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ELECTRONIC CITATION: 2003 FED App. 0195P (6th Cir.)
File Name: 03a0195p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

In re: CARDIZEM CD ANTITRUST LITIGATION.

LOUISIANA WHOLESALE DRUG CO., *et al.*,
Plaintiffs-Appellees,

v.

HOECHST MARION ROUSSEL, INC., and ANDRX PHARMACEUTICALS, INC.,
Defendants-Appellants.

No. 00-2483

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
No. 99-01278—Nancy G. Edmunds, District Judge.

Argued: April 30, 2002

Decided and Filed: June 13, 2003

Before: SILER and CLAY, Circuit Judges;
OBERDORFER, District Judge.*

*The Honorable Louis F. Oberdorfer, United States District Judge for the District of Columbia, sitting by designation.

COUNSEL

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OPINION

OBERDORFER, District Judge. This antitrust case arises out of an agreement entered into by the defendants, Hoescht Marion Roussel, Inc. ("HMR"), the manufacturer of the prescription drug Cardizem CD, and Andrx Pharmaceuticals, Inc. ("Andrx"), then a potential manufacturer of a generic version of that drug. The agreement provided, in essence, that Andrx, in exchange for quarterly payments of $10 million, would refrain from marketing its generic version of Cardizem CD even after it had received FDA approval (the "Agreement"). The plaintiffs are direct and indirect purchasers of Cardizem CD who filed complaints challenging the Agreement as a violation of federal and state antitrust laws. After denying the defendants' motions to dismiss, *see In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) ("Dist. Ct. Op. I") and granting the plaintiffs' motions for partial summary judgment, *id*., 105 F. Supp. 2d 682 (E.D. Mich. 2000) ("Dist. Ct. Op. II"), the district court certified two questions for interlocutory appeal:

> (1) . . . In determining whether Plaintiffs have properly pled antitrust injury, does the language of the Sixth Circuit's decisions in *Valley Products Co. v. Landmark*, 128 F.3d 398, 404 (6th Cir. 1997) and *Hodges v. WSM, Inc*., 26 F.3d 36, 39 (6th Cir. 1994) require dismissal of Plaintiffs' antitrust claims at the pleading stage if Plaintiffs cannot allege facts showing that Defendants' alleged anticompetitive conduct was a "necessary predicate" to their antitrust injury; *i.e*., that dismissal is required unless Plaintiffs plead facts showing that the alleged antitrust injury could not possibly have occurred absent Defendants' alleged anticompetitive conduct?
>
> (2) . . . In determining whether Plaintiffs' motions for partial judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the corresponding state antitrust laws at issue in this litigation.

JA 607. Our answers, explained more fully herein, are as follows:

Answer to First Certified Question: As framed, the certified question is not susceptible to a yes or no answer because it incorporates a definition of "necessary predicate" that we reject. *Hodges* and *Valley Products* stand for the proposition that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege that the antitrust violation is *either* the "necessary predicate" for its injury *or* the only means by which the defendant could have caused its injury. Under the "necessary predicate" option, dismissal is warranted only where it is apparent from the allegations in the complaints that the plaintiffs' injury would have occurred even if there had been no antitrust violation. Here, Andrx could have made a unilateral and legal decision to delay its market entry, but the plaintiffs have alleged it would not have done so but for the Agreement and HMR's payment to it of $40 million per year. The plaintiffs' allegations satisfy the "necessary predicate" test. The defendants' claim that Andrx's decision to stay off the market

was motivated not by the $40 million per year it was being paid by HMR, but by its fear of damages in the pending patent infringement litigation, merely raises a disputed issue of fact that cannot be resolved on a motion to dismiss. Accordingly, the district court properly denied the defendants' motions to dismiss for failure to allege antitrust injury.

Answer to Second Certified Question: Yes. The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws. Accordingly, the district court properly granted summary judgment for the plaintiffs on the issue of whether the Agreement was *per se* illegal.

I. BACKGROUND

As the district court has set forth a complete outline of the relevant statutory framework, *see* Dist. Ct. Op. I, at 627-29; Dist. Ct. Op. II, at 685-86, facts, *see* Dist. Ct. Op. I, at 629-32; Dist. Ct. Op. II, at 686-89, and procedural history, *see* Dist. Ct. Op. I, at 632-33; Dist. Ct. Op. II, at 689-90, we repeat here only what is necessary to our analysis of the issues on appeal.

A. Statutory Framework

In 1984, Congress enacted the Hatch-Waxman Amendments, *see* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399. Those amendments permit a potential generic[1] manufacturer of a patented pioneer drug to file an

[1]A "generic" drug contains the same active ingredients but not necessarily the same inactive ingredients as a "pioneer" drug sold under a brand name. *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983).

