UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE: CARDIZEM CD ANTITRUST LITIGATION,

Master File No. 99-md-1278
MDL No. 1278

THIS DOCUMENT RELATES TO:
ALL ACTIONS,

Honorable Nancy G. Edmunds

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ORDER NO. 12

MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS' MOTIONS TO DISMISS

Defendant Hoechst Marion Roussel, Inc. ("HMRI"), a wholly owned subsidiary of Defendant Hoechst Aktiengesellschaft ("Hoechst AG"), is the manufacturer of the brand name prescription heart drug Cardizem CD which consists of a once-daily dosage of the chemical compound diltiazem hydrochloride. Cardizem CD is widely prescribed for the treatment of chronic chest pains (angina), high blood pressure (hypertension), and for the prevention of heart attacks and strokes. Until June 23, 1999, when Defendant Andrx Pharmaceuticals, Inc. ("Andrx") began to sell Cartia XT, the first generic bioequivalent to Cardizem CD, Defendant HMRI had a monopoly in the $700-million-plus annual United States market for Cardizem CD and its generic bioequivalents.

These cases involve claims that the Defendants violated section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and various state antitrust and unfair competition statutes.

Plaintiffs allege the following contract, combination or conspiracy in restraint of trade: Defendant Andrx developed a generic drug which is the bioequivalent to the Hoechst Defendants' prescription drug Cardizem CD. Andrx's generic drug was approved by the FDA for sale and could have entered the U.S. market on or about July 9, 1998. Andrx, however, did not enter the market at that time because it had agreed with its horizontal competitor, HMRI, that it would delay the entry of its generic version of Cardizem CD in exchange for, *inter alia*, non-refundable payments of $40 million per year from HMRI. Plaintiffs allege that this agreement is embodied in a September 24, 1997 document executed by Defendants HMRI and Andrx (the "HMRI/Andrx Agreement").

The HMRI/Andrx Agreement was executed eight days after the FDA preliminarily approved Defendant Andrx's generic drug as the first AB-rated generic bioequivalent for Cardizem CD. It is alleged that, under the terms of the Agreement, Defendant Andrx agreed not to market its generic drug when it received FDA approval and not to transfer, assign, or relinquish its right to a 180-day exclusivity period that Andrx would enjoy once it finally did begin to market its generic version of Cardizem CD, and Defendant HMRI paid Andrx $89.83 million, beginning on the date the Andrx product received FDA approval. Thus, it is alleged that the HMRI/Andrx Agreement not only protected HMRI from competition from Andrx, but it also protected HMRI from competition from other generic competitors because Andrx agreed not to give up its FDA first-filer status, thus blocking and delaying other drug manufacturers from introducing generic versions of Cardizem CD in the United States market; i.e., Andrx's delayed entry would postpone the start of its 180-day exclusivity period, and Andrx's agreement not to give up or transfer its right to that

180-day period of exclusivity would preclude other generic competitors from entering the market until that 180-day exclusivity period expired.

After these actions were first filed in August 1998, Defendants' HMRI/Andrx Agreement was widely publicized in the media, was condemned by public officials and health care payors injured by Defendants' acts, and was investigated by the FTC.[1] As a result, Plaintiffs' allege that, in June 1999, HMRI and Andrx terminated their Agreement, settled their patent infringement action, and Andrx began to market Cartia XT, its generic version of Cardizem CD.

In addition to the above, it is also alleged that Defendants have engaged in a continuing pattern of unlawful anticompetitive conduct to delay the introduction of generic bioequivalent versions of Cardizem CD in the United States. The targets have included, at varying times, co-Defendant Andrx, and Hoechst AG's former joint venture partner, Biovail International Corporation ("Biovail"). The alleged pattern includes the Hoechst Defendants' filing and continued prosecution of a baseless patent infringement action, breached agreements with Biovail, false misrepresentations made to the United States Food & Drug Administration ("FDA"), and manipulation of a Consent Decree with the United States Federal Trade Commission ("FTC") which was designed to prevent the anticompetitive trade practices which are the subject of Plaintiffs' suits.

This matter is now before the Court on numerous motions brought by Defendants requesting dismissal of Plaintiffs' complaints in this multidistrict antitrust litigation pursuant

[1]The FTC recently filed suit against Defendants HMRI and Andrx based on its investigation of this matter. See Plfs.' 3/22/00 Notice of FTC Action and Defendant Andrx's 4/18/00 Resp. to Plfs.' Notice.

to Rules 12(b)(2) and (12)(b)(6) of the Federal Rules of Civil Procedure. At issue are: (1) State Law Plaintiffs' Coordinated First Amended Class Action Complaints alleging that Defendants HMRI, Hoechst AG, and Andrx committed a per se violation of various state antitrust laws and were unjustly enriched in violation of various states' common laws; (2) Sherman Act Class Plaintiffs' Consolidated Amended Class Action Complaint alleging a section 1, Sherman Act violation against Defendants HMRI and Andrx under either a per se or rule of reason analysis of the reasonableness of the Defendants' alleged restraint of competition; (3) Individual Sherman Act Plaintiffs' Amended Complaint brought by the Kroger Co., Albertson's, Inc., the Stop & Shop Supermarket Co., Eckerd Corporation, Walgreen Co. and Hy-Vee, Inc. against Defendants HMRI and Andrx alleging a per se violation of section 1 of the Sherman Act; and (4) Individual Sherman Act Plaintiffs' Complaint brought by Plaintiffs CVS Meridian, Inc. and Rite Aid Corporation against Defendants HMRI and Andrx alleging a violation of section 1 of the Sherman Act under either a per se or rule of reason analysis.

For the reasons stated below, this Court **DENIES**: (1) Defendant Hoechst AG's motion to dismiss the Minnesota action (Aetna U.S. Healthcare, No. 99-73329) for lack of personal jurisdiction and failure to state a claim; (2) Defendant Hoechst AG's motion to dismiss the Tennessee action (Larry S. Sizemore, No. 99-73345) for lack of personal jurisdiction and failure to state a claim; (3) Defendant HMRI's motion to dismiss the Sherman Act Class Plaintiffs' Amended Complaint (Louisiana Wholesale, No. 99-73259, and Duane Reade, No. 99-73870); (4) Defendant HMRI's motion to dismiss Sherman Act Individual Plaintiffs' Amended Complaint (Kroger, et al., No. 99-73735); (5) Defendant

HMRI's motion to dismiss Sherman Act Individual Plaintiffs' Complaint (CVS Meridian and Rite Aid Corp., No. 99-75036); (6) Defendant HMRI's motion to dismiss State Law Plaintiffs' Coordinated First Amended Complaints (Nos. 99-75070, 99-73422, 99-73412, 99-73871, 99-74262, 99-73667, 98-74043, 99-73239, 99-73845, 99-73713, 99-74377, 99-73190, 99-73345, 99-73981, and 99-73666); (7) Defendant Andrx's motion to dismiss the Coordinated "Indirect Purchaser" Complaints (Nos. 98-74043, 99-75070, 99-73422, 99-73412, 99-73871, 99-74262, 99-73239, 99-73667, 99-73845, 99-73713, 99-74377, 99-73190, 99-73345, 99-73981, and 99-73666); and (8) Defendant Andrx's motion to dismiss the Consolidated "Direct Purchaser" Complaint and the two additional "Direct Purchaser" Complaints (Nos. 99-73870, 99-73259, 99-73735, and 99-75036).

I. Facts

A. The Parties

1. Defendants

a. Hoechst Defendants

On or about June 25, 1995, Defendant Hoechst AG bought Marion Merrell Dow, Inc. ("Dow"), a major pharmaceutical company. Dow's best-selling prescription drug product was Cardizem CD. After the acquisition, Dow's name was changed to HMRI.[2] HMRI is responsible for developing, distributing, advertising and selling Cardizem CD throughout the United States.

[2]As of December 15, 1999, HMRI has changed its name again to Aventis Pharmaceuticals, Inc. See HMRI's 3/2/00 Notice of Name Change and Disclosure of Corporate Affiliations and Financial Interest.

HMRI is an indirectly wholly owned subsidiary of Hoechst AG, a German company, whose stock is publicly traded on the Frankfurt Stock Exchange and until November 26, 1999 was traded on the New York Stock Exchange. Hoechst AG is a 96% owned, direct subsidiary of Aventis, a French corporation, which prior to December 15, 1999, was named Rhone-Poulenc, S.A. Aventis stock is publicly traded on the Frankfurt Stock Exchange, the Paris Bourse, and the New York Stock Exchange. State Law Plaintiffs sue both Hoechst Defendants. All other Plaintiffs sue only HMRI.

b. Andrx

Andrx develops, manufactures and markets controlled-release drugs. It has developed a generic bioequivalent to Cardizem CD, recently marketed under the trade name of Cartia XT. Andrx's generic version of Cardizem CD was preliminarily approved by the FDA for sale in the U.S. in 1997, was given final FDA approval in July 1998, and was licensed for sale in Canada during the alleged class periods.

Plaintiffs allege that, pursuant to the illegal HMRI/Andrx Agreement, the Hoechst Defendants paid Andrx $89.83 million not to sell its generic version of Cardizem CD in the U.S. before June 1999 and to use its FDA first filer status to block other manufacturers from introducing generic Cardizem CD in the U.S.

2. Plaintiffs

a. State Law Plaintiffs

Plaintiffs are indirect purchasers of Cardizem CD or Cartia XT in Alabama, California, D.C., Illinois, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin. Plaintiffs claim violations of the antitrust and consumer protection statutes in eight of the states (California, D.C., Michigan, Minnesota, New York, North Carolina, Tennessee and Wisconsin)[3] and seek recovery based on common law claims of unjust enrichment in all ten states. Plaintiffs bring their respective actions on behalf of state-wide indirect-purchaser classes defined as (1) all persons and entities who or which have paid and/or co-paid pharmacies in the Indirect Purchaser States for Cardizem CD and Cartia XT

[3]State Law Plaintiffs allege that the HMRI/Andrx Agreement is a conspiratorial, horizontal market allocation agreement that was designed to prevent any generic competition for Cardizem CD in the United States marketplace. Specifically, Plaintiffs allege that: (1) the Agreement is between horizontal competitors in the same chain of distribution and has the effect of allocating market share, restraining trade, and fixing prices; (2) the purpose and effect of the Agreement was to allow the Hoechst Defendants to continue their monopoly market share while continuing to set artificially high prices for Cardizem CD in the indirect purchaser states and throughout the United States; and (3) constitutes a per se violation of the antitrust laws in the states of California, North Carolina, Wisconsin, Tennessee, New York, Minnesota, Michigan and in the District of Columbia (¶¶ 111, 124, B(v-viii), C(vi), E(iii), F(v), G(iv), H(viii), I(vi) and J(v)). Plaintiffs further allege that the relevant product and geographic market is the market for Cardizem CD and its FDA-approved AB-rated generic bioequivalents in the United States (¶ 133). They also allege the following anticompetitive effects (¶ 135): As a result of Defendants' illegal acts, combinations, conspiracies and their resulting exclusionary, monopolistic and unlawful trade restraints described in the complaint, the prices for Cardizem CD and its generic bioequivalents have been fixed, raised, maintained and stabilized at artificially high and noncompetitive levels by Defendants while a 100% market share has been maintained between them, free from natural competition, thus causing those who pay for Cardizem CD and Cartia XT sold in the Indirect Purchaser States to pay annually many millions of dollars more for Cardizem CD and Cartia XT than they would have had to pay under normal conditions of competition in the absence of such illegal restraints of trade.

