

# A Response to Chief Justice Roberts: Why Antitrust Must Play a Role in the Analysis of Drug Patent Settlements

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The Supreme Court's decision in *FTC v. Actavis, Inc.*<sup>1</sup> has justly received widespread attention for its antitrust analysis of settlements by which brand-name drug companies pay generics to delay entering the market. Much of the attention has focused on the application of the Court's standard and the logistics of applying its rule of reason analysis to "reverse payment" settlements.<sup>2</sup>

One overlooked issue, however, has been the position of Chief Justice Roberts in dissent that the antitrust analysis of these settlements must assume that the patent at issue is invalid or not infringed, since these inquiries present a problem of patent, not antitrust, law.

This Essay critiques Roberts' position. After presenting his argument, it explains that the dissent (1) presents an incomplete view of patent policy; (2) downplays the significance of antitrust law; and (3) ignores the Hatch-Waxman Act, Congress's resolution of the patent-antitrust intersection in the pharmaceutical industry.

## I. ROBERTS' ARGUMENT

A central concern with reverse payment settlements is that a brand firm could pay a generic to delay entering the market even though its patent is invalid or not infringed. In this

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1. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

2. The term reveals a difference from typical licensing payments that flow from challengers to patentees. *See, e.g.*, Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39 (2009).

scenario, the conduct resembles market division, with two competitors dividing the market and agreeing not to compete.<sup>3</sup>

Roberts recognized in his dissent in *Actavis* that “[t]he problem” is that “we’re not quite certain if the patent is actually valid, or if the competitor is infringing it.”<sup>4</sup> But he then swept these difficult issues under the patent rug by concluding that “that is always the case, and is plainly a question of patent law.”<sup>5</sup>

Roberts stated that a patentee’s “behavior would be unlawful only if its patent were invalid or not infringed” and that “the scope of the patent—i.e., what rights are conferred by the *patent*—should be determined by reference to *patent law*.”<sup>6</sup> He continued: “While it is conceivable to set up a legal system where you assess the validity of patents or questions of infringement by bringing an antitrust suit, neither the majority nor the Government suggests that Congress has done so.”<sup>7</sup>

Roberts combined his exclusive preference for patent law with the position that activity within the nominal scope of the patent is immune from the antitrust laws. A patentee “acting within the scope of its patent has an obvious defense to any antitrust suit: that its patent allows it to engage in conduct that would otherwise violate the antitrust laws.”<sup>8</sup>

Continuing the argument, Roberts lamented that the majority “seems to have in mind a regime where courts ignore the patent, and simply conduct an antitrust analysis of the settlement without regard to the validity of the patent.”<sup>9</sup> The problem is that “a patent holder acting within the scope of its patent does not engage in any unlawful anticompetitive behavior” but “simply exercis[es] the monopoly rights granted to it by the Government.”<sup>10</sup>

Relatedly, Roberts worried about applying antitrust law in this setting, with the majority inappropriately “assess[ing] . . . patent law issues according to ‘antitrust

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3. See, e.g., *id.* at 72.

4. *Actavis*, 133 S. Ct. at 2240 (Roberts, C.J., dissenting).

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

policies.”<sup>11</sup> Similarly, the majority “says that any questions regarding the legality of the settlement should be ‘measur[ed]’ by ‘procompetitive antitrust policies,’ rather than ‘patent law policy.’”<sup>12</sup>

[A]lthough the question posed by this case is fundamentally a question of patent law—*i.e.*, whether Solvay’s patent was valid and therefore permitted Solvay to pay competitors to honor the scope of its patent—the majority declares that such questions should henceforth be scrutinized by antitrust law’s unruly rule of reason.<sup>13</sup>

Finally, Roberts responded to the majority’s suggestion that a right to settle “makes it harder to ‘eliminat[e] unwarranted patent grants.’”<sup>14</sup> He recognized that “[t]hat may be so, but such a result—true of all patent settlements—is no reason to adjudicate questions of patent law under antitrust principles.”<sup>15</sup> “[A]ntitrust law,” says Roberts, “has no business prying into a patent settlement so long as that settlement confers to the patent holder no monopoly power beyond what the patent itself conferred—unless, of course, the patent was invalid, but that again is a question of patent law, not antitrust law.”<sup>16</sup>

## II. CRITIQUE

Chief Justice Roberts’ dissent is subject to several critiques. First, Roberts ignored the patent law policy of challenging and eliminating invalid patents. Second, he downplayed the role of antitrust law. And third, he neglected the importance of the Hatch-Waxman Act, Congress’s resolution of the patent-antitrust tradeoff in the pharmaceutical industry.<sup>17</sup>

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11. *Id.*

12. *Id.* at 2239 (quoting *id.* at 2231 (majority opinion)).

