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Expert Analysis

The Supreme Court Adopts the Rule of Reason In Antitrust Challenges to Reverse-Payment Patent Settlements: Now what?

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The Supreme Court's recent decision in *Federal Trade Commission v. Actavis Inc.* deferred to the lower courts the application of the "rule of reason" to antitrust cases involving reverse-payment settlements between brand-name drug manufacturers and generic drug manufacturers.[1] In doing so, the court provided very little guidance as to how the rule of reason should be applied. What will a rule of reason analysis look like in such cases?

BACKGROUND

Actavis involved a Federal Trade Commission challenge to the settlement of a patent infringement lawsuit. The underlying suit was filed by the holder of a patent for a synthetic testosterone sold under the name AndroGel. The defendants manufactured a generic version of the drug. Under the settlement agreement, the generic drug manufacturers agreed to not enter the market until 65 months before the patent expiration date. They also agreed to market AndroGel to urologists. In return, the patent holder agreed to pay the generics manufacturers millions of dollars.

The FTC challenged the settlement as an antitrust violation. It asserted that the generics companies would have entered the market sooner had they continued the litigation and secured a determination that the patent was invalid. According to the FTC, the true purpose of the payments was to compensate the generic drug manufacturers for agreeing not to compete with AndroGel. To the FTC, the payment was part of an illegal agreement to share in the monopoly profits of the patent holder.[2]

The trial court dismissed the FTC's complaint, concluding it did not set forth an antitrust violation. The 11th U.S. Circuit Court of Appeals affirmed, holding that a reverse-payment settlement is immune from antitrust attack as long as it was not the settlement of sham litigation, the patent was not obtained by fraud and the anti-competitive effects "fell within the exclusionary potential of the patent." In other words, it found there is no antitrust violation if the agreed-upon delayed entry date is within the term of the patent. The 11th Circuit's approach is often called the "scope of the patent" test.

The Supreme Court reversed the 11th Circuit's decision, holding that the FTC should have been allowed to further pursue its antitrust challenge. The court held that the policies of both the antitrust laws and the patent laws must be considered in determining the scope of the patent monopoly and the consequent antitrust immunity.

At the same time, the high court rejected the FTC's assertion that a reverse-payment settlement agreement should be presumed to be unlawful and that a truncated, "quick-look" version of the rule of reason should be applied. Had the FTC's suggested approach prevailed, the mere fact of the reverse-payment settlement would have created a presumption of anti-competitive effect, shifting the burden to the defendants to justify their conduct. But the Supreme Court instead held that the FTC must prove its case "as in other rule-of-reason cases."

Under the classic articulation of the rule of reason in the Supreme Court's 1918 decision in* Chicago Board of Trade v. United States, *many facts are relevant to the rule-of-reason analysis but none are dispositive.

HOW SHOULD THE RULE OF REASON APPLY?

Under the classic articulation of the rule of reason in the Supreme Court's 1918 decision in *Chicago Board of Trade v. United States*,[3] many facts are relevant to the rule-of-reason analysis but none are dispositive. Ultimately, the aim is to determine whether the anti-competitive effects outweigh the pro-competitive benefits. To prove anti-competitive effect, the plaintiff typically must establish a relevant market and create an inference of market power through the defendants' shares in that relevant market. Market power is circumstantial evidence of anti-competitive effect.[4]

In *Actavis*, the Supreme Court implicitly suggested that the full rule-of-reason approach associated with *Chicago Board of Trade* may not be necessary. Citing its prior decision in *California Dental Association v. Federal Trade Commission*, 526 U.S. 756 (1999), the court remarked:

> To say [that the FTC must prove its case under the rule of reason] is not to require the courts to insist … 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."' *California Dental*, 526 U.S. at 780 (quoting with approval 7 Areeda ¶ 1507, at 402 (1986)).
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> As in other areas of the 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. *See* 7 [Areeda], ¶ 1508c, at 438-440.[5]

With this language, the court clearly suggested that district courts adopt an approach that falls somewhere between the per se rule, which is the "antitrust theor[y] too abbreviated to permit proper analysis," and the full-blown rule of reason, which contemplates "consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question."[6]

The court's citations to the Areeda treatise are significant. The first reference is embedded within its citation to *California Dental*. The relevant section of the treatise, and the corresponding discussion in *California Dental*, reference a flexible approach to the rule of reason that varies the degree of inquiry depending on the restraint at issue. Although not explicitly stated as such, the treatise and commentators essentially refer to a "stepwise approach" to the rule of reason.[7]

The second Areeda reference relates to the idea that a trial court can establish categorical or presumptive rules that operate within a rule-of-reason analysis.[8] For example, one categorical rule is that the justifications must advance competition rather than challenge it. A defendant's justification of the restraint that consists of a frontal attack on the value of competition — such as "competition results in unsafe engineering practices" — could be rejected by a trial court as not cognizable under the antitrust laws.

