COMPULSORY LICENSING UNDER *ACTAVIS*

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This Article examines the implications of the Supreme Court's 2013 decision in FTC v. Actavis *for patent law and policy. In* Actavis*, the Court held that "reverse payment" settlements of patent litigation between brand-name and generic drug manufacturers are subject to antitrust scrutiny and that only those settlements that effectively incorporate compulsory patent licensing can avoid liability for anticompetitive effects. The Article contends that* Actavis*'s embrace of probabilistic patent theory and compulsory licensing is problematic for several reasons. First, by discounting patent term based on the likelihood that a patent is invalid or not infringed, probabilistic patent theory limits a patent holder's ability to use their patents. Second, the rule announced in* Actavis *is based on questionable inferences and assumptions about the motives and incentives of parties in pharmaceutical patent litigation. Finally, by routinely subjecting valuable patents to compulsory licensing,* Actavis *risks undermining the security that patents are meant to provide.*

INTRODUCTION

The general consensus is that drug prices in the U.S. are too high.[1] There consequently have been many attempts to lower drug prices, particularly by restricting patent protections and their perceived effect in deterring lower cost, generic copies of drugs from entering the market.[2] Critics of the pharmaceutical industry allege that the industry has been abusing such patent protections by, among other strategies, protecting patents that are likely invalid or not infringed — that is to say, patents that are "weak." Specifically, the critics allege that the industry uses "reverse-payment settlements"

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[1] *See* Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/Q835-MD4V].

[2] *See* KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46741, DRUG PRICING AND INTELLECTUAL PROPERTY: THE LEGISLATIVE LANDSCAPE FOR THE 117TH CONGRESS 30–34 (2021).

of patent litigation to protect weak patents, thereby delaying competition from generic drug manufacturers.[3]

Many lower courts held reverse-payment settlements to be lawful as long as they remained within the scope of the patent, while others declared these settlements to be *per se* violations of antitrust law.[4] The Supreme Court's 2013 decision in *FTC v. Actavis*[5] took a very different view, however, marking a significant shift in the treatment of patent settlements under antitrust law, particularly for the pharmaceutical industry. While declining to hold that reverse-payment settlements are *per se* illegal, the Court embraced the idea that only pharmaceutical companies who believe their patents are weak would be willing to settle.[6] As a result, the Court majority indicated that the only acceptable way to settle would be to grant generic manufacturers what are in effect compulsory licenses to the patents at issue. Only by that means can the public be protected from the necessarily anticompetitive effects of weak patents.[7] This Article examines the implications of *Actavis* and its underlying "probabilistic patent" theory for the broader patent system.[8]

While *Actavis* sought to protect consumer welfare by facilitating generic drug competition, its reasoning raises concerns about undermining the certainty and incentives patents are meant to provide. The decision imposes a form of compulsory licensing on pharmaceutical patents, departing from long-standing U.S. reluctance to mandate patent licensing. It also does so on a surprisingly flimsy basis, both as a theoretical matter and a factual matter.[9] This Article argues that *Actavis*'s approach, as strictly construed, risks eroding patent rights and reducing innovation incentives, particularly in the pharmaceutical sector where patents play a crucial role.[10]

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[3] *See, e.g.*, Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

[4] John R. Thomas, CONG. RSCH. SERV., RL33717, PHARMACEUTICAL PATENT LITIGATION SETTLEMENTS: IMPLICATIONS FOR COMPETITION AND INNOVATION 10–18 (2006).

[5] 570 U.S. 136 (2013).

[6] *Id.* at 157–59.

[7] *See id.* at 154; *see also* Hovenkamp et al., *supra* note 3, at 1760–61.

[8] *See* discussion *infra* Section III.A.

[9] *See* discussion *infra* Section III.B.

[10] *See* discussion *infra* Section III.C.

The analysis proceeds in three parts. Part I examines the *Actavis* decision and how lower courts and settling parties have interpreted it. Part II then shows how *Actavis* fits within the larger context of how compulsory licensing has been used in antitrust law. Part III critiques the *Actavis* decision both in terms of its foundations in probabilistic patent theory and in terms of the speculative factual basis on which it relies. Part III goes on to consider *Actavis*'s potential effects on the patent system if taken to its logical extremes. The Article concludes by suggesting that a more nuanced, fact-intensive approach to evaluating patent settlements would better balance antitrust and patent law concerns.

I. THE SUPREME COURT'S DECISION IN *ACTAVIS*

The Supreme Court's decision in *FTC v. Actavis* was long awaited, as it addresses a subject of many years of debate: is it an antitrust violation for owners of pharmaceutical patents to pay generic drug manufacturers to settle litigation over those patents?[11] The Court's opinion was brief but has been construed by many as stating that so-called reverse-payment settlements of pharmaceutical patent infringement suits can be understood only as attempts to protect weak patents and to delay generic drug competition. As such, the only way to settle such litigation without anticompetitive effect is not by paying the generic competitor but instead by ceding some part of the patent's term so that the generic can enter the market early. Although the lower courts have varied in their interpretation of *Actavis*, often taking a more flexible view of it, both the Federal Trade Commission ("FTC") and many commentators have embraced this stricter construction.[12]

To understand what a reverse-payment settlement is, how the Supreme Court reached its decision in *Actavis*, and how that decision has been interpreted, one must first understand the unusual statutory structure that it addresses. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known informally as the Hatch-Waxman Act after its two leading sponsors.[13] The Act was designed to facilitate and expedite market

[11] *See* Kent Bernard, *Hatch-Waxman Patent Case Settlements — The Supreme Court Churns the Swamp*, 15 MINN. J.L. SCI. & TECH. 123, 123 (2014).

[12] *E.g.*, Thomas F. Cotter, FTC v. Actavis, Inc.*: When Is the Rule of Reason Not the Rule of Reason?*, 15 MINN. J.L. SCI. & TECH. 41, 43 (2014); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, 28 ANTITRUST, Fall 2013, at 16, 16.

[13] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *amended by* Medicare Prescription Drug,

entry of lower priced, generic versions of brand-name drugs while at the same time maintaining incentives for brand-name pharmaceutical companies to continue investing in the development of new drugs.[14]

The first of many pharmaceutical-specific statutes that target drug patents, the Hatch-Waxman Act focuses specifically on small-molecule drugs, which have relatively simple molecular structures that are easy to copy.[15] For generic manufacturers, this means that the only two real barriers to Food and Drug Administration ("FDA") approval and market entry are the clinical trials necessary for approval and any patents on the brand-name drug that the generic seeks to copy.[16] Because generic drugs are for all clinically relevant purposes exact copies of brand-name drugs, the Hatch-Waxman Act created an Abbreviated New Drug Application ("ANDA") that enables a generic to save millions to billions in cost and time by free-riding on the testing that the brand-name drug manufacturer has already done.[17] This leaves only patents standing between brand-name and generic drug manufacturers.

To address this, an important part of Hatch-Waxman was to create procedures not only to make it easier for generic manufacturers to challenge patents they suspect to be invalid but in fact to incentivize them to do so.[18] To this end, the Hatch-Waxman Act includes two unusual provisions that have led to the equally unusual way in which parties have settled such challenges.

The first of these grants generic manufacturers special standing to challenge drug patents.[19] Ordinarily, justiciable patent infringement cases arise only after the alleged infringer has invested in infringing activities, putting it at risk of liability for often substantial damages.[20] The Hatch-Waxman Act relieves generic

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Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[14] *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 389 (1999).

[15] *See* WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., RL33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 1 (2009).

[16] Emily Michiko Morris, INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES: TRIPS AGREEMENT, HEALTH, AND PHARMACEUTICALS 381–83 (Srividhya Ragavan & Amaka Vanni eds., 2021).

[17] *See, e.g.*, *id.* at 380-82; Nora Xu, *AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs*, 66 EMORY L.J. 1007, 1012–13 (2017).