13. *Id.* at 2245.

14. *Id.* at 2243 (quoting *id.* at 2233 (majority opinion)).

15. *Id.*

16. *Id.*

17. Roberts also mischaracterized the majority’s position when he lamented its use of antitrust “rather than” patent law to address reverse payment settlements. *Id.* at 2240. The majority suggested not that antitrust law *replace* patent law, but that it *supplement* it. *Id.* at 2231 (majority opinion) (“[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies *as well.*” (emphasis added)).

## A. PATENT POLICY

Roberts claimed that the assessment of reverse payment settlements should be conducted solely pursuant to patent law. But even under this excessively constricted view, scrutiny is warranted.

Patents are often viewed in absolute terms. They give a blanket right to exclude. They are presumed valid. Any incursion on their domain is inconsistent with the grant of the right. But these assertions do not present the whole story.

Empirical studies have consistently shown that at least 40% of patents issued by the U.S. Patent and Trademark Office (USPTO) that are litigated to decision are invalid,<sup>18</sup> with one FTC study finding that generics prevailed in 73% of challenges between 1992 and 2000.<sup>19</sup>

These figures are not a surprise. The grant of a patent reflects an initial judgment by the USPTO that an invention is patentable. Such a judgment comes after limited scrutiny with examiners having, on average, less than twenty hours to read an application, search for prior art, evaluate patentability, and reach and write up conclusions.<sup>20</sup> Because of this limited

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18. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (finding that courts invalidated 46% of patents between 1989 and 1996); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 384–85 (2000) (finding that alleged infringers prevailed in 42% of patent cases that reached trial between 1983 and 1999); *Decisions for 2000–2004*, U. HOUS. L. CENTER, <http://www.patstats.org/2000-04.htm> (last visited Aug. 28, 2013) (stating that, in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed).

19. The study considered “Paragraph IV” certifications, by which generics claim that patents are “invalid or will not be infringed by the generic drug.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012); see *infra* note 51 and accompanying text. FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 9–10, 16 (2002)*, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. Portions of this and the next three paragraphs are adapted from Brief *Amici Curiae* of 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioners at 15–17, *FTC v. Actavis, Inc.*, 133 S. Ct. 2233 (2013) (No. 12-416), 2013 WL 391001 [hereinafter Professor Brief].

20. FTC, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 9–10 (2003)*, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

examination, litigation plays a crucial role in ensuring that invalid patents do not block competition.<sup>21</sup>

The *Actavis* Court recognized the “patent-related policy of eliminating unwarranted patent grants so the public will not continually be required to pay tribute to would-be monopolists without need or justification.”<sup>22</sup> The Court had recognized, more than four decades earlier in *Lear, Inc. v. Adkins*, that a patent “simply represents a legal conclusion reached by the Patent Office . . . in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.”<sup>23</sup>

Challenging invalid patents is even more important today than it was at the time the Court decided *Lear*. The burdens on the Patent Office have only increased, with the number of patent applications skyrocketing to over 500,000 per year, more than five times the number filed when *Lear* was decided.<sup>24</sup>

In short, even an exclusive focus on patent policy must include the goal of testing (and eliminating) invalid patents through litigation. Roberts’ suggestion to decide the issue solely on grounds of patent law does not include this important aspect of patent policy.

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21. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1531–32 (2001).

22. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2233 (2013) (internal quotation marks omitted).

23. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969); see also *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2253 (2011) (Breyer, J., concurring) (offering measures designed to “increase the likelihood that discoveries or inventions will not receive legal protection where none is due”); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (finding that licensees have standing to challenge patent validity or infringement without repudiating their licenses); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973) (emphasizing “public interest in free competition” in concluding that a licensee in an antitrust suit “may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license”); *Blonder-Tongue Labs. v. Univ. of Ill. Found.*, 402 U.S. 313, 349–50 (1971) (allowing alleged infringer to claim estoppel where patent was previously declared invalid).

