PHARMACEUTICAL SETTLEMENTS AND JUDICIAL ERROR

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The intersection of patent and antitrust law presents challenges for courts. Some of the most complex issues have arisen in the pharmaceutical industry. What should courts do when drug companies engage in conduct that may be allowed under patent law but threatens significant anticompetitive effects? The question arises in multiple settings. In this article, I focus on patent settlements, analyzing four mistakes courts have made: (1) resurrecting the "scope of the patent" test, (2) bestowing immunity on patent licenses, (3) imposing high causation standards for patent invalidity, and (4) resuscitating a "risk aversion" defense. Courts are continuing to make these errors, as shown by the patent-immunity mistake underlying the D.C. district court's March 2022 decision in *FTC v. Endo Pharmaceuticals*.

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I. THE SETTING

The pharmaceutical industry is unique in its complexity, with nuanced markets and regulatory regimes. Unlike other markets, "the consumer who pays does not choose, and the physician who chooses does not pay."[5] This disconnect has created a gap that can be exploited, as brand-name drug firms convince doctors to prescribe expensive drugs even though equally effective cheaper drugs are available.

The industry also is characterized by complicated regulatory regimes. Most relevant here is the Hatch-Waxman Act, Congress's calibration of the patent and antitrust laws in the industry.[6] This legislation fostered innovation through patent term extensions, periods of market exclusivity not based on patents, and an automatic 30-month stay of generic approval.[7] At the same time, the Act increased generic competition by allowing experimentation on a drug during the patent term, letting generics rely on brands' safety and effectiveness studies, and providing 180 days of marketing exclusivity to the first generic to challenge a brand firm's patent.[8]

The setting for this article involves agreements by which brand drug companies pay generic firms to delay entering the market. In 2013, in the case of FTC v. Actavis, the U.S. Supreme Court concluded that these "reverse payment"[9] settlements could have "significant anticompetitive effects" and violate the antitrust laws.[10] In ensuring a robust role for antitrust analysis, the Court handed down one of the most important business cases in the past generation. And it articulated a blueprint for future analysis based on antitrust law's "rule of reason."[11] But given how much brand firms gain from delaying generic entry,[12] the settling parties have every incentive to muddy the waters, claim the ruling is unclear, and resuscitate defenses that the *Actavis* Court seemingly buried. As discussed throughout this piece, courts sometimes take the bait.

II. ERROR 1: RESUSCITATING THE "SCOPE OF THE PATENT" TEST

The most fundamental error involves the "scope of the patent." Between 2005 and 2012, courts upheld reverse-payment settlements that allowed generic entry (even with payment) at or before the end of the patent term. For example, the *Ciprofloxacin* court found that "[t]he essence

2 For a discussion of settings involving "product hopping" (in which a brand firm switches from one version of a drug to another to stifle generic entry), citizen petitions (which are designed to raise safety concerns with the U.S. Food and Drug Administration ("FDA") but have been used to delay generic entry), and Risk Evaluation and Mitigation Strategies ("REMS") programs (which brand firms have employed to deny samples generics need for testing), see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 Santa Clara L. Rev. 615 (2020).

3 For a discussion of two additional errors that preceded the Supreme Court's decision in *FTC v. Actavis*, 570 U.S. 136 (2013), see Carrier, *supra* note 2, at 618-20 (discussing the policy in favor of settlement and presumption of patent validity, both of which courts treated as dispositive in upholding settlements).

4 2022 WL 951640 (D.D.C. Mar. 30, 2022). For a discussion of more justifiable analysis, see Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, Christopher R. Leslie, & Michael A. Carrier, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 16.01[D], at 16-36 to 16-41 (form of payment), § 16.01[D], at 16-41 to 16-47 (pleading standard), § 16.01[J], at 16-66.48 to 16-66.62 (causation) (3d ed. 2017 & 2021 Supp.).

5 Drug Product Selection, Staff Report to the FTC 2-3 (Jan. 1979).

6 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355). For a discussion of another regime — state drug product selection laws — see Carrier, *supra* note 2, at 617-18.

7 See generally Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 43-45 (2009).

8 21 U.S.C. § 355(j)(5)(B)(iv).

9 These are called "reverse payments" because the consideration flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay patentees).

10 570 U.S. 136, 137 (2013).

11 *Id.* at 159-60.

