THE FEDERAL TRADE COMMISSION'S HEARINGS ON COMPETITION AND CONSUMER PROTECTION IN THE 21ST CENTURY, REVERSE-PAYMENT SETTLEMENTS, COMMENT OF THE GLOBAL ANTITRUST INSTITUTE, ANTONIN SCALIA LAW SCHOOL, GEORGE MASON UNIVERSITY

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The Federal Trade Commission's Hearings on Competition and Consumer Protection in the 21st Century, Reverse-Payment Settlements, Comment of the Global Antitrust Institute, Antonin Scalia Law School, George Mason University[1]

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This Comment is submitted in relation to the Federal Trade Commission's ("FTC") Hearings on Competition and Consumer Protection in the 21st Century. Specifically, we address the United States Supreme Court's holding in *FTC v. Actavis, Inc.* that reverse-payment settlements should be analyzed under the rule of reason.[2] The Court also held that since a full rule of reason analysis is costly and difficult, the size of the settlement may be used a proxy.[3] The idea is that, if a settlement is greater than the potential litigation costs, then this is an indicator of a weak patent, or an attempt by the patent holder to exclude competition—in sum, it indicates that consumer

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[2] 570 U.S. 136 (2013).

[3] *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), https://www.crai.com/sites/default/files/publications/Actavis-and-Multiple-ANDA-Entrants-Beyond-the-Temporary-Duoply-Antitrust-Spring-2015.pdf.

welfare has decreased.[4] We submit this comment based upon our extensive experience and expertise in antitrust law and economics.

Introduction

Reverse-payment settlements are a unique type of settlement where the patent holder pays the alleged infringer to settle the infringer's patent challenge. In layman's terms, it is looks like the patent holder paying an infringer to go away rather than litigate the validity of the patent.

In this Comment, we discuss the economics of litigation and settlement of patent disputes arising from Paragraph IV of the Abbreviated New Drug Application ("ANDA") filings.[5] First, we discuss a single-entrant model and discuss the merits of adopting a standard whereby reverse-payment settlements that exceed the patentee's litigation costs reduce consumer welfare and should be deemed *per se* anticompetitive.[6]

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[4] *Id.*

[5] An ANDA is the application for a new generic drug when a brand drug has already garnered approval from the Food and Drug Administration ("FDA"). It is abbreviated because generic filers "generally [are] not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is performs in the same manner as the innovator drug." This demonstration, termed bioequivalence, is the basis for approval for the generic drug under the Hatch-Waxman Act. An approved ANDA drug can challenge the validity of the brand drug's patent and also gains 180-days of generic exclusivity, during which time no other generic drugs can enter the market. *See* ABBREVIATED NEW DRUG APPLICATION (ANDA), U.S. FOOD AND DRUG ADMIN. (2018), https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/default.htm.

[6] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, 28 ANTITRUST 16 (2013); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, Actavis *and Error Costs: A Reply to Critics*, THE ANTITRUST SOURCE, at *1, *4 (2014). *But see* Barry C. Harris, Kevin M. Murphy, Robert D. Willig & Matthew B. Wright, *Activating* Actavis*: A More Complete Story*, 28 ANTITRUST 83, 83-84 (2014) (using a single-entrant model, but criticizing antitrust limits on reverse payment settlements).

Next, taking into account the institutional features of the Hatch-Waxman Act's regulatory regime, we examine a more general model that assumes multiple firms will enter the market following patent invalidation and expiration of the 180-day marketing exclusivity period.[7] The Comment then examines alternatives to the static consumer-welfare standard used to evaluate reverse-payment settlements.[8] This comment concludes that using the size of the reverse payment settlement is a poor proxy for full blown rule of reason analysis under either model, because doing so may decrease consumer welfare and may induce parties to inefficiently settle.

