO in evaluating their patents' merits. Patent applicants owe a duty of candor and good faith to the USPTO, which prohibits them from withholding known information that is material to the validity of their patents.³²⁶ Violation of this duty constitutes inequitable conduct, which is an affirmative defense in patent litigation and triggers the equitable sanction of patent unenforceability.³²⁷

Under the current law, however, the prerequisites for proving inequitable conduct are notoriously difficult to satisfy.³²⁸ To prove that a patent applicant has engaged in inequitable conduct, a prospective challenger must prove by the heightened evidentiary standard of clear and convincing evidence: (1) a misrepresentation that is material enough that in its absence, the patent grant would have been denied; and (2) specific intent on behalf of the patent applicant to deceive the USPTO.³²⁹ This standard essentially mirrors the antitrust standard for imposing liability for the same conduct if coupled with market monopolization under the *Walker Process* doctrine.³³⁰

324. See *infra* Section III.B.2.b.i.

325. See *infra* Section III.B.2.b.ii.

326. 37 C.F.R. § 1.56(a) (2020).

327. For a concise summary of the doctrine's development, as well as a literature review, see Thomas F. Cotter, *An Economic Analysis of Patent Law's Inequitable Conduct Doctrine*, 53 ARIZ. L. REV. 735, 741–45 (2011).

328. See Ryan Davis, *Inequitable Conduct a Dying Defense 2 Years Post-Therasense*, LAW360 (May 23, 2013, 9:13 PM), <https://www.law360.com/articles/444480/inequitable-conduct-a-dying-defense-2-years-post-therasense> [<https://perma.cc/WVE7-TTC8>] (noting that the use of the doctrine has dropped sharply since the Federal Circuit heightened its prerequisites); see also *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

329. DARYL LIM, PATENT MISUSE AND ANTITRUST LAW: EMPIRICAL, DOCTRINAL AND POLICY PERSPECTIVES 129–30 (2013); see also Chiang, *supra* note 12, at 1268 (explaining that the pleading standard for inequitable conduct “is the most onerous in all of civil litigation”).

330. See *supra* notes 275–276 and accompanying text (discussing *Walker Process*). These heightened standards emerged from the common law of fraud. See John F. Carney, *Misrepresentations Before the Patent Office: Antitrust and Other Legal Effects*, 12 B.C. L. REV. 1005, 1006 (1971). The Federal Circuit has made clear that conduct beneath the level of fraud

Once a patent issues, patent owners no longer have duties concerning the validity of their patents. They are not required to initiate reexamination of newly available evidence that is material to their patent's validity; they are not required to disavow their patents even if they know for certain that their patents are invalid; and they are free to enforce dubious patents for as long as their enforcement action is not deemed a sham.³³¹ Similarly to the case of the inequitable conduct doctrine, the standard for proving sham litigation, which also emerged from the antitrust laws, is exceptionally demanding.³³²

It is not surprising that antitrust standards are rigorous. As explained in Section III.A.2, guided by their punitive remedy, antitrust laws are justifiably more concerned with "false positives" (condemning lawful conduct) than with "false negatives" (condemning unlawful conduct).³³³ Patent misuse policy, on the other hand, is equitable in nature, not punitive, and it is not bound by antitrust principles.³³⁴

Broadening patent owners' obligations, at least for follow-on pharmaceutical patents, would do a great deal to improve patent quality, and doing so is squarely within the equitable powers of the court.³³⁵ Courts

that would sustain a *Walker Process* claim can still be characterized as inequitable conduct. See *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007). It is unclear what is left of this distinction post-*Therasense*. Of course, a *Walker Process* claim must also satisfy antitrust requirements, such as those regarding monopoly power. See Chiang, *supra* note 12, at 1298.

331. Cf. Eugene R. Quinn Jr., *Abusing Intellectual Property Rights in Cyberspace: Patent Misuse Revisited*, 28 WM. MITCHELL L. REV. 995, 996–98 (2002) (suggesting the imposition of post-issuance responsibilities on patent owners); Leslie, *supra* note 15, at 113–39 (exploring the adverse social impact of unenforced and invalid patents); *supra* notes 272–274; *infra* notes 382–384 and accompanying text (exploring the limited role and impact of sham litigation in patent cases).

332. See *supra* notes 271–274 and accompanying text.

333. See Frank H. Easterbrook, *On Identifying Exclusionary Conduct*, 61 NOTRE DAME L. REV. 972, 977 (1986) ("[F]alse positives are much more harmful than false negatives."); see, e.g., *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (justifying leniency for refusals to deal in response to the costliness of false condemnations); *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) (justifying leniency for predatory pricing in response to the "intolerable risks of chilling legitimate price-cutting").

334. See *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1376 (Fed. Cir. 2001); Cotropia, *supra* note 69, at 728 (noting that inequitable conduct is rooted in equity). For criticism of the merger between patent misuse and antitrust standards, see generally Christina Bohannon, *IP Misuse as Foreclosure*, 96 IOWA L. REV. 475 (2011); Feldman, *supra* note 260.

335. *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288, 335 (1960) (noting that "unless otherwise provided by statute, all the inherent equitable powers of the district court are available" and, where public interest is involved, "equitable powers assume an even broader and more flexible character"); Allison Pruitt, Note, *Keeping Patent Applicants Honest: A Proposal to Apply Disgorgement Remedies to Findings of Inequitable Conduct During Patent Prosecution*, 13 J. INTELL. PROP. L. 465, 481 (2006) ("As an equitable remedy, disgorgement has been routinely imposed . . . even when not specifically authorized by statute."); Pamela Samuelson, John M. Golden & Mark P. Gergen, *Recalibrating the Disgorgement Remedy in Intellectual Property Cases*, 100 B.U. L. REV. (forthcoming 2020) ("Indeed, courts, in exercising equitable discretion, can tailor disgorgement awards in much

could, for example, replace the requirement of specific intent to deceive the USPTO with an objective negligence-based standard.³³⁶ The Federal Circuit specifically rejected this standard in its guiding en banc decision in *Therasense v. Becton, Dickinson & Co.*³³⁷ Nevertheless, before that decision, courts were far more willing to infer intent to deceive in cases where material information was omitted and where the patent applicant who should have known of its materiality failed to provide a credible explanation for the nondisclosure.³³⁸ A relaxed standard of intent would go a long way in encouraging patent applicants to take greater care when prosecuting multiple pharmaceutical patents.³³⁹

Cracks in the rigid *Therasense* stonework are already emerging. Recently, in *Regeneron Pharmaceuticals, Inc. v. Merus N.V.*,³⁴⁰ the Federal Circuit endorsed a more relaxed view of specific intent by finding that the district court did not abuse its discretion by drawing an adverse inference of specific intent to deceive the USPTO by considering, among other things, post-prosecution behavior such as misconduct during litigation.³⁴¹ The *Regeneron* decision has emboldened more courts to consider a wider range of misconduct to draw adverse inferences regarding inequitable conduct.³⁴²

Courts could potentially go even further by imposing an ongoing affirmative obligation on patent owners to reexamine their follow-on patents before asserting them.³⁴³ Such a duty could be triggered when new material information becomes available to the patent owner.³⁴⁴ Brand-name manufacturers could then satisfy this duty by initiating supplementary examination at the USPTO and allowing the office to examine new suspected evidence.³⁴⁵ By initiating supplementary examination before asserting their patents, brand-name manufacturers

the same way that they can decide whether to order injunctive relief, how to tailor any injunction, or whether to award treble damages.”). See generally BURK & LEMLEY, *supra* note 96 (emphasizing the value of judicially made policy levers).