Another type of categorical or presumptive rule established by the trial court would be "burden shifting." For example, once the plaintiff establishes a *prima facie* case of anti-competitive effect, the trial court could require the burden of going forward to shift to the defendant to proffer pro-competitive justifications. The Areeda treatise describes this concept as follows:

> The fact that something is not unlawful per se does not necessarily mean that every question of its effect, justification or available alternatives must be decided by the jury. Whether the rule of reason or the per se rule is to be applied presents a question of law, but so does the set of presumptions and burden shifts that govern decision making within the rule of reason.[9]

WHAT FRAMEWORK WILL LOWER COURTS APPLY?

The court's discussion in *Actavis* appears to reinforce an appellate trend toward use of a "structured" rule of reason that includes the stepwise approach based on the burden-shifting referenced in *California Dental*. Under such a structured rule of reason, the plaintiff has the burden of establishing a *prima facie* case of anti-competitive effect. If the plaintiff does so, the burden shifts to the defendants to establish cognizable pro-competitive justifications. If the defendant is able to do so, the burden shifts back to the plaintiff to attack those justifications as pretextual or a sham.

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Plaintiffs who successfully establish that the justifications are pretextual or a sham prevail without having to introduce evidence of the relevant market and market shares.[10] But plaintiffs who fail to show that the justifications are pretextual or a sham have the ultimate burden of persuasion to establish that the anti-competitive effects outweigh the pro-competitive benefits. In most instances, proving anti-competitive effects will require the plaintiff to show a relevant antitrust market and market shares.

HOW WOULD A STRUCTURED RULE OF REASON WORK?

Anti-competitive effect

As set forth above, the first step of a structured rule of reason requires that the plaintiff establish a *prima facie* case of anti-competitive effect. In *Actavis*, the Supreme Court rejected the idea that a reverse-payment settlement, without more, presumptively establishes an anti-com-petitive effect. But the court recognized the potential for pernicious effects where "[t]he 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 was held invalid or not infringed by the generic product."[11] Such underlying fundamental anti-competitive effect, of course, may be proven by direct evidence of the settlement's purpose.

The court also provided examples of circumstantial evidence that might enable a plaintiff to meet its burden, including the size of the reverse payment, its scale in relation to the payer'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 court further suggested that the two most important factors from the above list are the size of the payment and its justifications. In the court's view, "a reverse payment, where large and unjustified, can bring with it the risk of significant anti-competitive effects."[12] An example would be where "patentees … pay a generic challenger a sum even larger than what the generic would gain in profits if it won the [infringement] litigation and entered the market." Such a payment is strong evidence "that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[13]

***"[A] reverse payment, where large and unjustified, can bring with it the risk of significant anti-competitive effects," the Supreme Court said in* Actavis.**

Pro-competitive justifications

When a structured rule of reason is applied, a plaintiff who establishes a *prima facie* case of anti-competitive effect shifts the burden to the defendant to establish pro-competitive justifications for the reverse-payment settlement. The *Actavis* majority implicitly suggested that the mere fact of settlement between a brand-name manufacturer and a generic drug manufacturer may not be a sufficient pro-competitive justification when there is a reverse payment. In the lower courts, the defendants had argued that a settlement within the "scope of the patent" was pro-competitive because the generic drug was permitted to enter the market sooner than it would have if the patent had been held valid in the infringement litigation. The court said there must be something more.

The facts of *Actavis*, however, appear to support a classic case of a pro-competitive justification for an agreement between horizontal competitors that will increase efficiencies and expand output. The patent owner in *Actavis* apparently did not have the marketing expertise to effectively penetrate the urologist market, but the generic manufacturers did. Arguably, the large range of payments between $19 million and $30 million suggests that the patent holder's payment to the generic manufacturer was keyed to the generic manufacturer's success in marketing AndroGel.[14]

Challenges to proffered pro-competitive justifications

Under the structured rule of reason, if the defendant proffers plausible and cognizable pro-competitive justifications, the burden shifts back to the plaintiff to show those justifications are specious. In addition, the plaintiff could assert that the restraint (the reverse payment coupled with a delayed entry date) is greater than needed to achieve the identified efficiencies. In *Actavis,* the Supreme Court suggested that the size of the reverse payment alone may be evidence that the payment was pretextual or a sham. Internal company documents undermining the alleged pro-competitive purpose of the payment may serve the same purpose.

Balancing the anti-competitive effects against the pro-competitive benefits

Finally, if the plaintiff is unable at the summary judgment or directed verdict stages of litigation to establish that the defendants' justifications are phony, and it does not wish to take its chances that a jury would find the justifications appropriate, then the case enters a balancing stage. At that stage, the anti-competitive effect is weighed against the pro-competitive benefit.

Too prove anti-competitive effect, the plaintiff generally must define a relevant antitrust market and prove the market shares of the parties. High market shares are circumstantial evidence of market power, which in turn is circumstantial evidence of anti-competitive effect. The majority in *Actavis* suggested that one indication of market power is the size of the reverse payment, noting that a firm without the power to charge prices higher than competitive levels is unlikely to pay "large sums" to induce others to stay out of the market. The court referenced studies cited by the FTC showing that reverse-payment agreements are associated with the presence of higher-than-competitive profits, which to the FTC was a strong indicator of market power.[15]

Will rule-of-reason trials test patent validity?