[18] FTC v. Actavis, Inc., 570 U.S. 136, 143–44 (2013).

[19] *See id.* at 143.

[20] *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUT. & HIGH TECH. L.J. 489, 523 (2006).

drug manufacturers of this risk by establishing that simply filing an ANDA is an artificial act of infringement if the filing generic manufacturer certifies that any unexpired patents on the drug at issue are either not infringed or invalid.[21] (These certifications often are called "Paragraph IV certifications," in reference to the statutory subsection under which they are made.[22])

A second provision provides the first generic manufacturers to file ANDAs on a particular drug product eligibility for 180 days of exclusivity as the only generics on the market.[23] This exclusivity can be quite valuable: where there is only one such first-filer, the resulting 180-day duopoly between the generic and brand-name manufacturers can be worth hundreds of millions of dollars.[24]

Generic manufacturers thus have ample incentive to challenge patents and nothing to lose by doing so other than filing and litigation costs.[25] The brand-name patent holder, on the other hand, risks the loss of its patents. For patents on the few drugs profitable enough to reach blockbuster status, invalidation can mean the loss of billions of dollars per year of revenue.[26]

Patent holders therefore have very strong incentives to settle these cases while generics, who have nothing at risk, have little incentive to do so. Prior to the Supreme Court's decision in *Actavis*, brand-name patent holders often would offer to pay generics to induce them to settle.[27] Payments to settle any type of litigation, including patent suits, are not uncommon, but Paragraph IV settlements in effect reversed the usual flow of payment.[28] Rather than the alleged infringer agreeing to pay the patent holder some amount less than what they might have owed as damages at trial, settlement payments in Paragraph IV litigation flowed from patent holder to alleged infringer.

Because these "reverse-payment settlements" also frequently involved millions of dollars, they raised the suspicion that patent holders essentially were paying potential competitors not to challenge their patents and to stay off the market.[29] This created a circuit split, with most circuits holding that reverse-payment

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[21] *Actavis*, 570 U.S. at 143.

[22] *See* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 263–64 (2012) (referring to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

[23] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[24] Hemphill, *supra* note 3, at 1579.

[25] *See* Morris, *supra* note 22, at 271.

[26] Hemphill, *supra* note 3, at 1580–81.

[27] FTC v. Actavis, Inc., 570 U.S. 136, 140–41.

[28] *See id.* at 140, 151–52.

[29] *See, e.g.*, Carrier, *supra* note 3, at 39–40; Hemphill, *supra* note 3, at 1557.

settlements that fell squarely within the scope of the patent were lawful, while some circuits held that these settlements were *per se* antitrust violations.[30]

This cued up the Supreme Court's 2013 opinion in *FTC v. Actavis, Inc.*, in which the divided Court held that, while not *per se* antitrust violations, reverse-payment settlements are inherently suspect, especially when they involve large transfers of value.[31] According to the majority's logic, any sizable settlement payment to a generic beyond its litigation costs is "strong evidence" that the challenged patents are invalid or not infringed.[32] The size of such payments also may be a "strong indicator" of market power — otherwise, why would a patent holder be willing to pay so much to keep a generic off the market?[33] Such payments cannot be condoned simply because they are otherwise within the scope of a patent.[34]

And although the Court held that rule-of-reason analysis applies, the Court agreed that actually determining whether the patents at issue are invalid or not infringed would be cumbersome and unnecessary.[35] The Court majority said that the patents' weakness can instead be inferred from the size and direction of settlement payments. The more that the brand name is willing to pay, the more likely it believes that its patents are weak.[36] Critics of reverse-payment settlements refer to this as the "*Actavis* Inference."[37]

Importantly, the majority suggested that only two forms of settlement do not fall within the purview of the *Actavis* inference. First, patent holders may pay generic challengers only for the litigation costs the patent holders otherwise would have incurred.[38] Any transfers of value above that amount would have to be justified essentially as legitimate ancillary agreements in which the brand-

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[30] *See* Carrier, *supra* note 3, at 52–59.

[31] *See* FTC v. Actavis, Inc., 570 U.S. 136, 147–48, 159–60.

[32] *Id*. at 153–54.

[33] *See id*. at 157.

[34] *Id.* at 148, 151.

[35] *Id*. at 153, 158–59.

[36] *Id*. at 157–59.

[37] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *The* Actavis *Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585, 587 (2015).

[38] *Actavis*, 570 U.S. at 156; *see also* Edlin et al., *supra* note 12, at 16 (interpreting *Actavis* as allowing payment only for litigation costs plus any ancillary agreements). The FTC has since defined a benchmark threshold of $7 million or less as consistent with a payment for litigation costs. Zarema Jaramillo, Jonathan Lewis, Sydney Kaplan & Josh Morris, *Status of Reverse Payment Cases Against Pharmaceutical Companies*, GLOB. COMPETITION REV. (July 28, 2023), https://globalcompetitionreview.com/review/us-courts-annual-review/2023/article/status-of-reverse-payment-cases-against-pharmaceutical-companies [https://perma.cc/36C9-7B26].

name's payment is in exchange for the generic manufacturer's services or products.[39]

Second, and the focus of this Article, brand-names can induce generic manufacturers to settle not by offering them payment but instead by offering the generic market entry before patent expiration. The more likely the patent at issue is invalid or not infringed, the earlier the discounted entry date the patent holder should cede to its generic challenger.[40] If, for example, the patents at issue had four years before they expired but have a fifty percent chance of being found invalid or not infringed, the brand-name patent holder should allow the generic to enter the market at least two years before expiration. This way, the public gains earlier access to lower-cost generic drugs than it would have if the generic had to wait for the patents to expire.[41]

Many critics of reverse-payment settlements, including the FTC, have construed the majority's decision in *Actavis* rather strictly.[42] Per this view, *Actavis* limits brand-name manufacturers who face Paragraph IV certifications to a binary choice: either proceed with litigation and risk losing your patents, or share your patents with the challenging generic and lose your place as the sole manufacturer on the market. Although not acknowledged by the *Actavis* Court or the FTC as such, the latter option — having to give another the ability to make and sell your patented drug — is tantamount to a compulsory license.

Most Paragraph IV settlements have hewed closely to the Court's guidance in *Actavis*. The FTC's 2020 report on Paragraph IV settlement agreements made during fiscal year 2017 shows that over ninety-five percent — 215 of 226 — of the agreements involved compulsory licenses for the generic challengers to one or more patents on the drug product at issue.[43] Most of these settlements included not only the patents litigated but also patents that may cover that drug product in the future.[44]

Notably, the FTC has made clear *Actavis* applies to settlements of proceedings before the Patent Trial and Appeal Board

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[39] *Actavis*, 570 U.S. at 156; Edlin et al., *supra* note 12, at 18 (interpreting the majority's opinion as allowing only payments for other goods and services and deeming any other payment as paying for delayed entry).

[40] *Actavis*, 570 U.S. at 157–58; *see also* Edlin et al., *supra* note 12, at 16.

[41] *Actavis*, 570 U.S. at 154; *see also* Edlin et al., *supra* note 12, at 20.

[42] *See supra* note 12 and accompanying text.

[43] *See* BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2017, at 1–2 (2020).

[44] *Id*. at 3–4.

("PTAB").[45] These proceedings, which have become more common since the Patent Act was reformed under the America Invents Act, were designed to provide a less costly alternative venue for parties to challenge patent validity.[46] Those challenging small-molecule drug patents may not have incentives to opt for PTAB proceedings, however, as only litigation in court offers the benefit of the 180-day exclusivity period.[47]

Like Paragraph IV litigation, however, PTAB proceedings are not constrained by standing or justiciability.[48] The risk dynamics in PTAB proceedings are thus similar to those in Paragraph IV litigation — great risk for the pharmaceutical patent holders but little to none for generic challengers — with a similar tendency for any settlement to include payments flowing from patent holder to challenger.[49] Under the *Actavis* rule, these settlements now also are limited to compulsory licensing.

