Minnesota Journal of Law, Science & Technology

Volume 15 | Issue 1 Article 7

2014

Actavis, the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions

Daniel A. Crane

Actavis, the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions

Daniel A. Crane*

The Supreme Court's decision in *FTC v. Actavis, Inc.*[1] provided an incomplete and unsatisfying response to the issue that has provoked far more antitrust scholarship than any other in the past decade—patent settlements between branded and generic drug companies where the branded makes a "reverse payment" to the generic to stay off the market for some period of time before the expiration of the branded's patent.[2] In brief, Justice Breyer's majority opinion rejected the Eleventh Circuit's standard under which settlements within the patent's exclusionary potential were presumed lawful.[3] It also rejected more draconian rules, like the per se illegal rule adopted by the Sixth Circuit[4] and the quick look approach urged by the FTC.[5] It opted instead for a rule of reason analysis, where the defendant is free to show that the reverse payment is a "rough approximation of the litigation expenses

---

* Associate Dean for Faculty and Research and Frederick Paul Furth, Sr. Professor of Law, University of Michigan.

1. 133 S. Ct. 2223 (2013).

2. *See, e.g.*, Brief *Amici Curiae* of 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioners at 11–12, FTC v. Actavis, Inc., 133 S. Ct. 2233 (2013) (No. 12-416), 2013 WL 391001.

3. *Actavis*, 133 S. Ct. at 2237–38. In addition to the Circuit Court opinion in *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev'd sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), the Eleventh Circuit had followed this rule in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005), and *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003).

4. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 907–09 (6th Cir. 2003) ("There is simply no escaping the conclusion that the [reverse payment] Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.").

5. *Actavis*, 133 S. Ct. at 2237.

saved through the settlement," that the "payment may reflect compensation for other services that the generic has promised to perform," or that the settlement was motivated by other competitively benign considerations.[6]

The *Actavis* decision punted more than it decided. Although narrowing the range of possible outcomes by rejecting the legal rules at the extremes and opting for a rule of reason middle ground, the opinion failed to grapple with the most challenging issues of regulatory policy raised by pharmaceutical patent settlements. In particular, it failed to clearly delineate the social costs of permitting and disallowing patent settlements, avoided grappling with the crucial issues of patent validity and infringement, and erroneously focused on "reverse payments" as a distinctive antitrust problem when equally or more anticompetitive settlements can be crafted without reverse payments.

Although *Actavis* is a frustrating opinion, it is perhaps too much to expect judges to solve the patent settlements challenge. As we enter the post-*Actavis* phase of antitrust litigation over branded-generic settlements, it will become increasingly clear that a comprehensive regulatory solution is needed.

I. THE SOCIAL COSTS OF PATENT SETTLEMENTS

For all of the complexity around the patent settlements issue, a foundational observation regarding the social costs of patent settlements is quite clear—making it all the more frustrating that it is so frequently ignored. When a pioneer drug company sues a generic entrant for patent infringement, there is some probability, x, that the pioneer company will win and obtain an injunction keeping the generic product off the market until the expiration of the patent.[7] (We can slightly complicate the analysis by adding that a successful suit by the pioneer may set a precedent that discourages other generics from the market too).[8] $1 - x$ renders the remaining probability, y, the chance that the pioneer company will lose the lawsuit

6. *Id.* at 2236.

7. *See* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 91 (2005).

8. *Cf. id.* (assuming for purposes of the article's analysis that no other potential generic entrants exist).

and that the generic product will enter before the patent expires.[9] If the generic product is forced to stay off the market until the patent expires, the pioneer will be able to charge a supracompetitive price, yielding a social loss of p, which consists of just deadweight losses or deadweight losses plus wealth transfers, depending on one's denominational persuasion.[10] The social cost of patent settlements involving delayed generic entry is yp, or the probability that (but for the settlement) the generic would have entered times the monopoly overcharge costs to society.[11]

The immediate implication of this bivariate social cost formula is that one cannot assess the social costs of patent settlements without some understanding of the probability of generic entry absent the settlement. The *Actavis* majority dismissed the need to understand the strength of the patent invalidity or non-infringement defenses of the generic,[12] relying instead on evidence of what the economics of the settlement might reveal about the branded firm's intent.[13] But, unlike the probability of generic entry, the branded firm's intent with respect to the settlement is not a direct input into the social cost equation. Indeed, it would only be relevant at all if it revealed the pioneer's implicit understanding of y. To be sure, the economics of the settlement may reveal *something* about the pioneer's implicit understanding of y, but probably less than the majority believed and certainly less than a direct assessment of y.