Single-Entrant Model

Kobayashi *et al.* (2015) show that the single-entrant model can be used to provide analytical support that reverse-payments that exceed the anticipated litigation costs are likely to harm competition and should be treated as *per se* unlawful.[9] The single-entrant model assumes that the first ANDA entrant and the patent holder will earn duopoly profits until the patent expires. Further, this model assumes there are three possible outcomes after the ANDA filing: (1) the brand firm wins in court; (2) the generic firm wins in court; or (3) the two firms settle. If the brand wins, the brand will continue to earn monopoly profits for the duration of the patent. If the generic wins, the generic and brand will obtain duopoly profits until the patent expires. If the parties decide to

[7] Kobayashi, *supra* note 3, at 89.
[8] *Id.* at 93-95.
[9] *Id.* at 90.

settle and agree to an early entry date, the brand will continue to obtain monopoly profits until the early entry date. After entry, the parties will obtain duopoly profits until the patent expires.

Under the single-entrant model, there are a range of settlements the brand and generic could rationally agree to, assuming, say, a 90 percent probability that the patent will be upheld.[10] Within this range of settlements, the payments could be between 8 and 12 times the patentee's anticipated litigation costs. In considering settlement, an important benchmark for consumer welfare is the litigation-adjusted expected patent life, which is equal to the probability the patent is upheld if litigated multiplied by the remaining patent life. Consumer welfare from litigation will equal consumer welfare from settlement if the early entry date is equal to the litigation-adjusted expected patent life. If the settled entry date is before the expected patent life, consumer welfare will be larger than expected under litigation. If the settled entry date is after the expected patent life, the opposite is true.

Courts could adopt a rule that requires entry before the expected patent life to increase consumer welfare, but this would require the courts to analyze the strength and validity of the patent.[11] Under these assumptions, the brand's earliest acceptable entry date is equal to the expected life of the patent when the size of the reverse-

[10] *Id.*
[11] *Id.*

payment is equal to the brand's litigation costs. Therefore, any reverse-payment that exceeds the brand's expected litigation costs will reduce consumer welfare. However, these equilibrium settlements will result in entry dates that are later than the litigation-adjusted life of the patent since the generic's latest acceptable entry date is later than the brand's earliest acceptable entry date.

Limiting reverse-payment settlements to this size can also prevent settlements that would result in litigation cost savings that are greater than the loss of consumer welfare.[12] The single-entrant model also fails to consider that when a patent is upheld or invalidated, it confers benefits to other generic entrants and consumers more generally. The shortcomings of the model, and the fact that in reality there is typically more than one generic entrant, provide reasons to expand the analysis past the assumption of a temporary duopoly in the period following a settlement.

Multiple Entrants Model

The single-entrant model fails to consider the realistic expectation that if the generic wins in court, multiple entrants, will appear and eliminate any duopoly between the brand and the generic.[13] The same three potential outcomes exist in the multiple entrants model as in the single-entrant model.[14] If the brand wins through litigation, the brand still obtains monopoly profits. If the parties settle and agree to an

[12] *Id.* at 91.
[13] Kobayashi, *supra* note 3, at 91
[14] *Id.* at 92.

earlier entry date, the parties can expect to earn the same duopoly profits. The key difference between the models occurs when the generic wins through litigation.

Within 45 days of an entrant filing an ANDA, if the branded firm files an infringement suit, then FDA action on the ANDA is stayed for 30 months. The brand continues to make monopoly profits during this period. Further, "the first generic to file a Paragraph IV certification is entitled to 180-day marketing exclusivity under some circumstances, including when the patent is invalidated in litigation."[15] This creates a 6-month period for the brand and generic to earn duopoly profits. After this period, additional generics will enter, and vigorous competition will ensue. The generic that invalidates the patent provides a positive externality to other generics, which can now enter the market at the end of the 6-month period. This benefit is also passed on to consumers, who can expect to pay lower prices due to increased competition.[16]

Assuming a discount rate of zero and again assuming a 90 percent probability of the patent being upheld, there is a greater range of potential settlements than in the single-entrant model.[17] Collateral estoppel imposes additional litigation costs on the brand because of the potential risk of multiple firms entering if the patent is invalidated.[18] The generic's latest acceptable entry date is shifted later in time due to

[15] 21 U.S.C. § 355(j)(5)(B)(iv).
[16] Kobayashi, *supra* note 3, at 92.
[17] *Id.*
[18] *Id.*

the generic's lower payoff in obtaining duopoly profits for only 180 days rather than indefinitely as in the single-entrant model.[19]

Settlements that increase consumer welfare will have to set an entry date that is earlier than the expected patent life because litigation that invalidates the patent produces a greater static welfare gain.[20] This is because the parties will obtain duopoly profits for only the 180-day period in the multiple entrant model, followed by a period of vigorous competition.[21] This breakeven date is earlier than the brand's earliest acceptable entry date. Litigation is also less likely in this model due to the broader range of settlements available.