dispensed pursuant to doctors' prescriptions; and (2) in Alabama, California and New York, separate classes of retail pharmacies located in such Indirect Purchaser States which have purchased Cardizem CD or Cartia XT for resale to individual users of Cardizem CD and Cartia XT during the Conspiracy Class Period or Monopolization Class Period.

b. Sherman Act Class Plaintiffs

Plaintiffs Louisiana Wholesale Drug Co., Inc., Duane Reade, Inc., and Kinray, Inc., bring this action alleging a violation of section 1 of the Sherman Act on behalf of themselves and as representatives of a class defined as "all persons, or assignees of such persons, who have directly purchased Cardizem CD from Hoechst at any time during the period July 9, 1998 through and after the date hereof until the effects of Defendants' illegal contract, combination or conspiracy cease" (Complaint, ¶ 11).[4]

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[4]The Sherman Act Class Plaintiffs allege (¶ 59) that Defendants HMRI and Andrx engaged in a continuing agreement, combination or conspiracy in restraint of trade and commerce in violation of section 1 of the Sherman Act, 15 U.S.C. § 1. Specifically, they allege that the Defendants' contract, combination, or conspiracy has included concerted action and undertakings between Defendants with the purpose and effect to fix, raise, maintain and stabilize the price of Cardizem CD (¶ 60). They further allege that Defendants entered into an illegal agreement where Andrx agreed not to sell its generic version of Cardizem CD in U.S. commerce in exchange for payments of tens of millions of dollars by HMRI; thereby depriving all purchasers of the ability to purchase Cardizem CD at a competitive price (¶ 61). Plaintiffs allege that the HMRI/Andrx Agreement is either a per se violation of section 1 of Sherman Act or, in the alternative, a violation of § 1 under a rule of reason analysis, because its purpose and effect was to unreasonably restrain competition in the sale of Cardizem CD and generic versions of Cardizem CD (¶¶ 64, 65).

The Sherman Act Class Plaintiffs allege that the HMRI/Andrx Agreement is a horizontal market allocation agreement and is illegal per se under controlling federal case law because the Agreement allocated the entire United States market to HMRI and required HMRI to pay Andrx a portion of its illegally inflated profits. They further allege that the Agreement was an illegal price-fixing agreement because its purpose and effect was to ensure that HMRI would continue to be able to market Cardizem CD free from generic competition and thus would be able to charge supra-competitive prices for

Plaintiff Louisiana Wholesale is a Louisiana corporation that has purchased the prescription drug Cardizem CD directly from Hoechst during the class period. Plaintiff Duane Reade is a publicly held corporation organized under Delaware laws and has its principal place of business in New York, New York. During the class period, Duane Reade purchased annually between $500,000 and $800,000 of Cardizem CD from Defendant HMRI through its wholesaler Kinray, Inc. Duane Reade is the assignee of Kinray, Inc.'s antitrust claims with respect to these Cardizem CD purchases from Defendant HMRI. Plaintiff Kinray, Inc. is a New York Corporation with its principal place of business in Whitestone, New York. It purchased Cardizem CD directly from Defendant HMRI and sold it to Duane Reade during the class period. Kinray has assigned its antitrust claims with respect to these purchases to Duane Reade.

c. Individual Sherman Act Plaintiffs

There are two Individual Sherman Act actions and two different sets of Individual Sherman Act Plaintiffs.

The first action, No. 99-73735, is brought by the following Plaintiffs who own and operate retail stores in several states where prescription drugs are dispensed to the public

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Cardizem CD (¶ 50). Plaintiffs allege that the HMRI/Andrx Agreement brought HMRI protection not only from Andrx's generic version of Cardizem CD but also protection from generic competition from Biovail and Faulding (which had received tentative FDA approval for its product on or about October 26, 1998) because these generic competitors could not market their products until Andrx's 180-day exclusivity period ended (¶ 51). They allege that the anticompetitive effects of Defendants' acts included: (1) fixing, raising, maintaining, or stabilizing the prices for Cardizem CD at an artificially high and non-competitive level; (2) restraining, suppressing, and eliminating competition in the production and sale of Cardizem CD; and (3) depriving Cardizem CD purchasers of the benefits of free and open competition (¶ 66).

and who purchased Cardizem CD directly from Defendant HMRI during the relevant time period: (1) The Kroger Co., an Ohio corporation with its principal place of business in Ohio; (2) Albertson's Inc., a Delaware corporation with its principal place of business in Idaho; (3) The Stop & Shop Supermarket Co., a Delaware corporation with its principal place of business in Massachusetts; (4) Eckerd Corporation, a Delaware corporation with its principal place of business in Florida; (5) Walgreen Co., an Illinois corporation with its principal place of business in Illinois; and (6) Hy-Vee, Inc., an Iowa corporation with its principal place of business in Iowa. Plaintiffs Eckerd, Walgreen, and Hy-Vee also bring this action as an assignee of their pharmaceutical wholesalers with respect to those companies' purchases of Cardizem CD directly from Defendant HMRI that were subsequently resold to them during the relevant time period.[5]

The second Individual Sherman Act case, No. 99-75036, is brought by two Plaintiffs: (1) CVS Meridian, Inc., a New York corporation with its principal place of business in Rhode Island; and (2) Rite Aid Corp., a Delaware corporation with its principal place of business in Pennsylvania. Each Plaintiff purchases substantial quantities of

[5]The Individual Kroger Sherman Act Plaintiffs similarly allege that Defendants HMRI and Andrx violated section 1 of the Sherman Act. They similarly allege that the HMRI/Andrx Agreement is a horizontal market allocation agreement and illegal per se (¶ 39, 42). They allege that the Agreement ensured that HMRI would continue to be able to market Cardizem CD entirely free from generic competition and ensured that HMRI would continue to impose supra-competitive monopoly prices on Plaintiffs and other purchasers. They further allege that, but for the HMRI/Andrx Agreement, other generic competitors like Biovail and Faulding would have been able to enter the market sooner and would have been able to compete with Cardizem CD, and Plaintiffs would have been free to substitute lower-priced generic versions of Cardizem CD thus allowing competition and market pressure to decrease the price for Cardizem CD (¶¶ 39-40). These Plaintiffs do not allege a section 1, Sherman Act violation under a rule of reason analysis.

pharmaceutical products and other goods for resale to the public, and, during the relevant time period, purchased Cardizem CD from Defendant HMRI through wholesalers who have assigned their antitrust claims with respect to these purchases to Plaintiffs.[6]

B. Relevant Statutory and Regulatory Framework

The manufacture and distribution of pharmaceutical drugs are regulated by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (1994). Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 after concluding that the Act's

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[6]These Individual Sherman Act Plaintiffs similarly allege that Defendants HMRI and Andrx violated section 1 of the Sherman Act under either a per se or rule of reason analysis. Specifically, Plaintiffs allege that, under the terms of the HMRI/Andrx Agreement, Andrx agreed not to market its generic version of Cardizem CD in the United States until a final and appealable judgment was entered in a pending patent infringement action between HMRI and Andrx; HMRI agreed to make nonrefundable payments of $40 million per year to Andrx, to be increased to $100 million per year retroactively if Andrx prevailed in the patent suit; and both agreed that Andrx was free to (and did in fact) market a generic version of Cardizem CD outside the United States (¶ 16). They further allege that the purpose and effect of the HMRI/Andrx Agreement was to eliminate all competition to HMRI in the United States by generic manufacturers of Cardizem CD; that, because generic drugs are typically priced at 30% or more below brand-name drugs, the Agreement deprived consumers of lower-priced alternatives to Cardizem CD; and the Agreement protected HMRI from competition from Andrx for approximately one year and also protected HMRI from competition from Biovail and Faulding and any other generic manufacturer because of the 180-day exclusivity period that Andrx would enjoy once it did go to market with its generic version of Cardizem CD (¶¶ 18, 19). The alleged anticompetitive effects of Defendants' illegal conduct include decreased competition and thus fewer choices and artificially higher prices for Plaintiffs (¶ 24).

Plaintiffs allege that the HMRI/Andrx Agreement had no reasonable pro-competitive objective and thus constitutes a per se violation of section 1 of the Sherman Act (¶ 25). They alternatively allege that the Agreement violates section 1 under a rule of reason analysis because it has unreasonably restrained competition in the market for Cardizem CD and its bioequivalents in the United States (¶ 26). Finally, Plaintiffs allege that they have been injured in the form of overcharges as a result of Defendants' illegal acts which forced them to pay artificially high prices for Cardizem CD and denied them the opportunity to purchase a less expensive generic equivalent to Cardizem CD (¶ 27).

"cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the market place." Mylan Pharm., Inc. v. Shalala, 81 F. Supp.2d 30, 32 (D. D.C. 2000). The Hatch-Waxman Amendments, 21 U.S.C § 355 (1994), embody Congress' intent "to make available more low cost generic drugs" and its attempt "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Id. (internal quotes and citations omitted).

"[T]he Hatch-Waxman Amendments established new guidelines for the approval of generic drugs. Generic drug makers were permitted to file an Abbreviated New Drug Application ("ANDA") which incorporated data that the 'pioneer' manufacturer had already submitted to the FDA regarding the pioneer drug's safety and efficacy. In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is 'bioequivalent' to the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv). As protection for pioneer drug makers, the applicant is also required to certify in one of four ways that the generic drug will not infringe on any patent which claims the pioneer drug. See id. at § 355(j)(2)(A)(vii)." Mylan Pharm., 81 F. Supp. 2d at 32.

Applicable here is the fourth type of certification. Paragraph IV certification "permits the applicant to allege that the patent for the pioneer drug is either invalid or will not be infringed by the marketing of the generic drug. See id. at § 355(j)(2)(A)(vii)(IV)." Mylan Pharm., 81 F. Supp. 2d at 32. As the District Court for the District of Columbia recently observed, "[a] generic drug manufacturer's filing of a so-called 'Paragraph IV' certification

has important legal ramifications. It automatically creates a cause of action for patent infringement. Upon receiving notice of a Paragraph IV certification's filing, the patent holder or pioneer manufacturer has 45 days within which to file suit against the generic manufacturer. See id. at § 355(j)(5)(B)(iii). If such an action is brought, the FDA cannot approve the generic manufacturer's ANDA for 30 months. See id. However, if the court hearing the infringement action rules before the expiration of the 30-month period that the patent at issue is 'invalid or not infringed,' then 'the approval shall be made effective on the date of the court decision[.]' Id. at § 355(j)(5)(B)(iii)(I)." Mylan Pharm., 81 F. Supp. 2d at 32-33.

