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When is the lion neither inside nor outside the den?[1]

The U.S. Supreme Court's recent decision in *FTC v. Actavis, Inc.*[2] brings some resolution to the decade-long dispute over the level of antitrust scrutiny that is appropriate for evaluating the legality of "reverse payment" or "pay-for-delay" agreements settling pharmaceutical patent infringement litigation between brand-name and generic drug companies. I have written at length about this topic before and need not devote time and space to rehashing the facts or the arguments in favor of various proposed approaches.[3] Suffice to say that in the past I argued against the Eleventh Circuit's "scope-of-the-

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1. Whalen Lai, *Koan*, *in* ENCYCLOPEDIA OF ASIAN PHILOSOPHY 287, 288 (Oliver Leaman ed., 2001) (attributing the saying to Mazu Daeyi).

2. 133 S. Ct. 2223 (2013).

3. *See* Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?,* 47 ANTITRUST BULL. 491 (2002); 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 (2004); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789 (2003) [hereinafter Cotter, *Presumptive Illegality*]; *see also* Thomas F. Cotter, *FTC v. Actavis: An Analysis*, INTELLECTUALIP.COM (Feb. 25, 2013) http://intellectualip.com/2013/02/25/ftc-v-actavis-an-analysis/ [hereinafter Cotter, *FTC v. Actavis: An Analysis*]; Thomas F. Cotter, *FTC v. Actavis, Case Law*, INTELLECTUALIP.COM (Feb. 22, 2013), http://intellectualip.com/2013/02/22/ftc-v-actavis-case-law/ [hereinafter Cotter, *FTC v. Actavis, Case Law*]; Thomas F. Cotter, *FTC v. Actavis: The Hatch-Waxman Framework*, INTELLECTUALIP.COM (Feb. 20, 2013), http://intellectualip.com/2013/02/20/ftc-v-actavis-the-hatch-waxman-framework/; Thomas F. Cotter, *FTC v. Actavis: Reverse Payments*, INTELLECTUALIP.COM (Feb. 21, 2013), http://intellectualip.com/2013/02/21/ftc-v-actavis-reverse-payments/.

patent" test, under which the agreement would be legal as long as the terms fell within the exclusionary *potential* of the patent, and the infringement action was not merely a sham or fraud.[4] Instead, I argued for a "presumptive illegality" approach, under which proof that a brand-name company paid a generic company to settle would shift the burden to the settling parties to rebut the presumption of illegality.[5] In this regard, I proposed that the most important factor in determining whether the settling parties have rebutted the presumption should be

> the amount of consideration flowing from the brand-name to the generic firm. Where that amount is less than the amount of the patent owner's expected litigation costs, this fact alone may be sufficient to rebut the presumption, and thus shift to the antitrust plaintiff the burden of proving that the anticompetitive harm outweighs the procompetitive benefit of the settlement. Under these circumstances, the payment may represent nothing more than a good-faith effort to avoid litigation costs . . . . Other relevant evidence may include the presence of other agreements between the settling parties (for example, authorizing the defendant to market an authorized generic drug, or licensing the defendant other intellectual property rights), which should be taken into account for the limited purpose of accurately estimating the value of the consideration flowing from plaintiff to defendant; whether the generic is "cash-strapped," and therefore willing to accept a later entry date to remain in business; whether the patent owner sought, and succeeded in obtaining, a preliminary injunction against the generic manufacturer; whether the generic manufacturer agrees to waive its 180-day exclusivity, thus removing the risk of a bottleneck potentially blocking other ANDA applicants; and whether the patent in suit has withstood other validity challenges arising after the filing of the settled action. On the other hand, where the amount of consideration flowing from patent owner to generic manufacturer exceeds the generic firm's expected profit from the sale of the generic drug in question, the inference that the patent owner is simply paying a potential competitor to exit the market is much stronger, and the presumption of illegality should be very difficult to rebut. Moreover, although it probably would not be advisable to require the factfinder to estimate the ex ante probability that the patent would have been found valid and infringed had the infringement action not been settled—a matter that courts in some of the reverse payment cases understandably have been reluctant to undertake—all that the proposed approach requires is for courts to draw appropriate inferences from the amount of the settlement in

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4. *See* Cotter, *FTC v. Actavis, Case Law*, *supra* note 3.
5. *See, e.g.*, Blair & Cotter, *supra* note 3, at 534–35.

> comparison to other expected costs and benefits, along with any other relevant facts and circumstances.[6]

Writing for a 5-3 majority in *Actavis*, Justice Breyer rejected both the scope-of-the-patent test and the presumptive illegality approach and held instead that courts should review reverse payment settlements under the rule of reason.[7] Or so the opinion states. In reality, the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject. One might speculate about the political or prudential considerations that went into the majority's characterization of what it was actually doing, but as I read the opinion, reverse payment settlements of the type at issue in *Actavis* are now subject to a de facto regime of presumptive illegality. In my view, this is a welcome result.