In other words, whether in federal district court or in PTAB proceedings, almost every small-molecule drug patent — at least, those valuable enough to challenge — regularly are subject to compulsory licensing. Compulsory patent licensing is rare and disfavored in the United States, but as the next Part discusses, not entirely unprecedented under antitrust law. Nonetheless, such persistent use of compulsory licensing is unprecedented in the United States. And, as Part III explains, compulsory licensing based solely on purely speculative apprehensions about patent invalidity is most certainly antithetical to patent policy.

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[45] Jamie Towey & Brad Albert, *Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements After* FTC v. Actavis, FED. TRADE COMM'N (May 28, 2019), https://www.ftc.gov/enforcement/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent-settlements-after-ftc-v-actavis [https://www.ftc.gov/enforcement/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent-settlements-after-ftc-v-actavis].

[46] Saurabh Vishnubhakat, *Patent Inconsistency*, 97 IND. L.J. 59, 61 (2022).

[47] Matias Ferrario, Jennifer Giordano-Coltart & Leslie Grab, *The Use of* Inter Partes *Review Petitions in ANDA Litigation*, KILPATRICK TOWNSEND (Aug. 4, 2014), https://ktslaw.com/~/media/The%20Use%20of%20Inter%20Partes%20Review%20Petitions%20in%20ANDA%20Litigation.ashx [https://perma.cc/DE6D-K6AN].

[48] *See* Vishnubhakat, *supra* note 46, at 75.

[49] Although PTAB proceedings — and settlements thereof — may involve patents from any technology, only settlements involving patents challenged in Paragraph IV certifications must adhere to *Actavis*. Towey & Albert, *supra* note 45 (noting that settlements of PTAB proceedings are governed by the same pharmaceutical-specific statute as settlements of Paragraph IV litigation).

II. *ACTAVIS* AND COMPULSORY LICENSING

The fact that *Actavis* created a new compulsory licensing rule may not be obvious, especially as compared to more overt forms of compulsory licensing. The *Actavis* rule nonetheless clearly comports with other uses of compulsory licensing under antitrust law.

In its simplest terms, a compulsory license is an authorization for a third party to make, use, or sell a patented invention without the consent of the patent owner.[50] The most obvious compulsory licenses thus are those such as the U.S. government's powers under 42 U.S.C. § 1498 or a federal court's power to deny permanent injunctive relief in cases of patent infringement.[51] In these situations, the patent holder has no control over whether the patented invention is licensed to a third party.

Compulsory licenses also have long been used to address various types of anticompetitive behavior where patents are involved, however. [52] Government antitrust enforcement often requires patent holders in anticompetitive mergers and acquisitions either to divest their patents, allow them to be compulsorily licensed, or both.[53] Compulsory licensing frequently has been applied when patents are used to support price-fixing or exclusionary cartels as well. [54] In fact, Article 40 of the TRIPS Agreement specifically provides for the use of compulsory licensing to remedy anticompetitive practices.[55]

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[50] F. M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT'L ECON. L. 913, 914 (2002).

[51] 42 U.S.C. § 1498 (effectively allowing the federal government to use or manufacture patented inventions without license of the owner); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (affirming that courts may grant compulsory licenses when equity demands under a traditional four-factor test for permanent injunctions). Similar statutory provisions allow compulsory licensing. *E.g.*, 35 U.S.C. § 203 (compulsory licensing by the government of patents on government-funded research under certain circumstances); 42 U.S.C. § 2183 (compulsory licensing of certain "public interest" patents by the Atomic Energy Commission); 42 U.S.C. § 7608 (compulsory licensing of patents to meet emission requirements under certain conditions).

[52] *See, e.g.*, Colleen V. Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 862–69 (2003); Makan Delrahim, *Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust*, 15 EUR. BUS. L. REV. 1059, 1065 (2004).

[53] *See* Chien, *supra* note 52, at 862; Delrahim, *supra* note 52, at 1059.

[54] Chien, *supra* note 52, at 862, 868.

[55] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 40, 33 I.L.M. 81, 98–99; *see also* Scherer & Watal, *supra* note 50, at 915–16 (noting common interpretation of Article 40 as allowing compulsory

The *Actavis* rule in this way is consistent with antitrust law's history of using compulsory licensing. Under neither *Actavis* nor these other areas of antitrust law are compulsory licenses truly "compulsory." The brand-name patent holders facing Paragraph IV litigation under Hatch-Waxman have a choice of whether to settle and thus any decision to permit a generic early entry is technically voluntary. Only around half of all Paragraph IV certifications result in settlement, suggesting that brand-name manufacturers see litigation as a viable alternative.[56] Likewise, parties in other cases involving compulsory licensing under antitrust law have a choice whether to merge, to acquire other companies, or to engage in cartelization or price fixing. And just as brand-name patentees typically negotiate the discounted date of entry with generics, parties in other antitrust cases typically negotiate with the FTC or Department of Justice ("DOJ") to agree on divestiture, compulsory patent licensing, or both as a way to relieve market concentration.[57]

That being said, unlike *Actavis*, these other antitrust cases employing compulsory licensing do not revolve around questions of patent validity or infringement. Indeed, the use of compulsory licensing in mergers and acquisitions or horizontal agreements necessarily presumes that the patents are valid and therefore have the power to exclude others in anticompetitive ways. Otherwise, compulsory licensing would be unnecessary. Licensees and potential infringers of course could argue that the patents are invalid, but such invalidity arguments would be peripheral. Again, in these other antitrust cases, patents are seen as anticompetitive because they are assumed to be valid, not invalid. Furthermore, unlike under *Actavis*, compulsory licensing in other types of antitrust cases is used as a remedy not for the anticompetitive effects of simply possessing and protecting one's patents but rather for using the market power supported by the patents toward anticompetitive ends.

That is not to say that patent invalidity and infringement are never the focus of antitrust law. Much ink has been spilled debating issues at the interface between antitrust doctrine and patents (as well as other types of intellectual property).[58] Antitrust courts have also had to deal with issues of patent invalidity and noninfringement but

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licensing in antitrust cases).

[56] Kiefer Ahn, Antonio Trujillo, Jason Gibbons, Charles L. Bennett & Gerard Anderson, *Settled: Patent Characteristics and Litigation Outcomes in the Pharmaceutical Industry*, INT'L REV. L. ECON., Oct. 2023, at 3.

[57] *See* Delrahim, *supra* note 52, at 1060; Scherer & Watal, *supra* note 50, at 916.

[58] *See, e.g.*, Hemphill, *supra* note 3, at 1558–59.

have taken a much less aggressive approach than the Court in *Actavis*.

For example, suing to enforce your patent rights in court is not an antitrust violation, even if you suspect there is a chance that your patent might be invalid or not infringed. The Supreme Court in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*[59] held that asserting one's patent rights in litigation cannot be an antitrust violation unless the patentee engaged in fraudulent or intentionally deceptive conduct before the United States Patent and Trademark Office ("USPTO") during the patent prosecution process, as proven by clear and convincing evidence.[60] Establishing a *Walker Process* claim also requires proof that the patentee's misrepresentations or omissions related to material fact such that, but for the fraudulent conduct, the patent would not have been granted.[61] Unless a patentee knows that it obtained its patent through intentional fraud, it may try to enforce its patent rights in court without antitrust liability, no matter how much the patentee fears potential invalidation.[62]

Likewise, a patentee may lawfully assert its patent rights in court even if it suspects that the alleged infringer may ultimately be found not to infringe. The Supreme Court's decision in *Professional Real Estate Investors v. Columbia Pictures Industries, Inc.*[63] held assertion of even questionable claims in court cannot incur antitrust liability unless the lawsuit is purely a "sham."[64] As applied in the patent law context, this means that the patentee's infringement claims are "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[65] The patentee must also have brought those claims solely for the anticompetitive effects of the lawsuit itself, regardless of its outcome.[66] As Chief Justice Roberts noted in his dissent, a patent's

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[59] 382 U.S. 172 (1965).