To encourage competitors to bring cheaper generic drugs to market, and acknowledging that they will likely incur "potentially substantial litigation costs associated with challenging pioneer drug makers' patents, the Hatch-Waxman Amendments provide an added incentive for generic drug producers to file Paragraph IV certifications. The first generic manufacturer to file an ANDA containing a Paragraph IV certification with respect to a specific patent is awarded a 180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent. In other words, no other ANDA for the same generic drug product will be approved during those 180 days." Id. at 33.

Section 355(j)(5)(B)(iv) provides that:

> If the [ANDA] contains a certification described in [Paragraph IV] and is for a drug for which a previous application has been submitted under this subsection [containing a Paragraph IV] certification, the application shall be made effective not earlier than one hundred and eighty days after –

> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
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> whichever is earlier.

Id. (quoting 21 U.S.C. § 355(j)(5)(B)(iv)). Accordingly, the 180-day period of exclusivity "can be triggered in one of two ways–either (1) when the generic producer begins commercial marketing of its drug (the 'commercial marketing trigger'), or (2) when there is a court decision finding the pioneer drug maker's patent invalid or not infringed (the 'court-decision trigger')." Mylan Pharm., 81 F. Supp. 2d at 33 (footnote omitted).

C. Background

1. Cardizem CD

In 1982, Marion Merrell Dow ("Dow"), HMRI's predecessor, introduced the pioneer drug in the United States containing diltiazem hydrochloride as an active ingredient for treating hypertension and angina. This drug used an immediate release delivery method and was patented and sold under the brand name "Cardizem." The problem with immediate release drugs is that they do not provide for a continuing and slow release of a drug into the patient's bloodstream, so Cardizem patients had to take three or four doses a day. Some patients would forget a dose and this in turn would cause undesirable fluctuations in diltiazem concentrations in the blood. To remedy this problem, Dow introduced an improved, twice-a-day product called "Cardizem SR" in 1989. In 1992, Dow introduced its once-a-day diltiazem hydrochloride formulation under the name Cardizem

CD. Cardizem CD's single administration of diltiazem hydrochloride is based on a sustained-release delivery method patented by Elan Corp., P.L.C. ("Elan"), an Irish company. Dow and Carderm Capital L.P., a limited partnership, were the licensees of Elan's U.S. patents for sustained release delivery and absorption of Cardizem CD. Cardizem CD quickly replaced Cardizem SR as the most popular hydrochloride product in the U.S.

The U.S. patent on the compound diltiazem hydrochloride, the active ingredient in Cardizem CD, originally expired in February 1988 but was extended by legislation until November 1992. Thus, it is alleged that after November 1992, Dow for the first time began to face the threat of competition from generic pharmaceutical manufacturers. (State Law Plfs. Complt. ¶ 58).

2. Development of Generic Bioequivalent - Biovail

As the Eighth Circuit recently observed, "[d]iltiazem was a pioneer new drug, which means that the Cardizem products enjoyed a ten-year period of market exclusivity under the Hatch-Waxman amendments to the Food, Drug, and Cosmetics Act." Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc., 93 F.3d 511, 513 (8th Cir. 1996). "Cardizem products were immensely successful, generating sales of $1.1 billion in 1992 alone. By the early 1990's, competing drug manufacturers were anxious to penetrate the diltiazem market with less costly alternatives." Id.

In 1993, Biovail, a Canadian corporation, was in the process of developing a bioequivalent formulation of once-daily diltiazem hydrochloride ("QD Diltiazem") to compete with Cardizem CD. In June 1993, Hoechst AG, through its subsidiary Hoechst-

Roussel Pharmaceuticals, Inc. ("HRP"), entered into an Agreement with Biovail for the joint development and exploitation of QD Diltiazem drugs which HRP and Biovail intended to sell under the trademark "Tiazac." Tiazac, like Cardizem CD, is administered once a day and provides the patient with diltiazem hydrochloride in the bloodstream throughout the day. (¶¶ 59-62).

HRP filed a New Drug Application (NDA) for Tiazac with the FDA certifying its safety and effectiveness. On September 30, 1993, HRP gave notice to Dow and Carderm of HRP's NDA and certified that HRP's submission of its NDA to the FDA did not constitute an act of infringement of the Elan-licensed patents. Dow and Carderm responded on November 11, 1993 with a patent infringement lawsuit in the District of New Jersey which HRP characterized as frivolous. The filing of this suit served to stay HRP's NDA for 30 months. In late 1994, Hoechst (parent of HRP) agreed to acquire Dow and HRP terminated its joint venture with Biovail. After the acquisition, Dow became HMRI. (¶¶ 63-69).

In April 1995, Biovail sued Hoechst and others for breach of contract and antitrust violations, and Hoechst, Dow and Biovail then entered into a Settlement Agreement and Release resolving the pending Dow/HRP patent infringement action and the Biovail litigation against Hoechst and others. As part of the Settlement Agreement, Dow (HMRI's predecessor) agreed not to "initiate any regulatory proceedings or legal actions challenging or contesting in any manner whatsoever the Product, infringement relating to the Product or regulatory approvals of the Product now or in the future." "Product" was defined to include Tiazac and "any improvements thereto or any formulation thereof alone

or in combination with at least one other active ingredient." Biovail was also assigned the rights to the NDA for Tiazac previously filed by HRP. (¶¶ 70-73).

Subsequently, the FTC investigated the proposed acquisition of Dow by Hoechst, and that investigation was settled when the parties agreed to enter into a Consent Order that was proposed on September 26, 1995 and became final on April 17, 1996. That Consent Order contained an express provision requiring that the Hoechst Defendants give Biovail a letter of reference to the toxicology data filed with the FDA in support of Dow's NDA covering Cardizem CD. Specifically, the FTC Consent Order compelled the Hoechst Defendants to "make the necessary filings with the FDA authorizing the FDA to refer to the appropriate section(s) of Dow's [now HMRI's] NDA No. 18-602 for such data (including, but not limited to, pharmacology and toxicology data) in support of Biovail NDA No. 20-401 for Biovail Diltiazem Products, including any supplemental NDAs or related NDAs." (¶¶ 74-78). "Biovail Diltiazem Products" were defined in the FTC Consent Order as "the sustained release and/or extended release diltiazem products that Hoechst was developing with Biovail pursuant to the Rights Agreement that Hoechst and Biovail entered into on June 30, 1993." (¶ 79).

On December 18, 1995, HMRI wrote to the FDA authorizing Biovail to reference the data discussed in the Consent Order "in support of Biovail's NDA No. 20401 for once-a-day dosage form of diltiazem hydrochloride, including any supplemental NDAs or NDAs related to that product." (¶ 80). Also by letter dated April 8, 1996, the FDA confirmed to Biovail that the "right of reference" was broad enough to cover "any diltiazem hydrochloride new drug application or supplement that Biovail submits." (¶ 82). Plaintiffs allege that the

purpose and intended effect of the Biovail/Hoechst Settlement Agreement, the FTC Consent Order, and the Letter of Reference was to ensure that the Hoechst Defendants would not attempt to prevent Biovail from obtaining FDA approvals for its diltiazem products, including any supplemental or related NDAs.

In the summer of 1996, the Hoechst Defendants learned that Biovail was: (1) resolving its patent dispute with Elan, which in light of the December 18, 1995 letter of reference, would have been the only remaining impediment to the FDA's approval of Biovail's generic version of Cardizem CD; (2) preparing to file an ANDA seeking approval of its generic drug; and (3) preparing to submit an NDA for its generic version of Cardizem CD which required, as a precondition to filing, the December 18, 1995 letter of reference. (¶ 86). Since drugs covered by NDA's are not subject to Para. IV Certification or the 180-day exclusivity period imposed on all ANDA filers except the first ANDA filer, Biovail's NDA filing would have been unaffected by Andrx's 1995 first-filed ANDA for its generic version of Cardizem CD. Biovail's generic version would have been promptly approved for marketing under the NDA route and allegedly would have been available in the U.S. no later than April 1998, before Andrx's ANDA was approved. (Id., ¶ 88).

Accordingly, it is alleged that the Hoechst Defendants wrote to the FDA on July 11, 1996 to attempt to limit the scope of the right of reference to Tiazac only. The Hoechst Defendants wrote to the FDA, renouncing the wording of its December 18, 1995 "right of reference" letter, and telling the FDA that the right of reference did not apply to any QD diltiazem formulations other than the one originally submitted for Tiazac, and telling the FDA that the right of reference could not be used for any new NDAs submitted by Biovail

for diltiazem-based drug products. (¶¶ 86-91). In October 1996, the Hoechst Defendants delivered a second letter to the FDA renouncing the wording of their earlier December 18, 1995 right of reference letter and stating that it did not apply to any QD diltiazem formulation other than the one originally submitted for Tiazac and further stating that it could not be used for any new NDA submitted by Biovail for diltiazem-based drug products. (Id., ¶ 91).

On November 8, 1996, the FDA advised Biovail that Defendant HMRI had expressly limited the right of reference and thus "the broader interpretation by the agency of the possible scope of the right of reference, which was conveyed to [Biovail] by letter of April 18, 1996" was inapplicable. (¶ 92). Plaintiffs allege that the Hoechst Defendants' limitation of the right of reference: (1) "plainly contradicted" the "clear wording" of the December 18, 1995 letter of reference itself; (2) constituted a breach of the Settlement Agreement and the FTC Consent Order; (3) compelled the FDA to reject Biovail's NDA filing; (4) precluded Biovail from filing an expedited NDA for generic Cardizem CD; (5) prolonged Defendants' monopoly over the Cardizem CD market; and (6) was done despite the absence of any reasonable belief in its merits and for the sole purpose of prolonging the Cardizem CD monopoly. (¶¶ 93-95).

The Hoechst Defendants also allegedly sent an Hoechst/HMRI representative to meet with Biovail's executives at Biovail's Canadian headquarters on a Sunday in August 1997, where the Hoechst/HMRI representative offered Biovail a payment of at least $20 million cash not to market its generic version of Cardizem CD before January 2000 and threatened a patent infringement suit, notwithstanding its covenant not to sue, if Biovail

filed an NDA. Biovail refused the offer and indicated its intent to file an NDA using the right of reference to expedite the process. (¶¶ 89-90).

Biovail has filed suit against Hoechst, HMRI and Carderm in the United States District Court for the District of New Jersey for, inter alia, violations of antitrust laws in connection with this conduct. On June 1, 1999, that court denied each of defendants' motions to dismiss Biovail's complaint. 39 F. Supp. 2d 750 (D. N.J. 1999). (Id., ¶¶ 94-96).

3. Development of Generic Bioequivalent - Andrx

Prior to August 1995, Defendant Andrx had been developing its own generic version of Cardizem CD, and provided samples of its proposed generic substitute for Cardizem CD to the Hoechst Defendants so they could perform their own tests to confirm that there was no infringement of the patents claiming Cardizem CD and thus avoid litigation.

On September 22, 1995, Andrx filed an ANDA for a generic version of Cardizem CD and made a Paragraph IV Certification with regard to all unexpired patents listed in the FDA's Orange Book[7] allegedly claiming Cardizem CD.