abbreviated application for approval with the Food and Drug Administration ("FDA") (known as an Abbreviated New Drug Application ("ANDA")). *See* 21 U.S.C. § 355(j)(1). Instead of submitting new safety and efficacy studies, an ANDA may rely on the FDA's prior determination, made in the course of approving an earlier "pioneer" drug, that the active ingredients of the proposed new drug are safe and effective. *Id.* § 355(j)(2)(A). Every ANDA must include a "certification that, in the opinion of the applicant and to the best of his knowledge, the proposed generic drug does not infringe any patent listed with the FDA as covering the pioneer drug." *Id*. § 355(j)(2)(A)(vii). That certification can take several forms. Relevant here is the so-called "paragraph IV certification" whereby the applicant certifies that any such patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id*. § 355(j)(2)(A)(vii)(IV). An applicant filing a paragraph IV certification must give notice to the patent-holder, *id*. § 355(j)(2)(B); the patent-holder then has forty-five days to file a patent infringement action against the applicant. *Id*. § 355(j)(5)(B)(iii). If the patent-holder files suit, a thirty-month stay goes into effect, meaning that unless before that time the court hearing the patent infringement case finds that the patent is invalid or not infringed, the FDA cannot approve the generic drug before the expiration of that thirty-month period. *Id*. § 355(j)(5)(B)(iii)(I). In order to encourage generic entry, and to compensate for the thirty-month protective period accorded the patent holder, the first generic manufacturer to submit an ANDA with a paragraph IV certification receives a 180-day period of exclusive marketing rights, during which time the FDA will not approve subsequent ANDA applications. *Id*. § 355(j)(5)(B)(iv). The 180-day period of exclusivity begins either (1) when the first ANDA applicant begins commercial marketing of its generic drug (the marketing trigger) or (2) when there is a court decision ruling that the patent is invalid or not infringed (the court decision trigger), whichever is earlier. *Id*.

B. Facts

Unless otherwise noted, the following facts are undisputed. HMR manufactures and markets Cardizem CD, a brand-name prescription drug which is used for the treatment of angina and hypertension and for the prevention of heart attacks and strokes. The active ingredient in Cardizem CD is diltiazem hydrochloride, which is delivered to the user through a controlled-release system that requires only one dose per day. HMR's patent for diltiazem hydrochloride expired in November 1992.

On September 22, 1995, Andrx filed an ANDA with the FDA seeking approval to manufacture and sell a generic form of Cardizem CD. On December 30, 1995, Andrx filed a paragraph IV certification stating that its generic product did not infringe any of the patents listed with the FDA as covering Cardizem CD. Andrx was the first potential generic manufacturer of Cardizem CD to file an ANDA with a paragraph IV certification, entitling it to the 180-day exclusivity period once it received FDA approval.

In November 1995, the United States patent office issued Carderm Capital, L.P. ("Carderm") U.S. Patent No. 5,470,584 ("'584 patent"), for Cardizem CD's "dissolution profile," which Carderm licensed to HMR. JA 1796-1810. The dissolution profile claimed by the '584 patent was for 0-45% of the total diltiazem to be released within 18 hours ("45%-18 patent").[2]

In January 1996, HMR and Carderm filed a patent infringement suit against Andrx in the United States District Court for the Southern District of Florida, asserting that the generic version of Cardizem CD that Andrx proposed would infringe the '584 patent. *See* JA 1240-1257 (Complaint,

[2]Two other patents for the dissolution profile of Cardizem CD had previously been issued, one in February 1994 and one in August 1995. Neither is relevant to the present litigation.

Hoescht Marion Roussel, Inc. v. Andrx Pharmaceuticals, Inc., No. 96-06121 (S.D. Fla. filed Jan. 31, 1996)). The complaint sought neither damages nor a preliminary injunction. *Id.* However, filing that complaint automatically triggered the thirty-month waiting period during which the FDA could not approve Andrx's ANDA and Andrx could not market its generic product. In February 1996, Andrx brought antitrust and unfair competition counterclaims against HMR. JA 1717-47. In April 1996, Andrx amended its ANDA to specify that the dissolution profile for its generic product was not less than 55% of total diltiazem released within 18 hours ("55%-18 generic"). HMR nonetheless continued to pursue its patent infringement litigation against Andrx in defense of its 45%-18 patent. On June 2, 1997, Andrx represented to the patent court that it intended to market its generic product as soon as it received FDA approval. JA 1758.

On September 15, 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period in early July 1998, or earlier if the court in the patent infringement action ruled that the '584 patent was not infringed.

Nine days later, on September 24, 1997, HMR and Andrx entered into the Agreement. JA 1363-73. It provided that Andrx would not market a bioequivalent or generic version of Cardizem CD in the United States until the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; *or* (3) HMR entering into a license agreement with a third party. Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, to diligently prosecute its ANDA, and to not "relinquish or otherwise compromise any right accruing thereunder or pertaining thereto," including its 180-day period of exclusivity. In exchange, HMR agreed to make interim payments to Andrx in the amount of $40 million per year, payable quarterly, beginning on the date Andrx received final

FDA approval.[3] HMR further agreed to pay Andrx $100 million per year,[4] less whatever interim payments had been made, once: (1) there was a final and unappealable determination that the patent was not infringed; (2) HMR dismissed the patent infringement case; or (3) there was a final and unappealable determination that did not determine the issues of the patent's validity, enforcement, or infringement, and HMR failed to refile its patent infringement action.[5] HMR also agreed that it would not seek preliminary injunctive relief in the ongoing patent infringement litigation.[6]

On July 8, 1998, the statutory thirty-month waiting period expired. On July 9, 1998, the FDA issued its final approval of Andrx's ANDA. Pursuant to the Agreement, HMR began

[3]The payments were scheduled to end on the earliest of: (1) a final and unappealable order or judgment in the patent infringement case; (2) if HMR notified Andrx that it intended to enter into a license agreement with a third party, the earlier of: (a) the expiration date of the required notice period or (b) the date Andrx effected its first commercial sale of the Andrx product; or (3) if Andrx exercised its option to acquire a license from HMR, the date the license agreement became effective.

[4]HMR and Andrx stipulated that, for the purposes of the Agreement, Andrx would have realized $100 million per year in profits from the sale of its generic product after receiving FDA approval.

[5]HMR had to notify Andrx within thirty days of such a determination that it continued to believe that Andrx's generic version of the drug infringed its patent and that it intended to refile its patent infringement action.