336. David McGowan, *Inequitable Conduct*, 43 LOY. L.A. L. REV. 945, 976 (2010) (advocating for a recklessness-based standard).

337. 649 F.3d 1276, 1290 (Fed. Cir. 2011).

338. See, e.g., *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008).

339. Chiang, *supra* note 12, at 1271 (criticizing the standard of specific intent); see *Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1311 (Fed. Cir. 2013) (presenting the difficulty of establishing a case with subjective factors).

340. 864 F.3d 1343 (Fed. Cir. 2017).

341. *Id.* at 1364; see also Matthew Avery et al., *The Return of the Plague: Inequitable Conduct After Regeneron v. Merus*, 34 SANTA CLARA HIGH TECH. L.J. 328, 349 (2018).

342. Avery et al., *supra* note 341, at 352.

343. Cf. Leslie, *supra* note 15, at 161 (offering imposing a duty on right holders to disavow patents known to be invalid); Quinn, *supra* note 331, at 996–97 (suggesting imposing an affirmative duty on right holders to prove validity before enforcing patents for the first time).

344. Cf. Avery et al., *supra* note 341, at 359 (noting that if patent holders become aware of material references post-prosecution, “there is no duty to disclose at this point”).

345. 35 U.S.C. § 257 (2018).

could then be granted “amnesty” from future claims of inequitable conduct.³⁴⁶ This procedure already exists with respect to conduct during patent prosecution and could potentially be expanded to post-prosecution conduct as well.

Molding the standards of due diligence and bad faith to reflect the realities of pharmaceutical abuse would be a necessary first step for policing such behaviors.³⁴⁷ Once more expansive duties are set in place, however, a second policy change is needed — imposing a disgorgement remedy. There are two ways this policy goal can be achieved. One, discussed in Section III.B.2.a.i, is to have the courts utilize their equitable discretion and prescribe disgorgement directly. Another way, discussed in Section III.B.2.a.ii, is to facilitate disgorgement or restitution claims by third parties.

i. Disgorgement Imposed by the Courts

Disgorgement is an equitable remedy, and, similarly to the judicially-made unenforceability remedy adopted to sanction patent misuse and inequitable conduct, disgorgement can be imposed at the court’s discretion.³⁴⁸ A precedent for such an approach can be found in *Unipharm Ltd. v. Sanofi et al.*,³⁴⁹ a recent Israeli District Court decision currently pending Supreme Court review.³⁵⁰

Until February 2008, Plavix, one of Sanofi’s top-selling drugs, was protected in Israel by a pioneering patent that claimed the drug’s active ingredient, clopidogrel, as well as all of its salts and crystalline

346. 35 U.S.C. § 257(c)(1) (2018); Jason Rantanen & Lee Petherbridge, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24, 25 (2011) (calling this provision “a patent amnesty program”).

347. See FELDMAN *supra* note 271, at 167 (noting that the standards governing sham litigation should also be reconsidered).

348. See *supra* note 335.

349. CA (TA) 33666-07-11 Unipharm Ltd. v. Sanofi et al. (published on Nevo, Oct. 8, 2015) (Isr.). For overviews of this groundbreaking decision, see generally Yonah Jeremy Bob, *Background: Unipharm’s Decision over Sanofi May Change Patent Realm*, JERUSALEM POST (Nov. 24, 2015, 3:09 AM), <https://www.jpost.com/Israel-News/Background-Unipharms-decision-over-Sanofi-may-change-patent-realm-435133> [<https://perma.cc/H8MK-8QDX>]; Karen Elburg, *Client Update — Antitrust and Patent Rights — “Winter Is Coming” for Patent Owners*, LEXOLOGY (Oct. 22, 2015), <https://www.lexology.com/library/detail.aspx?g=b752b88c-a3f2-48c7-8dfb-1799c2370666> [<https://perma.cc/84T4-KKFD>]; Michael Factor, *Is Evergreening Unjust Enrichment? Unipharm Successfully Sues for Sanofi’s Profits*, IP FACTOR (Oct. 20, 2015), <https://blog.ipfactor.co.il/2015/10/20/is-evergreening-unjust-enrichment-unipharm-successfully-sues-for-sanofis-profits> [<https://perma.cc/5R7V-9YN4>].

350. At the time of this writing, Sanofi’s decision is pending Supreme Court review. Eran Bareket, *Israel: Disgorgement of Profits as Punitive Damages for Misleading a Patent Office*, AIPPI (Nov. 7, 2016), <https://aippi.org/no-show/israel-disgorgement-of-profits-as-punitive-damages-for-misleading-a-patent-office> [<https://perma.cc/63YX-N2QE>].

forms.³⁵¹ In November 2000, Sanofi filed for an Israeli follow-on patent claiming a new polymorph of clopidogrel.³⁵² Several generic manufacturers challenged the patent's validity, and a pre-grant opposition process began.³⁵³ In 2010, Sanofi abandoned its patent application voluntarily.³⁵⁴

Five years later, Unipharm, one of the generic manufacturers to challenge Sanofi's follow-on patent at the Israeli patent office, filed an independent lawsuit against Sanofi in the Tel-Aviv District Court. Unipharm claimed that Sanofi's follow-on patent was fraudulently produced and sought opportunistically in an attempt to depress generic competition. Unipharm boldly advanced a claim that in return for unveiling Sanofi's immoral behavior, it should be allowed to capture Sanofi's past monopoly profits made during the opposition process while generic competition was discouraged.³⁵⁵

The Israeli court accepted Unipharm's novel approach even though a disgorgement remedy was not available under the Israeli Patent Law nor the Israeli Law of Monopolies.³⁵⁶ After reviewing all existing remedial approaches and finding them inadequate, the Israeli court decided that judicial activism was required to scale back brand-name manufacturers' overreaching incentives and to preserve the integrity of the patent prosecution process. A court-imposed disgorgement-based bounty in favor of the first generic whistleblower would advance this goal by converting self-interested competitors into effective enforcement agents.³⁵⁷ The court's decision was grounded in unjust enrichment theory, which has a very broad reign in Israeli jurisprudence.³⁵⁸

The approach taken by the Israeli court is even more powerful when applied to U.S. law. The policies that govern patentees' inequitable conduct under U.S. patent and antitrust laws are far more restrictive

351. Israeli patent IL 85294, filed February 2, 1988, was set to expire February 3, 2008. See *Unipharm*, CA (TA) 33666-07-11 at 3. Plavix's annual revenue was \$8.6 billion in 2009. Ron Winslow, *Plavix Rival Gains from Studies*, WALL ST. J. (Aug. 30, 2010, 12:01 AM), <https://www.wsj.com/articles/SB10001424052748703618504575459651352553236> [<https://perma.cc/NM7M-AUTQ>].

