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Expert Analysis

'Pay For Delay' Pharmaceutical Settlements And The 'Quick Look' — What Does It All Mean?

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The "quick look" approach to antitrust analysis has come into heightened focus with the recent oral arguments before the U.S. Supreme Court in the government's challenge to pay-for-delay settlements between brand-name drug manufacturers and generic-drug manufacturers. In *Federal Trade Commission v. Actavis Inc.*, the government urged the court to adopt a "quick look" form of antitrust scrutiny.[1]

WHAT IS THE 'QUICK LOOK'?

To understand the "quick look" approach, it is important to understand the classic methods of antitrust analysis. The standard mode of analysis is the rule of reason. Indeed, the Supreme Court has said the rule of reason should be the presumptive or default standard.[2] The rule of reason essentially asks whether the anti-competitive effects of the challenged restraint outweigh the pro-competitive benefits.

The most well-known articulation of what has been called the "full" rule of reason was by Justice Louis Brandeis in 1918 in the Board of Trade decision.[3] This articulation appears to make many facts relevant but none dispositive.

Part of this full rule-of-reason analysis generally involves the plaintiff establishing an anti-competitive effect. Such evidence of anti-competitive effect can either be direct or circumstantial. Because direct evidence is often not available, proof of an anti-competitive effect by circumstantial evidence is necessary. This often requires proof of a relevant market and proof of market power. Proof of the latter is typically inferred from market shares.

The other principal mode of analysis is the per se rule, a shortcut developed by the Supreme Court. The per se rule applies when a trial court can say with confidence based on prior experience that the restraint will always or almost always have a net anti-competitive effect.

If the defendant proffers plausible pro-competitive justifications, then the trial court can no longer say with confidence that the restraint will always or almost always have a net anti-competitive effect. In such a case, the rule of reason must apply. The same is true if the trial court does not have sufficient experience with a restraint.[4]

The per se rule is considered a shortcut, because the anti-competitive effect is irrefutably presumed. The plaintiff in a per se case does not need to establish the existence of an anti-competitive effect by direct or circumstantial evidence.

The apparent dichotomous nature of the full rule of reason and the per se rule has caused considerable debate over the last 30 years. The per se rule is considered less expensive to administer and provides both courts and the business community clear guidance as to what is lawful and what is unlawful. On the other hand, there is concern that the per se rule may result in many false positives, condemning conduct that would be found lawful upon application of the full rule of reason.

In contrast, the full rule of reason is considered expensive, time-consuming to administer and does not give the business community much guidance.

The "quick look" became a middle ground between the two extreme modes of analysis. The "quick look" is sometimes referred to as a "truncated" rule-of-reason analysis.

The two Supreme Court decisions most associated with the "quick look" are *NCAA v. Board of Regents of the University of Oklahoma*[5] and *FTC v. Indiana Federation of Dentists*,[6] although the term "quick look" was not used in either case.

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NCAA stands for the proposition that, once the plaintiff establishes a prima facie case of anti-competitive effect, the defendant must come forward with a pro-competitive justification for the challenged restraint. If none is forthcoming, or the proffered justification is not cognizable under the antitrust laws, then the case is over. The full rule of reason is truncated in that the plaintiff does not have to ultimately prove anti-competitive effect.

NCAA involved a television plan adopted by the members of the association. This plan limited the number of times a member institution could appear on television in a given year. The plan also stipulated that no member was permitted to make any sales of television rights except in accordance with the plan. The NCAA awarded rights to negotiate television contracts in accordance with this plan to two networks and a cable channel. The NCAA also set a total aggregate price the teams were required to apply in their negotiations with those networks and cable channel.

The Supreme Court characterized the NCAA's plan as a horizontal output restraint and said such an output restraint was typically condemned as per se unlawful. The court nevertheless applied the rule of reason. The court said some horizontal restraints on competition were essential if the product of collegiate football was to be available as well.

The court said that though the case involved restraints on the ability of member institutions to compete on price and output, the NCAA's justifications for these restraints had to be considered.

The District Court had found clear anti-competitive consequences to the NCAA's restraint, but the NCAA argued that its television plan could have no significant anti-competitive effect, because the NCAA had no market power. The court ultimately rejected the NCAA's argument as a matter of law, holding that proof of market power is not necessary when there is no competitive justification for the restraint.

Indiana Federation of Dentists similarly involved a "quick look" or truncated rule of reason where the plaintiff did not have to prove the relevant market and introduce evidence of market shares to establish market power. Rather, the rule-of-reason case was truncated because the defendants did not advance a cognizable pro-competitive justification. Furthermore, the plaintiff had direct evidence of anti-competitive effects and, therefore, did not need the circumstantial evidence of the relevant market and market shares to prove such anti-competitive effect.