Antitrust Rules

The Court in *Actavis* considered two bright-line rules.[22] The first, *i.e.*, the patent test, recognized the brand's legal ability to use its patent to prevent all entry by generics.[23] Under this rule, however, invalid patents would remain viable creating significant Type II error costs. The Court rejected this approach out of concern with allowing a monopoly to persist without justification or need.[24]

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[19] *Id.*
[20] *Id.* at 92-93.
[21] *Id.* at 93.
[22] FTC v. Actavis, Inc., 570 U.S. 136 (2013).
[23] Kobayashi, *supra* note 3, at 93.
[24] *Actavis*, 570 U.S. at 151 (quoting Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969)).

The second rule was *per se* condemnation of reverse-payments.[25] This would eliminate Type II errors but increase the cost of Type I errors.[26] The Court rejected the *per se* rule realizing that some settlements could be welfare enhancing, but the Court left it to the lower federal courts to apply the rule of reason and to determine exactly which settlements would be legal.[27]

One way to fashion an accurate rule that minimizes error costs is to conduct an inquiry into the validity of the patent as part of the antitrust case.[28] However, due to the difficulty of conducting this inquiry, the Court rejected that approach. The Court instead examined the subset of settlements that are greater than litigation costs would suggest is optimal, and stated that this could be used as a reliable indicator to predict a weak patent without having to do a full inquiry into the validity of the patent.[29] In

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[25] *See, e.g.*, in re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (holding a reverse payment per se unlawful because the agreement "was, at its core, a horizontal agreement to eliminate competition in the market for [the pharmaceutical] throughout the entire United States, a classic example of a per se illegal restraint of trade"); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 306 (2009) (arguing reverse payments should be per se unlawful because the "general tendency will be to delay generic entry beyond the expected value entry date, resulting in unnecessary error costs . . . ." and "judicial attempts to scrutinize reverse payments will be unlikely to succeed and will entail substantial transaction costs").

[26] Kobayashi, *supra* note 3, at 93-94.

[27] *Id.*

[28] *Id.* at 94.

[29] *Id. See also Actavis*, 570 U.S. at 158 ("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."). The Court also acknowledged "[t]he reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That 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. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 156.

these large settlements, the Court is assuming that it would be rational for the patent holder to litigate, but the fact that it chooses not to suggests that the patent holder thinks it has a weak patent. Our prior analysis of the two models suggests strong incentives for parties to settle, even more so in the multiple entrants model. This shows that a rule based simply upon the size of the reverse-payments will not preserve settlements that increase consumer welfare net of litigation costs.

Kobayashi *et al.* (2015) emphasize that a "static consumer welfare standard is incomplete as it ignores direct costs and considers only some of the error costs."[30] A better standard involves minimizing deadweight loss rather than measuring the loss of consumer surplus, assuming both calculations are net of litigation costs.[31] That standard would include the costs borne by third parties. Under this standard, in the multiple entrant model, there is a large range of reverse-payments that are above litigation costs and increase total welfare.[32] However, this standard still fails to address dynamic Type I errors, *i.e.*, the lost innovation that results from the invalidation of valid patents and from settlements paid to avoid that result.[33] Including these dynamic Type I errors would most likely shift the early entry date even later, which could in turn

[30] Kobayashi, *supra* note 3, at 95.
[31] *Id.*
[32] *Id.*
[33] *Id.*

increase dynamic welfare when agreements do not allow generic entry before the expiration of the patent.[34]

Conclusion

In *Actavis,* the Supreme Court rejected using bright line rules for reverse-payment settlements, and instead decreed that lower courts should apply a rule of reason analysis. To that end, we have shown that using the size of a settlement as a proxy for a full-blown rule of reason analysis may condemn welfare-increasing settlements as anticompetitive. Further, it can encourage parties to use other, possibly more inefficient means, to settle, which can increase the Type I error cost under both a single-entrant model and a multiple entrant model.

[34] *Id.*