352. *Unipharm*, CA (TA) 33666-07-11 at 12. Israeli patent IL 139790 was a national-stage application of PCT/FR99/01371; it was published for opposition purposes in October 2006.

353. Immediately after the application was published in October 2006, two generic manufacturers, Teva and Unipharm, expressed opposition.

354. See *Unipharm*, CA (TA) 33666-07-11 at 12–13.

355. *Id.* at 21.

356. *Id.* at 39–55.

357. Cf. Ofer Grosskopf, *Protection of Competition Rules via the Law of Restitution*, 79 TEX. L. REV. 1981, 2000 (2001) (discussing the benefits of turning competitors into enforcement agents).

358. The law of unjust enrichment allowed Israeli courts to both widen existing legal entitlements and create new ones, as well as to impose disgorgement in cases for which no such remedy was available. See CA 5768/94 A.Sh.I.R. v. Forum Accessories & Commodities, IsrSC 52 (4) 289 (1998) (Isr.); Factor, *supra* note 349 (“[T]he law of Unjust Enrichment is a tort in and of itself.”).

than their Israeli counterparts, which the Israeli court correctly labeled as insufficient. Unlike the U.S. patent laws, Israeli patent law does empower the court to shorten the duration of the patent, order compulsory licenses, or impose monetary fines in cases of inequitable conduct;³⁵⁹ and unlike U.S. antitrust laws, the Israeli Law of Monopolies does not require deceptive intent or monopolization as prerequisites for sanctioning misrepresentation before the patent office.³⁶⁰

Moreover, one adverse side effect that the Israeli court decision unintentionally generates would be mitigated substantially if applied to the U.S. system. Unlike in the United States, the Israeli patent system features a pre-grant opposition proceeding at the patent office. During these proceedings, generic manufacturers are discouraged, but not legally prevented, from entering the market — they are permitted to do so at the risk of paying damages retroactively if the patent is found valid.³⁶¹ Because launching at risk is a perilous venture, however, generic manufacturers' incentives to launch at risk during the opposition process are relatively modest.³⁶² In Sanofi's case, for example, no generic manufacturer entered the market during the fifteen-month opposition. Nevertheless, at least in some cases, generic challengers would take their chances and launch at risk. The Sanofi decision, however, is threatening to eliminate whatever is left of the incentive to launch a generic product at risk. Under the court's precedent, a prospective generic challenger would be far better off sitting idly throughout the opposition proceedings and claiming disgorgement of the brand-name manufacturer's profits retroactively than assuming the massive risk associated with premature market entry.³⁶³ To prevent this adverse result, the Israeli court suggested limiting disgorgement awards only to those generic challengers who actually launched at risk.³⁶⁴

In the United States, this concern is substantially moderated. Unlike in Israel, a generic manufacturer seeking regulatory approval in the United States is obliged to file a Paragraph IV certification, inform the brand-name manufacturer of its attempt to secure approval, and subject

359. See Patent Law 5727-1967, § 18(C) (2014) (Isr.); cf. Chiang, *supra* note 12, at 1286–91 (suggesting fines for inequitable conduct).

360. The Israeli Law of Monopolies, § 29 (A)(a), draws from article 82 of the EC Treaty; it is much broader in reach than the equivalent U.S. antitrust laws. See *Unipharm*, 33666-07-11 at 47–48. On the other hand, unlike in U.S. antitrust policy, the Israeli law of monopolies does not provide for treble damages. Patent Law 5727-1967, § 18(C) (2014) (Isr.).

361. During the opposition period, Sanofi could not secure an injunction to prevent generic competitors from entering the market because its patent had not yet been issued. According to Israeli law, however, Sanofi could sue retroactively to recover any damages that it sustained due to premature generic launches during the opposition period. See Patent Law, 5727-1967, § 179–183 (2014) (Isr.); CA 6025/05 Merck & Co. Inc. v. Teva Ltd. (published on Nevo, May 19, 2011) (Isr.).

362. See *Unipharm*, CA (TA) 33666-07-11 at 20.

363. See *id.* at 53–54 (discussing this outcome).

364. See *id.*

itself to suit.³⁶⁵ At this point, generic market entry would be blocked either by the operation of the statutory thirty-month automatic stay or by a court-granted preliminary injunction. In both cases, market entry is denied by the operation of law, not by the generic manufacturer's discretion. Prescribing disgorgement in such cases would not reduce the incentives to launch at risk because launching at risk is not an available option. There would still be cases where generic manufacturers could enter the market at risk and would opt not to do so — e.g., if brand-name manufacturers did not secure a preliminary injunction and the thirty-month stay was exhausted — but in such cases, as the Israeli court suggested, the bounty could simply be denied.

ii. Legal Actions Advanced by Third Parties

Even without imposing disgorgement directly, courts could achieve a similar policy goal by accommodating disgorgement or restitution claims advanced by third parties. For example, after the Supreme Court of Canada invalidated Pfizer's patent on Viagra in 2012,³⁶⁶ purchasers of the drug filed an unjust enrichment class action against Pfizer, seeking disgorgement of the monopoly profits that Pfizer made by blocking generic competition due to the pending trial.³⁶⁷ While this legal theory fits the framework advanced in this article, its application is problematic. Opening the floodgate for various common law and state law actions might easily result in over-deterrence, which is detrimental to innovation incentives.³⁶⁸ Also, the threat of bottomless liability might foster rather than curtail anticompetitive settlements between brand-name and generic manufacturers in an attempt to block follow-on lawsuits. The Canadian Court of Appeals ultimately dismissed the consumer class action on the grounds of preemption.³⁶⁹ This theory will not necessarily prevail in the United States, although similar attempts to impose liability under various state laws have been preempted.³⁷⁰

365. See *supra* Section II.B.1.

366. See *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, 657 (Can.).

367. See *Low v. Pfizer Canada Inc.*, 2014 BCSC 1469, ¶¶ 1, 73, 79 (Can. B.C.); Junyi Chen, *B.C. Supreme Court Finds Class Action Claim Based on Invalidation of Pfizer's Viagra (Sildenafil) Patent Discloses Causes of Action*, SMART & BIGGAR (Sept. 8, 2014), http://www.smart-biggarr.ca/en/articles_detail.cfm?news_id=889 [<https://perma.cc/H5C2-DZNW>].