[60] *Id.* at 177–78; *see also* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1070–71 (Fed. Cir. 1998) (discussing strict standard for proving *Walker Process* fraud).

[61] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1295 (Fed. Cir. 2011).

[62] *Id.* at 1290–91 (emphasizing that inequitable conduct requires specific intent to deceive the USPTO).

[63] 508 U.S. 49 (1993).

[64] *Id.* at 59–60.

[65] *Id.* at 60.

[66] *See* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1071–72 (Fed. Cir. 1998).

invalidity or noninfringement is irrelevant to a patentee's ability to assert its rights without violating antitrust law.[67]

Both *Walker Process* and *Professional Real Estate Investors* involve litigation, however, which necessarily entails a defendant's right to challenge the validity and infringement of a patent. It is precisely this point that concerned the *Actavis* majority — if a patentee pays the alleged infringer to settle, the patentee can prevent validity and infringement from becoming an issue.[68] Furthermore, both *Walker Process* and *Professional Real Estate Investors* set such high standards for antitrust liability only in order to protect litigants' First Amendment rights to gain access to the court system (or otherwise petition the government for redress).[69] *Settling* a case brought before a court, on the other hand, is private action and does not fall under the umbrella of the First Amendment.[70]

III. *ACTAVIS* AND THE PROBLEM WITH PROBABILISTIC PATENT THEORY

The most concerning issue with the Court majority's decision in *Actavis* is its apparent embrace of what is commonly referred to as probabilistic patent theory.[71] Probabilistic patent theory quite rightly acknowledges the inherent uncertainty as to the scope and validity of a patent. It is the conclusions that the theory draws from this uncertainty that makes it problematic. The first conclusion the theory draws is that the law should preserve and insist on as many opportunities to litigate patents as possible so that their validity can be tested.[72] This means mistrusting all attempts to settle patent

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[67] FTC v. Actavis, Inc., 570 U.S. 136, 162–65 (2013) (Roberts, C.J., dissenting); *see also* C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1369 (Fed. Cir. 1998) ("Neither the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability.").

[68] *Actavis*, 570 U.S. at 151, 153–54.

[69] *See In re* Lipitor Antitrust Litig., 868 F.3d 231, 264–66 (3d Cir. 2017).

[70] *Id*. at 264–66 (and cases cited therein). *See generally* Abiel Garcia, Noerr-Pennington *and Reverse Payment Agreements: A Match Not Made in Heaven*, 67 RUTGERS U. L. REV. 755 (2015) (explaining how courts have decided cases involving reverse-payment settlements under the *Noerr-Pennington* doctrine).

[71] *Cf. In re* Cipro Cases I & II, 348 P.3d 845, 859 (Cal. 2015) ("Indeed, a critical insight undergirding *Actavis* is that patents are in a sense probabilistic, rather than ironclad: they grant their holders a potential but not certain right to exclude.").

[72] *See* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPS. 75, 76, 88–89 (2005); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 51 (2004).

disputes "because litigating patent disputes to completion tends to generate positive externalities, by clarifying the limits of patent protection if the patent is upheld or encouraging wider use of the innovation if the patent is invalidated."[73] In this way, probabilistic patent theory espouses the view that patents are innately and inevitably anticompetitive.[74] The second conclusion is that, unless and until a patent has been litigated, its strength and therefore value must always be discounted for antitrust purposes, including through compulsory licensing.[75] Both conclusions constrain not only the ability to settle patent litigation but also to transact and invest in patents or to rely on them in any other fashion. When taken to extremes, treating patents as merely probabilistic rights risks undermining the patent system.

A. The Metes & Bounds of Probabilistic Patent Theory

Commonly attributed to Professor Carl Shapiro, probabilistic patent theory views patents not as concrete rights to exclude others from one's invention but merely as a game of chance that you cannot know if you have won until you try your hand in asserting those rights in court.[76] Patents are merely "a right to *try* to exclude" because patents are by design constantly subject to invalidation if later evidence reveals that the patented invention actually fails one or more of the patentability requirements.[77] Estimates suggest that approximately half of all litigated patents are ultimately declared invalid.[78] Patents have in this way been compared to "lottery tickets."[79]

Two further points follow from this view of patent rights. First, until a court declares a patent not invalid, a patentee has merely an expectation of protection.[80] The strength of that protection depends entirely on the odds that the patent later may be invalid. Second,

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[73] Lemley & Shapiro, *supra* note 72, at 76.

[74] *See* Edlin et al., *supra* note 12, at 17.

[75] *See* Lemley & Shapiro, *supra* note 72, at 75, 76, 94; Hovenkamp et al., *supra* note 3, at 1739–40, 1760–61; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395, 407–08 (2003); *see also* Bryan Gant, *Patents Are Not Probabilities: Refuting the Probabilistic Patent Theory*, 20 CHI.-KENT J. INTELL. PROP. 299, 301 (2021) (noting this viewpoint as discounting patent value).

[76] Lemley & Shapiro, *supra* note 72, at 75–76; Shapiro, *supra* note 75, at 395.

[77] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1801 (2014); Hovenkamp et al., *supra* note 3, at 1761; Shapiro, *supra* note 75, at 395.

[78] Lemley & Shapiro, *supra* note 72, at 76.

[79] *Id*. at 80–83.

[80] *In re* Cipro Cases I & II, 348 P.3d 845, 850–60 (Cal. 2015); Lemley & Shapiro, *supra* note 72, at 75.

because all patents are potentially invalid, using patents to exclude others is anticompetitive — the higher a patent's odds of invalidity, the more anticompetitive its use becomes.[81] It is this second point on which the *Actavis* majority based its decision.[82] Because Paragraph IV settlements remove patents from litigation, they are inherently suspect unless they allow the generic challenger early market entry under an effective compulsory license.[83]

Taken to its extremes, probabilistic patent theory argues too much. As noted above, more moderate critics worry about settlements that protect weak patents, but for some adherents to the probabilistic patent theory no settlement (other than early generic market entry) is acceptable, even if the subject patent likely is valid.[84] This seems to have been the line that the *Actavis* Court took with regard to Paragraph IV settlements, although the Court's underlying assumption also may have been that Paragraph IV patents in particular are more likely to be invalid.[85] Regardless, the Court appears to have espoused the idea that patents underlying Paragraph IV settlements should therefore be subject either to litigation or to compulsory licensing.[86]

Moreover, Professor Shapiro and his co-authors have interpreted *Actavis* as applying not only to Paragraph IV settlements but to potentially all patent litigation settlements.[87] Although both the *Actavis* Court and commentators agree that most patent settlement payments present no anticompetitive concerns as long as no payment flows from the patentee to the alleged infringer,[88] others have pointed out that this "reversed" flow of payment can be seen as occurring in any patent settlement.[89]

Any time a patentee allows an alleged infringer to settle by paying anything less than the expected damages they would owe at trial (which occurs in just about all litigation settlements), the patentee can be seen as "paying" the alleged infringer. A significant

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[81] *See* Lemley & Shapiro, *supra* note 72, at 94–95.

[82] FTC v. Actavis, Inc., 570 U.S. 136, 157–58 (2013).

[83] *See id*. at 147–58, 154, 159–60.

[84] *See* Edlin et al., *supra* note 12, at 17.

[85] *See infra* Section III.B.

[86] *See Actavis*, 570 U.S. at 158.

[87] Edlin et al., *supra* note 12, at 16; *see also* Lemley & Shapiro, *supra* note 72, at 94.