A significant issue in reverse-payment settlement cases is whether the parties must litigate the validity of the patent. Parties settle infringement claims in part to avoid litigating patent validity. But if a post-settlement antitrust challenge results in a finding that the patent is valid, then a settlement providing for entry by the generic manufacturer before the expiration of the patent term is, by definition, pro-competitive. This is true because the patent holder lawfully could have excluded the generic product until the end of the patent term.

Under the structured rule of reason, if the defendant proffers plausible and cognizable pro-competitive justifications, the burden shifts back to the plaintiff to show those justifications are specious.

The majority in *Actavis* concluded that it would not normally be necessary to litigate patent validity to answer the question of whether the reverse-payment settlement unreasonably diminished competition. It reasoned that an unexplained large reverse payment would suggest that the patentee has serious doubts about the patent's validity and that the main objective is to "buy" exclusivity to maintain competitive prices.

The dissent disagreed, noting that a patent holder cannot violate the antitrust laws by a reverse-payment settlement if it has a valid patent and merely excludes an infringing challenger within the scope of the patent. Consequently, the dissent opined that, in any antitrust suit, the validity of the patent should be a defense.

The dissent also challenged that the majority's assumption that a payment of a large sum is reliable evidence that the patent holder has serious doubts about the patent. After all, it said, even if a patent holder is 95 percent confident that the patent is valid, it might pay a good deal of money to rid itself of a 5 percent chance of a finding of invalidity.

Logically, however, the dissent's reasoning about the risk of a finding of invalidity might deter a patent holder from litigating the validity of the patent. Perhaps if the patent holder had a 99 percent confidence level that its patent would be upheld, it might want to litigate validity. But the risk of invalidity, as well as the risk of incurring antitrust liability, might deter defendants with a 60/40 percent chance or even a 75/25 percent chance of establishing validity. In such situations, the defendant may conclude that there is less risk in contesting a challenge that the reverse-payment is "excessive."

NOTES

1. 570 U.S. ___, 133 S. Ct. 2223 (2013).
2. The payments from the patent holder to the generic challenger are called "reverse payments" because they are the reverse of what one might expect to see in patent infringement litigation. Often, when a patent holder has a claim for damages against an alleged infringer, the case is settled with the infringer making a payment to the patent holder. But in reverse-payment cases, the opposite is true: that is, the patent holder pays the alleged infringer. In addition, because the settlement includes an agreed-upon entry date into the market at a date later than might have applied had the litigation continued, the settlements are also referred to as "pay-for-delay" settlements.

[3] 246 U.S. 231 (1918).

[4] One commentator has described the *Chicago Board of Trade* articulation of the rule of reason as the "Full Monty," referring to a movie about out-of-work, middle-aged Englishmen who put together a strip-tease act. *See* Stephen Calkins, *California Dental Association: Not a Quick Look But Not the Full Monty,* 67 Antitrust L.J. 495 (2000).

[5] 133 S. Ct. at 2237-38.

[6] *Id.* at 2238.

[7] *See Cal. Dental Ass'n v. FTC,* 526 U.S. 756, 780 and 780, n.15 (1999).

[8] 7 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 1508c at 438-440 (2010 ed.).

[9] 7 Areeda ¶ 1508c at 440.

[10] This stepwise, burden-shifting approach has support from commentators and courts. *See, e.g.,* Joel I. Klein, Assistant Att'y Gen., Antitrust Div., A Stepwise Approach to Antitrust Review of Horizontal Agreement, Address to the ABA Antitrust Section Semi-Annual Fall Policy Program (Nov. 7, 1996); Joel I. Klein, *Point: A "Stepwise" Approach For Analyzing Horizontal Agreements Will Provide A Much Needed Structure for Antitrust Review,* 12 Antitrust Mag. 41 (Spring 1998); William J. Kolasky, *Counterpoint: The Department of Justice's "Stepwise" Approach Imposes Too Heavy A Burden of Parties to Horizontal Agreements,* 12 Antitrust Mag. 41 (Spring 1998); *Polygram Holding Inc. v. FTC,* 416 F.3d 29 (D.C. Cir. 2005) (supporting a burden-shifting approach); *Agnew v. NCAA,* 683 F.3d 328, 336 (7th Cir. 2012) (stating that "if no legitimate justifications for facially anticompetitive behavior … are found, no market power analysis is necessary and the court 'condemns the practice without ado'"); *In re Sulfuric Acid Antitrust Litig.,* 703 F.3d 1004, 1007-08 (7th Cir. 2012) (same). The authors, along with their partner, David Gustman, represented the Noranda defendants in the *Sulfuric Acid* case. Gustman argued the case for the defendants in the 7th Circuit.

[11] 133 S. Ct. at 2234.

[12] *Id.* at 2237.

[13] *Id.* at 2235.

[14] *Id.* at 2229.

[15] *Id.* at 2236.

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