In focusing on the subjective motivation for the settlement, the *Actavis* majority appeared to suggest that any motivation by the pioneer to eliminate y is inherently anticompetitive and damning—what Learned Hand referred to in *Alcoa* as "*caput*

---

9. *See id.*

10. *See id.* at 83 ("[W]hen patents are improperly issued for rights that are not novel, or are 'obvious,' the public suffers without justification by paying supracompetitive prices.").

11. *Cf.* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 754–55 (2002).

12. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question . . . .").

13. *Id.* at 2237 ("Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons?").

lupinum" (the head of a wolf).[14] This is an odd assumption and one at odds with the ordinary operation of the rule of reason. The motivation to suppress competition is often a small piece of many business arrangements that easily satisfy the rule of reason.[15]

Take, for example, the classic rule of reason case—*Mitchel v. Reynolds*—which involved a bakehouse lease with a covenant not to compete in the same parish for five years.[16] It is certainly conceivable that, absent the lease, the lessor and lessee would have entered into competition within the relevant geographic market. Each may have had some incentive to agree to the lease in order to eliminate that possibility. But any elimination of *y* in that case was swamped by the procompetitive effects of the deal—that the lessee was apparently in a better position to exploit the bakehouse assets than the lessor. These efficiencies could not have been realized if the lessor had been able to re-capture some of the bakery's goodwill by opening a nearby competitive facility.

Oddly, *Actavis* seemed to suggest that any residual trace of insurance against *y* in a complex settlement agreement renders the settlement anticompetitive as a whole. This approach ignores that *yp* may be considerably smaller than the procompetitive benefits of a settlement. As is well documented in the literature, these include not only the elimination of direct litigation costs, as the majority assumed,[17] but many others. Indirect litigation costs often exceed attorney's and expert witness fees.[18] The early elimination of uncertainty around generic entry can allow for better planning by both pioneers and generics, and invention around the patent.[19] The settlement option increases the generic's flexibility in challenging the pioneer's patent and hence decreases the costs

---

14. United States v. Aluminum Co. of Am., 148 F.2d 416, 426 (2d Cir. 1945) ("[F]or not all that even a monopolist may earn is caput lupinum.").

15. *See* Crane, *supra* note 11, at 778 ("A patentee's intentions are virtually always explicitly 'anticompetitive' in the precise sense in which antitrust lawyers mean those words—the patentee wishes to suppress the competition for its patented good in order to preserve a stream of monopoly rents from that good.").

16. Mitchel v. Reynolds, (1711) 24 Eng. Rep. 347 (B.R.) 347; 1 P. Wms. 181, 181.

17. *Actavis*, 133 S. Ct. at 2236.

18. *See* Crane, *supra* note 11, at 757–58.

19. *Id.* at 762–63.

of generic challenges.[20] Many settlements allow for entry years before the expiration of the patent, a possibility that would be eliminated by the pioneer's victory in the patent litigation.[21] In ordinary rule of reason analysis, one would analyze and weigh these factors against *yp*, something the *Actavis* majority seemed reluctant to permit.

II. CONCENTRATING ON THE DIRECTION OF PAYMENT

Like some courts and commentators before, the *Actavis* majority saw something unnatural and inherently suspect in reverse payments, observing that the reverse payment "form of settlement is unusual."[22] But, as has been observed on many occasions, the reverse payment form is a byproduct of the Hatch-Waxman Act's regulatory framework.[23] Because of the Hatch-Waxman Act's automatic thirty-month stay of the generic's right to enter the market and the branded firm's obligation to file a patent challenge within forty-five days of a generic company's ANDA filing,[24] the patent litigation usually unfolds in a time period when the generic product will not yet be on the market.[25] Indeed, even if the Hatch-Waxman Act's

---

20. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (citing expert declaration of Dr. Jerry Hausman for the proposition that "[t]o maximize these incentives [for generics to challenge branded patents], a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it" (citation omitted)).