12 Brand firms can make millions each day generic entry is delayed, sharing some of the extra profits with the settling generic. The FTC found that reverse-payment settlements cost consumers $3.5 billion a year. FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 10 (2010).

of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent"[13] and the *Tamoxifen* court found that the settlement did not "unlawfully extend the reach" of the patent.[14]

The Court in *Actavis* correctly rejected the scope test, understanding that "[t]he patent . . . may or may not be valid, and may or may not be infringed" but that "*an invalidated* patent carries with it no . . . right . . . [to] permit the patent owner to charge a higher than competitive price for the patented product."[15] Importantly, the Court made it clear that the relevant question was not merely what rights patent law would have conferred. It concluded that "[i]t would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent policy, rather than by measuring them against procompetitive antitrust policies as well."[16] Instead, "patent and antitrust policies are both relevant in determining the proper 'scope of the patent monopoly' — and consequently antitrust immunity — that is conferred by a patent," as "[w]hether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* that flows from [traditional antitrust] analysis and not . . . its starting point."[17]

It thus seemed clear after *Actavis* that the scope-of-the-patent test no longer provided a justification that the settling parties could rely on. But the difficulties of finally burying this argument are revealed by the lure of the claim that generic entry before patent expiration is procompetitive. On its face, and with *Actavis* receding ever further into the rearview mirror, courts are tempted to find that pre-expiration entry provides "extra" competition that is good for the consumer.

One example[18] of this error was provided by the Federal Trade Commission ("FTC") Administrative Law Judge ("ALJ") in *In the Matter of Impax Laboratories*.[19] In that case, the ALJ concluded that it was "procompetitive" for a settlement to permit a generic "to enter the market eight months before the original patents expired."[20] Such entry allowed "consumers [to] benefit[] . . . by having uninterrupted and continuous access" to the generic, which was "on the market and available to consumers" because the generic "had the foresight to negotiate licenses to future patents."[21] The ALJ stated that entry before the end of the patent term "can be considered in assessing the [settlement's] competitive consequences."[22] And the ALJ even downplayed the anticompetitive harm at the heart of *Actavis* by claiming that "the magnitude or extent of such harm is largely theoretical, based on an inference" that the generic's entry date would have been earlier without the reverse payment, and that this theoretical harm was outweighed by the settlement's "substantial . . . real world procompetitive benefits."[23]

Generic entry before the end of the patent term is procompetitive only if the patent is valid and infringed. But whether there is a valid, infringed patent is *precisely* the inquiry short-circuited when a brand pays a generic to drop its patent challenge. And given that 89 percent of patents in settled litigation cover not the active ingredient but only ancillary aspects (with the majority of these patents ultimately overturned),[24] the revival of the scope test threatens significant harms.

13 *In re Ciprofloxacin*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

14 *In re Tamoxifen*, 466 F.3d 187, 213 (2d Cir. 2006).

15 570 U.S at 147 (emphasis in original).

16 *Id.* at 148.

17 *Id.* at 149 (emphasis in original).

18 For another example, see Carrier, *supra* note 2, at 632 (discussing *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), where court upheld settlement that "allow[ed] [generic] to enter the . . . market almost six years" before patent expired even though court recognized that "the FTC correctly alleges that something of large value passed" from brand to generic).

19 Dkt. No. 9373 (FTC ALJ Chappell May 18, 2018).

20 *Id.* at 144, 146.

21 *Id.* at 146.

22 *Id.*

23 *Id.* at 156-57.

24 C. Scott Hemphill & Bhaven Sampat, Drug Patents at the Supreme Court, 339 Science 1386, 1387 (2013) (finding companies less likely to win on secondary patents (32%) than on active ingredient patents (92%)).

III. ERROR 2: BESTOWING IMMUNITY ON PATENT LICENSES

The second error involves bestowing immunity on patent licenses. In March 2022, the D.C. district court in *FTC v. Endo Pharmaceuticals* dismissed the FTC's case against Endo on this ground.[25] The court found that brand firm Endo "had a valid license and a right to exclude, which allowed it to maintain a patent monopoly and charge supracompetitive prices."[26] The court stated that "[t]he Patent Act provides Endo the right" to decide to exclusively license its patent.[27] And because "the Patent Act expressly provides for both exclusive licenses and patent monopolies," the court concluded that the FTC "failed to allege that the [a]greement or the resulting patent monopoly violate" antitrust law.[28]

The setting in *Endo* was not exactly the same as one where a brand pays a generic to delay entering the market. Instead, Endo (1) withdrew its branded product in response to the FDA's safety concerns, (2) provided a license only to generic firm Impax, and (3) obtained injunctions that, for years, kept all the other potential generics off the market.[29] As a result, the case involved a *generic* monopoly, and the generic's sharing monopoly profits with the brand.[30]

But this different setting does not affect the question of immunity. The *Actavis* Court, relying on cases analyzing patent-based conduct as far back as the 1920s, concluded that antitrust law has a robust role to play within the scope of the patent. In other words, the fact that patent law allows the conduct is not dispositive. Antitrust law does not bestow immunity on patent-based conduct.

