Articles

Sensible Antitrust Rules for Pharmaceutical Competition

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AS THE TOPIC selection for this symposium indicates, maintaining competition in pharmaceutical markets is a top priority in United States antitrust policy today. Further, it is no easy task. While the pharmaceutical industry contains numerous firms, it also has several other characteristics that have historically made collusion and high prices easy to achieve. One is relatively low elasticity of demand. Consumers often need drugs badly and are willing to pay a great deal to have them. Further, employee-paid health insurance and other third party payors tend to insulate consumers from drug costs, both by making prices less transparent and shielding the consumers themselves from the full impact. In addition, the pharmaceutical industry is characterized by a high degree of product differentiation. While there are hundreds of drugs out there, typically only a small number are suitable for a particular diagnosis, and in many cases there are only one or two that a physician believes to be suitable for a patient. This fact makes collusion within relatively small groupings possible, and cartels with small numbers of members are always more threatening than cartels with greater numbers.[1] Most pharmaceuticals are also characterized by high fixed costs and a great deal of innovation risk, which tends to make entry barriers into the pharmaceutical industry rather high.

At the same time, however, the pharmaceutical industry is a very difficult one for antitrust policy to deal with. First of all, it is technologically complex, and generalist Article III federal judges and particularly juries are not good at dealing with technological complexity. Antitrust's tools of measurement are crude, particularly for such

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1. *See* 12 HERBERT HOVENKAMP, ANTITRUST LAW & 2002 (2005) [hereinafter HOVENKAMP, ANTITRUST LAW, 2005].

things as determining a firm's market power.[2] Its ability to recognize and adequately deal with anticompetitive conduct that implicates intellectual property rights is at best severely limited. Further, pharmaceutical markets are characterized by a high degree of innovation, a place where antitrust must always step lightly.[3] Antitrust remedies that unnecessarily deprive defendants of patent rights or that reduce the value of prospective patenting are likely to do more harm than good to the long run performance of the industry.

Nevertheless, with careful thought we can make antitrust perform well. Here, I suggest a few basic principles for antitrust analysis in the pharmaceutical industry:

First, antitrust decision-makers should be careful but not timid.
Second, antitrust must always be sensitive to the regulatory environment in which a challenged restraint occurs.
Third, the so-called "per se rule" and the "rule of reason" are highly artificial constructs whose gross definitions often serve to obscure rather than illuminate antitrust analysis.

I. Caution, but Not Paralysis

The history of the antitrust laws is cluttered with examples of excessive enthusiasm, imagined injuries to competition, and overly aggressive remedies.[4] Far too often we have condemned practices that were procompetitive or applied remedies that were even more harmful to the economy than the conduct they were intended to correct. Conduct that is merely tortious, or that harms a rival, is not actionable under the antitrust laws unless it also harms competition,[5] and harm to competition is fairly exceptional. At the same time, however, antitrust should not be reluctant to become involved in a market when a genuine threat to competition appears. This is true even when the conduct at issue implicates patent or other intellectual property laws.

With few notable exceptions, such as the Robinson-Patman Act,[6] the antitrust laws are public regarding legislation that is not under the control of any special interest group.[7] The antitrust laws are spare in

2. *See* 2A PHILLIP E. AREEDA, HERBERT HOVENKAMP & JOHN L. SOLOW, ANTITRUST LAW, ch. 5 (2d ed. 2002).

3. *See generally* HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW (2002 & Supp. 2005).

4. For a good presentation of such excesses, see ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF (1978).

5. *See generally* Sherman Act of 1890 §§ 1–2, 15 U.S.C. §§ 1–2 (2000).

6. Robinson-Patman Act, 15 U.S.C. § 13(a) (2000).

7. *See generally* 14 HERBERT HOVENKAMP, ANTITRUST LAW, ch. 23 (1999).

their wording and exhort courts to condemn practices only when they restrain trade, monopolize markets, or lessen competition.[8] To be sure, the courts have not consistently interpreted this exhortation and have often favored particular interest groups at the expense of the economy as a whole. For example, in the 1960s the courts were excessively concerned with the welfare of small business.[9] However, no special interest group has managed to control Congress's overall antitrust agenda.

Traditionally, the intellectual property laws were also public regarding legislation. Increasingly, however, IP law-making has been captured by special interests. This is particularly true of the Copyright Act[10] since 1976, but it is also true of many "specialty" amendments to the patent statute.[11] While the basic patent provisions remain general and give the federal courts considerable discretion to fashion patent policy in the public interest, the more recent detailed amendments are not necessarily of that nature. In general, detailed statutory provisions are a sign that Congress has made special deals with various interest groups in fashioning legislation.[12]

In such a setting the courts need not be too hesitant to step in. Indeed, a good way to combat special interest capture is to interpret "public regarding" provisions broadly and special interest provisions narrowly. When statutory provisions suggesting "capture" are interpreted narrowly, with ambiguities resolved against the special interest responsible for them, it forces Congress to be more transparent about what it wants, thus exposing them to the political costs of what they are doing. Alternatively, it places the burden of getting the statute amended on the special interest group that obtained the statute in the first place, and their previous success indicates that they are in the best position to do so. Interpreting such a provision to favor the spe-

8. *See, e.g.*, 15 U.S.C. § 1 (restraint of trade); *id.* § 2 (monopolies); Clayton Act, ch. 323, §§ 3, 7, 38 Stat. 730, 731–32 (1914) (current version at 15 U.S.C. §§ 14, 18 (2000) (tying, exclusive dealing, and mergers that substantially lessen competition).

9. *See* BORK, *supra* note 4, at 202–06.

10. 17 U.S.C. §§ 101–1332 (2000).