On November 28, 1995, two months after Andrx's ANDA, the U.S. Patent and Trademark Office issued the "584 Patent" to Carderm which then licensed it to HMRI. (Id., ¶ 101).

In January 1996, HMRI and Carderm filed a patent infringement suit against Andrx in the District Court for the Southern District of Florida ("HMRI/Andrx patent case"). The filing of the suit triggered the 30-month Hatch-Waxman waiting period, which expired on July 3, 1998. (Id. ¶ 102).

[7]The FDA Orange Book apparently lists the patents covering FDA approved drugs.

On April 4, 1996, Andrx amended its ANDA to specify a dissolution profile that was even more clearly distinct from that claimed by the '584 patent. (Id., ¶ 103). Despite notice of this, HMRI continued to prosecute the HMRI/Andrx patent case. Andrx also filed antitrust counterclaims against HMRI in the patent case.

On September 17, 1997, the FDA gave preliminary approval to Andrx's amended ANDA for its generic version of Cardizem CD. Thus, upon expiration of the 30 month waiting period in early July 1998, Andrx would be able to introduce its generic version of Cardizem CD into the U.S. market. Plaintiffs allege (¶ 108) that unless the Hoechst Defendants could come up with a way to keep their competitor's generic version off the market, they would lose their monopoly over the market for Cardizem CD and its generic bioequivalents by no later than July 9, 1998. On that date, the 30-month Hatch-Waxman waiting period would expire, and the FDA's approval of Andrx's ANDA would allow Andrx to begin marketing its generic drug notwithstanding the continued pendency of the HMRI/Andrx patent case.

On or before September 24, 1997, HMRI and Andrx entered into the HMRI/Andrx Agreement. Plaintiffs allege (¶ 111) that this collusive and anticompetitive agreement had the effect and purpose of allowing the Hoechst Defendants to continue to maintain their monopoly market share while continuing to set artificially high prices for Cardizem CD throughout the U.S. Under the Agreement, HMRI was obligated to start, as of July 9, 1998 (the date the 30-month freeze ended), making quarterly payments to Andrx of ten million dollars. The payments were to end when the HMRI/Andrx patent case, including all appeals, was finally over.

It is alleged that but for the HMRI/Andrx Agreement, Andrx would have begun marketing is generic version of Cardizem CD on or shortly after July 9, 1998, and the FDA could have approved other generic versions of Cardizem CD after the 180-day period of exclusivity granted to Andrx under Hatch-Waxman expired.

On August 20, 1998, the first of these state law class actions was filed in California, and on June 9, 1999, HMRI and Andrx announced that they had agreed to settle the HMRI/Andrx patent suit. They claim here that the settlement was possible because Andrx amended its ANDA and reformulated its generic version of Cardizem CD. At the time of settlement, HMRI paid Andrx an additional $50,700,000, bringing its total payments to Andrx to $89,830,000.

Since June of 1999, Cartia XT, Andrx's generic version of Cardizem CD, has been sold at a substantial discount to the price of Cardizem CD, and it has captured nearly half of the U.S. market for Cardizem CD and its generic bioequivalents.

D. Defendants' Motions to Dismiss

Presently pending before the Court are Defendants' motions to dismiss raising issues concerning:

1. Defendants' immunity from antitrust liability under the *Noerr-Pennington* Doctrine;
2. State Law and Sherman Act Plaintiffs' failure to allege antitrust injury–an essential element of Plaintiffs' antitrust claims;
3. State Law and Sherman Act Plaintiffs' failure to allege any legally cognizable anticompetitive effects;
4. Preemption/Exemption of Plaintiffs' claims;

5. Plaintiffs' lack of standing to enforce the FTC Consent Order regarding Biovail;
6. State Law Plaintiffs' failure to state claims under the antitrust statutes of Tennessee and Wisconsin (interstate vs. intrastate commerce issue);
7. State Law Plaintiffs' failure to state claims based on principles of unjust enrichment;
8. Whether the Tennessee or Minnesota Plaintiffs have personal jurisdiction over Defendant Hoechst AG; and
9. Plaintiffs' failure to state an antitrust claim that allows the reasonableness of the alleged restraint of trade to be analyzed under either a *per se* or rule of reason analysis.

II. Standard of Review - Motion to Dismiss

To survive a motion to dismiss under Rule 12(b)(6), a "complaint must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under some viable legal theory." Scheid v. Fanny Farmer Candy Shops, Inc., 859 F.2d 434, 436 (6th Cir. 1988) (internal quotation marks and citations omitted). The Court "must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of his claims that would entitle him to relief." In re DeLorean Motor Co., 991 F.2d 1236, 1240 (6th Cir. 1993). "[W]hen an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." Sinay v. Lamson & Sessions Co., 948 F.2d 1037, 1039-40 (6th Cir. 1991). "[A] complaint should be dismissed for failure to state a claim only where 'it appears beyond a doubt that the plaintiff can prove no set of

facts in support of his claim which would entitle him to relief.'" Monette v. Electronic Data Sys. Corp., 90 F.3d 1173, 1189 (6th Cir. 1996) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)).

"Although this standard for Rule 12(b)(6) dismissals is quite liberal, more than bare assertions of legal conclusions is ordinarily required to satisfy federal notice pleading requirements." Scheid, 859 F.2d at 436 (citing 5 C. Wright & A. Miller, Federal Practice & Procedure § 1357, at 596 (1969)). "The essential elements of a private antitrust claim must be alleged in more than vague and conclusory terms to prevent dismissal of the complaint on a defendant's 12(b)(6) motion." Crane & Shovel Sales Corp. v. Bucyrus-Erie Co., 854 F.2d 802, 805 (6th Cir. 1988).

III. Analysis

A. Immunity under the *Noerr-Pennington* Doctrine

Issues: (1) Whether the HMRI/Andrx Agreement is "incidental to" a valid effort to influence governmental action and thus immune from antitrust liability under the *Noerr-Pennington* Doctrine; (2) Whether Plaintiffs have failed to allege facts showing that the HMRI/Andrx Patent Infringement Litigation was a Sham; and (3) Whether Hoechst's communications with the FDA regarding the scope of the Right of Reference Granted to Biovail are protected under the *Noerr-Pennington* doctrine?

1. *Noerr-Pennington* Immunity for Conduct "Incidental To" Non-Sham Governmental Petitioning

Defendant HMRI argues that, because the HMRI/Andrx Agreement is an "incidental effect" of non-sham patent infringement litigation; i.e., it is conduct reasonably attendant to litigation (a protected activity), it is immune from antitrust liability under the *Noerr-Pennington* doctrine. HMRI's argument has two premises; the first presents a legal

argument, and the second presents a factual one: (1) private agreements, like the HMRI/Andrx Agreement, can be considered "incidental effects" of litigation and thus fall within the protection of the *Noerr-Pennington* immunity doctrine; and (2) HMRI's initiation and continued prosecution of the HMRI/Andrx patent infringement litigation was a valid effort to influence government action; i.e., it was not sham litigation. If the Court disagrees with HMRI's initial legal argument and finds that the HMRI/Andrx Agreement is separate and distinct activity that cannot be considered an incidental effect of the HMRI/Andrx patent litigation, there is no need to address the factual premise of Defendant's argument; i.e., that Plaintiffs have failed to alleged facts showing that HMRI's filing and continued prosecution of the HMRI/Andrx patent case was a sham. Accordingly, this Court addresses the legal argument first.

a. *Noerr-Pennington* Doctrine

The *Noerr-Pennington* doctrine immunizes defendants from antitrust liability for anticompetitive harm that results from government-petitioning activity, including litigation. "Concerted efforts to restrain or monopolize trade by petitioning government officials are protected from antitrust liability". Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988). "The doctrine stands for the proposition that the exercise of First Amendment rights in seeking governmental action -- including litigation -- cannot form the basis of antitrust liability, even if the action injures a competitor." TRW Financial Sys., Inc. v. UNISYS Corp., 835 F. Supp. 994, 1011, n. 25 (E.D. Mich. 1993).

The doctrine has developed from a trio of Supreme Court decisions. See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine

Workers of Am. v. Pennington, 381 U.S. 657 (1965); and California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972). "In Noerr and Pennington, the Court held that 'the Sherman Act does not prohibit . . . persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or monopoly.' Noerr, 365 U.S. at 136, 81 S. Ct. at 529; Pennington, 381 U.S. at 669, 85 S. Ct. at 1592. In California Motor Transport, the Court extended Noerr to protect from antitrust liability citizens engaging in adjudicatory actions before administrative agencies and the courts. 404 U.S. at 510, 92 S. Ct. at 611." TRW Financial Systems, 835 F. Supp. at 1011 n. 25. The Supreme Court has observed, however, that "[t]he scope of this protection depends . . . on the source, context, and nature of the anticompetitive restraint at issue." Allied Tube, 486 U.S. at 499.

As Professors Areeda and Hovenkamp observe:

> [m]onopolists or collaborators are privileged to pursue their private and selfish objectives through legislation, adjudication, or executive and administrative machinery. This right is founded in our Constitution but is also said to be independently derived from statutory interpretation of the antitrust laws. But even setting aside the Constitution and the substantive meaning of the statute, when the anticompetitive harm results from the government action – as when a private petitioner requests and receives anticompetitive legislation – then the government itself becomes the "cause" of the restraint, and the private petitioner is relieved from liability.

1 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 201a at 148 (Rev. ed. 1997) (emphasis added). Elaborating further, Professors Areeda and Hovenkamp explain that "[t]o be sure, private parties may have influenced or persuaded the government to act, but the government's decision to act reflects an independent governmental choice, constituting

the supervening 'cause' that breaks the link between a private party's request and the plaintiff's injury." Id. ¶ 202c at 160.

In the context of successful litigation, these commentators observe that "[i]n that case the premise must be that judge and jury are politically 'neutral' decision makers and that established law entitled the petitioner to the requested relief." Id. at 161. "[C]ourts distinguish between harm caused directly by the private parties from that caused by the government itself." Id. at 163. When the anticompetitive harm is the result of a court decision, although requested by a private party, there "is no private restraint of trade." Id. at 163-64.

b. Analysis

Defendant HMRI's Rule 12(b)(6) motion to dismiss is premised on its legal argument that purely private agreements, like the HMRI/Andrx Agreement, that are entered into during the course of pending litigation but are not filed with, presented to, or approved by the court presiding over that litigation, fall within the protection of the *Noerr-Pennington* immunity doctrine because they are "incidental to" that pending litigation. See Allied Tube, 486 U.S. at 499 (citing Noerr, 365 U.S. at 143). Specifically, HMRI argues that the HMRI/Andrx Agreement is "incidental to" the HMRI/Andrx patent infringement action because, contrary to Plaintiffs' allegations in their complaints, it merely maintained the status quo and managed the risks the parties faced while the HMRI/Andrx patent suit was being litigated. Defendant calls the Agreement an "interim stipulation" and a "stipulated preliminary injunction" despite the fact that the Agreement was never filed in that case and was never presented to or approved by the court presiding over the HMR/Andrx patent infringement action. Defendant also describes the Agreement as "akin to a settlement agreement of portions of the infringement action" despite the fact that the Agreement settled none of the infringement claims pending in the HMRI/Andrx patent infringement action. Rather, as Plaintiffs allege, in addition to refraining from going to market with its generic version of Cardizem CD in exchange for $10 million per quarter, Andrx agreed to dismiss, without prejudice, its antitrust and unfair competition counterclaims against HMRI which asserted that HMRI's patent infringement claims were a sham.