[88] *See Actavis*, 570 U.S. at 152.

[89] *See, e.g.*, Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1071–76 (2004); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1046–49 (2004).

discount could be seen as signifying the patentee's lack of confidence in the strength of its case, and the "payment" may be the patentee's way of avoiding patent invalidation at trial. If this is the case, consumer welfare is reduced as least as much by these settlements as they are by Paragraph IV settlements, even though the patentee never wrote a check to the infringer.[90] In fact, if the alleged infringer stands to lose enough in profits from settling and the patentee is risk-averse enough or otherwise at a bargaining disadvantage, even normal patent litigation may result in payment from patentee to infringer — even when the patentee has a strong chance of prevailing at trial.[91]

Per a strict application of probabilistic patent theory, any such exchange of payment from either party is necessarily anticompetitive. Only a settlement that allows the alleged infringer free access to the patented invention prior to patent expiration (in proportion to the parties' joint estimate of the patent's likely validity) benefits consumer welfare.

Indeed, a strict version of the probabilistic patent theory goes even further. Professors Shapiro and Lemley also posit that even a licensing agreement is, in effect, "the settlement of a potential patent dispute" [92] and, by implication, subject to *Actavis*. Although conscientious patentees would license their patents at royalty rates that reflect the perceived strength of their patents,[93] the cost of challenging the patents in court to verify that the royalty rate is fair allows some fudging by the patentees.[94] Licensees who successfully prove patents to be invalid free not only themselves from the burden of paying royalties but also from all potential competitors. Licensees therefore do not have strong incentives to take on litigation costs whose benefits they cannot keep to themselves. As a result, unjustifiably high royalty rates, at least as measured by the strength of the patent licensed, may be common.[95]

Furthermore, probabilistic patent theory could be interpreted in its purest form as forbidding patentees to charge royalty rates at all, or at least not for the full patent term. Because all patent validity is questionable under a strict application of the theory, patentees must allow would-be licensees to use their patented inventions for at least some period prior to patent expiration — and to do so for *free*. Charging any royalty after the discounted entry date for the patent

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[90] Cotter, *supra* note 89, at 1078–80; *see* Schildkraut, *supra* note 89, at 1047.
[91] Cotter, *supra* note 89, at 1071–76.
[92] Lemley & Shapiro, *supra* note 72, at 94.
[93] *See* Edlin et al., *supra* note 37, at 618–19.
[94] *See* Lemley & Shapiro, *supra* note 72, at 88–89.
[95] *See id.*

would be anticompetitive. Only by imposing a *royalty-free* compulsory license and allowing competitors unconditional early entry is consumer welfare protected.

Under this paradigm, then, the only circumstance under which patentees can charge royalties without anticompetitive effect is when licensees want access to the patented invention earlier than the patent's discounted entry date. For example, per probabilistic patent theory, if a licensee wanted access to an invention covered by a patent with ten years remaining on its term, the patent holder should allow the licensee access five years before patent expiration if they both believe the patent to have only a fifty percent chance of being found both not invalid and infringed. If the licensee wanted immediate access rather than waiting five years, on the other hand, it could then pay the patentee royalties for the earlier access.

Of course, patentees who generally do not license their patents and would rather maintain their exclusivity in the market would be justified in doing so — as long as they allow would-be competitors access to the patented invention on a discounted entry date. This perhaps is why Paragraph IV settlements after *Actavis* rarely entail royalty payments. Brand-name pharmaceutical patent holders typically do not license their patents, and they would rather keep generic imitators out of the market as long as possible.

In this way, the probabilistic patent theory applied in its purest, most rigorous form, could profoundly change the patent system. The overall effect would be to erode the value of patents and drastically diminish investment in reliance on them. This in turn would undermine any incentives that patents provide.

B. Overdependence on Inference and Assumption

In addition to its use of compulsory licensing, the *Actavis* rule is problematic because of the numerous inferences and assumptions on which the *Actavis* majority based its call for compulsory licensing. Specifically, the *Actavis* majority relied on inferences drawn from questionable assumptions about the motives and incentives of parties to the patent system, particularly under the Hatch-Waxman Act. Imposing compulsory licenses on patents under these circumstances is unsound and erodes the value of patents.

The question the *Actavis* majority tried to answer is how to determine the odds that a patent is invalid or not infringed when subjecting it to litigation to ascertain its validity is exactly the proceeding settlement seeks to avoid. The majority found a simple proxy — how strong the patentee and others think the patent

is.[96] We can assume that the weaker that patent holders believe their patents to be, the more they will try to shield them from litigation, where they likely will be invalidated. This brings the logic full circle — the more parties seek to settle, the more suspect we can infer that settlement to be.[97]

Furthermore, according to the majority's logic, to measure the brand-name patent holder's eagerness to settle — and hence the likely weakness of the patent it is trying to protect — one need look only at the size of the payment it is willing make to the generic challenger.[98] Because we can safely infer that such payments reflect the strength of the underlying patent, any payment beyond the patentee's saved litigation costs must reflect a desire to protect weak patents. These payments thus are necessarily anticompetitive and harmful to consumer welfare and can be grounds for compulsory licensing.

The problem with this reasoning, the inferences it draws, and the assumptions on which it relies, is that it ignores alternative explanations. There are many other factors that could affect the size of the payment a patentee is willing to make to settle a Paragraph IV case. Patentees may be quite risk averse, leading them to pad their settlement payments to ensure that generics accept and agree to settle.[99] As both the Court and other commentators have noted, even a five percent chance of losing a multi-billion dollar per year revenue stream could induce a patentee to be quite generous in its settlement offer.[100] Likewise, a payment could represent the differences between brand-name and generic manufacturers in their estimations of patent invalidity and noninfringement.[101] The

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[96] FTC v. Actavis, Inc., 570 U.S. 136, 157–59 (2013).

[97] *Id.*

[98] *Id.*

[99] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, Actavis *and Error Costs: A Reply to Critics*, ANTITRUST SOURCE, Oct. 2014, at 5.

[100] *Actavis*, 570 U.S. at 172 (Roberts, C.J., dissenting); Cotter, *supra* note 89, at 1073. *But see* Edlin et al., *supra* note 38, at 20 (arguing for a heightened standard of proof for justifying reverse-payment settlements on risk aversion).

[101] *See* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. BAR J. 617, 630 (2006); Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 94–95 (2010). Professor Carl Shapiro doubts that such asymmetries happen often; information asymmetries tend to discourage settlement, but ninety-five percent of all patent infringement cases are settled. Shapiro, *supra* note 75, at 397. If this is true, however, parties to Paragraph IV litigation must be more likely to experience information asymmetries, given that these cases settle only around half the time. Ahn et al., *supra* note 56, at 3.

payment necessary to induce settlement may also differ based on how many other generics are expected to enter after the first to file.[102]

To see why the size of a settlement payment does not automatically connote doubts about a patent's strength, consider the possibility of highly risk-averse patent holder. Under the Hatch-Waxman Act, generic manufacturers clearly have significant leverage in settlement negotiations.[103] The pharmaceutical industry is well known for its heavy reliance on patent protections, in large because drug development is both expensive and time consuming.[104] Copying small-molecule drugs, on the other hand, is relatively inexpensive and simple.[105] Patents thus serve as the most significant barrier to generic market entry. If patents on a blockbuster drug are invalidated (or even designed around), a brand name could stand to lose billions. Pharmaceutical companies are understandably quite risk-averse when it comes to Paragraph IV litigation, and generics quite understandably can extract large settlement payments from brand-names as a result.[106]

A recent study illustrates this point. The study found that patent holders were more likely to settle if they had more patents at stake and more years of patent term remaining.[107] This again suggests that the more the patent holder has at risk, the more likely they will feel compelled to settle. Patent holders who had higher total asset value and more experience with Paragraph IV litigation, by contrast, were less likely to settle, consistent with risk aversion as a driver of settlement.[108] And now that such payments have been deemed

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Moreover, the point is that generics may need more cajoling to settle if they disagree with brand-names on the likely outcome of their cases.