In addition to emphasizing antitrust's role within the scope of the patent, the Court cited numerous precedents to explain how "patent-related settlement agreements can sometimes violate the antitrust laws."[31] For that reason, "the Court has struck down overly restrictive patent licensing agreements — irrespective of whether those agreements produced supra-patent-permitted revenues."[32]

It thus should not be a surprise that the lower courts have appropriately recognized that "formally classifying an agreement a 'license' ought not halt further inquiry into the actual nature of the underlying arrangement";[33] that settling parties "cannot shield themselves with the argument that patent licenses are common and authorized, if such licenses disguise unlawful reverse payments";[34] and that exclusive licenses "can be worth money, and granting them can thus be the equivalent of transferring money," which is why "[t]he issue is not whether the *form* of the payment was legal, but whether the *purpose* of the payment was legal."[35]

For example, the court in *King Drug Co. of Florence v. Smithkline Beecham Corporation* explained that "the 'right' defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise," but "[i]nstead . . . is a right to use valuable licensing in such a way to induce a patent challenger's delay," which was "rejected" by Actavis.[36] Just because a patent holder "may generally have the right to grant licenses, exclusive or otherwise, does not mean it also has the right to give a challenger a license along with . . . a promise not to compete.'"[37] "[E]ven exclusive

25 2022 WL 951640 (D.D.C. Mar. 30, 2022).

26 *Id.* at *11.

27 *Id.*

28 In addition to relying on immunity, the *Endo* court's framework for analysis was highly questionable. Instead of recognizing that the cases on which it relied supported the general point — not limited to reverse-payment settlements — of longstanding antitrust scrutiny of patent-based conduct (including licenses), it pulled miscellaneous phrases from the decades-old rulings to manufacture a 6-part test having no support in the caselaw.

29 *Id.* at *2.

30 See Complaint for Injunctive and Other Equitable Relief, *FTC v. Endo Pharms. Inc.*, Case No.: 1:21-cv-217-RCL (filed Jan. 25, 2021) at ¶ 3 (Impax agreed to pay Endo percentage of profits, "but only so long as [it] refrain[ed] from competing"); ¶ 4 (agreement's purpose was "to ensure that Endo, the gatekeeper to competition in the . . . market, ha[d] every incentive to preserve Impax's monopoly," which "eliminate[d] any potential for . . . competition, allowing Endo and Impax to share in the monopoly profits"); ¶ 99 (agreement "amount[ed] to an incumbent competitor (Impax) paying its only potential challenger (Endo) to stay off the market").

31 570 U.S. at 149.

32 *Id.* at 150.

33 *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 265 (D. Mass. 2014).

34 *Id.*

35 *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015).

36 791 F.3d 388, 406-07 (3d Cir. 2015).

37 *Id.* at 407.

licenses," the court concluded, "cannot avoid antitrust scrutiny where they are used in anticompetitive ways."[38] Relatedly, the Intellectual Property Guidelines issued by the U.S. Department of Justice and FTC, while recognizing possible efficiencies from the "integration of . . . [patents] with complementary factors of production,"[39] warn of "antitrust concerns" from licensing arrangements between "potential competitors."[40] In short, patent licenses are not immune from antitrust scrutiny.

IV. ERROR 3: IMPOSING HIGH CAUSATION STANDARDS FOR PATENT INVALIDITY

The third error involves the analysis of patent invalidity in determining causation. The plaintiff in *Actavis* was the FTC. As a government agency, the FTC does not need to demonstrate causation because it automatically has standing. In contrast, private plaintiffs need to make such a showing. And some courts have required plaintiffs to "prove precisely how, absent the illegal settlement agreement, generic entry would have happened earlier."[41] Plaintiffs have offered three alternative paths to showing this: patent litigation resulting in a finding of invalidity or noninfringement, generic entry "at risk" during the patent litigation, and a settlement without payment allowing earlier entry. Courts applying a rigid approach to causation require plaintiffs to select among these paths and "prove specifically how entry would have occurred in the absence of the illegal settlement agreement."[42]

For example, in *In re Wellbutrin XL Antitrust Litigation*, the Third Circuit rejected the plaintiffs' argument that the generic would have launched at risk since this did not "take into account [a] blocking patent."[43] The court stated that the plaintiffs were required to "show that the launch would have been legal" because "if the launch were stopped because it was illegal," then the plaintiffs' injury "would be caused not by the settlement but by the patent laws prohibiting the launch."[44]

The court also rejected plaintiffs' "litigation-based scenario" by which the generic would have prevailed in patent litigation. Downplaying *Actavis* and drawing curious distinctions, the court asserted that "[w]hile the size of the reverse payment may have some relevance in determining how confident a litigant is in the strength of its case," it "is far from dispositive," especially where "the settlement is complex and multi-faceted" and "there are multiple plausible ways to interpret the reverse payment."[45]