The reason I characterize the majority holding as adopting a de facto rule of presumptive illegality is that, as antitrust lawyers are well aware, in practice the rule of reason is hardly the sort of open-ended, totality-of-the-circumstances approach suggested by Justice Brandeis's classic definition of the rule of reason in the old *Board of Trade* case.[8] Rather, courts tend to apply a structured version of the rule of reason,[9] which Professor Hovenkamp nicely summarizes in his hornbook[10] and

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6. Cotter, *FTC v. Actavis: An Analysis*, *supra* note 3 (citing MICHAEL A. CARRIER, INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW 378–82 (2009); Cotter, *Presumptive Illegality*, *supra* note 3, at 1812–15).

7. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230–38 (2013).

8. *See* Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918). Justice Brandeis wrote for the Court:

> The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.

Id.

9. *See, e.g.*, Polygram Holding, Inc. v. FTC, 416 F.3d 29, 33–38 (D.C. Cir. 2005).

10. HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 279–80 (4th ed. 2011).

which I paraphrase in the following manner in my own antitrust classes:

1. Consider first whether there is a "contract, combination, or conspiracy" that restrains trade (in some sense).

   If yes (conscious parallelism coupled with plus factors?), go on.

   If not, § 1 doesn't apply (the "§ 1 gap").

2. If necessary, consider next whether the restraint poses any possible risk to competition. I.e., is the restraint at issue one that poses a substantial risk of increasing price, lowering quantity, or causing some other anticompetitive harm?

   If yes, go on.

   If no, stop; judgment for defendant.

3. If necessary, consider next whether the restraint is likely to generate any plausible, cognizable, procompetitive benefits.

   For example, does the restraint plausibly relate to the core activities of a lawful joint venture?

   Is it plausibly ancillary in the sense of being reasonably necessary to promote the legitimate activities of a joint undertaking? Reasonably necessary for the provision of some good or service that consumers demand but which might not be provided optimally if each competitor merely followed its own individual self-interest?

   If yes, go on.

   If no, stop; it is a naked restraint of trade, likely only to increase price or reduce output or quality, and is per se illegal.

4. If necessary, consider next whether the defendant has market power (e.g., through substantial market share coupled with barriers to entry), or alternatively whether there is proof of actual anticompetitive effects, such as a reduction of output.

   If yes, go on.

   If no, stop; judgment for defendant.

5. If necessary, consider next whether the restraint at issue provides actual (not just plausible) procompetitive benefits.

   If yes, go on.

   If no, stop; judgment for plaintiff.

6. If necessary, consider next whether the restraint is the least restrictive means of attaining those benefits.

   If yes, go on.

   If no, stop; judgment for plaintiff.

7. If necessary, balance the procompetitive benefits against the anticompetitive costs (good luck!).[11]

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11. Thomas F. Cotter, PowerPoint Presentation, *Antitrust Overview* (unpublished document) (on file with author) [hereinafter Cotter PowerPoint];

Assuming that this analysis is correct, what exactly will courts be doing when they apply the rule of reason approach to pay-for-delay cases such as *Actavis*? Will they be starting from step 1 above? No, because in any case in which a patentee agrees to pay money to an alleged infringer in return for the latter's agreement to settle the case and temporarily exit the market there is obviously a contract that potentially restrains trade; that much is indisputable. Equally obvious is the potential risk to competition (step 2). At the same time, there are potential procompetitive benefits (step 3), because (as a general matter) settlement conserves social resources that otherwise would be devoted to litigation and (in this specific context) in theory the settlement could speed up the entry of generic drugs to the market.[12]

Crucially, according to the majority, step 4 above is also likely to be present in the context of pay-for-delay settlements. As Justice Breyer wrote:

> *First*, the specific restraint at issue has the "potential for genuine adverse effects on competition." 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 and the patent were held invalid or not infringed by the generic product. Suppose, for example, that the exclusive right to sell produces $50 million in supracompetitive profits per year for the patentee. And suppose further that the patent has 10 more years to run. Continued litigation, if it results in patent invalidation or a finding of noninfringement, could cost the patentee $500 million in lost revenues, a sum that then would flow in large part to consumers in the form of lower prices.
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> *Second*, these anticompetitive consequences will at least sometimes prove unjustified . . . .
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> *Third*, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. At least, the "size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power"—namely, the power to charge prices higher than the competitive level. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay "large sums" to induce "others to stay out of its market." In any

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see also Thomas F. Cotter, *Patent Holdup, Patent Remedies, and Antitrust Responses*, 34 J. CORP. L. 1151, 1205–06 (2009).

12. *See Actavis*, 133 S. Ct. at 2234–35.

> event, the Commission has referred to studies showing that reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.[13]

If we have made it all the way through steps 1 through 4, what remains? Step 5 asks (in my formulation) "whether the restraint at issue provides actual (not just plausible) procompetitive benefits."[14] Importantly, the burden of proof on step 5 *normally rests with the defendant*.[15] So if, under the Court's own analysis, steps 1 through 4 are satisfied in the typical pay-for-delay case and review really kicks in at step 5—at which point the defendant has the burden of coming forward with exonerating evidence—it is a little hard to see how that framework differs in any functional manner from presumptive illegality.[16]

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13. *Id.* at 2234–36 (citations omitted).