368. See *supra* Section III.A.2.

369. See *Low v. Pfizer Canada Inc.*, 2015 BCCA 506, ¶ 106 (Can. B.C.); Lynn Ing, *BC Court of Appeal Dismisses Consumer Class Action Based on Invalidation of Viagra Patent*, SMART & BIGGAR (Dec. 11, 2015), http://www.smart-biggarr.ca/en/articles_detail.cfm?news_id=1084 [<https://perma.cc/AY2L-JRN4>].

370. Cf. Louis M. Bograd & Andre M. Mura, *Buckman Stops Here! Limits on Preemption of State Tort Claims Involving Allegation of Fraud on the PTO or the FDA*, 41 RUTGERS L.J. 309, 309–10 (2009) (asserting that “[w]here plaintiffs allege, and can offer evidence of, fraud . . . plus all of the necessary elements of a traditional state-law cause of action, federal law should not be understood to preempt their claims”).

In addition to state law claims, interested third parties also attempted to harness the False Claims Act — which empowers private plaintiffs to file a *qui tam* lawsuit on behalf of the U.S. Government — to compel brand-name manufacturers to give up overpayments. In 2016, for example, Lower Drug Prices for Consumers LLC attempted to impose liability on Allergan and Forest Laboratories under the False Claims Act based on the theory that invalid patents served to unlawfully inflate the price of the branded drug Bystolic.³⁷¹ While the legal theory is sound, the False Claims Act is an improper vehicle to enforce the broader duties of care advanced in this article. Like the antitrust laws, the False Claims Act provides for a mandatory punitive damages remedy, not for disgorgement.³⁷² Under these circumstances, lowering the bar of inequitable behavior and expanding the reach of the False Claims Act would result in over-deterrence.³⁷³

One silver lining, however, can be found in the FTC's broad enforcement and remedial authority.³⁷⁴ The Commission was long determined only to "seek disgorgement and restitution in *exceptional cases*," despite their broad authorization.³⁷⁵ In recent years, however, the FTC

371. See Dennis Crouch, *Bad Patents and the False Claims Act*, PATENTLY-O (Oct. 17, 2016), <https://patentlyo.com/patent/2016/10/patents-false-claims.html> [<https://perma.cc/9J8Q-34HN>] (explaining the case).

372. 31 U.S.C. § 3729 (2018).

373. Even without relaxing the liability standard (to anything less than fraud), a False Claims Act might still have a policing role to play by broadening the scope of actionable misbehaviors. Currently, under a *Walker Process* theory, the accused infringer needs to show not only that the enforced patent was fraudulently procured from the patent office, but also that the patent holder was aware of that fraud at the time of the lawsuit. See *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069–70 (Fed. Cir. 1988). Under a False Claims Act claim based on inequitable conduct, by contrast, a relator need only show that the patentee billed the government while deliberately ignoring or recklessly disregarding the fraudulent circumstances under which the patent was obtained. See 31 U.S.C. § 3729(b)(1) (defining knowledge as (1) having actual knowledge, (2) acting in deliberate ignorance, or (3) acting in reckless disregard of the truth or falsity of the information). For this reason, among others, a False Claims Act theory may capture bad-faith acts that fall short of the *Walker Process* standard. For analysis, see Gregory Michael, William Newsom & Matthew Avery, *The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution*, 25 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 747, 774–75, 777 (2015).

374. See 15 U.S.C. § 53(b) (2018); *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FED. TRADE COMM'N (Oct. 2019), <https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority> [<https://perma.cc/MT4P-YPAD>]. Recently, the FTC's authority under 13(d) — at least when applied to past conduct — has been called into serious doubt. See, e.g., Robin P. Sumner, et al., *Third Circuit Affirms Limit on FTC's Authority to Sue in Federal Court*, PEPPER HAMILTON LLP (Mar. 1, 2019), <https://www.pepperlaw.com/publications/third-circuit-affirms-limit-on-ftcs-authority-to-sue-in-federal-court-2019-03-01> [<https://perma.cc/55LU-KB7A>]. Nevertheless, the FTC's enforcement authority is still unchallenged under Section 13(d) (as long as the Commission can demonstrate that the defendant "is violating or is about to violate" a law enforced by the FTC), or under Section 5. Enforcement actions under Section 5 should be favored to achieve optimal deterrence. See *infra* notes 386–389 and accompanying text.

375. Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 *Fed. Reg.* 45,820, 45,821 (Aug. 4, 2003) (emphasis added); see also Einer Elhauge, *Disgorgement*

has been rethinking its restrictive policy both in rhetoric and action. In 2012, the Commission declared that “competition cases may often be appropriate candidates for monetary equitable relief.”³⁷⁶ Following that statement, the FTC sought disgorgement in two important pharmaceutical cases, both involving a violation of patent owners’ duties of good faith.³⁷⁷

In *FTC v. Cephalon, Inc.*,³⁷⁸ the Commission entered into a settlement agreement with Cephalon and its parent company Teva, resolving an enforcement action that challenged Cephalon’s pay-for-delay arrangements with several generic manufacturers.³⁷⁹ The settlement with the FTC compelled Teva to disgorge a total of \$1.2 billion to purchasers and other parties who overpaid for Cephalon’s blockbuster drug Provigil.³⁸⁰ Although the unlawful conduct targeted in that case was the pay-for-delay arrangements, the FTC’s motivation to pursue disgorgement was heavily influenced by the fact that Cephalon had also violated its duty of candor to the USPTO when the company applied for patents subject to the conspiracy.³⁸¹ In a similar vein, in *FTC v. AbbVie Inc.*,³⁸² the court accepted the FTC’s allegation that AbbVie initiated sham patent infringement lawsuits to delay generic entry and preserve its monopoly of the testosterone replacement drug Androgel.³⁸³ The court

as an Antitrust Remedy, 76 ANTITRUST L.J. 79, 79 (2009) (noting that disgorgement is rarely used).

376. See Withdrawal of the Commission Policy Statement, *supra* note 314, at 47,070.

377. See Thomas A. Donovan, Francesco Carloni & Neil Baylis, *How Often Will the FTC Use Its Recently Reaffirmed Authority to Compel Disgorgement?*, K&L GATES (Sept. 6, 2018), <http://klgates.com/how-often-will-the-ftc-use-its-recently-reaffirmed-authority-to-compel-disgorgement-09-06-2018> [https://perma.cc/VY5K-ARNN].

378. Stipulated Order for Permanent Injunction and Equitable Monetary Relief, *FTC v. Cephalon, Inc.*, No. 2:08-cv-02141-MSG (E.D. Pa. June 17, 2015).

379. Press Release, Fed. Trade Comm’n, *FTC Settlement of Cephalon Pay for Delay Case Ensures \$1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go to Purchasers Affected by Anticompetitive Tactics* (May 28, 2015), <https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill> [https://perma.cc/Z67D-SVMB].

