Symposium

Efforts to Delay Competition from Generic Drugs: Litigation Along a Seismic Fault Between Antitrust and Intellectual Property Law

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PRESCRIPTION DRUGS are unlike almost all other goods. They can mean the difference between relief and pain, even life and death. The stakes are thus exceptionally high when it comes to creating the legal framework for the prescription drug market.

One problem, however, is that a profound tension exists between, on one hand, creating incentives to develop new life-saving treatments and, on the other hand, ensuring competition that will drive down prices and make prescription drugs available and affordable to those who need them.[1] This tension creates a seismic fault at the boundary between patent law and antitrust law as applied to prescription drugs. This symposium issue of the *University of San Francisco Law Review* is dedicated to analyzing litigation arising from activity along that fissure.

In particular, this symposium addresses antitrust litigation that ensues when a patent-holder on a brand-name prescription drug attempts to delay competition from a generic drug. These efforts can be unilateral, including the fraudulent procurement or enforcement of patents or sham patent infringement litigation against a generic drug manufacturer. The efforts can also involve agreements, as when a brand-name drug manufacturer makes a large payment to a generic drug manufacturer in exchange for an agreement not to sell generic drugs for some period of time, either in settlement of patent litigation

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1. Note, however, that the analysis is not quite this simple. Competition can create incentives for innovation.

or during the pendency of that litigation. In each case, the issue is whether the deleterious effects to competition—and the resulting higher prices for drugs paid by consumers—should give rise to liability under antitrust law. Impose liability on brand-name drug companies inappropriately, and they will be discouraged from creating new drugs that may save lives. Fail to impose liability when it is appropriate, and the drug companies will grow rich while patients who cannot afford prescription drugs suffer, or even die. The right balance is not easy to strike.

The first article in this issue that addresses this knotty problem, *Sensible Rules for Pharmaceutical Competition*, is by a national authority on antitrust doctrine, Professor Herbert Hovenkamp. He offers a great breadth of perspective. Relying on that perspective, he places disputes over delayed entry of generic drugs within a broader context. His project in part is to encourage courts to look beyond the sometimes overly rigid doctrine that has developed for assessing antitrust liability. In particular, courts generally rely on one of two standards in applying the antitrust laws: the per se rule or the rule of reason.

The per se rule applies to conduct that has such a strong tendency to be anticompetitive that courts will find antitrust liability simply on proof that the conduct occurred. Courts will not consider whether defendants possess market power,[2] the actual anticompetitive effects of defendants' conduct, or any justifications defendants may offer for their behavior, considerations that would apply if the court were to look to the first principles of antitrust law. An agreement among competitors to fix prices is a paradigmatic example of conduct that is per se illegal under federal antitrust law.[3]

In contrast, the rule of reason requires a more searching inquiry. It applies to behavior that is ambiguous in its effect on competition.

2. Market power may be defined as the ability to raise prices above the levels that would exist in a competitive market. *See* DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 0.1 (1997); William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937, 937, 939 (1981).

3. Nat'l Collegiate Athletic Ass'n v. Bd. of Regents, 468 U.S. 85, 100–01 (1984) ("[J]udicial 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).

The court will consider the benefits and costs of the conduct in terms of competitive efficiency, including whether the participants in the conduct have sufficient control over the market to raise or maintain prices above competitive levels and any beneficial effects for competition or other salutary characteristics of the conduct.[4] Most unilateral action falls into this category.

Professor Hovenkamp notes that, in the last couple of decades, some courts have sought a more subtle approach to antitrust issues than would be allowed by the formalistic application of either of these two tests. He suggests key factors for adjusting the standard for legality along a continuum between the two. Specifically, he contends aggressive judicial enforcement of the antitrust laws is appropriate when courts can apply relatively simple antitrust rules (the analysis will not get too complicated to be manageable by the courts) and when no other government institution is actively involved in "antitrust like" regulation of private business practices (no governmental agency is overseeing the industry to make sure it remains competitive).

Both considerations, Hovenkamp explains, apply to key conduct in the pharmaceutical industry. In particular, his analysis indicates that when brand-name drug manufacturers make large payments to generic drug manufacturers in exchange for an agreement not to sell, or to delay sale of, generic drugs, a standard very close to a per se rule, if not a per se rule, should apply. Among the circumstances he considers are: (1) whether the brand-name manufacturer makes such a large payment that its apparent aim is not merely to avoid the cost of litigation, but rather to prevent what is likely to be legal competition that would drive down prices and (2) whether the agreement will delay competition from *additional* generic drug manufacturers as a result of special legal rules imposed by the Hatch-Waxman Act.[5] Hovenkamp

4. *See, e.g.*, Cal. Dental Ass'n v. FTC, 526 U.S. 756, 780–81 (1999).

5. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)). The Hatch-Waxman Act may delay generic competition with a branded drug in various ways. First, if a manufacturer of a generic drug seeks Food and Drug Administration ("FDA") approval, and in the process challenges the validity or applicability of a related patent on a brand-name drug, the initiation of patent infringement litigation by the brand-name drug manufacturer automatically delays final approval of the generic drug until the earliest of (1) the lapse of thirty months, (2) resolution of the patent litigation in favor of the generic drug manufacturer, or (3) expiration of the patent. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 7 (July 2002). Second, no other manufacturer may bring its generic drug to market until 180 days from the earliest of (1) the first commercial marketing of the first generic drug seeking FDA approval or (2) resolution of the patent litigation in favor of the first generic drug manufacturer. *Id.* at 7, 57; 21 U.S.C. § 355(j)(5)(B)(iv) (2004). In other words, the brand-

discusses two recent decisions along these lines: *In re Cardizem CD Antitrust Litigation*,[6] in which the Sixth Circuit found a per se violation of the antitrust laws, and *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*,[7] in which the Eleventh Circuit required a full rule of reason analysis. His conclusion is that the Sixth Circuit was probably right to apply a per se rule under the antitrust laws, at least in light of the facts in that case, and that the Eleventh Circuit was probably wrong in straying so far from a per se analysis.

The next two articles deal with a similar issue, although from a very different vantage. In contrast to Professor Hovenkamp's attention to a broad view of antitrust laws, two articles by economists apply technical economic arguments. Some distinctions and definitions are helpful to understand their claims. A first distinction is between "static" and "dynamic" economic efficiency.

The primary goal of an economic analysis of the law is efficiency, which ordinarily means the provision and allocation of goods and services as they would occur in a perfectly competitive market. "Static efficiency" as used by the economists in this symposium addresses the short-run benefits, especially in terms of price, of allowing the unfettered production and sale of existing drugs. An emphasis on "static efficiency" tends to favor a broad reading of antitrust law and a narrow reading of patent law or other regulatory exclusivity. Antitrust law tends to drive down prices by preventing restrictions on competition. Patent law provides a legal restriction on competition, designed to reward and encourage innovation. In general, robust competition, and limited restraints on that competition through patent laws or regulatory exclusivity, will allow the market to drive down prices to competitive levels, promoting static efficiency. In contrast, "dynamic efficiency" as used by the same economists takes into account long-run incentives, including those that encourage the creation of new drugs. Concern for dynamic efficiency is likely to support a narrow reading of the antitrust law and a broad understanding of patent rights and regulatory exclusivity, lest drug manufacturers lose incentive to innovate because of an anticipated loss of profits from generic competition.

Both forms of efficiency are implicated in assessing so-called "reverse payments." A "reverse payment" occurs after a dispute arises over

name manufacturer may delay competition from the first generic drug manufacturer and from all other generic manufacturers.

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

7. 344 F.3d 1294 (11th Cir. 2003) (petition for certiorari pending).

whether a generic drug infringes the patent for a brand-name drug. The payment is called "reverse" because it is the opposite of what one might ordinarily expect. The payment is made by the brand-name drug manufacturer (the patent holder) to the generic drug manufacturer (the alleged infringer), generally to delay entry of the generic drug into the market. Ordinarily, one would anticipate the brand-name drug manufacturer, the plaintiff in a lawsuit for infringement or potential infringement of a patent, to demand payment from the defendant generic drug manufacturer, the alleged infringer. In a "reverse payment" the patent holder instead agrees to pay the generic drug manufacturer, the alleged infringer. In part because of the odd structure of these payments, they often lead to antitrust litigation. Two articles in this issue by economists contest the correct antitrust test to apply to these payments—a per se rule banning them, a full rule of reason analysis, or some hybrid of the two.

The article by Keith and Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements? Analysis Gone Astray*, argues that "reverse payments" generally should be subject to a per se rule under antitrust law. Specifically, the authors contend that the driving force behind reverse payments is the potential they create for the brand-name drug manufacturer and the generic drug manufacturer to share increased overall profits from a delay in competition. The source of these increased profits, according to the authors, is consumers, who pay high prices for prescription drugs for a longer period of time than they would on average if the patent litigation were to proceed to completion or if it were settled without a reverse payment. Other possible benefits from the reverse payment agreements, the authors suggest, are relatively insignificant, including avoiding the costs of litigation or encouraging the creation of new drugs.

Central to these claims is the assumption that the balance between static efficiency (which focuses on short-term benefits from competition, including regarding price) and dynamic efficiency (which focuses on the long-term benefits of inventing new drugs) has already been struck by Congress in the patent laws. This balance is reflected, they argue, in the value of the probability that the patent holder will prevail in litigation against any alleged infringer (in this case, the generic drug company). Not only substantive patent law, then, but also the rules for enforcing patent rights are perfectly calibrated. Increasing the value of patent rights above their likelihood of prevailing in litigation, which they claim is the goal of reverse pay-

ments, is contrary to a policy judgment immanent in the legal framework.