IFD involved a conspiracy among dentists to withhold X-rays from insurers. The court found the defendants' practice was a form of horizontal agreement to withhold services requested by patients and insurers. The court held that such an agreement limiting consumer choice could not be sustained under the rule of reason, because the defendants did not advance any credible argument that the challenged conduct had any pro-competitive effect.

The defendants argued on appeal that their conduct could not be an unreasonable restraint of trade absent specific findings by the FTC of the definition of the market and the defendants' market power. Like it did in NCAA, however, the court held that the absence of a pro-competitive justification ends the case.

The court further said the FTC had found direct evidence of anti-competitive effect by the fact that the defendants were successful in certain markets by withholding X-rays from insurers. The court said the purpose of market definition and market power was to provide circumstantial evidence of anti-competitive effect, and therefore, direct evidence of such effect obviated the need for such circumstantial evidence.

The per se rule is considered a shortcut, because the anti-competitive effect is irrefutably presumed.

The 7th U.S. Circuit Court of Appeals, in a recent decision by Judge Richard Posner, *In re Sulfuric Acid Antitrust Litigation*,[7] set forth another version of a truncated rule of reason. The court suggested that under the rule of reason, the plaintiff had the burden of establishing a prima facie case of anti-competitive effect, but the defendants were allowed to put forth pro-competitive justifications. Judge Posner said the plaintiffs could attack those pro-competitive justifications as pre-textual or a sham. If the plaintiffs successfully did so, they would prevail even if they failed to introduce evidence of the relevant market or market shares to infer market power and anti-competitive effect. In other words, the rule-of-reason case would be truncated.

The Supreme Court used the term "quick look" in *California Dental Association v. FTC*.[8] In California Dental, the court rejected the FTC's attempt to follow a "quick look" approach. The court did, however, offer some thoughts for its application in the future. The court said the categories of analysis of anti-competitive effect are less fixed than the terms "per se," "quick look" and "rule of reason" tend to make them appear.

The court said the appropriate inquiry must be tailored to the particular case, depending on the circumstances, details and logic of the restraint. The approach for a case must reflect the purpose of determining whether the experience of the market has been so clear that a confident conclusion can be made about the tendency of the restriction after a quick look, or if a more complete analysis is necessary. The court also said as trial courts develop experience with a particular restraint, the contours of the analysis may change.

THE PAY-FOR-DELAY CASE

In the "pay for delay" case before the Supreme Court, plaintiff Solvay Pharmaceuticals patented a gel form of synthetic testosterone in 2000 under the brand name AndroGel.

Solvay's patent was to expire in 2020. Defendants Watson Pharmaceuticals and Paddock Laboratories filed abbreviated new drug applications in January 2003 for Food and Drug Administration approval of their generic version of Solvay's patented product.

Pursuant to the Hatch-Waxman Act, Watson and Paddock certified under paragraph IV of the act that their products did not infringe Solvay's patent or that Solvay's patent was invalid. Solvay sued for infringement in August 2003. Solvay, Watson, Paddock and a company named Par Pharmaceuticals settled the litigation (Par had joined with Paddock to fund the litigation). Under the settlement agreement, Watson and Paddock were permitted to enter the market with their generic versions of AndroGel in 2015, five years before the patent expired. Solvay agreed to pay Watson $19 million to $30 million annually to market AndroGel to urologists. The amount of the payment varied based on Watson's success in marketing AndroGel. Under the settlement, Solvay agreed to pay Paddock $2 million annually to be a backup supplier and to pay Par $10 million annually to market AndroGel to primary care physicians.

The FTC and private plaintiff purchasers sued companies in the U.S. District Court for the Northern District of Georgia, alleging the settlement violated antitrust laws. The court dismissed their suit for failure to allege that the settlements exceeded the "scope of the patent."

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The 11th Circuit affirmed. The appeals court held that, if the reverse payments from the brand-name manufacturers to the generics manufacturers were made for entry by the generic before the expiration of the patent, then the settlement was immune from antitrust attack as with the "scope of the patent."

The Supreme Court granted the FTC's petition for certiorari Dec. 7, 2012. Oral argument was held March 25.

Interestingly, the FTC had convinced the 3rd Circuit to adopt a form of the "quick look" in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012). The K-Dur defendants have sought certiorari from the Supreme Court, but the petition is still pending.

The government in *FTC v. Actavis* argued for a well-defined, but narrow, version of the "quick look." The government said a reverse-payment settlement was sufficient to establish a prima facie case of anti-competitive effect. It based this assertion on the fact that the restraint resembled cases where the court had applied a per se rule. Under the government's version of the "quick look," once it has established a prima facie case, the burden shifts to the defendants to come forth with appropriate justifications. The government narrowly limited those justifications to three types:

- The reverse payment was consideration for unrelated property or services.
- The payment was commensurate with the litigation costs that the brand-name manufacturer would otherwise have borne.
- In rare circumstances, other unusual business or litigation justifications.