11. *See* Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900-2000*, 88 CAL. L. REV. 2187, 2190 (2000); JESSICA LITMAN, DIGITAL COPYRIGHT 26–29 (2001); John R. Allison & Emerson H. Tiller, *The Business Patent Myth*, 18 BERKELEY TECH. L.J. 987, 1007–08 (2003); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1637 (2003); William F. Patry, *Copyright and the Legislative Process: A Personal Perspective*, 14 CARDOZO ARTS & ENT. L.J. 139, 141 (1996).

12. *See* Frank H. Easterbrook, Foreword, *The Court and the Economic System*, 98 HARV. L. REV. 4, 16–18 (1984); Merges, *supra* note 11, at 2190.

cial interest places that burden with those interests, including perhaps the public interest, that lost the legislative battle to begin with.[13]

The lesson for antitrust is that, when a real anticompetitive threat appears on the horizon, antitrust should not be too timid to intervene and should not be detained by highly generalized concerns for intellectual property rights that Congress has not articulated with clarity. This gives antitrust a significant role in limiting IP licenses, settlement agreements, and other practices that limit competition.

II. Sensitivity to the Regulatory Environment

In our system antitrust is only the "residual" regulator of markets. It is not the only regulator in any market, and in some it is a relatively minor regulator or has been completely ousted by the regulatory regime.

To give a couple of examples, virtually every market in the United States is subject to the regulation imposed by the labor laws or the civil rights laws. The civil rights laws rarely create conflicts with antitrust policy, but the labor laws do.[14] Other forms of regulation impact price, output, or the possibilities for collusion or exclusionary practices much more directly, and, in these, antitrust always exists in some tension with the regulatory regime.[15] The more the regulatory regime in question takes competition into account in making its decisions or the greater the degree to which practices challenged under the antitrust laws have been explicitly mandated or approved by a regulatory enterprise, the less room there is for antitrust in that particular market. When the regulatory agency fully considers competitive concerns in making a decision, or when Congress or sometimes an agency compels or explicitly approves conduct that is later challenged under the antitrust laws, then we may conclude that antitrust is "ousted" from that market to that extent. Alternatively, we may say that the defendant enjoys a regulatory immunity from antitrust challenge to that particular conduct.[16] A corollary of these propositions is that as a mar-

13. *See, e.g.*, Einer Elhauge, *Preference-Eliciting Statutory Default Rules*, 102 COLUM. L. REV. 2162, 2169–70 (2002).

14. *See, e.g.*, Clarett v. NFL, 369 F.3d 124 (2d Cir. 2004) (exempting from antitrust challenge NFL rule limiting eligibility of draftees who were not at least three full seasons beyond high school); *see also* 1A PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶¶ 255–257 (2d ed. 2002).

15. *See* 1A AREEDA & HOVENKAMP, *supra* note 14, ¶¶ 240–243; Herbert Hovenkamp, *2003 Milton Handler Antitrust Review: Antitrust and the Regulatory Enterprise*, 2004 COLUM. BUS. L. REV. 335.

16. 1A AREEDA & HOVENKAMP, *supra* note 14, ¶¶ 240(c)–(d), 242(a).

ket goes through "deregulation," or loosening up of regulatory standards, the role for antitrust can be expected to increase.[17]

While the production and distribution of pharmaceuticals is heavily regulated, mainly by the Food and Drug Administration, very little of this regulation directly implicates the antitrust law's concern for maintaining competition. As a result, there are relatively few decisions arising in the pharmaceutical industry that have found an antitrust immunity.

The intellectual property laws are also a regulatory regime, however, and one that is more expressly concerned with the maintenance of competitive markets. To be sure, the IP laws are concerned with a different aspect of maintaining competition than antitrust is. The IP laws are not particularly concerned about price or output in the short run, but they are heavily concerned with encouraging the optimal amount of innovation.

Determining the proper relationship between the antitrust laws and any particular regulatory regime has always been a difficult task that has required a great deal of appellate court oversight and resulted in many divided Supreme Court decisions.[18] At one time the Supreme Court was inclined to say that if regulation in a market was "pervasive," then the antitrust laws were completely ousted from that market. Thus most of the conduct in that market enjoyed a kind of blanket antitrust immunity.[19]

But this type of global immunity is out of fashion now. Today, immunity decisions are much more conduct specific. In general, the greater the degree to which an agency actively supervised conduct, taking competitive concerns into account, the more likely the conduct is to be found immune. What we really want to know is whether a challenged act was a product of effectively unsupervised private firm

17. *See id.* ¶ 241.

18. *See, e.g.*, United States v. Nat'l Ass'n of Secs. Dealers, 422 U.S. 694 (1975); Gordon v. New York Stock Exch., 422 U.S. 659 (1975); Silver v. New York Stock Exch., 373 U.S. 341 (1963).

19. *See, e.g.*, Hughes Tool Co. v. TWA, 409 U.S. 363, 385 (1973) (pervasive regulation leads to antitrust immunity); Pan Am World Airways v. United States, 371 U.S. 296, 300–01 (1963) (similar); Otter Tail Power Co. v. United States, 410 U.S. 366, 374 (1973) (congressional rejection of comprehensive regulatory scheme for electric industry supports rejection of antitrust exemption claim); United States v. Phila. Nat'l Bank, 374 U.S. 321, 352 (1963) (regulation not pervasive; agency approval does not immunize merger); United States v. RCA, 358 U.S. 334, 348–51 (1959) (similar); United States v. Borden Co., 308 U.S. 188, 197–98 (1939) (similar).

discretion, or whether the conduct, including anticompetitive threats, was thoroughly reviewed by the regulator.[20]