[6]HMR also agreed that it would give Andrx copies of changes it proposed to the FDA regarding Cardizem CD's package insert and immediate container label, that it would notify Andrx of any labeling changes pending before or approved by the FDA, and that it would grant Andrx an irrevocable option to acquire a nonexclusive license to all intellectual property HMR owned or controlled that Andrx might need to market its product in the United States.

making quarterly payments of $10 million to Andrx, and Andrx did not bring its generic product to market.

On September 11, 1998, Andrx, in a supplement to its previously filed ANDA, sought approval for a reformulated generic version of Cardizem CD. Andrx informed HMR that it had reformulated its product; it also urged HMR to reconsider its infringement claims. On February 3, 1999, Andrx certified to HMR that its reformulated product did not infringe the '584 patent.

On June 9, 1999, the FDA approved Andrx's reformulated product. That same day, HMR and Andrx entered into a stipulation settling the patent infringement case and terminating the Agreement. At the time of settlement, HMR paid Andrx a final sum of $50.7 million, bringing its total payments to $89.83 million. On June 23, 1999, Andrx began to market its product under the trademark Cartia XT, and its 180-day period of marketing exclusivity began to run. Since its release, Cartia XT has sold for a much lower price than Cardizem CD and has captured a substantial portion of the market.

C. Procedural History

The first complaint challenging the legality of the Agreement was filed in August 1998, shortly after the FDA issued its final approval for Andrx's generic version of Cardizem CD. That complaint, and the other complaints that were subsequently filed, have been consolidated by the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, for coordinated or consolidated pretrial proceedings in the Eastern District of Michigan.[7] JA 56-58.

[7]As described by the district court, the plaintiffs fall into three groups: (1) the "State Law Plaintiffs," indirect purchasers, and class representatives, from various states whose complaints, initially filed in state court and then removed to federal district court by defendants, allege violations of state antitrust and consumer protection statutes, JA 908-

For all of the plaintiffs, the foundation for their claims is the allegation that but for the Agreement, specifically the payment of $40 million per year, Andrx would have brought its generic product to market once it received FDA approval and at a lower price than the patented Cardizem CD sold by HMR. They further allege that the Agreement protected HMR from competition from both Andrx and other potential generic competitors because Andrx's delayed market entry postponed the start of its 180-day exclusivity period, which it had agreed not to relinquish or transfer. The Sherman Act Class Plaintiffs and the Individual Sherman Act Plaintiffs bring claims under the federal antitrust laws, specifically section 1 of the Sherman Act, 15 U.S.C. § 1; they seek treble damages under section 4 of the Clayton Act, 15 U.S.C. § 4. The State Law Class Plaintiffs bring claims under various state antitrust laws.[8]

The defendants, HMR and Andrx, filed various motions to dismiss, all of which were denied. *See* Dist. Ct. Op. I, at 624. Of relevance to the present appeal, the defendants argued that all of the plaintiffs had failed to allege and could not allege an "antitrust injury" cognizable under section 1 of the Sherman Act or under the respective state antitrust statutes. *Id*. at 645. The district court concluded that the plaintiffs had adequately alleged "antitrust injury." *Id*. at 645-58. In reaching its

1011; (2) the "Sherman Act Class Plaintiffs," direct purchasers, and class representatives, whose complaint, filed in federal district court, alleges a violation of federal antitrust law, JA 139-159; and (3) the "Individual Sherman Act Plaintiffs," two groups of purchasers, not representatives of any class, whose complaints, filed in federal district court, allege violations of federal antitrust law, JA 860-881 (filed by The Kroger Co., Albertson's, Inc., The Stop and Shop Supermarket Co., and Eckerd Corp.); JA 887-896 (filed by CVS Meridian, Inc. and Rite Aid Corp.). *See* Dist. Ct. Op. I, at 625-27. Each group has filed a brief on appeal.

[8]Of the State Law Plaintiffs, the plaintiffs from seven states (California, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin) and the District of Columbia claim violations of state antitrust law. Dist. Ct. Op. I, at 625 n.3.

conclusion, the district court first considered whether the plaintiffs' allegations satisfied the test articulated by the Supreme Court in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.,* 429 U.S. 477, 489 (1977). In *Brunswick*, the Supreme Court defined "antitrust injury" as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." 429 U.S. at 489. The district court explained its conclusion that the plaintiffs satisfied this test as follows:

> As to the first prong of the antitrust injury test, the Supreme Court has observed that "[t]he Sherman Act was enacted to assure our customers the benefits of price competition, and our prior cases have emphasized the central interest in protecting the economic freedom of participants in the relevant market." *Associated General*, 459 U.S. at 538. Plaintiffs are customers, not competitors of Defendants, and the injury claimed consists of higher prices paid for drugs as a result of the contractually mandated absence of competition between HMRI and Andrx. As to the second, or causal connection prong of the antitrust injury test, Plaintiffs have alleged that the HMRI/Andrx Agreement decreased generic competition, and that the decreased competition bargained for in the HMRI/Andrx Agreement caused their injuries. Thus, Plaintiffs' injuries coincide precisely with the rationale for finding a violation of the antitrust laws in the first place. Since the very purpose of antitrust law is to ensure that the benefits of competition flow to purchasers of goods affected by the violation, "buyers have usually been preferred plaintiffs in private antitrust litigation," and a purchaser's standing "to recover for an overcharge paid directly to an illegal cartel or monopoly is seldom doubted." 2 P. Areeda & H. Hovemkamp, supra, ¶ 370[,] at 253. Plaintiffs have sufficiently pled facts that show they satisfy the "antitrust injury" test set forth in *Brunswick*.