During oral argument, Justices Sonya Sotomayor and Stephen Breyer suggested the basic rule of reason might be the more appropriate approach than the government's version of the "quick look." Justice Breyer disapprovingly referred to the full rule-of-reason approach as the "kitchen sink" approach and appeared to advocate for the trial judge to structure the rule of reason.

If the Supreme Court rejects both the government's version of the "quick look" and the 11th Circuit's "scope of the patent" test, is there an alternative to the two extremes of the per se rule and the full rule of reason? One possibility is what has been called the "structured rule of reason." This approach has its genesis in cases such as *In re Massachusetts Board of Optometry*[9] *and Polygram Holding v. FTC*.[10] Under the structured rule of reason, the plaintiff would have the burden of establishing a prima facie case that the challenged restraint has an anti-competitive effect. If the plaintiff meets this burden, the burden of going forward shifts to the defendant to proffer pro-competitive justifications. If the defendant does so, the burden shifts back to the plaintiff to attack the justifications as pretextual or a sham. If the plaintiff is successful, the case is over. If not, then the plaintiff has the ultimate burden of persuasion to prove the anti-competitive effects outweigh the pro-competitive benefits.

The use of a structured rule of reason raises many questions that must be resolved by the Supreme Court. First, what is a sufficient prima facie case of anti-competitive effect? The government said the fact that there was a reverse payment is sufficient. The defendants argued, however, that patent settlements are pro-competitive. Furthermore, they argued it would be hard to contain the government's rule to drug patent cases.

Any settlement arguably has a reverse payment from the plaintiff to the putative infringer. For example, if the patentee believes damages from the alleged infringement are $100 million, but settles for $50 million, is the value "forgiven" in the settlement something of value "paid" to the infringer and therefore a reverse payment? In light of the foregoing, the plaintiff will probably be required to come up with something more than merely a reverse payment in establishing a prima facie case of anti-competitive effect.

If the plaintiff is successful in establishing a prima facie case, there are questions as to what should be adequate pro-competitive justifications. In the *FTC v. Actavis* case before the Supreme Court, the defendants appeared to have good arguments for pro-competitive justifications supporting the reverse payment. The patent holder did not have sufficient marketing resources to effectively market the drug at issue in the case. Its payments to one of the generic manufacturers were payment for the marketing of the drug to urologists. The payments were geared to the success of these marketing efforts. Such an arrangement seems to be a classic pro-competitive collaboration.

How does the plaintiff refute such claims? One way is by documents obtained through discovery that might establish that the claimed justifications are a sham. Another way suggested by Justice Breyer was that the restraint was more restrictive than necessary to satisfy the purported pro-competitive justifications.

Justice Antonin Scalia said the "elephant in the room" was the strength of the patent measured against the reverse payment settlement. He suggested that to prove whether the anti-competitive effects of the reverse payment outweighed the pro-competitive benefits, it might be necessary to establish the validity of the patent. It is unclear whether this means to try the patent validity/infringement case within the antitrust case, or something less burden-some. Justice Anthony Kennedy suggested one measure of the validity of the patent might be the size of the patent compared with what the generic manufacturer's profits might have been if it won the patent litigation.

Whatever the outcome of the case, it has the potential to shape the contours of the "quick look" and the structured rule of reason that will affect antitrust cases in general.

NOTES

1. *FTC v. Actavis Inc.,* No. 12-416, *oral argument held* (U.S. Mar. 25, 2013). The case in the 11th Circuit was *FTC v. Watson Pharmaceuticals*., 677 F.3d 1298 (11th Cir. 2012).
2. *Continental T.V. Inc. v. GTE Sylvania*, 433 U.S. 36, 49 (1977) (The prevailing standard for determining whether a restraint, on balance, harms competition is the rule of reason.); *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (The rule of reason's application is "presumptive.").
3. *United States v. Bd. of Trade of the City of Chicago*, 246 U.S. 231 (1918). Professor Stephen Calkins has described the 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).
4. Judge Richard Posner of the 7th U.S. Circuit Court of Appeals recently confirmed both tests for deciding when to apply the rule of reason versus the per se rule in *In re Sulfuric Acid Antitrust Litigation*, 703 F.3d 1004 (7th Cir. 2013). Jeffery Cross, along with his partners, David Gustman and Jill Anderson, represented the Noranda defendants in the *Sulfuric Acid* case both at the trial court level and in the court of appeals.
5. 468 U.S. 85 (1984).
6. 476 U.S. 447 (1986).
7. 703 F.3d 1004 (7th Cir. 2013).
8. 526 U.S. 756 (1999).
9. 110 F.T.C. 549 (1988).
10. 416 F.3d 29 (D.C. Cir. 2005).

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