Just last term the Supreme Court revisited this issue in *Verizon Communications, Inc. v. Law Offices of Curtin Trinko, LLP*.[21] That case raised issues about the relationship between the antitrust laws and the 1996 Telecommunications Act,[22] which requires incumbent telephone carriers, or Incumbent Local Exchange Carriers ("ILECs"), to interconnect with competitive carriers so that the latter can offer local telephone service in competition with the incumbent carriers.[23] The antitrust claim was one of unlawful unilateral refusal to deal, or a violation of antitrust's "essential facilities" doctrine, which requires a dominant firm to share certain inputs with smaller rivals. Refusal to deal doctrine involving single firms has been one of the most controversial and difficult-to-administer areas of antitrust. An overly broad right of rivals to share a dominant firm's facilities discourages rivals from building their own facilities, thus undermining the very competition that antitrust seeks to foster.[24] Indeed, a broad sharing obligation actually facilitates collusion by involving the dominant firm and its rivals in ongoing communications and shared use of common facilities.[25] Further, fashioning and enforcing orders against defendants faces severe obstacles. First, a court rather than the market must determine what must be shared. In addition, the price of sharing must be determined. Finally, the court has to monitor compliance. In sum, the essential facility doctrine threatens to turn antitrust courts into regulatory agencies, something for which courts of general jurisdiction are extremely poorly suited, particularly when they are required to proceed by means of jury trials in damages actions.

So, on the one side antitrust was a very crude and imprecise vehicle for enforcing interconnection agreements in the telecommunications industry. On the other side, the interconnection process was

20. *See, e.g.*, MCI Communications Corp. v. AT&T, 708 F.2d 1081 (7th Cir. 1983), *cert. denied*, 464 U.S. 891 (1984); Gordon v. New York Stock Exch., 422 U.S. 659 (1975); Silver v. New York Stock Exch., 373 U.S. 341, 357 (1963); *see also* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE §§ 18.1, 19.1–19.3 (forthcoming 3d ed. 2005).

21. 124 S. Ct. 872 (2004).

22. Pub. L. No. 104-104, 110 Stat. 56 (codified as amended in scattered sections of 47 U.S.C.).

23. 47 U.S.C. § 251(c) (2000); *see also* AT&T Corp. v. Iowa Utils. Bd., 525 U.S. 366, 371 (1999).

24. *See* 3A AREEDA & HOVENKAMP, *supra* note 14, ¶ 771.

25. *Id.* & 772(c)(4). Justice Scalia's *Trinko* opinion for the Court also made this observation. *See Trinko*, 124 S. Ct. at 879.

subject to intensive regulatory scrutiny by both the Federal Communications Commission ("FCC") on the federal level and state regulatory agencies. This made antitrust an inferior decision-maker. As the Court observed in *Trinko*,

> Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation. As we have noted, "careful account must be taken of the pervasive federal and state regulation characteristic of the industry." "[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[26]

In that particular case, an important element of this regulatory setting was

> the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny. Where, by contrast, "[t]here is nothing built into the regulatory scheme which performs the antitrust function," the benefits of antitrust are worth its sometimes considerable disadvantages. Just as regulatory context may in other cases serve as a basis for implied immunity, it may also be a consideration in deciding whether to recognize an expansion of the contours of § 2.[27]

Looking at the general structure and operation of the regulatory regime, the Court found that it

> demonstrates how, in certain circumstances, "regulation significantly diminishes the likelihood of major antitrust harm." Consider, for example, the statutory restrictions upon Verizon's entry into the potentially lucrative market for long-distance service. To be allowed to enter the long-distance market in the first place, an incumbent LEC must be on good behavior in its local market. Authorization by the FCC requires state-by-state satisfaction of [the Telecommunications Act] § 271's competitive checklist, which as we have noted includes the nondiscriminatory provision of access to UNEs.[28]
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26. *Trinko*, 124 S. Ct. at 881 (quoting United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 91 (1975); Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.)) (citations omitted).

27. *Id.* (quoting Silver v. New York Stock Exch., 373 U.S. 341, 358 (1963); United States v. Nat'l Ass'n of Sec. Dealers, 422 U.S. 694, 730–35 (1975)) (citations omitted).

28. UNEs, or "unbundled network elements," refers to individual inputs, services, or facilities that the incumbent carrier is required to share with rivals under the 1996 Telecommunications Act. *See* 47 U.S.C. § 251(c)(3) (2000).

> The FCC's § 271 authorization order for Verizon to provide long-distance service in New York discussed at great length Verizon's commitments to provide access to UNEs, including the provision of OSS. Those commitments are enforceable by the FCC through continuing oversight; a failure to meet an authorization condition can result in an order that the deficiency be corrected, in the imposition of penalties, or in the suspension or revocation of long-distance approval. Verizon also subjected itself to oversight by the PSC under a so-called "Performance Assurance Plan" (PAP). The PAP, which by its terms became binding upon FCC approval, provides specific financial penalties in the event of Verizon's failure to achieve detailed performance requirements. The FCC described Verizon's having entered into a PAP as a significant factor in its § 271 authorization, because that provided "a strong financial incentive for post-entry compliance with the section 271 checklist," and prevented "backsliding."[29]

In addition, the agencies' own record of disciplinary action in this particular case confirmed that they were performing their job as contemplated:

> The regulatory response to the OSS failure complained of in respondent's suit provides a vivid example of how the regulatory regime operates. When several competitive LECs complained about deficiencies in Verizon's servicing of orders, the FCC and PSC responded. The FCC soon concluded that Verizon was in breach of its sharing duties under § 251(c), imposed a substantial fine, and set up sophisticated measurements to gauge remediation, with weekly reporting requirements and specific penalties for failure. The PSC found Verizon in violation of the PAP even earlier, and imposed additional financial penalties and measurements with *daily* reporting requirements. *In short, the regime was an effective steward of the antitrust function.*[30]

This analysis is equally appropriate to the pharmaceutical industry, although the outcome differs. First of all, most of the antitrust challenges in the pharmaceutical industry are to such things as improper use of patents or anticompetitive settlements or other license agreements. Antitrust analysis of such claims is typically more manageable than the analysis of claims of unilateral refusal to deal as in the *Trinko* case. For example, the conduct at issue in the generic drug patent infringement suits, where settlement agreements have involved "exit payments",[31] is simple collusion or market division. Such agree-

29. *Trinko*, 124 S. Ct. at 882 (quoting *In re* Application by Bell Atlantic New York for Authorization Under Section 271 of the Communications Act To Provide In-Region, InterLATA Service in the State of New York, 15 F.C.C.R. 3953, 3958–59, ¶¶ 8, 12 (1999) (Memorandum Opinion and Order)) (citations omitted).