24. *U.S. Patent Statistics Chart, Calendar Years 1963–2012*, USPTO, [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\\_stat.htm](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm) (last visited Aug. 28, 2013) (showing 576,763 total patent applications filed in 2012, compared to 104,357 in 1969).

## B. ANTITRUST POLICY

As the majority in *Actavis* recognized, reverse payment settlements have the “potential for genuine adverse effects on competition.”<sup>25</sup> Of all the types of business activity subject to the antitrust laws, agreements by which competitors divide markets could be the most dangerous since “[m]arket division restricts *all* competition between the parties on *all* grounds.”<sup>26</sup>

Reverse payment settlements result in generics dropping patent challenges and, in exchange for significant payments, agreeing to delay entry into the market.<sup>27</sup> Because the brand makes more by keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to cede the market to the brand firm and split the monopoly profits.<sup>28</sup> The brand then can use a portion of this additional profit from delayed competition to pay the generic.

Reverse payments allow brands to delay entry longer than they could based on the strength of the patent itself. An agreement concerning the generic entry date, without any cash payment, will normally reflect the odds of the parties’ success in patent litigation: the more likely the patentee is to win the case, the more it can rely on the patent itself to exclude competition.<sup>29</sup> But by paying generics to stay out of the market, a brand is likely to gain additional exclusivity by supplementing this entry-date agreement with payment.<sup>30</sup> The quid pro quo for the payment would appear to be the generic’s agreement to stay out of the market beyond the expected entry date resulting from litigation.<sup>31</sup> As Justice Breyer explained: “The payment 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

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25. *Actavis*, 133 S. Ct. at 2234 (internal quotation marks omitted).

26. Professor Brief, *supra* note 19, at 11. Portions of this and the next two paragraphs are adapted from Professor Brief, *supra* note 19, at 11–12.

27. *See id.* at 11.

28. *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407 (2003).

29. HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 15.3, at 15-45 (2d ed. Supp. 2010).

30. Professor Brief, *supra* note 19, at 12.

31. *Id.*

and the patent were held invalid or not infringed by the generic product.”<sup>32</sup>

Finally, market power likely exists where there are reverse payments. Again, as the Court understood: “[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.”<sup>33</sup> At a minimum, the “size of the payment” is “itself a strong indicator of power,” in other words, “the power to charge prices higher than the competitive level.”<sup>34</sup> And a firm that lacks this power is not likely to pay “large sums” to induce “others to stay out of its market.”<sup>35</sup>

Nor, finally, did the Supreme Court’s precedents bar antitrust liability in this setting. As Roberts recognized, the array of cases the Court decided in the early and middle part of the twentieth century addressed conduct lying outside the scope of the patent.<sup>36</sup> But just because a settlement covering a product *outside* the scope of the patent violates the antitrust laws does not mean that one falling *within* the facial scope of the patent is automatically valid.<sup>37</sup> And courts can reflexively conclude that the settlement falls within the scope of the patent only by making the inappropriate assumptions that the patent is valid and infringed.<sup>38</sup>

In short, antitrust policy is relevant in determining the legality of agreements by which brand firms pay generics to delay entry.

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32. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234 (2013).

33. *Id.* at 2236 (citing 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 1503, at 392–93 (3d ed. 2012)).

34. *Id.* (internal quotation marks omitted) (citing 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 2046, at 351 (3d ed. 2012)).

35. *Id.*

36. *Id.* at 2241 (Roberts, C.J., dissenting) (“But each of those cases stands for the same, uncontroversial point: that when a patent holder acts *outside* the scope of its patent, it is no longer protected from antitrust scrutiny by the patent.”).

37. Michael A. Carrier, *Why the “Scope of the Patent” Test Cannot Solve the Drug Patent Settlement Problem*, 16 *STAN. TECH. L. REV.* 1, 5 (2012).

38. *Actavis*, 133 S. Ct. at 2231–32; Carrier, *supra* note 37, at 5–6 (explaining that the agreements “might or might not violate the antitrust laws,” but that “[t]hat depends on whether the patent is valid” and “cannot be determined by the mere existence of the patent”).