[102] *See* Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg & Joanna Tsai, Actavis *and Multiple ANDA Entrants: Beyond the Temporary Duopoly*, 29 ANTITRUST 89 (2015); Edlin et al., *supra* note 37, at 603–16.

[103] *See supra* notes 25–26 and accompanying text.

[104] Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation*, 2011 COLUM. BUS. L. REV. 637, 641–44; C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL L. STUD. 613, 614 (2011).

[105] JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 88–89 (2008).

[106] *See, e.g.*, *In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 168–69 (3d Cir. 2017) ("We think that [risk-aversion] serves as an effective rebuttal to the Appellants' claim that the size of the reverse payment is a 'surrogate' for the weakness of the '708 patent.").

[107] Ahn et al., *supra* note 56, at 3.

[108] *See id.* Another study also showed that, if the brand-name company has a new version of the drug waiting in the wings, it is less likely to offer much in settlement, perhaps making settlement less likely. *See* Jorge Lemus & Emil

anticompetitive, brand names may feel equally compelled to settle by allowing their generic competitors to enter the market early.

The *Actavis* majority made clear, however, that the only justifications it would consider are those that relate to the settlement's effect on competition, not those that relate to the size of the settlement payment.[109] This is puzzling, given that the majority endorsed reliance on the payment's size to measure a patent's potential anticompetitive effect.

Moreover, even if the size of the payment were an accurate reflection of the parties' subjective estimations of a patent's strength, those beliefs should not be confused with an objective reality or even estimate on which everyone agrees.[110] The parties' subjective beliefs about patent validity and infringement may be highly labile and situation dependent. A patent's validity (and infringement) can be highly uncertain, but this is in large part because patent litigation outcomes depend on a variety of factors that can be time- and even place-specific.[111] As with any trial outcome, validity determinations can hinge on the skill of each party's attorneys, the forum and its local jury pool, and the judge appointed to hear the case. Validity and infringement both will depend on the vicissitudes of how the patent's claims are interpreted and whether and how the doctrine of equivalents might be applied.[112] Parties who are quite confident that a patent will be invalidated may quickly change their minds as trial progresses.[113] Outside the litigation context, there may be no objective way to assess the likelihood of patent validity or infringement except in a very general sense.[114]

Nevertheless, for some, the simple fact of an otherwise unjustified settlement payment is all that matters, even in the face of evidence that the patent is likely valid.[115] For them, protecting even

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Temnyalov, *Pay-for-Delay with Follow-On Products*, 56 REV. INDUS. ORG. 697 (2020).

[109] FTC v. Actavis, Inc., 570 U.S. 136, 157–58 (2013).

[110] *See* Joshua B. Fischman, *The Circular Logic of* Actavis, 66 AM. U. L. REV. 91, 120 (2016).

[111] *See* Gant, *supra* note 75, at 309.

[112] *See id.*; *see also* Lemley & Shapiro, *supra* note 72, at 85–86; Jason Rantanen, *The Malleability of Patent Rights*, 2015 MICH. ST. L. REV. 895, 913–14.

[113] *See* Gant, *supra* note 75, at 309–10.

[114] Daniel A. Crane, Actavis*, the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions*, 15 MINN. J.L. SCI. & TECH. 51, 59 (2014); Fischman, *supra* note 110, at 103.

[115] *See* Edlin et al., *supra*, note 37, at 618; Edlin et al., *supra* note 12, at 17, 20 ("[P]ayments to avoid even a small risk of competition are antitrust violations.").

a small chance of anticompetitive effect is an antitrust violation.[116] Others have not espoused such extreme stances — at least, not outside of Paragraph IV settlements.

Some commentators, for example, call for antitrust review of patent settlements only when the underlying patents are weak.[117] Although not as extreme as forbidding all settlements, this more moderate version still raises the question of how to identify weak patents without in fact litigating them. This, in turn, once again requires inferences and proxies. The interesting trend for even the more moderate commentators, including the *Actavis* majority, is that the unusual nature of Paragraph IV settlements invariably is construed as protecting weak patents.[118] This trend is based not only on the belief that Paragraph IV settlements are particularly likely to protect weak patents but also on the belief that these settlements protect patents from further validity challenges.[119]

For example, in addition to the direction and size of Paragraph IV settlement payments, the *Actavis* majority and other critics focus on the unique incentives that patent holders have to initiate litigation, even when they perceive their patents to be weak. One such incentive is the automatic thirty-month stay on FDA approval, which in many ways is equivalent to a preliminary injunction because it prevents the generic from potentially infringing by entering the market.[120] A patentee in infringement cases outside of the Hatch-Waxman Act is not entitled to any such stay and must prove that it is more likely than not to prevail on the merits of its case.[121] A court's willingness to grant a preliminary injunction thus demonstrates a patent's relative strength. Because the thirty-month stay under Hatch-Waxman is automatic, patentees often have no analogous need to prove the merits of their cases, at least not until the thirty-month stay expires. In fact, some critics point out that this could incentivize patentees to file suit against Paragraph IV

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[116] *See supra* note 115.

[117] *See, e.g.*, Cotter, *supra* note 90, at 1082; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 750 (2002).

[118] FTC v. Actavis, Inc., 570 U.S. 136, 152–53 (2013); Cotter, *supra* note 90, at 1090–94; Crane, *supra* note 117, at 792–96.

[119] *See, e.g.*, *Actavis*, 570 U.S. at 154–56; Crane, *supra* note 117, at 792–96.

[120] Cotter, *supra* note 90, at 1078–79. Note that the thirty-month stay is automatic only if the patentee sues the generic within forty-five days of the generic filing a Paragraph IV certification. 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

[121] Crane, *supra* note 117, at 783–85.

certifications even when their patents are clearly weak as they still will be able to delay generic entry for at least thirty months.[122]

Critics therefore say that Paragraph IV settlements involving "reverse" payments should be presumed to protect weak patents. The thirty-month provision alone is not sufficient grounds to make such a presumption, however, as it is indiscriminate and overinclusive. Even Paragraph IV settlements involving strong patents would be deemed anticompetitive if they also involved any payments, such as might occur when the patentee is particularly risk averse.

Another provision to which critics point as increasing the anticompetitive effects of Paragraph IV settlements is the 180-day exclusivity granted to the first generic to file an ANDA. This exclusivity period does not commence until the generic begins marketing. If the first-to-file generic settles with the patentee by agreeing to enter the market later, the 180-day exclusivity can deter market entry by other generics for years.[123] Under the 2003 amendments to the Hatch-Waxman Act, the first-to-file generic may be deemed to have forfeited this exclusivity in various situations, including by entering into a settlement agreement found to be anticompetitive.[124] Settlements that concede the infringement and validity of the patents at issue or that require changing the Paragraph IV certification in the generics' ANDAs also lead to forfeiture.[125] A settlement that mentions neither the patent at issue nor the Paragraph IV certification but which delays the challenging generic's market entry also delays entry by any later ANDA filers by at least another 180 days.[126] Thus, even settlements that split a patent's remaining term by effectively granting the challenging generic a compulsory license to enter the market early may decrease consumer welfare by delaying additional generic entry.

It is not just the first-filing generic's ability to delay entry by other generics that is of concern to critics, however. They also point out that other generics lack incentives even to file subsequent Paragraph IV certifications — only first-filing generics enjoy the

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[122] *See* Cotter, *supra* note 90, at 1078–79; *see also* Lemley & Shapiro, *supra* note 72, at 93–94.

[123] Edlin et al., *supra* note 37, at 587.

[124] 21 U.S.C. § 355(j)(5)(D), *amended by* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(2), 117 Stat. 2066, 2458–59.