Plaintiffs argue that the anticompetitive harm caused by the purely private HMRI/Andrx Agreement is separate and distinct from any anticompetitive effects that would

have resulted from Defendant HMRI's successful prosecution of its patent infringement action against Andrx and thus cannot be considered an "incidental effect" of that patent infringement litigation. This, they argue, is not a situation where the anticompetitive harm is the result of a court's decision although requested by a private party. Rather, it is the result of purely private conduct and thus constitutes a private restraint of trade subject to liability under the antitrust laws.

Plaintiffs further argue that, despite HMRI's current characterizations of the HMRI/Andrx Agreement, there was no preliminary injunction hearing or injunction issued in the patent case, no stipulation filed in that case, and no partial settlement agreement presented to, filed in, or approved by the court presiding over that matter. Thus, any anticompetitive harms that flow from the HMRI/Andrx Agreement are the result of purely private action, not judicial action. This Court agrees with Plaintiffs. Construing the allegations in Plaintiffs' Complaints in the light most favorable to them, this Court is persuaded that *Noerr-Pennington* jurisprudence does not justify application of this doctrine

to immunize the anticompetitive harms caused by the HMRI/Andrx Agreement.[8] The decisions Defendant relies upon do not support a contrary conclusion.

i. The Decision in Noerr Does Not Support HMRI's Argument

Defendant's "incidental effects" argument finds its roots in Noerr. In that case, a group of railroads waged a publicity campaign against truckers and trucking companies in an effort to influence anti-trucking legislation. A group of trucking companies subsequently brought an antitrust suit against the railroads alleging a railroad conspiracy to monopolize the long-distance freight business and alleging that the government's veto of a Fair Truck Bill in response to the railroad's publicity campaign caused the trucking companies damage in the form of lost business. The Court held that the railroad group was immune from antitrust liability for the anticompetitive harms that resulted from its legitimate government petitioning activity despite the fact that the railroad's publicity

[8]Plaintiffs' complaints allege that: (1) the HMRI/Andrx Agreement is a private market-allocation agreement between private parties who are also horizontal competitors; (2) the Agreement was designed to protect HMRI from generic competition from Andrx and other potential generic competitors, such as Biovail and Faulding, by having Andrx delay the entry of its generic version of Cardizem CD into the U.S. market in exchange for tens of millions of dollars that HMRI would pay to Andrx for its cooperation in this anticompetitive scheme; (3) in addition to refraining from going to market with its generic version of Cardizem CD in exchange for $10 million per quarter, Andrx agreed to dismiss, without prejudice, its antitrust and unfair competition claims against HMRI which asserted that HMRI's patent infringement claims were a sham; (4) the Agreement was not filed in, presented to, or approved by the court presiding over the HMRI/Andrx patent litigation; (5) the court presiding over the patent case was never informed of its existence; (6) the Agreement has never been filed as an exhibit to any public filings filed by Defendants under the Securities Exchange Act despite the fact that they are publicly traded companies; and (7) no agency or official of any government, whether federal, state or local, has sanctioned or created this arrangement, or prevented Andrx's entry into the U.S. market until the conclusion of the HMRI/Andrx patent litigation.

campaign may have also inflicted some direct injury on the trucking companies. In Noerr, the Court observed that:

> [i]t is inevitable, whenever an attempt is made to influence legislation by a campaign of publicity, that an incidental effect of that campaign may be the infliction of some direct injury upon the interest of the party against whom the campaign is directed. . . . To hold that the knowing infliction of such injury renders the campaign itself illegal would thus be tantamount to outlawing all such campaigns.

Noerr, 365 U.S. at 143-44.

Accordingly, Noerr teaches that, in some circumstances, immunity is still warranted despite the presence of incidental effects of lobbying that might result in direct injury of an opponent. See 1 P. Areeda & H. Hovenkamp, supra, ¶ 202d at 164. "In Noerr, . . . , the plaintiffs alleged that one consequence of the railroads' campaign against truckers was the dissemination of information suggesting that the truckers were dangerous on the highway, that they did not pay their fair share of highway taxes, and similar charges. Whether true or not, these claims injured the truckers without regard to any action that the government might take in response to the railroads' petitions." Id. at 165 (footnote omitted). Nonetheless, "the Supreme Court held that there could be no recovery for any injury that was 'an incidental effect' of the legislative campaign. Every campaign for regulating someone else, the Court noted, would include factual statements casting the other in a bad light. It then concluded that making petitioners liable for incidental injuries caused by their petitions would be tantamount to condemning the petitions themselves." Id. (footnotes omitted).

The argument Defendant advances here is not supported by the Court's "incidental effects" analysis in Noerr. The source, context and nature of the anticompetitive restraint at issue here are readily distinguished from those present in Noerr. There is no claim of anticompetitive harm here resulting from the incidental effects of a publicity campaign waged by HMRI in connection with its litigation against Andrx. Rather, the source of the alleged anticompetitive harm is a private market allocation agreement between horizontal competitors who were adversaries in the pending HMRI/Andrx patent infringement action. Defendant does not explain how Noerr advances its claim that the purely private HMRI/Andrx Agreement is an "incidental effect" of pending litigation and thus entitled to immunity from antitrust liability. Applying Noerr in the litigation context, a more analogous "incidental effect" of non-sham litigation deserving of immunity would be the direct and indirect costs associated with defending the litigation. See 1 P. Areeda & H. Hovenkamp, supra, ¶ 202d at 164.

This Court agrees with Plaintiffs' argument that, rather than being analogous to Noerr, this case is more analogous to a situation where the Pharmaceutical Manufacturers Association petitions Congress for a law requiring drug makers to raise their prices by a specified amount per year (an immunized governmental petitioning activity) and then, because Congress isn't as quick as the Association would prefer, its members enter into a private, "interim" agreement where they accomplish the same thing while Congress deliberates (not immunized governmental petitioning activity). See, e.g., In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 789 (7th Cir. 1999) (observing that the *Noerr-Pennington* "doctrine does not authorize anticompetitive *action* in advance of

government's adopting the industry's anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action . . . .").

ii. Decisions Extending Immunity to Pre-litigation Conduct Do Not Advance HMRI's Arguments

Noerr-Pennington immunity has been extended to non-sham, pre-litigation threats of suit, demand letters, and communications about pending suits. See McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1558-60 (11th Cir. 1992)(pre-litigation threats of suit); Coastal States Marketing, Inc. v. Hunt, 694 F.2d 1358, 1366-67 (5th Cir. 1983) (same); and Barq's, Inc. v. Barq's Beverages, Inc., 677 F. Supp. 449, 453 (E.D. La. 1987) (observing that "threatened litigation and attending publicity" was considered "part and parcel of the petitioning immunity of *Noerr-Pennington* if the litigation itself was in good faith" and thus holding that the plaintiff's pre-litigation demand letters were "also protected under the *Noerr-Pennington* petitioning immunity"). See also AirCapitol Cablevision, Inc. v. Starlink Communications Group, Inc., 634 F. Supp. 316, 324-26 (D. Kan. 1986) (observing that publicity about non-sham litigation and its indirect threats of litigation against Starlink's customers were incidental to non-sham litigation and thus protected under the *Noerr-Pennington* immunity doctrine). Cf. Cardtoons v. Major League Baseball Players Ass'n, 182 F.3d 1132, reh'g en banc, ___ F.3d ___, ___, 2000 WL 358414 (10th Cir. 2000) (observing that *Noerr-Pennington* immunity is available to immunize prelitigation threats from liability only when antitrust claims are at issue). "Most lawsuits are prefaced by various communications, such as demand letters that expressly or impliedly threaten suit unless the addressee alters its conduct or provides other relief. Such prelitigation

communications provide useful notice and facilitate the resolution of controversies. It would be foolish to adopt antitrust rules encouraging suit before communication by penalizing the communication but not the suit." 1 P. Areeda & H. Hovenkamp, supra, ¶ 205e at 237.

Defendant's argument that the HMRI/Andrx Agreement is "reasonably and normally attendant upon effective litigation" and thus entitled to immunity is not advanced by decisions holding that pre-litigation conduct like threats of suit are entitled to the same immunity as the litigation itself. While it is true that the courts have extended *Noerr-Pennington* immunity to non-sham, pre-litigation threats of suit, demand letters, and communications about pending suits, the HMRI/Andrx Agreement does not fall within this category of immunized pre-litigation conduct. Accordingly, that line of authority does nothing to advance Defendant's position here.

Defendant HMRI's reliance on McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1560 n. 11 (11th Cir. 1992), is similarly misplaced. The Court in McGuire Oil did not, as Defendant HMRI argues, hold that "an interim stipulation entered into by opposing parties in ongoing litigation was protected by *Noerr-Pennington* immunity." HRMI Br. at 25. Rather, the McGuire Oil Court held that pre-litigation threats of suit enjoy the same immunity under the *Noerr-Pennington* doctrine as the litigation itself.

In McGuire Oil, the plaintiffs, petroleum wholesalers "engaged in the wholesale and retail sale of branded gasoline" first threatened suit and then sued defendant corporation, which was "engaged in the retail sale of unbranded petroleum products in Alabama," alleging that defendant had violated the Alabama Motor Fuel Marketing Act by selling or

offering to sell gas at prices below cost. McGuire Oil, 958 F.2d at 1554. The defendant filed a counterclaim alleging that "the plaintiffs engaged in a concerted effort to establish minimum prices for gasoline in the Mobile [Alabama] area, and that this effort manifested itself in threats and coercion of those independent retailers, like [defendant], who sought to preserve their market share by pricing gas one or two cents below major brand gas prices." Id. at 1557. Defendant's counterclaim alleged, in essence, "that plaintiffs violated the Sherman Act by engaging in concerted efforts to threaten and initiate litigation against [defendant] under the [Alabama Motor Fuel Marketing Act]." Id. at 1558. Affirming the district court's summary dismissal of defendant's antitrust claims, the Eleventh Circuit observed that, "[o]n its face, [defendant]'s Sherman Act counterclaim appears barred by the Noerr-Pennington doctrine: the raison d'etre of plaintiffs' alleged conspiracy was to threaten and ultimately initiate litigation against [defendant] under the [Alabama Act] in an attempt to get [defendant] to cease its below-cost sales of gas." Id. at 1559. After rejecting defendant's argument that the sham exception to the *Noerr-Pennington* immunity doctrine "applies in this case to strip the plaintiffs of immunity from Sherman Act liability under that doctrine", the McGuire Oil court held that "plaintiffs' concerted and repeated threats of litigation", as well as plaintiffs' "actual initiation of litigation," are immunized from antitrust liability. Id. at 1562, 1560.