Dist. Ct. Op. I, at 650-51. The district court then considered whether the Sixth Circuit's decisions in *Axis, S.p.A. v. Micafil*, 870 F.2d 1105 (6th Cir. 1989), *Hodges v. WSM, Inc.*, 26 F.3d 36 (6th Cir. 1994), and *Valley Products Co. v. Landmark*, 128 F.3d 398 (6th Cir. 1997) required a different conclusion, Dist. Ct. Op. I, at 651-57, particularly the statement in *Hodges* that "because plaintiffs did not allege, nor could they that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case." 26 F.3d at 39 (emphasis added). After closely examining the facts and holdings of those cases, it rejected the defendants' contention that the Sixth Circuit's "necessary predicate" test meant that an antitrust complaint should be dismissed "simply because the defendant can conjure up a set of facts, contradicting those alleged in the plaintiff's complaint, but supporting an alternative possible cause for Plaintiffs' injuries that would not offend the antitrust laws." Dist. Ct. Op. I, at 651. It explained further:

> While the Sixth Circuit language found in the last paragraph of *Hodges* and repeated in *Valley Products* appears to broadly apply to the facts presented here, careful examination of these decisions reveals otherwise. The quoted language goes well beyond the antitrust injury test announced in *Brunswick*, goes well beyond what the Sixth Circuit actually did in each of these cases, goes further than the underlying facts allow, and is mutually inconsistent with the material cause standard that is to be applied in antitrust cases.

Id. at 652. Accordingly, the district court denied the defendants' motions to dismiss for failure to allege antitrust injury.

The plaintiffs then moved for partial summary judgment on the issue of whether the Agreement was a *per se* illegal restraint of trade. The district court concluded that the

Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market with its generic version of Cardizem CD, was a naked, horizontal restraint of trade and, as such, *per se* illegal. Dist. Ct. Op. II, at 705-06.

Pursuant to 28 U.S.C. § 1292(b), the district court certified for interlocutory appeal the two questions quoted above.[9]

II. DISCUSSION

As we believe that our answer to the second question sheds light on our consideration of the first, we address first whether the Agreement was a *per se* illegal restraint of trade before considering whether the plaintiffs adequately alleged antitrust injury.

A. *Per Se* Illegal Restraint of Trade

We review *de novo* the district court's ruling on summary judgment that the Agreement was a *per se* illegal restraint of trade. *Holloway v. Brush*, 220 F.3d 767, 772 (6th Cir. 2000). Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

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[9] Since oral argument before this Court, the defendants have reached a settlement with the Sherman Act Class Plaintiffs. A settlement with the State Law Plaintiffs and the State Attorneys' General is subject for a final approval hearing before the District Court in October 2003. The Sherman Act Individual Plaintiffs have settled with HMR (now Aventis Pharmaceuticals), but have not settled with Andrx. The defendants have represented to the Court that these settlements have not mooted the certified issues presented by this appeal. *See* Letter to U.S. Court of Appeals for the Sixth Circuit, filed Feb. 20, 2003.

1. Relevant Antitrust Law

Section 1 of the Sherman Act[10] provides that "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . . ." 15 U.S.C. § 1. Read "literally," section 1 "prohibits *every* agreement in restraint of trade." *Arizona v. Maricopa Cty. Medical Soc.*, 457 U.S. 332, 342 (1982). However, the Supreme Court has long recognized that Congress intended to outlaw only "unreasonable" restraints. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *Maricopa Cty.*, 457 U.S. at 342-43 (citing *United States v. Joint Traffic Ass'n*, 171 U.S. 505 (1898)). Most restraints are evaluated using a "rule of reason." *State Oil*, 522 U.S. at 10. Under this approach, the "finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* (citing *Maricopa Cty.*, 457 U.S. at 343 & n.13).

Other restraints, however, "are deemed unlawful *per se*" because they "have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." *Id.* (citing *Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)). "*Per se* treatment is appropriate '[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.'" *Id.* (quoting *Maricopa Cty.*, 457 U.S. at 344); *see also Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 19-20 (1979) (a *per se* rule is applied when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."). The *per se* approach

[10] It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive. *See* State Law Pls. Br. at 41-44.

thus applies a "conclusive presumption" of illegality to certain types of agreements, *Maricopa Cty.*, 457 U.S. at 344; where it applies, no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition.[11] *National College Athletic Ass'n ("NCAA") v. Board of Regents*, 468 U.S. 85, 100 (1984). As explained by the Supreme Court, "[t]he probability that anticompetitive consequences will result from a practice and the severity of those consequences must be balanced against its procompetitive consequences. Cases that do not fit the generalization may arise, but a *per se* rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them." *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 n.6 (1977).

The Supreme Court has identified certain types of restraints as subject to the *per se* rule. The classic examples are naked, horizontal restraints pertaining to prices or territories. *See, e.g.*, *NCAA*, 468 U.S. at 100 ("Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high."); *Copperweld Corp. v. Independence Tube Corp.,* 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."); *United States v. Topco Assocs.*, 405 U.S.

[11] The risk that the application of a *per se* rule will lead to the condemnation of an agreement that a rule of reason analysis would permit has been recognized and tolerated as a necessary cost of this approach. *See*, *e.g.*, *Maricopa Cty.*, 457 U.S. at 344 ("As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a fullblown inquiry might have proved to be reasonable."); *United States v. Topco Associates, Inc.*, 405 U.S. 596, 609 (1972) ("Whether or not we would decide this case the same way under the rule of reason used by the District Court is irrelevant to the issue before us.").

