



CASE 27.1 In re Cardizem CD Antitrust Litigation

United States Court of Appeals, Sixth Circuit, 2003. 332 F.3d 896.

• **Background and Facts** Hoescht Marion Roussel, Inc. (HMR), is the manufacturer of the prescription drug Cardizem CD, which is used to treat angina and hypertension and to prevent heart attacks and strokes. HMR's patent for the drug expired in November 1992. Andrx Pharmaceuticals, Inc., developed a generic version. On receiving the approval of the Food and Drug Administration (FDA), Andrx would have 180 days within which to sell the generic without competition from other drugmakers. HMR and Andrx became involved in litigation over the patent, however, which delayed FDA approval. In 1997, after the FDA tentatively approved the generic, Andrx agreed not to market it in exchange for \$40 million per year from HMR until their dispute was resolved in an "unappealable determination." Louisiana Wholesale Drug Company and other buyers of Cardizem CD filed a suit in a federal district court against the two firms, challenging their agreement as a violation of antitrust law. The court issued a summary judgment in the plaintiffs' favor. The defendants appealed to the U.S. Court of Appeals for the Sixth Circuit.



IN THE LANGUAGE OF THE COURT OBERDORFER, District Judge.

* * * By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity * * *. There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

None of the defendants' attempts to avoid *per se* treatment is persuasive. * * * The 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. Nor does the fact that this is a "novel" area of law preclude *per se* treatment. To the contrary, whatever may be its peculiar problems and characteristics, *the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.* We see no reason not to apply that rule here, especially when the record does not support the defendants' claim that the district court made "errors" in its analysis. Finally, the defendants' claims that the Agreement lacked anticompetitive effects and had procompetitive benefits are simply irrelevant. * * * *The virtue/vice of the per se rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources*

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to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case.

* * * [Emphasis added.]

The respondents' principal argument is that the *per se* rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the *per se* concept. *The anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some.* Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application. [Emphasis added.]

Thus, the law is clear that once it is decided that a restraint is subject to *per se* analysis, the claimed lack of any actual anticompetitive effects or presence of procompetitive effects is irrelevant.

● **Decision and Remedy** The U.S. Court of Appeals for the Sixth Circuit held that the agreement between HMR and Andrx was illegal *per se* under Section 1 of the Sherman Act. The appellate court affirmed the lower court's summary judgment on this issue.

● **The Legal Environment Dimension** The defendants claimed that their agreement had procompetitive benefits. Why did the court hold that this claim was "simply irrelevant"?

● **The Ethical Dimension** Should it have made any difference to the court that Andrx could have unilaterally, and legally, decided not to bring its generic drug to market?