21. *See* Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HASTINGS SCI. & TECH. L.J. 441, 442–44 (2011) (discussing early entry provisions in agreements between pioneer and generic companies regarding the medication Provigil, wherein the generic companies agreed in 2006 to delay market entry until 2012, when the patents were set to expire in 2015).

22. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013); *see also id.* at 2233 ("In the traditional examples cited above, a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim. In reverse payment settlements, in contrast, a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market.").

23. *See, e.g.*, Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 51 (2009) (describing the increasing use of reverse payment settlements under the Act).

24. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

25. *See* Gregory Dolin, *Reverse Settlements As Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 293–94 (2011) ("[U]nlike usual patent litigation where the dispute touches on products that are already on or about to enter

automatic stay has lifted because of the expiration of the thirty months or the denial of a preliminary injunction, the generic may be reluctant to enter the market because of the asymmetry between the damages the pioneer can collect in the event of victory and the profits the generic can earn by marketing over the same period. All of this means that, at the time most pioneer-generic settlements occur, the branded has not yet been injured by generic entry. It has no damages to demand from the generic and any settlement payment in consideration of the cessation of litigation must thus proceed from the plaintiff to the defendant.[26]

The direction of payment in a patent settlement is only roughly correlated with *yp*. It certainly is not a direct input, which makes the concentration on the direction of payment a sideshow to the important economic questions that should be addressed. What's worse, by focusing on reverse payments as a distinctive issue requiring antitrust scrutiny, the Court ignored the fact that equally or more anticompetitive patent settlements can be constructed with no reverse payment at all, as discussed next.

III. EASY ANTICOMPETITIVE WORK-AROUNDS

One of the factors that Justice Breyer identified as supporting the legality of a reverse payment is evidence that the "payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item."[27] He apparently has in mind a circumstance, true in some of the patent settlement cases, where the generic agrees to distribute either the branded drug or an authorized generic and receives a promise of payment for its services as part of the settlement. Indeed, if a generic and pioneer want to avoid the stigma of the reverse payment altogether, it is simple to "naturalize" the direction of payment by having the generic promise to pay the

---

the market, Hatch-Waxman litigation occurs prior to the generic drug actually entering the market. Consequently, in the Hatch-Waxman litigation there are no damages (other than the cost of litigation for each party) to be had. Yet under a reverse settlement the patentee often pays amounts far exceeding the cost of litigation to the challengers.").

26. *See id.*; *see also supra* note 22.

27. *Actavis*, 133 S. Ct. at 2236.

patentee for the right to be a distributor.[28] Instead of an agency model where the generic collects on behalf of the brand and receives compensation for its efforts, the model can be reverted to a licensing model where the generic is authorized to distribute the drug, remitting some share of the proceeds to the pioneer as a royalty.[29] In that case, we have both the absence of a reverse payment and the fact of early generic entry, which should easily satisfy the *Actavis* rule of reason standard.

However, such agreements may be worse from a competition standpoint than the reverse payments at issue in *Actavis*.[30] Suppose, for example, that prior to generic entry, the monopoly mark-up per unit is equal to one dollar. Now suppose that the pioneer brings a patent infringement lawsuit with a low probability of success. Prior to adjudication of that lawsuit, the pioneer settles with the generic, making the generic its authorized generic distributor. The generic agrees to remit to the pioneer a royalty of one dollar per unit sale. Unless the generic's marginal costs of production or distribution are lower than that of the pioneer, we now have (1) early generic entry; (2) no reverse payment; and (3) a continuation of precisely the previous monopoly pricing.