596, 608 (1972) ("One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. Such concerted action is usually termed a 'horizontal' restraint, in contradistinction to combinations of persons at different levels of the market structure, *e.g.*, manufacturers and distributors, which are termed 'vertical' restraints. This Court has reiterated time and time again that horizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition. Such limitations are *per se* violations of the Sherman Act." (internal citations omitted)); *Northern Pacific Ry.*, 356 U.S. at 5 ("Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements." (internal citations omitted)).

2. Application

In answering the question whether the Agreement here was *per se* illegal, the following facts are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval, protecting HMR's exclusive access to the market for Cardizem CD throughout the United States until the occurrence of one of the end dates contemplated by the Agreement. (In fact, Andrx and HMR terminated the Agreement and the payments in June 1999, before any of the specified end dates occurred.) In the interim, however, from July 1998 through June 1999, Andrx kept its generic product off the market and HMR paid Andrx $89.83 million. 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, which Andrx had agreed not to

relinquish or transfer.[12] 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. As explained in greater detail in the district court's opinion, *see* Dist. Ct. Op. II, at 700-705, 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[13] in inhibiting competitors by paying the only

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[12] As the district court for the Eastern District of New York recently observed, in distinguishing the district court's opinion in the present case (*Cardizem II*),

> By agreeing both not to end the underlying patent dispute and not to market a generic drug product in the relevant domestic market, Andrx . . . effectively precluded or seriously delayed both the [patent] court decision and the commercial marketing trigger of the 180-day exclusivity period. As a result, any future [generic] filers were delayed in coming to market . . . .

In re Ciprofloxacin Hydrochloride Antitrust Litigation, MDL No. 1383, 2003 WL 21146562, at *46 (E.D.N.Y. May 20, 2003); *see also In re Tamoxifen Citrate Antitrust Litigation*, MDL No. 1408, 2003 WL 21196817, at *9 (E.D.N.Y. May 13, 2003).

[13] As the court in *In re Ciprofloxacin* observed,

> [w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.

potential competitor $40 million per year to stay out of the market. Individual Sherman Act Plaintiffs Br. at 26-30. Nor does the fact that this is a "novel" area of law preclude *per se* treatment, *see Maricopa Cty.*, 457 U.S. at 349. To the contrary, the Supreme Court has held that "'[w]hatever 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.'" *Id.* at 349 (quoting *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 222 (1940)). 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.[14] Finally, the defendants' claims that the Agreement lacked anticompetitive effects and had procompetitive benefits are simply irrelevant. *See*, *e.g.*, *Maricopa Cty.*, 457 U.S. at 351. To reiterate, 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 to evaluate the actual anticompetitive effects or

2003 WL 21146562, at *46.

[14]For example, the defendants charge that the district court erred in concluding that in the absence of the Agreement, Andrx *would* have marketed its generic product before the end of the patent litigation (once it had received FDA approval). However, the district court never held that Andrx *would* have launched the original formulation of its generic while the patent suit was pending, only that it *could* have. The defendants also contend that the district court erred in assuming that Andrx could have marketed its *reformulated* generic, which only received FDA approval in June 1999, before it did, but the district court made no such assumption. Finally, the defendants argue that the district court erred in reaching the conclusion that Andrx and HMRI were horizontal competitors. They maintain that it would be inconsistent with Hatch-Waxman scheme to allow a court to treat a generic manufacturer who is seeking FDA approval and has been charged with patent infringement and the patent holder as horizontal competitors. Hatch-Waxman notwithstanding, the defendants are potential rivals in the market for Cardizem CD; an agreement between them is thus an agreement between horizontal competitors.

procompetitive justifications in a particular case. As the Supreme Court explained in *Maricopa County*:

> 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.

457 U.S. at 351. 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. Of course, our holding here does not resolve the issues of causation and damages, both of which will have to be proved before the plaintiffs can succeed on their claim for treble damages under the Clayton Act.

B. Antitrust Injury

We now consider whether the district court properly denied the defendants' motion to dismiss the complaint for failure to allege an "antitrust injury."[15] A district court's denial of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is subject to *de novo* review. *Ziegler v. IBP Hog Market, Inc.*, 249 F.3d 509, 511-12 (6th Cir. 2001). In

[15]Our conclusion that the Agreement was a *per se* illegal restraint of trade does not obviate the need to decide whether the plaintiffs adequately alleged antitrust injury. *See Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 341-42 (1990) ("The *per se* rule is a method of determining whether § 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury and thus whether he may recover damages under § 4 of the Clayton Act.").

deciding a motion to dismiss, we, like the district court, "must construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of his claim that would entitle him to relief." *Id*. at 512. "When an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." *Helwig v. Vencor*, Inc., 251 F.3d 540, 553 (6th Cir. 2001) (internal citations omitted), *cert. dismissed*, 536 U.S. 935 (2002).

1. Relevant Antitrust Law

A private antitrust plaintiff, in addition to having to show injury-in-fact and proximate cause, must allege, and eventually prove, "antitrust injury." *Brunswick*, 429 U.S. at 489. "Antitrust injury" is (1) "injury of the type the antitrust laws were intended to prevent" and (2) injury "that flows from that which makes defendants' acts unlawful." *Id.* As explained by the Supreme Court in *Brunswick*, the antitrust injury doctrine is designed to ensure that "the injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Id.* The Supreme Court has further explained the requirement as "ensur[ing] that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place," and, more specifically, it "ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior." *Atlantic Richfield Co. v. USA Petroleum Co.* 495 U.S. 328, 342-343 (1990).