30. *Id.* (second emphasis added).

31. *See* discussion *infra* Part III.

ments lie much closer to the heart of antitrust's traditional expertise, their anticompetitive effects are much more widely appreciated, and antitrust is in a position to fashion more effective remedies. The problem of antitrust challenges to patent infringement suits is more complicated. Nevertheless, antitrust has developed some fairly clear rules for dealing with such claims.[32]

On the other side, while pharmaceuticals in general and generic entry in particular are heavily regulated, the regulatory regime rarely operates as an "effective steward of the antitrust function," as *Trinko* put it.[33] For example, while the Hatch-Waxman Act[34] establishes rules for facilitating the entry of generic competition into the pharmaceutical market, settlement agreements between pioneers and generics, under which a generic stays out of the market in exchange for a large payment, are largely private affairs. They are not required to be submitted to any agency for approval under a process that evaluates them for their impact on competition. Likewise, while "Orange Book" listing of New Drug Applications must be filed with the FDA, that agency assiduously avoids passing judgment on the merits of such filings.[35] This is a far cry from the situation in the *Trinko* case, where the regulatory agencies actively intervened to ensure that the competitive carriers were given ample opportunity to enter markets for local telephone service.

In sum, two factors—somewhat simpler antitrust rules to be applied and little or no antitrust-like scrutiny of private business practices—means that antitrust should not be reluctant to intervene against practices in the pharmaceutical industry when a true injury to competition is apparent.

III. The Antitrust Rules of Decision

It is commonly said that antitrust analysis proceeds under two different rules. The per se rule is reserved for a small subset of offenses that have been found to be clearly anticompetitive on a number of occasions. Courts sometimes say that after there is sufficient judicial experience with a type of restraint so that the court may conclude that

32. *See* 3 AREEDA & HOVENKAMP, *supra* note 14, ¶ 706.

33. *Trinko*, 124 S. Ct. at 882.

34. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)).

35. *See* aaiPharma Inc. v. Thompson, 296 F.3d 227, 230–32 (4th Cir. 2002), *cert. denied*, 538 U.S. 923 (2003); Xechem, Inc. v. Bristol-Myers Squibb Co., 372 F.3d 899, 900–02 (7th Cir. 2004); Andrx Pharms., Inc. v. Biovail Corp. Int'l, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002).

it is virtually always anticompetitive, from that point on the restraint can be condemned simply upon proof that it has occurred, without elaborate inquiry into the defendant's market power, the actual anticompetitive effects of the restraint in a particular case, or the rationales offered for it.[36] In antitrust we call this the per se rule. Today, naked horizontal agreements such as price fixing and market division, as well as resale price maintenance and most tying arrangements, are governed by per se rules.[37]

By contrast, the "rule of reason" is reserved for types of practices that are facially ambiguous.[38] Most practices challenged under the antitrust laws fall into this category. The practice might be anticompetitive under some circumstances but not others. Or the practice might have some offsetting benefits, and be seriously threatening only if the defendant or defendants have significant market power, which must then be determined. Or a practice, while prima facie anticompetitive, may have perfectly innocent or procompetitive explanations that can be raised as defenses.

Hornbook antitrust law has traditionally placed these two modes of antitrust analysis into fairly well-defined and mutually exclusive pigeonholes. In the past two decades, however, the courts have begun to see that the world of antitrust practices is both more complex and more ambiguous. Practices come in an infinite variety and their threats as well as their promises depend on the circumstances. To be sure, at the margins there are still plenty of well-defined practices. At one end, naked price fixing—that is, competitor agreement on prices that is not accompanied by any integration of production or distribution—is and should be unlawful per se, without an inquiry into power

36. Nat'l Coll. Athletic Ass'n ("NCAA") v. Bd. of Regents, 468 U.S. 85, 100–01 (1984) ("judicial experience" determines when per se rule should be applied); *see also* FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411, 433 (1990) ("Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable"); Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 2 (1979) ("It is only after considerable experience with certain business relationships that courts classify them as per se violations of the Sherman Act." (quoting United States v. Topco Assocs., Inc., 405 U.S. 596, 607–08 (1972)); Eastman Kodak Co. v. Image Tech. Servs., 504 U.S. 451, 486–87 (1992) (Scalia, J., dissenting).

> *Per se* rules of antitrust illegality are reserved for those situations where logic and experience show that the risk of injury to competition . . . is so pronounced that it is needless and wasteful to conduct the usual judicial inquiry into the balance between the behavior's procompetitive benefits and its anticompetitive costs.

Id.

37. *See* 11 HOVENKAMP, ANTITRUST LAW, 2005, *supra* note 1, ¶ 1909.

38. *See, e.g.*, California Dental Ass'n v. FTC, 526 U.S. 756, 780-81 (1999).

or effects. At the other pole, purely unilateral practices must generally be subjected to a full rule of reason analysis because unilateral practices are much more difficult for courts to characterize, and for a firm to attain power unilaterally is much more difficult than for a group of firms to attain it by agreement.[39]

In the middle are a fair range of practices that are not susceptible to per se illegality, but should not be subjected to a full rule of reason analysis either. These practices are competitively dangerous, perhaps highly so, but they may have socially beneficial explanations, and the defendant should be given an opportunity to give them. In such cases, the best rule is to use a set of shifting presumptions, with the burden of proof at each stage given to the person whose claim is least plausible. If the plaintiff succeeds in proving a highly dangerous sounding restraint in a market prone to monopoly power, then the defendant should be made to prove that the restraint is in fact efficient or at least benign. By contrast, if the plaintiff's proof of a restraint is fairly weak, then it should remain the plaintiff's burden to show that a proffered defense really does not apply.