A second distinction is useful to understand the article by James Langenfeld and Wenqing Li, *Economic Analyses of Patent Settlement Agreements: The Implementation of Specific Economic Tests, the Evaluation of Dynamic Efficiency, and the Scope of Patent Rights.* These authors note that there are two different kinds of "reverse payments": "complete" settlement agreements, which end litigation over patent rights and fix a date for generic entry, and "interim" (or "partial") settlement agreements, which set the terms for any generic competition and any payments between the parties to litigation while the litigation persists.

Langenfeld and Li agree that courts should presume that Congress has struck the optimal balance between static (short-run competition) and dynamic (long-run competition) efficiency. They nevertheless discuss several reasons from the economic literature why complete settlement agreements might be properly assessed under the more forgiving rule of reason, rather than treated as per se illegal: (1) the brand-name and generic drug manufacturers may save litigation costs; (2) the manufacturers may be averse to uncertainty regarding the outcome of patent litigation; and (3) the agreements may eliminate asymmetric information about the patent, including, for example, whether the generic drug really is ready to come to market.

Langenfeld and Li focus, however, on "partial" settlement agreements, a topic which they say has received limited attention. They analyze in-depth, in particular, the concern that partial settlements may correct for an under-payment to a patent holder, which in turn could lead to dynamic inefficiency, that is, insufficient incentive to create new drugs. Such "under-compensation" would occur if a patent holder is ultimately vindicated in court, but the patent infringer lacks the ability to pay the full damages awarded. They develop a model, based on a statistical analysis of the likelihood that a patent will ultimately be held valid, to assess whether a partial settlement can be justified as a means to prevent under-compensation to patent holders. Langenfeld and Li also note that entering a partial settlement agreement during the pendency of litigation may be preferable to seeking a preliminary injunction, which would entail litigation costs and the risk of losing the bond that must be posted to obtain a preliminary injunction.

The next article by Eric Cramer and Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Generic Drugs,* focuses on a particular issue in

assessing whether conduct violates the antitrust laws. The issue arises within the rule of reason analysis in a concerted action case and is a focus of any monopolization case. The issue is whether defendants have sufficient power to harm competition in the market in which the alleged antitrust violation occurs. Even if conduct has a tendency to undermine competition, and to maintain or raise prices above competitive levels, will that tendency be overwhelmed by countervailing competitive forces? In regard to efforts by a brand-name drug manufacturer to delay competition from a generic drug, a key issue along these lines is whether competition from different drug therapies provides a sufficient check on the risks to competition. Cramer and Berger's article promotes a particular approach to judicial resolution of this issue.

At the outset, Cramer and Berger note that to prove an antitrust violation under the rule of reason or a monopolization claim, it is not enough for a plaintiff to establish that the defendant or defendants engaged in conduct that can give rise to antitrust liability, such as committing fraud on the patent office or entering certain kinds of agreements to delay generic competition. Even though these kinds of conduct are suspect under the antitrust laws, the plaintiff must also prove that the conduct at issue was capable of having a deleterious effect on competition, most often through increased prices. If competition from other actors would render potentially anticompetitive conduct harmless, there would be no antitrust violation.

Co-authors Cramer and Berger suggest that there are two ways to prove that defendants have sufficient power in the market to harm competition. One way is through direct evidence, by showing, for example, that the eventual entry of a generic drug into the market did in fact increase competition, perhaps by decreasing prices. This effect on prices reveals that the delay in entry of the generic drug forestalled competition, harming consumer welfare. A second way to prove that conduct actually harmed competition is through indirect evidence, which involves defining a relevant market and then proving that the defendant or defendants control a sufficient portion of that market that one could predict they could set prices above competitive levels.

Cramer and Berger's central point is that direct evidence of an anticompetitive effect should be sufficient to establish that conduct with a tendency to undermine competition in fact did undermine competition. This direct evidence, they assert, is abundant and typically undisputed in cases involving delayed competition from a generic drug. They further claim that direct evidence of this sort of

anticompetitive effect is superior to *indirect* evidence of harm to competition. To oversimplify a bit, their point in essence is that the goal of antitrust doctrine is to eliminate restraints on competition that artificially inflate prices. Direct proof that behavior did in fact have an anticompetitive effect—that it did artificially inflate prices—establishes that the very harm occurred that antitrust law seeks to prevent. Indirect proof—for example, that a defendant or defendants had sufficient control over a market that they might have been able to inflate prices above competitive levels—is not necessary, nor is it desirable, when direct proof of an anticompetitive effect is available. As a result, Cramer and Berger claim, when plaintiffs provide evidence that entry of a generic drug onto the market increased competition, including by making the generic drug available at substantially lower prices than the brand-name drug, there is no need to define a relevant market to prove that delay of that generic was harmful to the market.