2. Plaintiffs' Allegations

In the present case, the plaintiffs' critical allegations include the following: (1) Andrx had developed and was ready to market a generic version of Cardizem CD; (2) Andrx had certified to the FDA that its generic product did not infringe any of the patents associated with Cardizem CD;

(3) the patent infringement litigation was a "sham"[16]; (4) prior to entering into the Agreement, Andrx had represented to the federal district court presiding over the patent infringement litigation that it intended to market and sell its generic version of Cardizem CD as soon as it received final FDA approval; (5) the Agreement entered into by Andrx and HMR provided, among other things, that once the FDA approved Andrx's ANDA, HMR would commence making quarterly payments of $10 million in exchange for Andrx not bringing its generic product to market; (6) Andrx did not enter the market upon receiving FDA approval on July 9, 1998; (7) pursuant to the Agreement, HMR ultimately paid Andrx $89.83 million; (8) "but for" the Agreement and the payment, Andrx would have begun to market its generic version of Cardizem CD on or shortly after July 9, 1998; (9) the Agreement effectively eliminated generic competition in the market for Cardizem CD from July 1998 through July 1999, when the Agreement was terminated; and (10) due to the lack of a competitive market, the plaintiffs were deprived of the option of purchasing a generic lower-priced drug and paid more than they otherwise would have for Cardizem CD. JA 908-1011 (State Law Pls. Compl.); JA 139-159 (Sherman Act Class Pls. Compl.); JA 848-859, 860-881, 887-896

[16]The State Law Plaintiffs allege that the '584 patent "represented no substantive change or improvement to Cardizem CD but rather was prosecuted and listed solely to give HMR a basis for initiating sham patent infringement litigation to delay and exclude Andrx's generic Cardizem CD from the Cardizem CD market for at least 30 months." JA 948, ¶ 101. They further allege that Andrx's specified dissolution profile, submitted to the FDA after the patent infringement litigation was filed, was "clearly distinct" from the '584 patent, JA 949, ¶ 103, and that HMR continued its pursuit of the patent infringement litigation "despite the absence of any reasonable belief that their claim would be held to be valid upon adjudication," *id.* ¶ 104. Finally, they allege that HMR's "goal and intention in pursuing [the patent infringement litigation] was solely to indefinitely delay and prevent the entry of Andrx's product into the marketplace and invoke the automatic 30-month administrative delay in the FDA approval process." *Id.*; *see also* JA 154, ¶ 53 (amended complaint of Sherman Act Class Plaintiffs alleging that "patent litigation" was "sham[]")).

(Individual Sherman Act Pls. Compls.); *see also* Dist. Ct. Op. I, at 647.

3. Application of *Brunswick*

The plaintiffs' allegations fall easily within the two critical *Brunswick* categories. It is clear, and not disputed on appeal, that the plaintiffs have alleged the "type of injury" the antitrust laws were meant to prevent. The plaintiffs are consumers of the patented drug Cardizem CD, who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint. Preventing that kind of injury was undoubtedly a *raison d'etre* of the Sherman Act when it was enacted in 1890. *See Associated Gen. Contractors v. California State Council*, 459 U.S. 519, 538 (1983).

There remains the issue of whether the alleged injury "flows" from that "which makes defendants' acts unlawful," i.e., its anticompetitive effects. The facts of *Brunswick* shed light on the meaning and purpose of this requirement. In *Brunswick*, a bowling alley owner claimed that another competitor's takeover of two failing bowling alleys was an illegal merger. The plaintiff alleged that it was injured by the merger because if the other bowling alleys had simply gone out of business, it would have increased its sales in the bowling alley market. What would have made the acquisition unlawful for antitrust purposes, however, was the risk that increased concentration in the bowling alley market would reduce future competition and cause prices to rise. The plaintiff's injury, on the other hand, flowed from the more immediate competition-enhancing effects of the merger; not its future potential to reduce competition. Accordingly, there was no antitrust injury because the plaintiff's injury did not "flow" from the anticompetitive effects of the alleged antitrust violation.

In the present case, the facts are much more straightforward. As explained above, the alleged antitrust violation, HMR's agreement to pay Andrx $40 million per year not to bring its generic product to market and compete with Cardizem CD, is a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers. Unlike in *Brunswick*, here there is no question that the alleged injury – paying higher prices for a product due to a lack of competition in the market – is the type of injury that can, and the plaintiffs have alleged did, flow from the anticompetitive effects of the Agreement (a horizontal market allocation agreement). Under these circumstances, dismissal would be appropriate only if the plaintiffs' allegations, taken as true and construed in their favor, somehow precluded the possibility that their injury flowed from the anticompetitive effects of the Agreement and payment. No such conclusion can be reached in this case. To the contrary, the complaint clearly alleges that but for the Agreement, specifically the payment of $40 million per year, the plaintiffs would not have suffered their injury; there is nothing in the complaint that belies this allegation or justifies this Court not accepting it as true. The defendants' argument to the contrary, that Andrx would not have entered the market even if there had been no Agreement and payment because of its fear of damages in the patent infringement litigation, creates a disputed issue of fact, not appropriately resolved on a motion to dismiss. Indeed, a trier of fact may well find that the $89 million payment renders incredible the defendants' claim that Andrx would have refrained from marketing simply because of its fear of infringement damages.

4. "Necessary Predicate" Test

We turn now to the defendants' contention, and the reason for this certified appeal, that the Sixth Circuit's "necessary predicate" test requires more than *Brunswick* and leads to a

different conclusion.[17] The defendants' argument arises out of a statement made in this Court's decision in *Hodges*. In that case, after having decided to affirm the district court's dismissal for failure to allege antitrust injury, the Court stated: "[b]ecause plaintiffs did not allege, nor could they, that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case pursuant to Federal Rule of Civil Procedure 12(b)(6)." *Hodges*, 26 F.3d at 39 (emphasis added).