Rather than being derived from the holding in McGuire Oil, Defendant's argument is gleaned from dicta in a footnote. There the court observed that the defendant in McGuire could not use the fact that it had suffered losses as a result of a stipulation it voluntarily entered into during the course of the plaintiff's litigation against it to bootstrap an

argument, in support of its antitrust counterclaim, that the plaintiff had sued it purely for anticompetitive purposes and without a legitimate expectation of winning or a desire for judicial relief. See McGuire Oil, 958 F.2d at 1560 n. 11.[9] When the court stated that the defendant "cannot treat as abuse of the judicial process the entry of a stipulation to which the parties voluntarily agreed, regardless of the injurious effect it had on [defendant]'s business", it was merely observing that the defendant could not argue that the lawsuit filed against it was a sham because, during the course of that litigation, it agreed with its opposing party that it would raise its gas prices and subsequently lost sales as a result of that voluntary agreement.

The facts presented here are readily distinguished from the facts presented in McGuire Oil. They are likewise distinguishable from the facts of other decisions Defendant relies upon in support of its argument that the HMRI/Andrx Agreement is conduct "reasonably and normally attendant upon litigation" and thus immunized from antitrust liability.

iii. Decisions Immunizing the Rejection of a Settlement Offer Do Not Advance HMRI's Arguments

Noerr-Pennington immunity has been extended to an antitrust defendant's refusal to accept the antitrust plaintiff's offer to settle pending, non-sham litigation between these parties. See Columbia Pictures Indus., Inc. v. Prof'l Real Estate Investors, Inc., 944 F.2d

[9]After the suit was filed, "the parties entered into a stipulation whereby [the defendant] agreed to raise its gas prices pending resolution of the lawsuit. In the six months following execution of the stipulation, [the defendant] lost a considerable amount of its sales volume." McGuire Oil, 958 F.2d at 1555.

1525, 1528-29 (9th Cir. 1991) (holding that the plaintiffs' refusal to accept the defendant's offer to settle a pending, non-sham copyright infringement case was conduct incidental to the prosecution of that non-sham case and thus was likewise immunized from antitrust liability), aff'd sub nom, Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 509 U.S. 49 (1993); PrimeTime 24 Joint Venture v. Nat'l Broadcasting Co., Inc., 21 F. Supp. 2d 350, 358-59 (S.D. N.Y. 1998) (similarly construing the antitrust defendants' concerted refusals, both to negotiate with the antitrust plaintiff and to grant the plaintiff the licenses it sought in an attempt to avoid liability for infringing the defendants' copyrights, as a rejection of a settlement offer and thus conduct incidental to the antitrust defendants' pending copyright infringement litigation against the antitrust plaintiff); Modesto Irrigation Dist. v. Pacific Gas & Elec. Co., 61 F. Supp. 2d 1058 (N.D. Cal. 1999) (construing the antitrust defendant's unilateral refusal to accept the antitrust plaintiff's request to provide transmission service to a certain power substation as analogous to a refusal to accept a settlement offer and thus finding the refusal "incidental to" the defendant's filing of a petition before a governmental agency, where it sought a declaration that it was not obligated to provide power to that substation, and entitled to immunity because, if the offer had been accepted, the agency action would have been moot). In Columbia Pictures, PrimeTime 24, and Modesta, the court reasoned that the antitrust defendant's conduct was "incidental to" the underlying litigation because the rejection allowed for continued prosecution whereas an acceptance of the antitrust plaintiff's offer would have rendered the underlying dispute moot.

Contrary to Defendant's argument here, the courts in Columbia Pictures, PrimeTime 24, and Modesta did not apply *Noerr-Pennington* immunity to a purely private agreement similar to the HMRI/Andrx Agreement. Rather, these court held that an antitrust defendants' refusal to accept the antitrust plaintiffs' offer to settle a pending, non-sham case was conduct "incidental to" the continued prosecution of that non-sham case and thus was entitled to the same immunity as that enjoyed by the underlying litigation. Thus, the principle to be gleaned from these decisions is that if the underlying litigation is not a sham and immune from antitrust liability, then, in a subsequent antitrust action, the antitrust defendant's refusal to settle the underlying suit is likewise immune from antitrust liability under the *Noerr-Pennington* doctrine. Columbia Pictures illustrates this point.

In Columbia Pictures, the plaintiffs sued the defendant hotel operators alleging that the defendants had violated the plaintiffs' "copyrights to certain motion pictures by renting videodiscs of those pictures" to its guests "for viewing on videodisc players placed in hotel rooms." Id. at 1527. Defendant Professional Real Estate Investors, Inc. ("PRE") filed a counterclaim against the plaintiffs alleging violations of the Sherman Act, state antitrust laws and state unfair competition laws. "PRE charged that the copyright infringement suit was a sham", and that the plaintiffs' "concerted refusal to grant licenses to PRE to rent the videos, as well as other unspecified activities, constituted a pattern of anticompetitive conduct." Id. Granting the plaintiffs' motion for summary judgment, the district court held that the plaintiffs' "copyright infringement action was not a 'sham', and that, as a result, the Movie Studios' bringing of that action was immune from antitrust liability under the Noerr-

Pennington doctrine." Id. at 1527-28. This decision was affirmed by the Ninth Circuit. Additional rulings in that appeal are germane to Defendant HMRI's argument here.

On appeal, PRE argued that summary judgment was improper because the district court failed to consider its additional allegation of anticompetitive conduct, including an allegation that the plaintiffs in the copyright infringement action had "concertedly refused to grant licenses to PRE to rent videodiscs to its guests". Id. at 1528. Despite the district court's failure to address PRE's additional allegations, the Ninth Circuit affirmed its decision granting summary judgment because reversal was not required. Id. at 1528. The court reasoned that reversal was not required because: (1) PRE's concerted-refusal-to-deal allegation related to "PRE's attempts, after Columbia Pictures instituted the copyright infringement action, to obtain licenses from the Movie Studios to use and install in-room videodisc systems in the guest rooms", id.; (2) "[o]n the facts of this case, PRE's request for licensing amounted to an offer to settle the lawsuit", id.; (3) "[a] decision to accept or reject an offer of settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis of antitrust liability", id. (emphasis added); (4) "PRE's ability to establish that the Movie Studios' refusal to deal violated the Sherman Act depends on its success or failure in showing that the copyright infringement action is actionable under the federal antitrust laws"; i.e., that it is not immune under the *Noerr-Pennington* doctrine, id. at 1529; (5) PRE had not shown that the copyright infringement lawsuit was a sham, and thus its filing was immune from the antitrust laws under the *Noerr-Pennington* doctrine, id. at 1529-32; and (6) consequently, the Movie

Studios' decision to reject PRE's offer of settlement was likewise immune from antitrust liability, id. at 1529.

The circumstances presented in Columbia Pictures, as well as the circumstances presented in PrimeTime 24 and Modesta, are distinguishable from those presented here. Unlike those cases, here there is no refusal by one of the Defendants to accept an offer to settle the underlying patent infringement suit, and there is no antitrust claim based on any such refusal. Rather, it is alleged here that the HMRI/Andrx Agreement is a private agreement between two horizontal competitors to allocate the U.S. market for Cardizem CD, not an agreement accepting or rejecting an offer to settle the pending infringement claims against Andrx.

Based on these allegations, the Court is not persuaded by Defendant's argument that the HMRI/Andrx Agreement is "incidental to" the HMRI/Andrx patent infringement action. Rather, Plaintiffs' allegations support its argument that the HMRI/Andrx Agreement is separate and distinct from prosecution of the HMRI/Andrx patent infringement litigation. Acceptance of the alleged terms of the HMRI/Andrx Agreement did not render HMRI's continued prosecution of its patent infringement action moot. Moreover, the alleged restraint of trade that results from the terms of that Agreement constitutes harm that is independent of the harm that would result from HMRI's successful prosecution of its pending patent litigation. Accordingly, this Court is not convinced that Defendants HMRI and Andrx may cloak their unlawful conduct in *Noerr-Pennington* immunity simply because the HMRI/Andrx Agreement was entered into while a patent infringement action was pending between the two parties to that Agreement. The Agreement did not take place

within the context of that suit; i.e., it was never filed with or approved by the court presiding over that matter, and the court was not even aware of its existence. Moreover, the alleged nature of the Agreement is far different from the refusals to accept settlement offers that were at issue in Columbia Pictures, PrimeTime 24, and Modesta.

Defendant's argument that the HMRI/Andrx Agreement is, in essence, a stipulated "preliminary injunction" and thus should be immunized from antitrust liability as conduct "incident to" the pending HMRI/Andrx patent litigation also lacks merit. Acceptance of Defendant's argument would improperly require the court to construe the allegations in Plaintiffs' complaint about the HMRI/Andrx Agreement in a light most favorable to Defendant, not Plaintiffs. The argument also ignores the fact that, although the anticompetitive effects flowing from any injunctive relief HMRI might have obtained from the court would have been immunized from antitrust liability under the *Noerr-Pennington* doctrine, HMRI did not obtain any such relief from the court. Accordingly, HMRI cannot argue that the anticompetitive effects resulting from its private agreement with Andrx warrant the same protections as would injunctive relief granted by the court presiding over the HMRI/Andrx patent infringement action.

iv. The Hise Decision Does Not Advance HMRI's Immunity Argument

Contrary to Defendant's contention here, the courts have not broadly applied *Noerr-Pennington* immunity to purely private settlement agreements. Rather, as Plaintiffs' point out, the courts have not hesitated to impose antitrust liability in cases arising out of anticompetitive settlement agreements. See, e.g., In re New Mexico Natural Gas Antitrust Litig., MDL No. 403, 1982 WL 1827 (D. N.M. January 26, 1982).

In New Mexico Natural Gas, the plaintiffs alleged that the settlement of a prior lawsuit among the defendants ("the Producer Litigation") constituted an antitrust violation. The defendants moved for summary judgment, arguing that the initiation, prosecution, and settlement of the Producer Litigation was immune from antitrust liability under the *Noerr-Pennington* doctrine. Rejecting the defendants' argument, the court observed that:

> [t]here may be some probative evidentiary value in the facts as to the initiation and prosecution of the *Producer Litigation*. However, the Court concludes that plaintiffs are correct in asserting that a private settlement agreement accomplished without Court participation should not be afforded *Noerr-Pennington* protection. When parties petition a Court for judicial action that protection attaches, but when they voluntarily withdraw their disputes from the court and resolve it by agreement among themselves there would be no purpose served by affording *Noerr-Pennington* protection. The parties by so doing must abide with any antitrust consequences that result from their settlement.

Id. at * 6 (emphasis added).

The decision in New Mexico Natural Gas is not unique. The courts have consistently observed that private agreements settling litigation may result in antitrust liability "when they are attended by anticompetitive results." Duplan Corp. v. Deering Milliken, Inc., 444 F. Supp. 648, 683 (D. S.C. 1979), rev'd in part on other grounds, 594 F.2d 979 (4th Cir. 1979). See also United States v. Singer Mfg. Co., 374 U.S. 174 (1963) (holding that settlement agreements between the Singer Company and its Italian and Swiss competitors violated the Sherman Act); Blackburn v. Sweeney, 53 F.3d 825, 828 (7th Cir. 1995) (holding that a dissolution agreement between former law partners settling a state court lawsuit was a horizontal agreement to allocate markets among competitors and thus a per se violation of the Sherman Act); Duplan Corp. v. Deering Milliken, Inc., 594 F.2d 979, 981 (4th Cir.