In a world where information is highly imperfect such a set of default rules often determines the outcome. That is, when information fails on a certain issue, the loser is the person who has the burden of proof on that issue. Assigning default rules in this fashion minimizes errors by placing the cost of information failure on the person with the least plausible claim.

A good illustration of the *in*correct application of such default rules is the Supreme Court's decision in *California Dental Association v. FTC (CDA)*[40] in 1999, where a 5-4 Court approved a professional association's restraints on dentist advertising characterized as "misleading," but that effectively prohibited virtually all forms of quality and price advertising.[41] The plaintiff, the Federal Trade Commission, proved a horizontal restraint of a kind that has always been recognized by the courts as highly suspicious—namely, prohibitions on advertising of quality and price.[42] Further, the Court conceded that this was a market that did not function very well.[43] Dentists had a consider-

39. *See* Herbert Hovenkamp, *Exclusion and the Sherman Act*, 72 U. CHI. L. REV. (forthcoming 2005).

40. 526 U.S. 756 (1999).

41. *Id.*

42. *See* 12 HOVENKAMP, ANTITRUST LAW, 2005, *supra* note 1, ¶ 2023.

43. *California Dental Ass'n*, 526 U.S. at 770–74 (citing Jack L. Carr & Frank Mathewson, *The Economics of Law Firms: A Study in the Legal Organization of the Firm*, 33 J.L. & ECON. 307, 309 (1990); George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market*

able advantage over their patients because the dentist knew best what the patient needed, communication about defective dentistry was poor, and patients often had to make decisions about specific procedures after they were seated in a dentist's chair, thus making the cost of comparative shopping very high.[44]

These market factors made the restraint at issue highly suspicious because they indicated a market that was excessively prone to collusion. This should have placed the burden on the defendants of showing that the restraints would in fact be beneficial to competition because they did no more than condemn false or misleading claims. Unfortunately, the Court drew precisely the opposite inference from the market imperfections that it described. It believed that these imperfections made consumers more vulnerable to false claims and that the dentists themselves were worthy policemen to protect them. As a result it held that the FTC was required to show that the restraints had an anticompetitive impact, something that is virtually impossible to do in many cases. Having shown a highly suspicious horizontal restraint in a market where sellers controlled all the important information, the burden should have shifted to the defendant to show that the restraints were procompetitive because they had by far the less plausible claim.

Patent settlement agreements that involve exit or non-entry payments should be subject to a similar analysis. While the facts of these cases differ considerably, many of them share a common kernel that exhibits the following pattern. The pioneer patentee of a drug files a patent infringement suit against a rival firm who has or is about to make a generic version of the drug. The rival may or may not have obtained requisite approval from the FDA. The two parties then settle their patent dispute. Under the settlement the generic firm who is the infringement defendant agrees not to enter the market for the drug in question, or else agrees to exit from the market if it has already begun entry, and agrees not to challenge the pioneer's patent. In exchange, the patentee/infringement plaintiff agrees to pay a significant sum of money to the infringement defendant. The result is that for a certain period of years this particular generic producer is disabled by the settlement agreement from entering the market. Under the Hatch-Waxman Act, which gives first comers to the generic market

Mechanism, 84 Q.J. ECON. 488, 490–91 (1970) (pointing out quality problems in market characterized by asymmetrical information)).

44. *California Dental Ass'n.*, 526 U.S. at 772.

a temporary exclusive right, the effect of the agreement may also be to keep other generics from entering as well.[45]

Agreements settling patent disputes are as old as the patent laws themselves and there are good reasons for courts to encourage good faith settlements. Litigated outcomes in patent cases tend to be difficult to predict, with many patents held invalid.[46] On the other side, often the consequence of settlement is no worse than the consequence of a litigated outcome. For example, probably the most common outcome of settlement in patent infringement litigation is some type of agreement in which the infringement defendant pays a fee to the infringement plaintiff for a license coupled with some restrictions on the production or sale of the patented article.[47] Leaving aside the question of patent validity, such an outcome is competitively preferable to an outcome under which the patent is declared valid and the infringement defendant is excluded from the market altogether. Of course, the outcome may not be as competitive as one where the patent is declared invalid and the infringement defendant plus anyone else who wants to may now enter competition with the patentee.

For these reasons antitrust courts have been somewhat deferential to settlement agreements, and many have been approved even though certain arrangements contained in the settlements would constitute per se violations if the agreements were not part of the settlement.[48] Perhaps the most famous of these is the *GE* rule, named after a 1926 decision upholding a settlement agreement under which the infringement plaintiff (GE) licensed the technology to the infringement defendant (Westinghouse) and also fixed the price at which Westinghouse was to sell goods manufactured under the license.[49]

45. *See* HOVENKAMP, JANIS & LEMLEY, *supra* note 3, § 7.4(e); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712, 717 & n.23 (2004).

46. *See* Burk & Lemley, *supra* note 11, at 1613–14; John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 224–25 (1998).

47. *See, e.g.*, United States v. Huck Mfg. Co., 227 F. Supp. 791 (E.D. Mich. 1964), *aff'd by divided court*, 382 U.S. 197 (1965) (settlement included cross-licensing with price restrictions); United States v. New Wrinkle, Inc., 342 U.S. 371 (1952) (similar); Hartford-Empire Co. v. United States, 323 U.S. 386, *clarified by* 324 U.S. 570 (1945) (settlement included horizontal customer restrictions); United States v. Masonite Corp., 316 U.S. 265, 277 (1942) (cross-licensing; price restrictions); Standard Oil Co. (Ind.) v. United States, 283 U.S. 163 (1931) (patent pool).