[17]It is noteworthy that the district court has responsibility for these cases by assignment of the Judicial Panel on Multidistrict Litigation, and we address this certified question in aid of the district court. This consolidated proceeding includes cases that were originally filed in various state and federal courts, raising state and federal antitrust claims. The state cases were first removed to federal district court and then transferred to the Eastern District of Michigan. In considering the issue of antitrust injury, the district court applied the same analysis, including the application of Sixth Circuit precedent, to all of the antitrust claims. *Id.* at 645-58. As no party has taken issue with this approach, either before the district court or on appeal, we have followed the same path. We note, however, that although it is clear and undisputed that the state antitrust laws at issue all "either follow federal Sherman Act precedent or find federal case law persuasive," Dist. Ct. Op. II, at 692 & n.6 (citing state cases); *see also* State Law Pls. Br. at 41-15, and that in a federal multidistrict litigation there is a preference for applying the law of the transferee district, *see In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050 (8th Cir. 1996); *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993), it is not clear that precedent "unique" to a particular circuit and arguably divergent from the predominant interpretation of a federal law, such as the Sixth Circuit's "necessary predicate" gloss on the antitrust injury doctrine, should be applied to state antitrust laws or federal antitrust claims that originated in other circuits, *see In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171 (2d Cir. 1987), *aff'd*, 490 U.S. 122 (1989) (law of transferor forum on federal question merits close consideration, but does not have *stare decisis* effect). As we agree with the district court that the plaintiffs have alleged antitrust injury as contemplated by the Sixth Circuit, this consideration is of academic interest only. Were the outcome otherwise, it might require further consideration.

The defendants contend that this statement means that in order to allege antitrust injury adequately, a plaintiff must allege that the only way the defendant *could* have caused the plaintiff's injury was by engaging in the antitrust violation. Defs. Br. at 32-33. In other words, if the defendant could have in theory caused the same injury without engaging in an antitrust violation, the plaintiff has not suffered an "antitrust injury," even if in fact it was the antitrust violation that caused the actual injury in a particular case. Applied to the present case, the defendants contend that the plaintiffs cannot allege an antitrust injury because Andrx *could* have unilaterally (and legally) decided not to market its generic version of Cardizem CD; they contend it is immaterial whether, in fact, it was the Agreement and the payment of $40 million per year that caused them to do so. *Id*.

We disagree.

First, simply looking at the actual language of the statement suggests that the defendants have conflated two ideas. What the court in *Hodges* said was that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege *either*: (1) that the antitrust violation was "a necessary predicate" to their injury; *or* (2) that the defendants could injure plaintiffs only by engaging in the antitrust violation. 26 F.3d at 39. The defendants' interpretation conflates these options, effectively requiring plaintiffs to satisfy the second one even if they have already satisfied the first.

Second, nothing in the facts or holding of *Axis*, *Hodges*, or *Valley Products*, the cases relied upon by the defendants, supports their interpretation. Although it does not use the "necessary predicate" language, we consider first the Sixth Circuit's decision in *Axis*, the starting point for this line of antitrust injury cases.

In *Axis*, 870 F.2d 1105, the plaintiff was a foreign manufacturer of armature winding machines which sought to enter the United States market. After another foreign

manufacturer purchased two American manufacturers, the plaintiff filed an antitrust suit against the purchaser claiming that the purchase was illegal because it reduced competition in the armature winding machine market. The plaintiff's alleged injury was its exclusion from the United States market. However, the plaintiff also alleged that it could not enter the market because it lacked access to indisputably valid and essential patents controlled by the defendant; the plaintiff did not challenge the legal right of the patent-holder to refuse to grant it a license. Nor did it or anyone else challenge the validity of the patents. We affirmed dismissal of the complaint because it failed to allege antitrust injury, noting that the "the anticompetitive act of purchasing [the American manufacturer] did not cause the plaintiff's alleged injury. The patents were an *impenetrable* barrier to the plaintiff's entry before [the defendant] purchased [the American manufacturer], and they remained as great a barrier afterwards." 870 F.2d at 1107 (emphasis added).

In *Hodges*, 26 F.3d 39, the plaintiff was an airport shuttle and tour bus operator who wanted to participate in the market for shuttle services from the Nashville airport to Opryland, an amusement park, hotel and convention center. It filed an antitrust suit against the companies that owned the Opryland site and operated the Grand Old Opry music radio program, as well as a sightseeing and tour company known as Grand Old Opry tours. The complaint alleged that those defendants had reached an illegal market division agreement with other shuttle and tour bus operators that the competitors would refrain from transporting passengers from the airport to the Opryland complex, leaving the airport shuttle market to the defendants themselves. In exchange, the defendants would hire vans and buses from their former competitors for Opryland's sightseeing tour business. The plaintiff's alleged injury was its exclusion from the airport to Opryland shuttle market. The plaintiff further alleged that the defendants policed their illegal agreement by refusing the plaintiff, and any other non-conspiring shuttle service companies, access to the Opryland property; the plaintiff did not challenge the

defendants' lawful right to exclude it from their private property. The case was dismissed for failure to allege antitrust injury.