Indeed, if the licensing agreement continues until the expiration of the patent, this scenario may be worse than some reverse payment settlements, particularly those that permit generic entry before the expiration of the patent. Further, we need not make the royalty equal to the full monopoly overcharge in order to produce anticompetitive results. Say the royalty is equal to 90% of the monopoly overcharge. Now, in addition to early generic entry and no reverse payment, we have the delightful bonus of immediate price reductions. But there is still potentially an enormous anticompetitive effect. Since the first generic to market ordinarily sets its price around 70%–80% of the brand,[31] this settlement deprives

28. *See* Crane, *supra* note 11, at 765.

29. *See id.*

30. *See id.* at 765–66.

31. *See* Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, *in* BROOKINGS PAPERS ON ECONOMIC ACTIVITY: MICROECONOMICS, 1991, at 1, 35 (Martin Neil Baily & Clifford Winston eds., 1991) ("[G]eneric drugs sell for a substantial discount from the price of the branded drug; the estimates suggest that with a single generic entrant, the generic price is roughly 60 percent of the branded drug price."); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV.

consumers of a much larger price decrease they might have received in the but-for world.

This example is not fanciful. The FDA currently lists 673 authorized generics on the market.[32] To the extent that these agreements do not involve reverse payments, they will not show up on the post-*Actavis* radar screen. But every antitrust lawyer worth his or her salt will be pushing clients in the direction of settlements of this nature that avoid reverse payments. Circumvention of the reverse payment rule established in *Actavis* is relatively easy.

To repeat an earlier point, what drives *yp* is not the direction in which payment flows in a patent settlement. It is the probability that but for the settlement, the generic and pioneer would have entered into price competition. There are ample means other than reverse payments to soften competition between branded and generic drug firms. *Actavis* does not merely ignore this possibility. By crediting licensing agreements as a robustly procompetitive defense, it compounds the error of the decision and appears to grant categorical immunity to other forms of anticompetitive agreement.

IV. THE CONTINUING NEED FOR REGULATORY SOLUTIONS

Actavis represents another instance of what my colleague Becky Eisenberg has called "patent punting" strategies—refusals by courts to engage with the strength of patents in cases other than patent infringement cases. It is understandable that judges prefer to treat patents as black boxes rather than to engage their merits. After all, patent is such a specialized and technical area of law that it is the one of the very few for which we have created a specialized court of appeals. Relitigating in the antitrust case the full merits of the

---

ECON. & STAT. 37, 44 (2005) (explaining that their study showed a single generic entrant would set its price at 88% of the branded price); *see also* Caves et al., *supra*, at 44–45 (finding that generic producers depress the branded drug's price and "enter the market quoting prices much lower than those of their branded competitors").

32. *FDA Listing of Authorized Generics as of July 22, 2013*, FOOD & DRUG ADMIN., *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM183605.pdf (last visited Aug. 28, 2013).

previously settled patent infringement litigation is a burden that neither the parties nor the courts wish to undertake.

But the fact that the undertaking is burdensome is not a good reason to eschew it if it provides one of the two necessary inputs to understanding whether the settlement is harmful to consumer welfare.[33] Unless we can determine *y* just by deconstructing the settlement economics—something far more difficult than the *Actavis* court seemed to assume—there is no substitute for direct engagement with the strength of the patent infringement claim, meaning both the patent validity and the defendant's non-infringement defense.

To say that there needs to be direct engagement with the strength of the patent infringement claim is not to say that courts need to do this. The analytical and practical gaps in *Actavis* point to the need for a greater degree of regulatory involvement in branded-generic contestation over patent rights. One could imagine a range of regulatory actors that already touch aspects of these problems—the PTO, FDA, or FTC, for example—playing a greater role in opening the black box of the patent infringement claim and hence providing information more directly relevant to the antitrust analysis than the direction of the settlement payment.

Actavis showed the courts grappling for solutions they are ill-equipped to provide. As the next wave of antitrust litigation around patent settlements unfolds in coming years and the vulnerability of courts in answering the relevant questions becomes more apparent, the need for regulatory solutions will become clearer. The door should now be opened for creative proposals for regulatory solutions.

---

33. Indeed, one might say that *y* is *the* crucial input, since it can reasonably be assumed that *p* will be large given economic evidence on the price reduction patterns upon generic entry. *See* Caves et al., *supra* note 31, at 44–45.

***