In requiring plaintiffs to prove that the patent definitively would have been ruled invalid, courts have imposed a standard that is nearly impossible to prove and flies in the face of the Court's direction in *Actavis* that patent validity need not be litigated.[46]

V. ERROR 4: RESUSCITATING A "RISK AVERSION" DEFENSE

The fourth error involves resuscitating the argument rejected in *Actavis* that brand firms have offered based on their desire to settle because of risk aversion. Such an argument can only be considered in the context of Actavis, in particular its emphasis on the instructive role played by payment. The Court in *Actavis* found that the settlement at issue had the "potential for genuine adverse effects on competition" since "payment in return for staying out of the market . . . keeps prices at patentee-set levels."[47] In addition, the Court highlighted the harms from a payment to a

38 *Id.*

39 U.S. Dept. of Justice & FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 2.3 (2017).

40 *Id.* § 3.1.

41 Kevin B. Soter, Note, *Causation in Reverse Payment Antitrust Claims*, 70 Stan. L. Rev. 1295, 1314 (2018).

42 *Id.* Another example was provided by the only completed trial on a reverse-payment settlement since *Actavis*, in which the jury found that "[h]ad it not been for" the settlement, AstraZeneca would not have "agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014" given the plaintiffs' failure to offer "direct evidence that the FDA was likely to grant final approval to Ranbaxy's generic Nexium product within the proposed timeline" as well as evidence that Ranbaxy would "never" have launched generic Nexium at risk. Jury Verdict in Favor of Defendants Against Plaintiffs Returned, *In re Nexium Antitrust Litig.*, No. 12-md-02409 (D. Mass. Dec. 8, 2014), ECF No. 1374; *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 272 (D. Mass. 2014). For a discussion of how a generic manufacturer could slow its responsiveness in obtaining FDA approval after entering into a settlement, see Hovenkamp et al., *supra* note 4, § 16.01[J], at 16-66.43 n.267.

43 868 F.3d 132, 165 (3d Cir. 2017).

44 *Id.*

45 *Id.* at 168.

46 See *infra* notes 49-50 and accompanying text.

47 570 U.S. at 154.

generic, which "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product."[48]

The Court revealed its strong preference for determining patent strength by examining the payment rather than the patent. The "size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[49] Even strong patents are not immune from the concern with payments, because an unexplained payment on a "particularly valuable patent . . . likely seeks to prevent the risk of competition," with this consequence "constitut[ing] the relevant anticompetitive harm."[50] In other words, the Court made clear that risk aversion was not an acceptable justification for a reverse-payment settlement.

In identifying the avoidance of the risk of competition as an antitrust violation, the Court dispensed with the risk-aversion defense long advocated by settling parties (and economists), including in *Actavis* itself. For example, in *Actavis*, a group of economists filed an amicus brief that asserted that reverse payments "may . . . be necessary for brand companies to overcome bargaining disadvantages caused by risk aversion."[51] The brief also stated that "[b]rand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome."[52] And it contended that "the size of a reverse payment generally does not provide a reliable benchmark to determine whether the payment is anticompetitive."[53] Faced squarely with these justifications, the Court refused to accept them.[54]

In direct contravention of *Actavis*, the Third Circuit in *In re Wellbutrin XL Antitrust Litigation* was "persuaded" by an economists' amicus brief that "explains why risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name's likelihood of success in litigation," even finding that this reasoning (which the Supreme Court rejected in calling the "prevent[ion of] the risk of competition" the "relevant anticompetitive harm"[55]) "serves as an effective rebuttal to the [plaintiffs'] claim that the size of the reverse payment is a 'surrogate'" for patent weakness.[56]

VI. CONCLUSION

Drug patent settlement cases can be challenging for courts. Although some courts have correctly applied *Actavis*, others have not. The scope-of-the-patent, causation, and risk-aversion arguments have continued to plague courts, while the patent immunity one beguiled the D.C. district court just a short time ago. Although the issues are complex, courts would benefit from applying analysis consistent with *Actavis*.

48 *Id.* at 153-54.

49 *Id.* at 158.

50 *Id.* at 157.

51 Brief of Antitrust Economists as Amici Curiae in Support of Respondents at 3, *FTC v. Actavis* (filed Feb. 28, 2013).

52 *Id.* at 20.

53 *Id.* at 21.

54 See generally Hovenkamp et al., *supra* note 4, § 16.01[D], at 16-26 ("[T]he Court did not accept as a justification risk aversion or the patentee's desire to convert an uncertain patent right into a certain one without litigation.").

55 570 U.S. at 157.

56 868 F.3d at 168-69.

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