In *Valley Products*, 128 F.3d 398, the plaintiff was a manufacturer of logo-bearing hotel soaps and other hotel amenities which wanted to supply its products to franchisees of a certain hotel franchisor. The hotel franchisor authorized certain vendors to use its trademark on products, which the franchisees would then purchase. After the plaintiff's vendor agreement was terminated, it filed an antitrust suit against the hotel franchisor and its two remaining authorized vendors, the plaintiff's competitors, alleging that their arrangement was an attempt to impose an illegal tying arrangement on franchisees (by conditioning the franchise agreement on the purchase of logoed amenities from the two preferred vendors). There was no allegation that the vendors and the franchisor had agreed to exclude the plaintiff. The plaintiff's alleged injury was its exclusion from the logoed amenity market for the defendant franchisor's franchisees. The case was dismissed for failure to allege antitrust injury. On appeal, we observed that the Sixth Circuit "has been reasonably aggressive in using the antitrust injury doctrine to bar recovery where the asserted injury, although linked to an alleged violation of the antitrust laws, flows directly from conduct that is not itself an antitrust violation." *Valley Products*, 128 F.3d at 403.

As the above discussion of *Axis*, *Hodges* and *Valley Products* demonstrates, the facts and holdings of those cases provide no support for the defendants' proposed interpretation of the "necessary predicate" language in *Hodges*. In none of these cases was a complaint dismissed for failure to allege antitrust injury based on a defendant's claim that it *could* have caused the same injury without committing the alleged violation. Rather, the complaints were dismissed for failure to allege antitrust injury because each of the defendants had taken an action that it was lawfully entitled to take, independent of the alleged antitrust violation, which was the actual, indisputable, and sole cause of the plaintiff's injury.

In *Axis*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury – its exclusion from competing in the armature winding machine market – admittedly flowed not from the anticompetitive effects of the allegedly illegal purchase, but from its lack of access to "impenetrable" patents. 870 F.2d at 1107. In *Hodges*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury – its exclusion from competing in the shuttle services from the airport to the Opryland site owned by defendants – actually flowed not from the anticompetitive effects of an allegedly unlawful market division agreement, but from the defendants' "lawful refusal to grant plaintiffs access to their private property." 26 F.3d at 39. In *Valley Products*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury – its exclusion from competing in the franchisor's logoed amenity market – actually flowed, not from the anticompetitive effects of an allegedly unlawful tying arrangement, but from the defendant's lawful termination of a vendor agreement.[18] Thus, in reality, we have only dismissed a case for failure to allege that an antitrust violation is the "necessary predicate" for the plaintiff's injury where it has been apparent from the face of the complaint that actual and unequivocally legal action by the defendant would have caused plaintiff's injury, even if there had been no antitrust violation.

Application to this case of the "necessary predicate" test, as we have applied it in the cases which are the subject of the certified question, demonstrates that the district court correctly refused to dismiss these complaints for failure to allege antitrust injury. In essence, as exposed by the *per se* analysis above, *see supra* Part II.A., the complaints allege a

[18]This court's decision in *Watkins & Son Pet Supplies v. Iams Co.*, 254 F.3d 607 (6th Cir. 2001), similarly found no antitrust injury where the plaintiff's alleged injury – its exclusion from the market – flowed from the termination of its distributorship, not from the defendants' allegedly illegal distribution restraints.

plain vanilla horizontal agreement to restrain trade in the form of a multi-million dollar cash payment in consideration for forbearance by Andrx from selling on the market a product that it was ready and able to sell at a price lower than that charged by HMR for the patented product. There is nothing on the face of the complaint that suggests, much less establishes as a matter of law, that there was any physical or "impenetrable" legal impediment to Andrx's production and sale of its FDA-approved generic product. Indeed, some plaintiffs allege that HMR's patent infringement suit against Andrx was a "sham." JA 948, ¶ 101; JA 949, ¶¶ 103-04; JA 154, ¶ 53. Nor can the defendants identify a lawful right that they had and exercised and that indisputably caused plaintiffs' injury. Thus, the complaint may be fairly construed as alleging that the *per se* illegal Agreement with its $89 million payment, not HMR"s disputed 45%-18 patent, constituted the "necessary predicate" for Andrx's decision to keep its FDA-approved 55%-18 generic product off the market and HMR free from *any* generic product competition. The fact that Andrx could have unilaterally, and legally, decided not to bring its generic product to a manifestly profitable market has no relevance in assessing whether the plaintiffs adequately alleged that the antitrust violation was the necessary predicate for their injury.[19]

What remains is the defendants' contention that Andrx would have stayed out of the market even absent the Agreement and the payment of $40 million per year because Andrx feared incurring damages in the patent infringement litigation. Proof of allegations on the face of this complaint and reasonable inferences therefrom, however, could persuade a trier of fact that had HMR been confident of the

[19]In addition, the defendants' position, if adopted, risks undermining a basic premise of antitrust law that, as the district court observed, in many instances, an otherwise legal action – *e.g.* setting a price – becomes illegal if it is pursuant to an agreement with a competitor. Under the defendants' view, such an action would never cause antitrust injury because a defendant *could* have unilaterally and legally set the same price.

independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished. Under the aegis of the complaint and inferences, a fact trier could also find that even if it is a "prudent" industry practice for a generic manufacturer to stay out of the market until the resolution of patent infringement litigation, Defs. Br. at 33, in this case, the patent infringement suit was a "paper tiger" incapable of deterring the generic producer from entering the market as soon as the FDA approved its product – as it had formally advised the patent court. If proved to be true, it would almost necessarily follow that the plaintiffs' injury flowed from the Agreement and payment of $40 million per year. At this stage of the litigation, we must leave this dispute for the trier of fact to evaluate.

III. CONCLUSION

For the foregoing reasons, we answer both of the district court's certified questions as follows: it properly resolved the questions that it put to us in the course of denying defendants' motions to dismiss and granting the plaintiffs' motions for summary judgment that the defendants had committed a per se violation of the antitrust laws.