48. For a detailed survey of the case law, see HOVENKAMP, JANIS & LEMLEY, *supra* note 3, at ch. 7.

49. United States v. Gen. Elec. Co., 272 U.S. 476, 488 (1926). *See* HOVENKAMP, JANIS & LEMLEY, *supra* note 3, §§ 31.1–31.2; 12 HOVENKAMP, ANTITRUST LAW, 2005, *supra* note 1, ¶ 2041.

Exit or non-entry payment cases are a novelty in antitrust. They became popular after the Hatch-Waxman Act took effect because of the unique effect that the statute has had on generic entry. The statute effectively gives a single firm the right to be the first generic entrant into a market when the relevant pioneer patent expires and also permits that generic firm's production decisions to determine when second, third, and subsequent generic producers can enter.[50] As a result an exit payment settlement can effectively prolong the life of the pioneer's patent by ensuring that no firm enters that market for some time.[51]

Recent congressional amendments have served to reduce the value of such agreements. They provide that the first generic to file its Abbreviated New Drug Application ("ANDA"), which contemplates FDA approval to market a new generic (provided that the product does not infringe any still valid patent) is entitled to only 180 days of generic exclusivity. Further, the exclusivity will be forfeited if the generic producer fails to enter the market within a reasonable time.[52] That provision reduces the value of anticompetitive settlements because they will be less likely to deter entry indefinitely. Nevertheless, the gains from an anticompetitive settlement agreement—and corresponding consumer losses—could still be significant.[53]

Applying the antitrust laws to such an agreement need not be so difficult. First, a "naked" exit payment agreement in which one competitor paid a rival to stay out of its market would be a per se unlawful conspiracy under Section 1 of the Sherman Act. Second, courts will grant some deference to such agreements if they appear to be part of a bona fide settlement of an intellectual property dispute. So, the agreements are not automatically illegal, but they are not automatically legal either. Thus, from that point, the analysis must mainly consist of looking for other danger signals, the most important of which

50. *See, e.g.*, Andrx Pharms., Inc. v. Biovail Corp. Int'l, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002); Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1325–27 (Fed. Cir. 2001); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1063–65 (D.C. Cir. 1998).

51. *See* HOVENKAMP, JANIS & LEMLEY, *supra* note 3, § 7.4(e). The statute produces this result by giving the first generic a 180-day exclusivity period which begins to run on (1) the date on which the first generic begins marketing the generic product or (2) the date of a court decision holding the patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). A properly crafted settlement may entail that the prospective generic entrant will never begin marketing the product and that the patent will never be declared invalid or not infringed.

52. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I) (2004) (amendments).

53. *See* HOVENKAMP, JANIS & LEMLEY, *supra* note 3, § 7.4(e).

are: (1) the size of the exit payment and (2) the impact of the exit payment on third party entry prospects.

The principal relevance of size is that litigation of patent infringement cases is both costly and rife with uncertainty. Even a patentee who is one hundred percent certain that its patent will be declared valid and infringed would be willing to make a payment that is lower than anticipated litigation costs. For that reason, relatively small payments or other compensation in exchange for the infringement defendant's promise to stay out of a market should be regarded as fairly benign. These are merely nuisance payments or a bit of insurance against an unanticipated declaration of invalidity. But as the payment becomes larger, going into several millions of dollars, then something else must be going on. Mainly, the infringement plaintiff must have significant doubts about the validity of its patent or the defendant's status as an infringer. Thus, a larger payment suggests a more socially costly outcome—namely, preserving the exclusion power of the patent, at least vis-a-vis this particular defendant, even though the patent is likely to be invalid. The result is to deny the public the benefits of competition that it could otherwise obtain.

The other factor that a court should assess in exit payment cases is the impact of the agreement on third parties. In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent invalid others will try the same thing. Of course, a series of exit payments to several potential entrants could indicate a wider cartel, and there is an ample history of litigation among large numbers of rivals being settled with a comprehensive licensing agreement.[54]

The peculiar circumstances of the Hatch-Waxman Act invite the court to consider the social, or public, impact of an exit payment settlement. The settlement itself may serve to delay entry by second or third generics.[55] In that case the combination of a high payment plus

54. However, the settlement of the litigation typically did not involve exit payments, but rather cross-licenses, pools, or agreements fixing prices or dividing markets. *See, e.g.*, E. Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70 (1902) (price fixing); United States v. Line Material Co., 333 U.S. 287, 318–19 (1948) (similar); Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456 (1940) (similar); United States v. Gen. Elec. Co., 82 F. Supp. 753, 814 (D.N.J. 1949) (output limitation); Duplan Corp. v. Deering Milliken, Inc., 444 F. Supp. 648, 683 (D.S.C. 1977), *aff'd in relevant part*, 594 F.2d 979 (4th Cir. 1979), *cert. denied*, 444 U.S. 1015 (1980) (cross-licensing); Hartford-Empire Co. v. United States, 323 U.S. 386, *clarified by* 324 U.S. 570 (1945) (market division).

55. *See supra* text accompanying notes 50–51.

an agreement that delays entry, not only by the settlor but also by other firms, simply poses competitive risks that are too large. For that reason, the Sixth Circuit's conclusion in *Cardizem CD Antitrust Litigation*[56] seems correct if limited to the facts of that case,[57] the Eleventh Circuit's *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*[58] decision seems wrong,[59] and the Federal Trade Commission's approach in *In re Schering-Plough*[60] seems about right.[61]

In *Cardizem* the Sixth Circuit applied the per se rule to an exit payment. However, there was more to the story, and the per se rule was probably justified on the facts of that case. After the pioneer patentee filed its infringement suit against the generic, the two firms settled under an agreement in which the generic agreed to stay out of the market in exchange for payments of $40 million per year.[62] However, the settlement agreement also restrained the generic firm "from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case."[63] Outside the context of a settlement agreement, a naked payment to another firm to stay out of one's market is per se unlawful.[64] In any event, the court focused on the principal agreement between the two firms, concluding:

> [T]he Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.[65]

In contrast, the Eleventh Circuit required a full rule of reason analysis in *Valley Drug*.[66] In that case Abbott held the pioneer patent

56. 332 F.3d 896 (6th Cir. 2003) (petition for certiorari pending).