1979) (affirming the district court's finding that a 1964 settlement agreement "was the core of a scheme to stabilize and maintain production royalties. . . and to monopolize the United States market"); Southex Exhibitions, Inc. v. Turner Exposition Corp, 6 Fla. L. Week. Supp. 551, 552 (Fla. 13th Cir. June 15, 1999) ("The Settlement Agreement clearly constitutes a horizontal restraint of trade between two competitors for allocation of markets and customers . . . [and] is a per se violation of the Sherman Antitrust Act . . . . This Court cannot find a single pro-competitive justification for the horizontal restraints of trade created by the Settlement Agreement").

The decision Defendant relies upon in support of its contrary position, Hise v. Philip Morris, Inc., 46 F. Supp. 2d 1201 (N.D. Okla. 1999), aff'd, 208 F.3d 226 (10th Cir. 2000), is easily distinguished from the facts of this case. In Hise, the underlying suit involved an action brought by over forty states against numerous tobacco companies and manufacturers "for the purposes of furthering their policies regarding public health and reducing underage consumption of tobacco products" and sought "monetary, equitable and injunctive relief." Id. at 1204. "[T]o avoid the enormous expense and delay inherent in such litigation, the states and tobacco companies agreed to enter into negotiations with the aim of settling their various disputes." Id. "Ultimately, the negotiations succeeded," and the parties "entered into a Master Settlement Agreement." Id.

After entering into the Master Settlement Agreement, the defendant tobacco companies "raised the price of their tobacco products, presumably to cover the costs of the settlement." Id. The plaintiffs in Hise then filed an action against some of the tobacco companies that had signed that Master Settlement Agreement "purportedly on behalf of

themselves and a class consisting of an estimated 40 million consumers of [the] defendants' tobacco products". Id. at 1203. The plaintiffs alleged, *inter alia*, that, as a result of the settlement agreement, the defendants had violated federal antitrust laws when they unlawfully "agreed to raise tobacco prices in order to pay the costs of the settlement." Id. The court dismissed the plaintiffs' section 1 Sherman Act claim, finding that "the *Noerr-Pennington* doctrine and the *Illinois Brick* indirect purchaser rule preclude recovery". Id. at 1205. As to the *Noerr-Pennington* doctrine, the court found "that the actions of [the] defendants in negotiating and executing" the Master Settlement Agreement fell "within the recognition that *Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose". Id. at 1206-07 (internal quotes and citations omitted). The Hise court then concluded that "the concerted effort by [the] defendants to influence public officials, i.e., the states' Attorneys General, to accept a settlement in exchange for dismissing the numerous lawsuits pending against defendants is among the activities protected by the *Noerr-Pennington* doctrine." Id. at 1207.

Unlike Hise, in this case the HMRI/Andrx Agreement is not a result of negotiations with a state attorney general or any government official, and therefore, unlike the Master Settlement Agreement in Hise, it cannot be considered as conduct incidental to litigation with a governmental entity.

v. Conclusion

Defendant HMRI has not presented the court with a persuasive argument as to why the private settlement agreements in the above-referenced cases were not immunized from antitrust liability notwithstanding the fact that each "related to" or was an "incidental effect"

of non-sham litigation. The Court is convinced that interim agreements, like the HMRI/Andrx Agreement here, that restrain trade through private rather than governmental conduct are subject to antitrust liability and are not entitled to immunity under the *Noerr-Pennington* doctrine. A final, private settlement that would resolve the HMRI/Andrx patent infringement litigation by entering into a market allocation agreement like the one alleged here would not enjoy *Noerr-Pennington* immunity and neither should the Defendants "interim" Agreement that accomplishes the same anticompetitive results.

2. Adequacy of Plaintiffs' Pleading that the HMRI/Andrx Patent Infringement Action is a Sham

In light of the above analysis, the Court may consider whether the HMRI/Andrx Agreement is subject to antitrust liability independent of any decision that the HMRI/Andrx patent infringement litigation was a sham.[10] State Law Plaintiffs, however, have asserted an additional reason for opposing Defendants' arguments that they have failed to sufficiently allege facts showing that HMRI's initiation and continued prosecution of the HMRI/Andrx patent litigation was both objectively baseless and brought for anticompetitive purposes; i.e., a sham. These Plaintiffs argue that, but for HMRI's initiation of the sham patent infringement action, the 30 month Hatch-Waxman period would not have gone into effect and generic versions of Cardizem CD would have entered the market much sooner than the July, 1998 date when that 30-month period expired. Accordingly, the following

[10]The Individual Sherman Act Plaintiffs' complaints allege no facts supporting an argument that the HMRI/Andrx patent litigation was a sham. This is not an omission by the Plaintiffs. Rather, these Plaintiffs argue that there is no need to make any such allegations in order to state a claim under section 1 of the Sherman Act. Plaintiffs are correct.

is a discussion of the sham exception to the *Noerr-Pennington* doctrine, the facts alleged in each of the Plaintiffs' complaints, and an analysis of whether the complaints sufficiently allege facts showing that the HMRI/Andrx patent litigation is a sham.

a. Sham Exception to Antitrust Immunity

Not all government-petitioning activity is immunized. "As a general matter petitions to the government are not immune when the petitioning action is a 'mere sham.'" Id. at 148-49. See Noerr, 365 U.S. at 144 and California Motor Transport, 404 U.S. at 510 (where the Court observed that application of the Sherman Act would be justified "where the litigation or the political activity is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor"). The Supreme Court has set forth a two-prong test for determining whether litigation is a "sham" and thus not entitled to antitrust immunity under the *Noerr-Pennington* doctrine. First, it must be shown that the litigation is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE"), 508 U.S. 49, 60 (1993). If the antitrust plaintiff satisfies the "objectively baseless" prong, the court then examines the plaintiff's allegations regarding the antitrust defendant's subjective motivation and determines "whether the baseless suit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" PRE, 508 U.S. at 60 (quoting Noerr, 365 U.S. at 144).

b. Analysis

The question presented here is whether, construing the Plaintiffs' allegations in the light most favorable to them, Plaintiffs have adequately alleged facts showing that HMRI's

initiation and continued prosecution of the HMRI/Andrx patent infringement action was a sham. This Court finds that the State Law Plaintiffs have sufficiently alleged facts that satisfy the objective and subjective prongs of PRE's sham litigation test.[11] Defendant HMRI argues facts that contradict those alleged by State Law Plaintiffs. On a Rule 12(b)(6) motion, this Court is required to construe the allegations in Plaintiffs' complaint as true and in the light most favorable to Plaintiffs.

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[11]State Law Plaintiffs allege the following. In August 1995, prior to filing its ANDA and Paragraph IV certification, Andrx gave samples of its generic version of Cardizem CD to the Hoechst Defendants so they could test it and confirm that it did not infringe the patents claiming Cardizem CD and thus avoid litigation. In September 1995, Andrx filed an ANDA and made a Paragraph IV certification regarding all unexpired patents listed in the Orange Book allegedly claiming Cardizem CD. Two months later, in November 1995, the U.S. Patent and Trademark Office issued the '584 patent to Carderm, which in term licensed it to HMRI. The '584 patent claims a "dissolution profile," which is the amount of diltiazem released over specified periods of time, and was listed by the Hoechst Defendants in the "Orange Book" as covering Cardizem CD. ¶¶ 98-101.

It is further alleged that the '584 patent did not represent a substantive change or improvement to Cardizem CD, but rather was prosecuted and listed solely to give HMRI a basis for initiating sham patent infringement litigation to delay and exclude Andrx's generic version of Cardizem CD from the Cardizem CD market for at least 30 months. HMRI and Carderm did, in January 1996, file a patent infringement suit against Andrx alleging that Andrx's generic drug infringed the '584 patent. ¶¶ 101-102.

In addition to claiming no infringement of the '584 patent, Andrx also amended its ANDA on April 4, 1996 to specify a dissolution profile that was even more clearly distinct from that claimed by the '584 patent; i.e., it claimed only a dissolution profile (not less than 55% of total diltiazem released after 18 hours) which was within the dissolution range that Carderm had specifically canceled from its application for the '584 patent. The dissolution profile claimed in the '584 patent (0-45% of total diltiazem released after 18 hours) plainly excluded that disclosed in Andrx's Amended ANDA. It is alleged that HMRI, Carderm and Hoechst AG pursued the HMRI/Andrx patent case despite: (1) notice of Andrx's April 1996 amended ANDA; (2) the absence of any reasonable belief that they would succeed on the merits of their claim; and (3) the fact that no reasonable litigant could realistically expect success on the merits. Rather, the suit was pursued solely for anticompetitive reasons. ¶¶ 103-104, 130.

The Sherman Act Class Plaintiffs, on the other hand, have not alleged facts that would satisfy both the objective and subjective prongs of PRE's sham litigation test. There is only a conclusory allegation that the patent infringement suit was a sham and an allegation that, in the HMRI/Andrx patent infringement action, Andrx had similarly alleged that HMRI was pursuing its patent infringement suit solely to harm Andrx and without any reasonable belief of success on the merits. See Complt. at ¶ 53. These Plaintiffs attempt to allege facts showing that the HMRI/Andrx patent litigation was a sham but fail to meet their burden. Rather than dismiss their antitrust claims, however, the proper remedy is for the Court to allow Plaintiffs the opportunity to amend their complaints so as to adequately plead facts showing that the HMRI/Andrx patent infringement litigation was a sham.

3. *Noerr-Pennington* Immunity for Hoechst's Communications with the FDA Regarding the Scope of the Right of Reference Granted to Biovail

State Law Plaintiffs allege violations of various state law statutes similar to § 2 of the Sherman Act, 15 U.S.C. § 2,[12] making it an offense for any person or persons to monopolize, attempt to monopolize, or to conspire to monopolize. In support of their

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[12]Section 2 of the Sherman Act provides in pertinent part that:

> Every person who shall monopolize, or attempt to monopolize, or combine with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations shall be deemed guilty of a felony.

15 U.S.C. § 2. Section 2 of the Sherman Act "addresses the actions of single firms that monopolize or attempt to monopolize, as well as conspiracies and combinations to monopolize." Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 454 (1993). Section 2 "makes the conduct of a single firm unlawful only when it actually monopolizes or dangerously threatens to do so." Id. at 459.

monopoly claims, State Law Plaintiffs allege that the HMRI/Andrx Agreement is evidence of the parties' conspiracy to maintain the Hoechst Defendants' monopoly over the market for Cardizem CD. Plaintiffs further allege that additional conduct is evidence of the Hoechst Defendants' attempt to maintain its monopoly over the Cardizem CD market: (1) the Hoechst Defendants' "baseless renunciation of the FTC-mandated right of reference" previously granted to Biovail in connection with Biovail's NDA for a generic version of Cardizem CD; and (2) HMRI's initiation and continued prosecution of the HMRI/Andrx patent infringement action. See State Law Plfs. Complt., Second and Third Claims for Relief under California, District of Columbia, Michigan, Minnesota, North Carolina, and Wisconsin state statutes, pp. 50-51, 57-58, 63-64, 69-70, 78-79, and 90-91.