Nonetheless, Cramer and Berger contend that direct evidence can be used to define a relevant market. This evidence, they claim, establishes, for instance, that in delayed generic competition cases the brand-name drug and its generic equivalents constitute the relevant market for an antitrust claim. Those drugs have in common a specific "molecule" that has therapeutic effects. Because a brand-name drug manufacturer need control only the market for the underlying drug molecule to support super-competitive prices, Cramer and Berger conclude that the "molecule" defines the relevant market in antitrust cases that are based on delayed entry of generic competition.

The last article, *Chimerical Class Conflicts in Federal Antitrust Litigation: The Fox Guarding the Chicken House in* Valley Drug, focuses on the procedure rather than the substance of antitrust litigation in the pharmaceutical industry. In particular, it deals with class certification under Federal Rule of Civil Procedure 23. When a court certifies a case for class treatment, it allows a small number of individual plaintiffs to pursue claims on behalf of a larger group. Often certification of a class action is the only viable means for a large number of potential plaintiffs with relatively small claims to seek vindication in court. One requirement for class certification is that the interests of the named plaintiffs are not in a fundamental conflict with the interests of the class members they seek to represent. A recent decision by the Eleventh Circuit, *Valley Drug,* highlights an issue about when a potential conflict between class members might make certification of a class inappropriate. The article by Professor Josh Davis and David Sorensen addresses this issue.

To understand the issue in *Valley Drug* one must first grapple with the so-called "direct purchaser rule" fashioned by the U.S. Supreme Court in *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*[8] and *Illinois Brick Co. v. Illinois.*[9] The direct purchaser rule governs which injured parties may seek damages under federal antitrust law and how those damages are measured. As applied to antitrust violations in the pharmaceutical industry, the rule provides that only a purchaser who bought prescription drugs directly from the manufacturer that allegedly violated the antitrust laws may seek damages. Further, direct purchasers are entitled to recover damages based on the full overcharge they paid, even if they passed on some of that overcharge by reselling the drugs at an inflated price. So, for example, a wholesaler who bought brand-name drugs at an inflated price because of an illegal delay in generic competition may recover damages based on the difference between the price the wholesaler paid and the price the wholesaler would have paid in the absence of an antitrust violation. On the other hand, a retailer who then bought the very same drugs from the wholesaler at an inflated price cannot seek any damages at all from the brand-name drug manufacturer under federal antitrust law.

The Eleventh Circuit in *Valley Drug* held that class certification may not be appropriate in an antitrust case based on delayed generic competition when some members of the class may have enjoyed a net economic gain from the antitrust violation while other class members suffered a net economic loss. In particular, the Eleventh Circuit suggested that large wholesalers may actually benefit on the whole from an illegal delay in generic competition. The court speculated that the increased prices that the wholesaler pays for brand-name drugs may be more than offset by countervailing gains. According to the court, such considerations might include, for example, that the large wholesalers mark up the prices they pay by a set percentage, that demand for prescription drugs does not decrease significantly when prices increase, and that wholesalers lose sales volume from generic competition because some generic drug manufacturers may circumvent the large wholesalers in distributing their drugs. The Eleventh Circuit worried that those direct purchasers who enjoyed a net gain from an antitrust violation might have interests at odds with those direct purchasers that suffered a net loss.

8. 392 U.S. 481 (1968).
9. 431 U.S. 720 (1977).

Davis and Sorensen argue that no conflict of interest warrants denial of class certification in these cases. Whether some class members enjoyed a net gain from an antitrust violation is irrelevant, they contend, because under the direct purchaser rule, all class members alike have an interest in proving the antitrust violation and recovering as much damages as possible based on the overcharge. The case law on which the Eleventh Circuit relied, they claim, comes from areas of the law where the direct purchaser rule does not apply. In those areas of the law, parties who benefit from illegal conduct are not ordinarily allowed to recover damages. As a result, Davis and Sorensen reason, courts addressing cases in those areas of the law may well have been right to find a fundamental conflict in a proposed class that included both parties who benefited and parties who were harmed by allegedly illegal activity. Davis and Sorensen contend that the Eleventh Circuit erred by relying on these cases to find a conflict between direct purchasers in an antitrust case.

Taken together, these articles frame many of the key issues underlying litigation based on brand-name drug manufacturers' efforts to delay competition from generic drugs. The hard work and valuable insights of the authors should contribute greatly to proper formulation and application of legal doctrine. These efforts have been expended on a truly worthy endeavor. At issue are the well-being and, indeed, at times the lives of patients who need prescription drugs. In few areas of contested legal doctrine are the stakes so extraordinarily high.