57. *Id.*

58. 344 F.3d 1294 (11th Cir. 2003) (petition for certiorari pending).

59. *Id.*

60. No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003).

61. *Id.*

62. *See In re Cardizem*, 332 F.3d at 902.

63. *In re* Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682, 697 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003); *see also In re Cardizem*, 332 F.3d at 908 & n.13.

64. *See, e.g.*, Palmer v. BRG of Ga., Inc., 498 U.S. 46, 49 (1990); *see also* United States v. Addyston Pipe & Steel Co., 85 F. 271, 274–79 (6th Cir. 1898), *modified and aff'd*, 175 U.S. 211 (1899) (cartel members paid each other "bonuses" for right to be winning bidder).

65. *In re Cardizem*, 332 F.3d at 908.

66. *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003); *see also In re* Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (agreement involving exclusion payments from pioneer drug to keep

on the drug Hytrin. While its original patent expired, Abbott had obtained additional patents for other forms of the compound, as well as for methods of preparing it.[67] Geneva and Zenith, two generic drug producers, filed ANDAs, signaling their intent to enter different portions of the market. Geneva and Zenith then sought to have Abbott's later patents delisted.[68] When Abbott filed an infringement claim the two firms settled with Abbott. Under the settlement agreement they acknowledged the validity of Abbott's patents and Zenith received a promise of $24 million per year until a different generic manufacturer entered the market.[69] Abbott also settled with Geneva, promising $4.5 million monthly,[70] and Geneva agreed not to market its generic drug until an infringement suit on the principal subsequent Abbott patent had been decided.[71]

The Eleventh Circuit accepted the defendant's argument that the per se rule is a function of judicial experience and that courts lacked sufficient experience with this type of agreement to apply the per se rule. However, antitrust rules of decision are not market specific. They apply to classes of agreements. Naked horizontal restraints have been unlawful per se for decades,[72] including some naked restraints contained in patent settlement agreements.[73]

The Eleventh Circuit required a full analysis of market power in the patented drug. But that seems unnecessary under the facts of a nearly naked horizontal agreement and a very large exit payment. The payment, which is a fixed cost, is valuable only to the extent that it permits the payor to charge prices above marginal cost. To be sure, measuring market power in pharmaceutical markets is difficult be-

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generics of the market should be addressed under the rule of reason where the agreement itself did not require greater exclusion than the patent itself would have required; agreement in this case did not restrain other generic producers from coming in).

67. *Valley Drug*, 344 F.3d at 1298.

68. *Id.* at 1298–99.

69. On March 31, 1998 Abbott and Zenith entered into an agreement under which Abbott would pay Zenith $3 million up front, $3 million after the first three months, and $6 million every three months thereafter until March 1, 2000, or until the agreement otherwise terminated. If another generic manufacturer entered the market and obtained a 180-day exclusivity period, Abbott's payments would be cut in half until the termination of the agreement. *Id.* at 1300.

70. *Id.*

71. The invalidity of that patent was later established. *See* Abbott Labs. v. Geneva Pharms., Inc., 182 F.3d 1315 (Fed. Cir.1999).

72. *See, e.g.*, United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290, 312 (1897); Addyston Pipe & Steel Co., 85 F. at 278–79.

73. *See, e.g.*, United States v. Singer Mfg. Co., 374 U.S. 174 (1963); Hartford-Empire Co. v. United States, 323 U.S. 386 (1945).

cause so many of the costs are fixed. A firm that recovered only its direct production and distribution costs would be losing money. But the best way to respond to this difficulty is to limit the market power query and consider only whether the agreement is likely to result in higher drug prices—or more precisely, drug prices that fail to come down. Generics also have production and distribution costs, presumably equal to those of the pioneer.

Thus, a very large payment indicates that the pioneer is earning profits well above its production costs and that these will be threatened by generic entry. This establishes short-run power. Of course, having power is not an antitrust offense, but the willingness to make such a large payment also indicates significant doubts about the validity of the patent. The ultimate question was not whether the pioneer had the power to charge prices well above cost—clearly it did—but whether the patent laws entitled it to those prices.

The Eleventh Circuit also noted that the existence of the '207 patent "may" have entitled Abbott to a preliminary injunction pending the appeal, which would also have had the effect of keeping the rivals out of the market.[74] But, the important point seems to be that rather than obtaining a preliminary injunction Abbott chose to pay very large sums of money in order to obtain its rivals' agreement not to enter its markets. A firm willing to pay roughly $75 million per year to keep an alleged infringer out of the market when a successful preliminary injunction would have done the same thing for the cost of obtaining the injunction indicates that the prospects for a preliminary injunction were very poor.

The remaining question was the impact of the settlement agreement on the ability of outsiders to challenge the Abbott patents and enter the market. If the effect of the settlement was to do no more than deter two potential entrants and there were several others legally and practically able to enter the market immediately, then a more searching inquiry into the rationale for such large payments would be appropriate. However, if the impact of these large payments was to make the extended patents free from challenge by anyone, then the risk of competitive harm is simply too great.