[125] Circumstances other than settlement, too detailed to recount here, also may lead to forfeiture of the 180-day exclusivity. *Id.*

[126] FTC v. Actavis, Inc., 570 U.S. 136, 154–55 (2013); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 948–49 (2011).

180-day exclusivity incentive to file.[127] The first-filing generic's decision to settle may therefore signal the end of any threat to the brand-name's patents, no matter how weak they might be. The benefit for patent holders of settling with first-filing generics is thus two-fold: settlement not only shelters their weaker patents from possible invalidation but also staves off additional generic market entry as well as additional patent challenges.

There is reason to question not only this narrative about the anticompetitive effects of the 180-day exclusivity incentive but also what the availability of that exclusivity reveals about the relative strength of patents under the Hatch-Waxman Act.

First, according to the FTC's data, other generics appear to have more than adequate incentives to file subsequent ANDAs challenging the patents on reference list drugs. From the FTC's study of settlements filed in 2017, only 72 of the 226 submitted — just over 30% — were between brand-names and first-filers.[128] The remainder of settlements involved later-filing generic challengers. Later-filing generics may very well be mounting additional challenges to weak drug patents.

This is because Hatch-Waxman allows later generics not only to file their own Paragraph IV certifications but also to try to trigger the first-filing generic's 180-day exclusivity period earlier than the discounted entry date on which the brand-name and first-filer agreed in their settlement. When another generic files a subsequent Paragraph IV certification, the brand-name patentee can either sue the later-filing generic or wait for the generic to file a declaratory judgement claim of patent invalidity, noninfringement, or both.[129] Some critics note that later filing generics may lack standing to file a declaratory judgment claim,[130] but this happens only if the case becomes moot or the later filing stipulates to the validity and noninfringement of the patents it later challenges.[131] If the later-filing generic prevails on either ground, the first filer must timely commence marketing or lose its 180-day exclusivity.[132]

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[127] *Actavis*, 570 U.S. at 154–55; Cotter, *supra* note 90, at 1078 n.27; Crane, *supra* note 117, at 794–95.

[128] BUREAU OF COMPETITION, *supra* note 43, at 3.

[129] 21 U.S.C. § 355(j)(5)(C); Hemphill & Lemley, *supra* note 126, at 964.

[130] *See* Hemphill & Lemley, *supra* note 126, at 964.

[131] *Id.* at 964 n.65.

[132] Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1357 (Fed. Cir. 2008). Technically, the 180-day exclusivity is not triggered unless an appellate court upholds the invalidity or noninfringement ruling or the losing patent holder declines to appeal. 21 U.S.C. § 355(j)(5)(D)(i). Any reversal by an appellate court would, of course, suggest that the underlying drug patent is not weak and is, perhaps, both not invalid and infringed.

Similarly, if the parties to later-filed Paragraph IV certification instead settle but concede that the patent at issue is invalid or not infringed, the first filer's 180-day exclusivity is triggered.[133] The process necessary for the later-filing generic to trigger the first filer's 180-day exclusivity can, of course, take years, regardless of whether it occurs by final judgment or even settlement.[134] Moreover, the brand-name patent holder could settle on the same terms on which it settled with the first-filing generic, in which case the status of the underlying patents remains unresolved. Nonetheless, the data shows that later generics do challenge drug patents.[135]

Second, and more significant, are the implications of the first filer's right to the 180-day exclusivity period. Because the 180-day exclusivity is designed to incentivize generic challenges to drug patents, and because that exclusivity can be worth billions with regard to highly profitable drugs, generics are incentivized to file Paragraph IV challenges to drugs even if the generics believe that the patents on those drugs are in fact strong and likely to be found valid and infringed.[136] For much the same reasons, fear of losing a particularly valuable 180-day exclusivity period may lead the first-filing generic to be more willing to settle than to follow through with litigation.[137] If a drug patent is weak, a generic profits much more if it pursues litigation, invalidates the patent, and is able to enter the market as soon as possible while retaining its valuable 180-day exclusivity.[138] If the patent is strong, by contrast, the generic's better strategy is to settle, extract the largest payment it can from a risk-averse patentee, and also retain the 180-day exclusivity.

Settlements under the Hatch-Waxman Act may for this reason be more likely to signal that the drug patents at issue are *stronger* rather than weaker. And in fact, a number of studies have shown that pharmaceutical patents are invalidated in court at markedly lower rates than other types of patents.[139] Both logic and data thus belie the assumption that pharmaceutical patent settlements under Hatch-Waxman generally protect weak patents.

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[133] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB).

[134] Hemphill & Lemley, *supra* note 126, at 964.

[135] BUREAU OF COMPETITION, *supra* note 43, at 3.

[136] Bernard, *supra* note 11, at 126; Cotter, *supra* note 11, at 1078–80; Lemley & Shapiro, *supra* note 72, at 90.

[137] Cotter, *supra* note 11, at 1079–80.

[138] *See supra* note 128 and accompanying text.

[139] *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1690 (2022); Allison et al., *supra* note 77, at 1801. *But see* Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AM. U. L. REV. 1177 (2023) (finding that most drug patents in PTAB proceedings are found invalid).

C. Effect on the Patent System

The accuracy of all the inferences and assumptions that probabilistic patent theory draws regarding pharmaceutical and other patents aside, the most troubling issue with *Actavis* is not its foundation in antitrust law but rather its comparatively weak foundation in patent law. Probabilistic patent theory cannot be condemned for acknowledging the uncertainty intrinsic to the patent system, but the theory overemphasizes certain aspects of the patent system while neglecting broader purpose and role of the patent system in an innovation economy. Patents are designed to incentivize and protect investments in innovation and thus to provide some measure of security.[140] As such, the patent system must cultivate certainty as much as possible rather than institutionalizing uncertainty. Imposing compulsory licenses on patents, especially in the targeted and routine manner contemplated by *Actavis*, could significantly erode patent incentives, particularly in the small-molecule pharmaceutical industry.

The United States has been loath to implement compulsory patent licensing, and for good reason. Although compulsory licensing is permitted, historically its use has been much more limited than under the *Actavis* rule.[141] Patents are designed to incentivize investments in research and development, but they also play a wide variety of other roles, depending on the technology at issue. Obtaining a patent helps to establish an innovator's reputation,[142] and in some industries patents provide leverage for negotiating patent cross-licensing and gaining access to complementary technologies.[143] Importantly, patent protections help attract investment funding from venture capitalists and other

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[140] Rebecca S. Eisenberg, *A Technology Policy Perspective on the NIH Gene Patenting Controversy*, 55 U. PITT. L. REV. 633, 636–37 (1994).

[141] *See, e.g.*, Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT'L L. 461, 479 (2011) (noting United States' reluctance to use compulsory licensing for pharmaceuticals); Tanya Saraswat, *Compulsory Licensing in the United States*, IIPRD (Sept. 7, 2022), https://www.iiprd.com/compulsory-licensing-in-the-united-states [https://perma.cc/EEE5-ZHBE] (noting that, compared to other countries, compulsory licensing is uncommon in the United States).

[142] Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 627–28, 650–51 (2002).

[143] Stuart J.H. Graham, Robert P. Merges, Pam Samuelson & Ted Sichelman, *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1297–1301 (2009); Michael Mattioli, *Communities of Innovation*, 106 NW. U. L. REV. 103, 113–14 (2012).

sources.[144] By guarding such investments in innovation, patents are vital to the success of technological enterprises.

This is all the more true in the pharmaceutical industry, where patents are pivotal. To gain FDA approval to market a new drug, pharmaceutical companies must conduct very expensive, multi-year clinical trials.[145] Because of these significant costs in developing and marketing new drugs, brand-name manufacturers are widely believed to depend on patent protection more than other industries.[146] Some technologies such as software have such short market lifespans and such high turnover rates that they do not need longer patent terms.[147] Studies have shown that biopharmaceutical patent terms, by contrast, are important for incentivizing investment in research and development.[148] Having to grant compulsory licenses to one or more ANDA filers could significantly lower the value of patents and the incentives they provide.