380. *Id.*

381. See FED. TRADE COMM’N, STATEMENT OF THE FEDERAL TRADE COMMISSION, *FTC v. CEPHALON, INC.* 4 (May 28, 2015) (“[T]he element of fraud is a relevant equitable consideration”); see also MAUREEN K. OHLHAUSEN & JOSHUA D. WRIGHT, FED. TRADE COMM’N, SEPARATE STATEMENT OF COMMISSIONERS MAUREEN K. OHLHAUSEN AND JOSHUA D. WRIGHT, *FTC v. CEPHALON, INC.* 4 (May 28, 2015) (“[S]hort of particularly egregious conduct or extraordinary circumstances, we would be hard-pressed to support disgorgement cases”).

382. *FTC v. AbbVie Inc.*, 329 F. Supp. 3d 98 (E.D. Pa. 2018).

383. See Press Release, Fed. Trade Comm’n, *FTC Sues Pharmaceutical Companies for Illegally Blocking Consumer Access to Lower-Cost Versions of the Blockbuster Drug Androgel* (Sept. 8, 2014), <https://www.ftc.gov/news-events/press-releases/2014/09/ftc-sues-pharmaceutical-companies-illegally-blocking-consumer> [https://perma.cc/2Z6Z-ANX4]; Press Release, Joe Simons, Statement of FTC Chairman Joe Simons Regarding Federal Court Ruling in *FTC v. AbbVie* (June 29, 2018), <https://www.ftc.gov/news-events/press-releases/2018/06/statement-ftc-chairman-joe-simons-regarding-federal-court-ruling> [https://perma.cc/HP28-PGCQ].

then ordered AbbVie to disgorge \$448 million in favor of consumers who overpaid for AbbVie's product.³⁸⁴

These cases suggest that the FTC might also be well situated to enforce the more expansive duties of due diligence and good faith of the type recommended above. Doing so without generating over-deterrence, however, would require that the FTC's enforcement action be exhaustive — i.e., not breed private follow-on actions at the state level. Such a limitation is difficult to achieve in most cases. For as long as the FTC's liability theory is based on general antitrust laws, as in the cases of Cephalon and AbbVie, numerous lawsuits at the state level are guaranteed to follow.³⁸⁵

The FTC could attempt to use its broader enforcement authority under Section 5 of the FTC Act.³⁸⁶ By pursuing a "pure" Section 5 action, the FTC could potentially compel disgorgement without "lead[ing] to well-founded treble damage antitrust claims in federal court."³⁸⁷ Even this approach is not riskless, however.³⁸⁸ Numerous state unfair competition statutes are modeled after the FTC Act and may be triggered once the FTC has established liability.³⁸⁹

384. The asserted patents here were not invalid. The proposed regime would affect such cases only if the liability standard for sham litigation is also adjusted. *See supra* note 271.

385. *See* Eric Sagonowsky, *CVS and Rite Aid, Riding on FTC Coattails, Sue AbbVie for "Sham" AndroGel Patent Claims*, FIERCEPHARMA (Aug. 21, 2018, 10:33 AM), <https://www.fiercepharma.com/pharma/cvs-rite-aid-sue-abbvie-for-sham-patent-cases-to-protect-andro-gel> [<https://perma.cc/FXZ9-A5ET>]; Dave Simpson, *Cephalon, Mylan, Ranbaxy Ink Combined \$65.8M Provigil Deal*, LAW360 (Mar. 26, 2019, 11:03 PM), <https://www.law360.com/articles/1143233/cephalon-mylan-ranbaxy-ink-combined-65-8m-provigil-deal> [<https://perma.cc/LB53-Q8CK>].

386. 15 U.S.C. § 45(a)(1) (2018) (declaring "[u]nfair methods of competition in or affecting commerce" to be unlawful). Older cases and commentary interpret Section 5 broadly. *See* *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972); *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986); Neil W. Averitt, *The Meaning of "Unfair Methods of Competition" in Section 5 of the Federal Trade Commission Act*, 21 B.C. L. REV. 227, 284–90 (1980). More recently, the FTC issued a more limited statement but still acknowledged that Section 5 is more encompassing than the Sherman or the Clayton Acts. *See* Press Release, Fed. Trade Comm'n, *FTC Issues Statement of Principles Regarding Enforcement of FTC Act as a Competition Statute* (Aug. 13, 2015), <https://www.ftc.gov/news-events/press-releases/2015/08/ftc-issues-statement-principles-regarding-enforcement-ftc-act> [<https://perma.cc/4ZC6-WQA8>].

387. *Negotiated Data Solutions LLC; Analysis of Proposed Consent Order to Aid Public Comment*, 73 Fed. Reg. 5,846, 5,849 n.9 (Jan. 31, 2008) (citing HERBERT HOVENKAMP, *FEDERAL ANTITRUST POLICY* 588 (W. Grp., Hornbook Series, 2d ed. 1999)); Justin J. Hakala, *Comment Letter on Public Workshop Concerning the Prohibition of Unfair Methods of Competition in Section 5 of the Federal Trade Commission Act* (Oct. 9, 2008), https://www.ftc.gov/sites/default/files/documents/public_comments/section-5-workshop-537633-00002/537633-00002.pdf [<https://perma.cc/VJ6Z-C576>].

388. Michael S. Wise, *Should You Settle with the FTC in a Section 5 Case?*, LAW360 (May 1, 2012, 1:35 PM), <https://www.law360.com/articles/335987/should-you-settle-with-the-ftc-in-a-section-5-case> [<https://perma.cc/HU3R-EJ96>] (noting that even pure Section 5 actions are not immune from follow-on state claims); Hakala, *supra* note 387 (same).

389. These statutes vary in scope, but many include private causes of action, and some even provide double or treble damages. *See* Hakala, *supra* note 387.

To summarize, relying on third-party actions to enforce patent owners' obligations concerning their patents' validity is theoretically workable but problematic in practice. Structural limitations — such as preemption — should be put into place to prevent a flood of private actions and the risk of over-deterrence. A constructive way to allow private plaintiffs to assist the government in cracking down on unlawful behavior while avoiding over-deterrence would be to introduce a private cause of action into the FTC Act and to provide rewards to whistleblowers when the FTC successfully compels monetary relief.³⁹⁰ This policy proposal would require minor legislative and administrative changes and would go a long way toward empowering the FTC's policing power.³⁹¹ Alternatively, an amendment to the FTC Act could empower the FTC to enforce certain good-faith or due-diligence duties with respect to follow-on pharmaceutical patents.³⁹²

b. Altering the Law of Preliminary Injunction

Courts have another, albeit more limited, approach to applying the ideas advanced in this article without remodeling patent owners' duties of good-faith behavior. In a perceptive article, Professor Douglas Lichtman claimed that courts engage in irrational analysis when they evaluate whether to grant a preliminary injunction in a given case.³⁹³ While emphasizing the irreparable harms that might flow from the grant of the injunction, courts are ignorant of the irreparable benefits that might flow from the same remedy. According to Lichtman, failing to account for irreparable benefits distorts the court's analysis of whether to grant

390. *Cf. Office of the Whistleblower*, SEC. EXCH. COMM'N, <https://www.sec.gov/whistleblower> [https://perma.cc/9C4Q-542X]. The FTC does not provide a comparable program, but it did consider such an approach in the past. *See* Press Release, Fed. Trade Comm'n, FTC Assesses Reward System for Catching Spammers (Sept. 16, 2004), <https://www.ftc.gov/news-events/press-releases/2004/09/ftc-assesses-reward-system-catching-spammers> [https://perma.cc/YET8-QR9W].