14. *See* Cotter PowerPoint, *supra* note 11. Professor Hovenkamp states this step somewhat more forcefully, namely whether there is "strong evidence that the challenged practice creates substantial efficiencies by reducing participants' costs or improving product or service quality." HOVENKAMP, *supra* note 10, at 280.

15. *See, e.g.*, Polygram Holding, Inc. v. FTC, 416 F.3d 29, 36 (D.C. Cir. 2005) ("[T]he evidentiary burden shifts to the defendant to show the restraint in fact does not harm consumers or has 'procompetitive virtues' that outweigh its burden upon consumers."); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065 (11th Cir. 2005) (stating that "[o]nce the plaintiff meets the burden of producing sufficient evidence of market power, the burden then shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective"); Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997) ("'[I]f the plaintiff succeeds [in showing an actual anticompetitive effect], the burden shifts to the defendant to establish the "pro-competitive 'redeeming virtues'" of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.'").

16. *See Polygram Holding*, 416 F.3d at 36. The *Polygram* court stated:

> For reasons we have already explained, we reject PolyGram's attempt to locate the appropriate analysis, and the concomitant burden of proof, by reference to the vestigial line separating per se analysis from the rule of reason. *See* Areeda & Hovenkamp, *Antitrust Law*, ¶ 1511a ("judges and litigants too often assume erroneously that the classification, per se or rule of reason, necessarily determines what must or may be alleged and proved, made the subject of detailed findings, or submitted to the jury"). At bottom, the Sherman Act requires the court to ascertain whether the challenged restraint hinders competition; the Commission's framework, at least as the Commission applied it in this case, does just that.
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> We therefore accept the Commission's analytical framework. If, based upon economic learning and the experience of the market, it is obvious that a restraint of trade likely impairs competition, then the

This is particularly so given the Court's further statements that "it is normally not necessary to litigate patent validity to answer the antitrust question" and its discussion of the type of procompetitive justifications that might excuse a reverse payment.[17] As for the first issue, Justice Breyer wrote:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, 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.[18]

In other words, the plaintiff is not going to have to prove, except inferentially by reference to the amount of the payment, that the probability of patent invalidity was high. As for the second, the Court noted that reverse payments

> 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. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences we mentioned above.[19]

All of this leads me to conclude that the reasons the Court chose not to characterize what it was doing as a presumptive illegality approach were either (1) political, e.g., to keep one or

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> restraint is presumed unlawful and, in order to avoid liability, the defendant must either identify some reason the restraint is unlikely to harm consumers or identify some competitive benefit that plausibly offsets the apparent or anticipated harm.

Id.

17. *See Actavis*, 133 S. Ct. at 2236.
18. *Id.* at 2236–37.
19. *Id.* at 2236.

more possibly gun-shy justices on board with the majority, on the theory that a rule of reason approach is not quite as pro-plaintiff as a presumptive illegality approach; or (2) based on concerns that courts might construe the adoption of a presumptive illegality approach in the present case as effectively holding that such an approach is appropriate in other cases, not arising in the byzantine shadow of Hatch-Waxman. The concluding section of the majority opinion seems to reflect this latter concern,[20] and thus may be viewed as a

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20. *See id.* at 2237–38. Justice Breyer concluded:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.
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> To say this is not to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory. As a leading antitrust scholar has pointed out, "'[t]here is always something of a sliding scale in appraising reasonableness,'" and as such "'the quality of proof required should vary with the circumstances.'"
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> As in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.

Id. (citations omitted). I would expect that settlements of patent infringement litigation outside of the Hatch-Waxman context will rarely give rise to plausible antitrust claims under the rule of reason. In a typical case, settlement may increase output (e.g., by resulting in a nonexclusive license of a patent that has withstood a validity challenge), thus failing step 2 above; or the patentee lacks market power (step 4); or courts will conclude, as a general rule, that a settlement lacking any red flags such as the presence of a reverse payment in excess of the defendant's expected profit (or other suspicious conditions) necessarily has procompetitive benefits that outweigh any anticompetitive consequences that could be proven without unraveling the reduction of adjudicative costs that is the primary social good that settlement produces (and thus will not countenance attempts to question patent validity or infringement absent good reason). But I tend to agree with the majority that patent settlements should not be effectively immune from antitrust scrutiny absent conduct such as sham or fraud, which arguably was the implication of the scope-of-the-patent test.

rejoinder to the dissent's concern that the majority approach renders vulnerable even conventional patent settlements.[21]

In conclusion, it seems to me that the majority adopted a (de facto) presumptive illegality approach to pay-for-delay settlements entered into in the shadow of Hatch-Waxman—precisely the approach that many of us were hoping for[22]—even if, for political or prudential reasons, it suggests that it did not. As long as the lower courts correctly interpret the message, this seems an acceptable resolution to the pay-for-delay problem.

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21. *See Actavis*, 133 S. Ct. at 2244–45 (Roberts, C.J., dissenting).

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

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