One of the problems that has sharply distinguished Hatch-Waxman settlement payments from other types of settlements is that under them the only parties legally in a position to challenge a patent become the participants in a cartel-like agreement perpetuating the

74. *See Valley Drug*, 344 F.3d at 1305–06.

patent and high drug prices. This is always an important point. As a general proposition, patent settlement agreements bind only the parties to the agreement; they do not serve to extend patent rights as against the world. For example, suppose Westinghouse disputes GE's light bulb patent and the two settle by a license agreement in which Westinghouse is authorized to make bulbs and must charge a certain price for them. While that agreement sounds anticompetitive, it nevertheless binds only GE and Westinghouse. If GE's patent really seems dubious other firms can also challenge it. The "first in line" requirements of the Hatch-Waxman Act change all that, however, by permitting a settlement agreement by the first generic to hold up entry by others.[75]

In explaining its decision to apply the rule of reason, the court reasoned:

> It may be that the size of the payment to refrain from competing, sometimes called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent, particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's acknowledgment of validity. Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent.[76]

The court is correct that on a limited record a great deal of uncertainty exists about many possibilities, particularly if they have not yet occurred. But asking the fact-finder to determine the size of anticipated future profits, the risk of the defendants' inability to satisfy a judgment, or anticipated litigation costs are monumental burdens, and under the rule of reason all of them lay with the defendant. Payments of the size in question in *Valley Drug* indicate extremely strong doubts about the validity of the patent. When coupled with the fact that Abbott had the right to pursue a preliminary injunction but

75. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000).
76. *Valley Drug*, 344 F.3d at 1310.

chose not to do so, the inference is strong that no one really expected that this patent would be upheld in litigation, and eventually it was found invalid.[77] That was enough information to identify a "highly suspicious" restraint and switch the burden of proof to the defendant to show that its payment was reasonable under the circumstances.[78]

The Federal Trade Commission was much more sensitive to the administrative difficulties and anticompetitive threats presented by such cases. In *Schering-Plough* it began with the premise that exit payments raise a "red flag" that merits deeper inquiry.[79] It observed:

> The appropriate antitrust analysis extends over a continuum, ranging from per se condemnation of particularly egregious conduct to a detailed examination of more ambiguous behavior, responsive to the facts of individual cases. Here, we will need to undertake a more detailed examination of market effects than was required either in California Dental[80] or in PolyGram Holding,[81] but the guiding principles are the same. We review the agreements in this case under the rule-of-reason standard, but apply a different methodology from that set out in the Initial Decision. We conclude that the Initial Decision's approach—which defines a relevant market, calculates shares, and then draws inferences from these shares and from other industry characteristics—is not the most appropriate way to proceed in cases like this one where more direct evidence of competitive effects is available.
>
> Once Complaint Counsel have demonstrated anticompetitive effects under the standard we apply, Respondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible.[82]

The FTC noted that Schering anticipated the loss of huge sales as a consequence of generic entry,[83] and cited studies showing drastic declines in drug prices once a generic entered the market in competition with a pioneer.[84] Indeed, the sheer magnitude of the payments in

77. *See supra* text notes 69–71 and accompanying text.

78. The court also noted that the agreement in question included a clause "prohibiting [the entrants from] marketing 'any' generic terazosin product." *Valley Drug*, 344 F.3d at 1311–12; *see also In re* Terozosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1346 (S.D. Fla. 2000) (opinion of the district court). As noted previously, an agreement requiring a rival not to produce a product that is not covered by the patent is unlawful per se.

79. *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003) (Opinion of the Commission Part II.B.4).

80. California Dental Ass'n v. FTC, 526 U.S. 756 (1999).

81. *In re* PolyGram Holding, Inc., No. 9298, 2003 WL 21770765 (F.T.C. July 24, 2003).

82. *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003) (Opinion of the Commission Part I.C).

83. *In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (Opinion of the Commission Part II.B.2).

84. *Id.* (citing Richard G. Frank & David S. Salkever, *Generic Entry and the Price of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75, 89 (1997) ("The substantial shift in mar-

this case was a major source of competitive concern. Nonetheless, the FTC refused to make reverse payments per se unlawful across the board. In this case, the evidence made out a prima facie case of anticompetitive effects. It was then up to the respondent to come forward with a procompetitive justification for the payment, and the general claim that patent settlements are good things was insufficient.[85]

Conclusion

Antitrust policy at the margin always involves making estimates in the face of uncertainty. When cases are clear, antitrust can proceed with confidence, but, when they are not, it must proceed cautiously and defer to the market itself unless it is reasonably sure.

But none of this means that antitrust policy should stubbornly insist on strict and exhaustive proof of marginally ambiguous practices. Rather, it means that those interpreting the antitrust laws make reasonable decisions under limited information. A rational actor does not collect every bit of information about a problem before making a decision. Particularly in cases where information is costly, she collects enough information to be reasonably sure. Even a rational actor also draws presumptions in favor of that which is most likely and requires hard evidence to defeat that presumption. Only when it follows this course can antitrust reduce its administrative costs and improve its results to the point that it becomes an effective tool of economic policy.

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ket share from brand-name to generic producers (40%–50%) along with the significantly reduced price of generic substitutes (25%–30% lower) means that the average price of a prescription for a compound subject to generic competition has fallen."); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 335 (1992) (the "general pattern is that generics enter at a significant discount to the pioneering product [and] . . . the prices of the pioneering brands remain higher than their generic competitors and actually increase in nominal terms" and "[a]verage market price [weighted by sales of the brand and generic] declined by a little more than 10 percent per year in the first two years after generic entry").

85. *See id.* (Opinion of the Commission Part III). The Commission stated:

> We conclude that Respondents' ancillarity defense has failed. A payment in the order of $60 million could not be defended under these facts as a reasonably necessary element of a settlement that is procompetitive overall. The parties did not show that the hypothetical situations where such a payment might be justified actually were present in this case. The ancillarity claim is rather based on after-the-fact rationalization.

Id.; *see also In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003) (noting that the justifications offered for large reverse payment settlements are unpersuasive).