391. A mechanism that coordinates action by the FTC and private parties could substitute for the numerous "little FTC Act" state claims, which are often criticized for being overly expansive. *See, e.g.,* Henry N. Butler & Jason S. Johnston, *Reforming State Consumer Protection Liability: An Economic Approach*, 2010 COLUM. BUS. L. REV. 1, 10–11.

392. The recently introduced Affordable Prescriptions for Patients Act would empower the FTC to prosecute patent thickets and product hopping, as well as to pursue disgorgement and restitution. *See* Press Release, U.S. Sen. John Cornyn, Cornyn, Blumenthal Introduce Bill to Prevent Drug Companies from Abusing Patent System (May 9, 2019), <https://www.cornyn.senate.gov/content/news/cornyn-blumenthal-introduce-bill-prevent-drug-companies-abusing-patent-system> [https://perma.cc/G8WU-8C6U]. But as currently drafted, the proposed legislation fails to define obligations for brand-name manufacturers to follow (and for the FTC to enforce). *See* Steve Brachmann, *Affordable Prescriptions for Patients Act Would Allow FTC To Prosecute Pharma Patent Thickets, Product Hopping*, IPWATCHDOG (May 20, 2019), <https://www.ipwatchdog.com/2019/05/20/affordable-prescriptions-patients-act-allow-ftc-prosecute-pharmaceutical-patent-thickets-product-hopping> [https://perma.cc/69N5-2Z6B] (criticizing the bill for being vague).

393. Douglas Lichtman, *Irreparable Benefits*, 116 YALE L.J. 1284, 1299 (2007).

an injunction that, in turn, impairs the parties' motivations to seek a preliminary injunction in the first place.³⁹⁴ The skewed incentives that emerge may have undesirable social ramifications.

The evergreening phenomenon colorfully demonstrates Lichtman's concerns.³⁹⁵ Granting a preliminary injunction in follow-on patent infringement cases would usually result in massive irreparable benefits on behalf of the brand-name manufacturer. By ignoring such benefits when evaluating the merits of an injunction request, courts would systematically favor issuance.³⁹⁶ The tendency to over-grant preliminary injunctions in favor of brand-name manufacturers creates skewed innovation incentives: it encourages monetization of dubious patents through frivolous litigation instead of directing those resources into riskier but socially desirable ventures.³⁹⁷

Given these considerations, courts should sometimes condition the grant of a preliminary injunction on disgorgement of profits instead of a bond based on damages.³⁹⁸ The threat of disgorgement would deter brand-name manufacturers from pursuing frivolous patent enforcement while minimizing the adverse impact on incentives to pursue meaningful claims. Section III.B.2.b.i includes a consideration of the option of having courts prescribe disgorgement for a wrongfully issued preliminary injunction; Section III.B.2.b.ii includes a discussion of the option of accommodating third-party restitutionary claims for overpayments made while wrongfully issued preliminary injunctions were enforced.

i. Disgorgement Imposed by the Courts

In an insightful article, Professors Ofer Grosskopf and Barak Medina explored the virtues of a judicial approach that favors disgorgement of profits instead of a damages-based bond in the case of wrongfully issued preliminary injunctions.³⁹⁹ Grosskopf and Medina have argued that, as opposed to the prevailing practice, a disgorgement

394. *Id.* at 1290 (“[W]rongful injunctions are also troubling because they might irreversibly benefit the plaintiff in a distributional sense and might distort important incentives relevant to patentees, such as the incentive for a patent holder to litigate a case that is questionable on the merits.”).

395. Cf. Ariel Porat, *When Do Irreparable Benefits Matter? A Response to Douglas Lichtman on Irreparable Benefits*, 116 YALE L.J. POCKET PART 385 (2007) (clarifying that irreparable benefits do not always have an independent value).

396. See Lichtman, *supra* note 393, at 1299.

397. See *supra* Part II; see also Lichtman, *supra* note 393, at 1297 (stating that incentives are distorted “[i]f the patentee is mistakenly awarded preliminary relief Patent law is intended to award this patentee a certain payoff — a payoff designed to create particular incentives”).

398. See FED. R. CIV. P. 65(c) (requiring an applicant for a preliminary injunction to give a security (a bond) “in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained”). Most states replicate Rule 65(c) with minor changes. See DAN B. DOBBS, *LAW OF REMEDIES: DAMAGES, EQUITY, RESTITUTION* 196 n.2 (2d abr. ed. 1993).

399. Grosskopf & Medina, *supra* note 314, at 906.

remedy is superior to damages because it is more likely to advance the aim of minimizing social harm without having a detrimental impact on the plaintiff's incentives.⁴⁰⁰

Grosskopf and Medina's approach is convincing when applied to follow-on pharmaceutical patent cases. In these instances, courts should condition the issuance of a preliminary injunction in favor of the brand-name manufacturers on an undertaking to disgorge interim monopoly profits if the injunction proves to be wrongfully issued. An inference for such an unconventional approach can be made from another Israeli court decision in the case of *Palimport Ltd. v. Ciba-Geigy Ltd.*⁴⁰¹ In *Palimport*, the Israeli Supreme Court allowed a competitor, who had been prevented from entering the market by a preliminary order issued in favor of a patent owner, to claim the interim profits made by the latter once the patent was deemed invalid.

The outcome of the *Palimport* case is instructive to this article's proposal, but the justification that was given in that case for reaching the outcome is not.⁴⁰² The court based its decision to compel disgorgement on the premise that the profits made by the patent owner due to the wrongfully issued court order came at the claimant's expense.⁴⁰³ This reasoning would rarely stand in most patent cases, as the patent owner's realized (monopoly) profits are likely to exceed the competitor's lost (competitive) profits. Allowing a competitor to assume these additional profits that came not at his expense but at the expense of consumers would enrich the former at the expense of the latter.⁴⁰⁴ Indeed, a disgorgement remedy in follow-on pharmaceutical patent cases is justified not by corrective justice principles (recovering losses for the competitor) but by economic incentive theory — countering brand-name manufacturers' over-incentive to procure dubious patents and frivolously enforce them in court.⁴⁰⁵

Little prevents courts from adopting the suggested approach.⁴⁰⁶ The decision of whether to grant a preliminary injunction is already

400. *Id.* at 940.

401. CA 280/73 *Palimport Ltd. v. Ciba-Geigy Ltd.*, 29 (1) PD 597 (1975) (Isr.). For a discussion of this case, see Daniel Friedmann, *Restitution of Benefits Obtained Through the Appropriation of Property or the Commission of a Wrong*, 80 COLUM. L. REV. 504, 537–38 (1980).