### C. HATCH-WAXMAN ACT POLICIES

As the Supreme Court has made clear, it is appropriate for courts applying antitrust law to “be attuned to the particular structure and circumstances of the industry at issue.”<sup>39</sup> Congress resolved the tension between the patent and antitrust laws in the pharmaceutical industry by enacting the Hatch-Waxman Act (the Act).<sup>40</sup> Any analysis of reverse payment settlements thus should at least consider the policies underlying the Act.<sup>41</sup>

A central aspect of this complex regulatory regime was to encourage generic entry.<sup>42</sup> At the time of the Act, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness even though they had the same active ingredients as brand drugs.<sup>43</sup> Approval by the U.S. Food and Drug Administration (FDA) took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term.<sup>44</sup> At the time Congress enacted Hatch-Waxman, there was no generic on the market for 150 brand-name drugs whose patents had already expired.<sup>45</sup> The Act’s drafters lamented the “practical extension” of the patentee’s “monopoly position” beyond the expiration of the patent,<sup>46</sup> and sought to “make available more low cost generic drugs.”<sup>47</sup>

The first tool the legislature created to accelerate generic entry was the Abbreviated New Drug Application (ANDA) process, which allowed generic firms to rely on the brand drug’s safety and effectiveness studies and avoid the expensive and lengthy new drug application process.<sup>48</sup> Second, Congress

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39. *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004).

40. Professor Brief, *supra* note 19, at 5; see Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

41. Portions of this and the next three paragraphs are adapted from Professor Brief, *supra* note 19, at 5–7, and Carrier, *supra* note 2, at 42–45.

42. See Carrier, *supra* note 2, at 41–42.

43. *Id.* at 42.

44. *Id.*

45. H.R. REP. NO. 98-857, pt. 1, at 17 (1984).

46. H.R. REP. NO. 98-857, pt. 2, at 4.

47. H.R. REP. NO. 98-857, pt. 1, at 14.

48. 21 U.S.C. § 355(j)(2)(A), (j)(8)(B) (2012).

resuscitated the experimental use defense, exempting from infringement the manufacture, use, or sale of a patented invention for uses “reasonably related to the development and submission of information” under a federal law regulating the manufacture, use, or sale of drugs.<sup>49</sup> Third, Congress increased competition by creating a 180-day period of generic marketing exclusivity, reserved for the first generic to certify that the brand firm’s patent was invalid or not infringed and enter the market before the patent expired.<sup>50</sup> The Act specified four avenues by which a generic could challenge a brand’s patent, but only the “Paragraph IV” route, which anticipates entry before the end of the patent term, received market exclusivity.<sup>51</sup>

In addition to promoting generic competition, the Act included several mechanisms to bolster incentives for brand-firm innovation. First, Congress increased the effective patent life by extending the patent term, with the extension currently amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials.<sup>52</sup> Second, Congress granted an automatic thirty-month stay of FDA approval for generic products if patent holders sue generic filers within forty-five days.<sup>53</sup> Finally, Congress provided for periods of market exclusivity not based on patents, such as the four-year exclusivity period for a drug with a new active ingredient.<sup>54</sup>

Courts cannot effectively analyze reverse payment agreements without considering the Hatch-Waxman Act. The Act had a central purpose of encouraging challenges to invalid or not infringed patents *during the term of the patent* to encourage early market entry. Reverse payment settlements directly contravene this goal by allowing brands to pay generics for delayed market entry. Not only does such conduct flout the patent policy of testing invalid patents and present significant antitrust harm, but it also disregards the Hatch-Waxman Act and the important public policy goal of increasing the number of affordable generic medicines.

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49. 35 U.S.C. § 271(e)(1) (2006 & Supp. V 2011).

50. 21 U.S.C. § 355(j)(5)(B)(iv).

51. *Id.*

52. 35 U.S.C. § 156(c) (2006 & Supp. V 2011).

53. 21 U.S.C. § 355(j)(5)(B)(iii).

54. *Id.* § 355(j)(5)(F)(ii).

## CONCLUSION

Chief Justice Roberts contended that in determining the legality of reverse payment settlements, antitrust analysis must assume that the patents at issue are valid and infringed. But that position shortchanges patent law, which includes a policy goal of testing invalid patents to make sure they do not block competition. It downplays antitrust law's role in monitoring behavior that can resemble market division between potential competitors. And it ignores the Hatch-Waxman Act's encouragement of challenges to patents that are invalid or not infringed.

In a nutshell, the appropriate antitrust treatment of reverse payment settlements is more nuanced than the version presented by Roberts.