The exact effects of compulsory licensing or other encroachments onto pharmaceutical patents on research and development incentives have been the subject of much debate. On the one hand, scholars such as Professor Chien argue that the occasional compulsory license of pharmaceutical patents under antitrust consent decrees has no measurable effect on inventive activities.[149] Others such as Professors Langenfeld and Li, on the other hand, have found that, if barring even "partial" reverse payment settlements (settlements in which the generic agrees not to enter only until patent litigation is complete) lowers the probability of new product development by as little as thirty percent, net consumer welfare will be decreased.[150] *Actavis* indicates that

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[144] Carolin Häussler, Dietmar Harhoff & Elisabeth Müller, *To Be Financed or Not –... - The Role of Patents for Venture Capital-Financing* 1 (Ctr. for Eur. Econ. Rsch. Discussion Paper, Paper No. 09-003, 2013).

[145] *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TECH. L. REV. 345, 356 (2007); Lemley, *supra* note 104, at 641–43.

[146] *See* BESSEN & MEURER, *supra* note 105, at 88–89; Mark Schankerman, *How Valuable Is Patent Protection? Estimates by Technology Field*, 29 RAND J. ECON. 77, 78 (1998).

[147] Verne A. Luckow & Steven C. Balsarotti, *Statistical Analysis of Federal District Court Cases Seeking Longer Patent Term Adjustments in the Wake of* Wyeth v. Kappos, 10 J. MARSHALL REV. INTELL. PROP. L. 1, 3 (2010).

[148] *See* Henry G. Grabowski & Jeffrey L. Moe, *Impact of Economic, Regulatory, and Patent Policies on Innovation in Cancer Chemoprevention*, 1 CANCER PREVENTION RSCH. 84, 86 (2008).

[149] *See generally* Chien, *supra* note 52.

[150] James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777, 803–04 (2003); *see also* Jonathan M. Barnett, *The Great Patent Grab*, *in* THE BATTLE

compulsory licensing in settlements of Paragraph IV cases should be the norm. Given that Paragraph IV certifications and settlements are on the rise, such routine use of compulsory licensing could unduly weaken pharmaceutical patent protections.[151]

Without taking into account the possible loss of incentives to develop new drugs and the resulting loss of social welfare, an antitrust approach that looks only at the downsides of patent protection is incomplete. The *Actavis* majority stated that it was considering patent law policy along with antitrust policies and adverted to the "redeeming virtues" of patents and the need to weigh whether "patent law policy offsets the antitrust law policy strongly favoring competition," but the court appeared to do neither.[152] While it is true that multiple policies favor the elimination of invalid patents, other policies, including those incorporated into the Hatch-Waxman Act, are designed to foster continued innovation by protecting valid patent rights as well. Although the short-term, static costs of patent protections may temporarily decrease consumer welfare, it was long ago recognized that the longer-term, dynamic benefits of patents may well outweigh the costs.[153] Focusing only on the short-term consumer welfare costs misses this larger picture. Rules that overly restrict settlement in patent litigation "may inadvertently undermine the goals of the Patent Act or of the competition laws themselves."[154]

Probabilistic patent theory tries to draw a balance between the dueling anticompetitive and innovation incentivizing aspects of patents by simply splitting the difference. The theory treats patents as if they could be a compromise in which they are simultaneously both valid and invalid.[155] A patent is not a statistical average that can

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OVER PATENTS: HISTORY AND POLITICS OF INNOVATION 208 (Stephen H. Haber & Naomi R. Lamoreaux eds., 2021) (finding a negative correlation between investment in research and development on the one hand and weak patent protection combined with strong antitrust enforcement on the other).

[151] *See* Bernard & Tom, *supra* note 101, at 621–28 (warning that emphasizing antitrust protections over patent protections, especially in pharmaceuticals, could decrease social welfare); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 843 (2001) (advising against compulsory licensing of pharmaceutical patents given the industry's heavy dependence on patent protections).

[152] FTC v. Actavis, Inc., 570 U.S. 136, 149, 151 (2013).

[153] *See* Thomas O. Barnett, *Maximizing Welfare Through Technological Innovation*, 15 GEO. MASON L. REV. 1191, 1194–96 (2008); Leffler & Leffler, *supra* note 72, at 33.

[154] Crane, *supra* note 117, at 749 (footnote omitted).

[155] *See* Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 ANTITRUST

be calculated over a hundred trials the way one might with coin flips.[156] As Chief Justice Roberts explained in his dissent in *Actavis*:

> First, a patent is either valid or invalid. The parties of course don't know the answer with certainty at the outset of litigation; hence the litigation. But the same is true of any hard legal question that is yet to be adjudicated. Just because people don't know the answer doesn't mean there is no answer until a court declares one.[157]

By avoiding the question of whether a patent underlying a Paragraph IV settlement is valid or invalid, the *Actavis* Court engaged in what some commentators have termed "patent punting."[158] It is not clear that such punting under probabilistic patent theory — and its accompanying use of compulsory licensing — is necessary.

Surprisingly, it is the lower courts that have demonstrated a more flexible and fact-intensive approach to *Actavis* — at least when it comes to determining damages from allegedly anticompetitive Paragraph IV settlement payments.[159] While the courts have refused to consider patent strength in establishing anticompetitive effect, they have been willing to look at evidence of patent validity in assessing whether, but for a settlement, generic challengers would have entered the market earlier.[160] This requires looking at the parties' subjective estimations of patent validity and infringement in deciding whether the generic would have negotiated an earlier discounted entry date in lieu of payment or even have launched at risk.[161] Similarly, objective estimations of patent validity and infringement are seen as relevant in determining whether, but for

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68, 68–69 (2003); Gant, *supra* note 75, at 313–14.

[156] *See* McDonald, *supra* note 155, at 68, 74.

[157] FTC v. Actavis, Inc., 570 U.S. 136, 171–72 (2013) (Roberts, C.J., dissenting).

[158] *See generally* Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TECH. L. REV. 197 (2015) (describing how courts often resort to antitrust law to avoid adjudicating validity of patents underlying infringement settlements).

[159] *See* Nathan Mendelsohn, *Revival of the Case-within-the-Case: The Importance of Patent Strength Considerations in Reverse-Payment Cases*, 37 ANTITRUST 40, 41–45 (2023); David Shotlander, Aakruti Vakharia, Ralph Labaton & Daniel Lichtenauer, *10 Years After* Actavis*, the Cases that Follow Tell a Story*, HAUG PARTNERS LLP, https://haugpartners.com/article/10-years-after-actavis-the-cases-that-follow-tell-a-story/ [https://perma.cc/M57Z-PMFJ].

[160] Mendelsohn, *supra* note 159, at 42; Shotlander et al., supra note 159.

[161] Mendelsohn, *supra* note 159, at 42–43.

settlement, the generic would have prevailed and entered immediately.[162]

In other words, even when antitrust plaintiffs succeed in proving a settlement to be anticompetitive, the courts must resort to looking at actual evidence of the patents' strength. Given that evidence-based decisions are more nuanced, fact-driven, and ultimately more in keeping with not only antitrust law policy but also patent law policy, resorting to probabilistic patent theory is both unnecessary and undesirable.

CONCLUSION

Although patent litigation settlements have the potential to quell competition, their legality should not depend on conjecture or even overly solicitous concerns about anticompetitive effects. Probabilistic patent theory, as applied to Paragraph IV patent litigation settlements — or any other aspect of patent law — argues too much and would undermine the function of the patent system.

[162] *Id.* at 43–44; Shotlander et al., *supra* note 159.