402. This is not to say that the *Palimport* decision was wrongly decided. Indeed, there are various justifications for prescribing a disgorgement remedy. See Porat, *supra* note 395.

403. *Palimport*, 29 (1) PD at 607 (Cahn, J.).

404. Grosskopf & Medina, *supra* note 314, at 920 (“[C]ompensation for deadweight-loss merely reallocates the burden from one party to another without eliminating the social cost.”).

405. *Id.* at 926–27; see also Grosskopf, *supra* note 357, at 1997–98.

406. Cf. Lichtman, *supra* note 393, at 1300 (emphasizing that an amorphous inquiry into the “public interest” can include various considerations); see also *Roland Mach. Co. v. Dresser Indus.*, 749 F.2d 380, 388 (7th Cir. 1984) (finding that, in cases in which “granting or denying a preliminary injunction will have consequences beyond the immediate parties . . . those interests — the ‘public interest’ if you will — must be reckoned into the weighing process”); *Am. Hosp. Supply Corp. v. Hosp. Prods., Ltd.*, 780 F.2d 589, 594 (7th Cir. 1986).

subject to courts' equitable discretion, which allows the courts to consider social policy concerns such as pharmaceutical evergreening.⁴⁰⁷ Indeed, courts could tinker with the equitable law of preliminary injunctions to address abusive behavior by patent owners, just as they did, for parallel reasons, in the neighboring realm of permanent injunctions.⁴⁰⁸

In the seminal decision in *eBay Inc. v. MercExchange, L.L.C.*,⁴⁰⁹ the Supreme Court openly considered patent owners' sunk-cost leverage when defining the equitable considerations that must be evaluated when courts prescribe a permanent injunction.⁴¹⁰ Courts could similarly consider the sunk-benefit leverage in deciding whether to grant a preliminary injunction in follow-on pharmaceutical cases.⁴¹¹ Imposing a

407. The traditional balance-of-hardship test requires the court to consider: (1) a reasonable likelihood of success on the merits, (2) irreparable harm if the injunction is not granted, (3) an evaluation of the balance of hardships, and (4) an assessment of the injunction's impact on the public interest. *See, e.g.,* *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997) (citing *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1988)).

408. *See generally* Mark P. Gergen, John M. Golden & Henry E. Smith, *The Supreme Court's Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203 (2012) (arguing that the *eBay* decision significantly changed the way courts have evaluated permanent injunctions in various fields).

409. 547 U.S. 388 (2006).

410. *Id.* at 396–97 (Kennedy, J., concurring) (“When the patented invention is . . . a small component of the product the companies seek to produce, and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.”). Indeed, many commenters agree that, by changing the remedy for patent infringement from a permanent injunction to damages, the courts could ameliorate the sunk-cost leverage discussed *supra* Section II.A.2. *See, e.g.,* BURK & LEMLEY, *supra* note 96, at 140 (“[I]njunctive relief may be inappropriate where patent rights are asserted primarily as holdups”); Menell & Meurer, *supra* note 70, at 52. Prior to the *eBay* decision, courts automatically granted permanent injunctions in most patent infringement cases. *See* 35 U.S.C. § 261 (2018) (“[P]atents shall have the attributes of personal property.”); Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 IOWA L. REV. 1949, 1959 (2016) (finding that, prior to *eBay*, courts were routinely prescribing injunctions).

411. Because, in the pharmaceutical sector, patent leverage is based on patent owners' sunk benefits and not on patent users' sunk costs (the opposite of the IT sector, *see supra* Section II.A.2), the remedies should also be different. Although the *eBay* solution works fine for the IT sector, it would have limited impact in the pharmaceutical sector. Even under a damages regime, brand-name manufacturers would still benefit from engaging in frivolous litigation that affords them both a profitable delay and an opportunity to settle the litigation for an even longer, and more profitable, delay. *See supra* Sections II.A.2, II.B.2. Conversely, a disgorgement-based regime would effectively curtail the sunk-benefit leverage by making opportunistic delays financially unattractive, at least in some cases. The same logic works in reverse: a disgorgement-based regime would be grossly ineffective at curtailing the sunk-cost leverage in the IT sector because aggressive patent-assertion entities in this sector usually do not practice their invention and would have nothing to disgorge. *See, e.g.,* BRIAN T. YEH, CONG. RESEARCH SERV., R42668, AN OVERVIEW OF THE “PATENT TROLLS” DEBATE 2 (2013) (noting that non-practicing entities do “not make or sell anything”). Without past profit from production, patent owners could litigate aggressively in the hope of securing attractive settlement agreements without fearing disgorgement in the case of a loss. This point highlights a major weakness in the approach of Miller, who sought to adapt a broad disgorgement-based bounty regime to all fields of innovation, with a major emphasis on the IT sector. *See* Miller, *supra* note 80, at 668 (using Amazon's one-click patent as a leading example).

disgorgement-based remedy instead of a damages-based remedy would serve to curtail the skewed incentives to pursue dubious patents and engage in frivolous litigation.⁴¹²

ii. Legal Actions Advanced by Third Parties

Instead of vesting the wrongfully gained profits with the successful generic challenger, courts could accommodate restitutionary claims advanced by third parties to recover overpayments made while the wrongfully granted preliminary injunction was in force. For example, in a pending Federal Court case against Sanofi-Aventis, the Australian government is seeking to recover \$54.8 million that the government overpaid for Sanofi's branded drug Plavix as a result of a wrongfully issued preliminary injunction that blocked generic entry.⁴¹³

As discussed in the preceding Section, however, accommodating third-party claims for recovery has major disadvantages that may very well outweigh their benefits. First and foremost, damages sought by third-party claimants might exceed the benefits assumed by the patent owner. In such cases, accommodating restitutionary claims would result in over-deterrence.⁴¹⁴ In the Australian case, for example, even though the damages sought by the government corresponded to Sanofi's benefits, Sanofi's overall liability is expected to be oversized

412. Unlike the more general approach offered in Section III.B.2.a, limiting disgorgement to cases of wrongfully issued injunctions would have a limited deterring impact on anticompetitive collusion. Because the disgorgement bounty is limited to the litigated case, the parties may still find it in their best interests to settle for a delay if the expected future profits are large enough. *Cf.* Miller, *supra* note 80, at 719.

413. Commonwealth of Australia v Sanofi-Aventis, [2015] FCA 384 (Austl.) (allowing the government to proceed with its restitutionary claim). The government's restitution claim is based on the Australian federal subsidy program, which mandates an automatic and irreversible reduction in the prices of branded drugs as soon as a generic substitute enters the market. *See* Jarrod Voss, *Australia: Protecting Pharmaceutical Market Share in Australia*, MANAGING IP (Mar. 22, 2019), <http://www.managingip.com/Article/3865388/Australia-Protecting-pharmaceutical-market-share-in-Australia.html> [<https://perma.cc/7ZRJ-UPVA>]; Mark Summerfield, *Australian Government Seeks \$60M Damages over Invalid Patent*, PATENTOLOGY (Apr. 28, 2015, 7:36 PM), <https://blog.patentology.com.au/2015/04/australian-government-seeks-60m-damages.html> [<https://perma.cc/3879-PKLS>] (explaining this regime). In this case, a preliminary injunction that was issued in Sanofi's favor, along with an undertaking provided by the generic competitor (Apotex) in a pending patent-infringement litigation, prevented the latter from entering the market and triggering the statutory price reduction. *See* Apotex Pty Ltd v Sanofi-Aventis, [2009] FCAFC 134, 7 (Austl.). Once the litigation ended with Sanofi's patent deemed invalid, the Australian government sought recovery for its overpayments. The Australian government also pursued similar claims in other proceedings. *See* John Collins, Ashley Cameron & Ethan Tindall, *Commonwealth Claims on Undertakings Continue to Be a Risk for Pharmaceutical Patent Owners*, CLAYTON UTZ (Dec. 20, 2018), <https://www.claytonutz.com/knowledge/2018/december/commonwealth-claims-on-undertakings-continue-to-be-a-risk-for-pharmaceutical-patent-owners> [<https://perma.cc/9HNR-NKMH>].

414. *Cf.* Grosskopf & Medina, *supra* note 314, at 933–34 (warning against over-deterrence).

because the company has already compensated Apotex for their own damages, which resulted from the same conduct.⁴¹⁵

In another example, after the United Kingdom Supreme Court's invalidation of Pfizer's patents on its blockbuster drug Lyrica,⁴¹⁶ a group of researchers urged the National Health Service to sue Pfizer to recover £502 million in excessive prescription costs that the service bore during prolonged litigation.⁴¹⁷ For reasons that were outside of Pfizer's control, however, the supra-competitive price for Lyrica during the pending litigation also impacted prices of generic substitutes for Lyrica that were widely available for a range of non-protected uses.⁴¹⁸ Because the National Health Service paid in excess regardless of whether a branded or generic version of Lyrica was prescribed, the Service's losses from overpayments far exceeded Pfizer's benefits from overcharging.⁴¹⁹ Requiring Pfizer to bear these additional costs would result in gross over-deterrence.⁴²⁰

Another downside of accommodating third-party restitutionary claims is that such a policy might adversely foster collusive settlements between brand names and generics in an attempt to preempt follow-on lawsuits. In the Australian case, for example, Sanofi reached an agreement with Apotex, the generic challenger in the underlying patent infringement case, that prevented the latter from assisting the government

415. See Summerfield, *supra* note 413 ("Sanofi could end up effectively 'doubling-up' on payments, in that it is being asked to pay not only for Apotex's lost sales, but also for the savings the Government says it would have made had it been able to buy from Apotex.").

416. Lyrica, one of Pfizer's flagship drugs, is prescribed for treating seizure disorders, notably epilepsy.

417. See Adam Houldsworth, *Pfizer Liable for £500 Million NHS Damages If Court Bid Is Unsuccessful, Says Study*, IAM (Mar. 2, 2018), <https://www.iam-media.com/litigation/pfizer-liable-ps500-million-nhs-damages-if-court-bid-unsuccessful-says-study> [https://perma.cc/RL7K-NDUE].

418. See Richard Croker et al., *The Clinician Impact and Financial Cost to the NHS of Litigation over Pregabalin: A Cohort Study in English Primary Care*, BMJ OPEN 7–8 (June 7, 2018), <https://bmjopen.bmj.com/content/bmjopen/8/6/e022416.full.pdf> [https://perma.cc/MER4-KTYH] (noting that the Category C Drug Tariff generic price was pegged to Lyrica's list price, causing the NHS to overpay for pregabalin, regardless of whether the branded or the generic formulation was prescribed).

419. Still, Warner-Lambert greatly benefited from delaying the final court decision that invalidated its patents. Although the patent was deemed invalid in 2015, Warner-Lambert continued to charge supra-competitive prices until August 2017. While generic pregabalin was already available, the court specifically required the NHS to instruct general practitioners to prescribe only the branded version for protected uses. See Croker, *supra* note 418, at 3 (noting that the NHS instruction increased Lyrica prescriptions from 0.3% to 25.7%); Houldsworth, *supra* note 417.

420. Unsurprisingly, the pharmaceutical industry is worried that these international developments "unfairly tip[] the scales in commercial patent disputes" in favor of generics. See Mark W. Lauroesch, Exec. Dir., Intellectual Prop. Owners Ass'n, Comment Letter on USTR 2018 Special 301 Review (Feb. 8, 2018), <https://www.regulations.gov/document?D=USTR-2017-0024-0014> [https://perma.cc/P4RU-LYFH]; Houldsworth, *supra* note 417.

in proving its restitutionary claim against Sanofi.⁴²¹ Because Sanofi's patent was already invalidated, it was easy for the Australian court to void Sanofi and Apotex's agreement as being contrary to the public interest;⁴²² many collusive settlement agreements, however, occur before the patent status is determined.⁴²³ To summarize, similarly to the suggestion advanced in Section III.B.2.a, third-party claims should not be accommodated without substantial safeguards in place to prevent over-deterrence.

IV. CONCLUSION

Dubious patents have oversized exclusionary power in the pharmaceutical industry. Oversized exclusion from pharmaceuticals is catastrophic to consumer welfare and human life. Just as generic manufacturers assume a risk when attempting to compete in a market muddled with weak and potentially meritless patents, this article proposes that brand-name manufacturers should assume a risk when attempting to block competition by muddling the market with such patents even further.

Specifically, this article would require brand-name manufacturers who obtain additional patents for drugs that already have obtained legal protection, and who plan to enforce these patents to prolong market exclusivity, to put far more effort into evaluating the merits of their patent claims. If proven invalid, brand-name manufacturers would be required to disgorge the monopoly premium attributed to these patents and to vest these wrongfully gained profits with the successful generic invalidator. The proposed disgorgement-based bounty aligns the incentives of both brand-name and generic manufacturers with social interest. It discourages the strategic accumulation of meritless patents by the former, and it encourages timely invalidation of meritless patents by the latter.

421. See Duncan Longstaff & Katrina Crooks, *Another Small Victory for Australian Government in Pursuit of Damages for PBS "Over-Payments,"* SHELSTON IP (Apr. 30, 2017), <https://www.shelstonip.com/news/another-small-victory-australian-government-pursuit-damages-pbs-payments-interlocutory-injunction-period> [<https://perma.cc/N6JP-7VN9>].

422. *Commonwealth of Australia v Sanofi (Formerly Sanofi-Aventis)*, [2017] FCA 382 (Austl.).

423. See, e.g., Dolin, *supra* note 148, at 292–93 (emphasizing that the legality of pay-for-delay settlements cannot be ascertained without appreciating the merits of patents).