Defendant HMRI challenges Plaintiffs' allegations regarding the Hoechst Defendants' communications to the FDA as to the right of reference it granted to Biovail in December, 1995. Specifically, HMRI argues that Plaintiffs have not adequately pled facts showing that this petitioning conduct falls within the sham exception to the *Noerr-Pennington* immunity doctrine. Asserting facts that dispute those alleged by Plaintiffs, HMRI claims that its post-December 1995 communications with the FDA did not renounce but merely: (1) clarified that the right of reference granted to Biovail was limited to a specific product--Tiazac--and was limited to supplemental or additional NDAs for Tiazac; and (2) petitioned the FDA to adopt its interpretation of its obligations under the FTC Consent Order rather than the interpretation Biovail was lobbying for and are thus immunized under the *Noerr-Pennington* doctrine. Defendant's arguments are factually and legally deficient.

First, construing the allegations in Plaintiffs' complaint in the light most favorable to them, this Court finds that Plaintiffs have adequately alleged facts showing that the Hoechst Defendants' post-December 1995 communications were objectively baseless as well as showing the Hoechst Defendant's subjective anticompetitive motivation. The essence of Plaintiffs' allegations is that the Hoechst Defendants intentionally narrowed the scope of the right of reference, despite their knowledge of what was directed by the FTC, so as to keep Biovail's generic products from being approved and thus competing in the U.S. market for Cardizem CD. See State Law Plfs' Complaint ¶¶ 59-95.

Second, as the Seventh Circuit Court of Appeals recently observed, it is error for the court to treat the *Noerr-Pennington* doctrine "as a rule of evidence that forbids the introduction of evidence . . . relating to efforts to obtain governmental protection" to show an antitrust violation. In Re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d at 789. State Law Plaintiffs confirmed at the hearing on this matter that they are not asserting a separate cause of action based on these FDA communications. Rather, Plaintiffs' allegations regarding the Hoechst Defendants' FDA communications are merely evidence in support of the Plaintiffs' state law claims. See 4/18/00 Hrg. Transcript at 81.

B. Antitrust Injury

Issue: Have Plaintiffs Sufficiently Pled the Fact of Antitrust Injury (Anticompetitive Effects)

Individual and Class Sherman Act Plaintiffs allege that Defendants violated section 1 of the Sherman Act, 15 U.S.C. § 1, with their horizontal market allocation and price-fixing agreement and further allege that they were injured by Defendants' antitrust violations, and seek treble damages pursuant to section 4 of the Clayton Act, 15 U.S.C. § 15. State Law Plaintiffs allege they were injured by Defendants' violation of state antitrust laws similar to section 1 of the Sherman Act and likewise seek treble damages under state law provisions similar to section 4 of the Clayton Act. Defendants' Rule 12(b)(6) motions to dismiss argue that Plaintiffs have not and cannot allege an antitrust injury cognizable under section 1 of the Sherman Act or under the respective state antitrust statutes.

1. Legal Principles

Section 1 of the Sherman Act prohibits any "'contract, combination . . ., or conspiracy' between two or more persons that unreasonably restrains trade in interstate commerce." Re/Max Int'l, Inc. v. Realty One, Inc., 173 F.3d 995, 1009 (6th Cir. 1999) (quoting 15 U.S.C. § 1), petition for cert. filed, 68 U.S.L.W. 3138 (U.S. August 17, 1999) (No. 99-294). Section 4 of the Clayton Act broadly defines the class of persons entitled to seek treble damages for an antitrust violation. 15 U.S.C. § 15. The relevant language provides, "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States. . . and shall

recover threefold the damages by him sustained, and the costs of the suit, including a reasonable attorney's fee." 15 U.S.C. § 15.

Although the language of the statute is sweeping on its face, the United States Supreme Court has limited its scope by setting forth several factors which must be considered before a private person is allowed to prosecute an antitrust claim. See Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters, 459 U.S. 519 (1983). The application of section 4 "has of necessity been judicially confined to limit the remedy available thereunder to particular classes of persons and for redress of particular forms of injury." Southhaven Land Co., Inc. v. Malone & Hyde, Inc., 715 F.2d 1079 (6th Cir. 1983); see also Valley Products Co., Inc. v. Landmark, A Division of Hospitality Franchise Sys., Inc., 128 F.3d 398, 402-03 (6th Cir. 1997). "The antitrust injury doctrine is one such constraint and an increasingly important one." Valley Products, 128 F.3d at 403.

A plaintiff must allege facts showing that it suffered an "antitrust injury," that is, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant's acts unlawful." Brunswick Corp., v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977).[13] See also William C. Holmes, Antitrust Law Handbook § 8.03[1][a]

[13]The plaintiff's injury in Brunswick did not qualify as an "antitrust injury" because it failed both prongs of the Brunswick test. "First, profits lost as a result of enhanced competition are not the type of injury the antitrust laws were designed to prevent", and the essence of the plaintiff's claim in Brunswick was that it was "deprived of the opportunity to profit from the exercise of the local market power it would have had if the merger had not saved its rival from bankruptcy." 2 P. Areeda & H. Hovenkamp, supra, ¶ 362a at 211. As to the second prong, "the plaintiff's injury (present competition from a rival that is enabled to survive through an acquisition) does not flow from the reason for finding a violation (hypothetical future predation or collusion made possible by that acquisition)."

at 791 (1999). This definition of "antitrust injury" involves "two separate analytical issues. First, the claimed injury must be of a type that the antitrust laws were meant to discourage. And second, the plaintiff's injury must be causally related to the defendant's anti-competitive acts." Id. "Issues of causation are, thus, brought into the analysis as a second step even after the determination has been made that the nature of the alleged harm is of potential antitrust concern." Id. at 798-800.

Explained more fully, the Brunswick "test forces antitrust courts to connect the alleged injury to the purposes of the antitrust laws. Compensation for that injury must be consistent with the purposes of antitrust law generally and with the rationale for condemning the particular defendant. . . . At its most fundamental level, the antitrust injury requirement precludes any recovery for losses resulting from competition, even though such competition was actually caused by conduct violating the antitrust laws." 2 P. Areeda & H. Hovenkamp, supra, ¶ 362a at 210. As the Brunswick Court stated, "[t]he injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation. It should, in short, be 'the type of loss that the claimed violations . . . would be likely to cause.'" Brunswick, 429 U.S. at 489 (footnote omitted) (quoting Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100, 125 (1969)). The antitrust injury requirement "ensures that the harm claimed by the plaintiff corresponds to the rationale for finding a violation in the first place." Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 342 (1990). Although antitrust violations may have three, often interwoven,

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Id. at 212.

effects, "[t]he antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior", not from a competition-increasing or competition-neutral aspect of the defendant's behavior. Id. at 343. See also Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1557 (Fed. Cir. 1997).

2. Analysis

a. Plaintiffs' Allegations of Antitrust Injury

Here, Plaintiffs are consumers not competitors of Defendants HMRI or Andrx. They have alleged that "but for" Defendants' anticompetitive conduct, they would not have suffered their alleged antitrust injury. Specifically, it is alleged that Defendants' September 1997 Agreement eliminated generic competition and deprived all U.S. purchasers of the ability to buy Cardizem CD at a competitive price and thus violated section 1 of the Sherman Act and various state antitrust statutes. It is further alleged that: (1) "but for" the illegal HMRI/Andrx Agreement and the payment of tens of millions of dollars, Andrx would have begun marketing its generic version of Cardizem CD on or shortly after July 9, 1998; (2) Andrx represented to the court presiding over the HMRI/Andrx patent case that it intended to market and sell its generic version of Cardizem CD as soon as it received FDA

approval;[14] and (3) as a result of the illegal HMRI/Andrx Agreement, Plaintiffs have paid more than they would have paid for Cardizem CD absent Defendants' illegal conduct.

b. Defendants' Rule 12(b)(6) Arguments

Defendants' motions to dismiss, in essence, argue that Plaintiffs' antitrust claims must be dismissed because their complaints do not, and cannot, sufficiently plead the fact of antitrust injury.[15] Defendant Andrx frames the argument differently; i.e., because the facts do not and cannot show that the HMRI/Andrx Agreement necessarily delayed Andrx's decision to market its generic version of Cardizem CD, Plaintiffs' complaints fail to allege any legally cognizable anticompetitive effects caused by that Agreement and thus must be dismissed. Defendants' arguments focus on the second, causation prong of the Brunswick antitrust injury test. They then argue that, under prevailing Sixth Circuit law, Plaintiffs must plead facts showing that their alleged antitrust injury would not have occurred in the absence of the HMRI/Andrx Agreement.

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[14]Defendants attempt to explain away Andrx's representations to the court by arguing Andrx didn't really mean what it said; i.e., when "[r]ead in context, the statement that Andrx intended to enter the market can only be understood to mean that Andrx was prepared to enter the market *if it could resolve* all of the potential patent infringement claims." See HMRI Br. at 34-35 n. 22. Defendants' arguments are to no avail. This Court must take Plaintiffs' allegations as true and cannot dismiss the Plaintiffs' complaints based on facts that contradict their factual allegations.

[15]The Individual Sherman Act Plaintiffs argue that the Hoechst Defendants are collaterally estopped from relitigating the lack of antitrust injury issue because it was already litigated and decided against these Defendants in Biovail Corp. Int'l v. Hoechst Aktiengesellschaft, 49 F. Supp. 2d 750, 767-78 (D. N.J. 1999). This Court agrees with Defendant HMRI that the doctrine of collateral estoppel does not apply here because the district court in Biovail based its decision on a complaint brought by a different plaintiff asserting different allegations affecting the court's analysis of the antitrust injury question. There is no collateral estoppel because the required identity of issues is lacking here. See Detroit Police Officers' Ass'n v. Young, 824 F.2d 512, 515 (6th Cir. 1987).

Defendant HMRI argues that the Sixth Circuit's "necessary predicate" test requires this Court to determine whether plaintiffs could have suffered the same injury from other conduct (under a hypothetical set of facts that contradict those alleged in the Plaintiffs' complaints) that does not violate the antitrust laws; and if it so finds, then the violation is not a necessary predicate of the Plaintiffs' injury, and there can be no antitrust injury. Defendant HMRI further argues that, because Plaintiffs cannot show that their alleged injuries necessarily flow from the HMRI/Andrx Agreement and the alleged anticompetitive conduct, the Court must conclude Plaintiffs suffered no antitrust injury. Defendant Andrx similarly argues that Plaintiffs must plead a coherent factual basis to conclude the injury they allege would not have occurred in the absence of the HMRI/Andrx Agreement.

Defendants argue that Plaintiffs cannot meet this Sixth Circuit "necessary predicate" test because there are three plausible explanations why Andrx may have delayed going to market even though it could have done so as early as July 1998: (1) the HMRI/Andrx Agreement – which is what Plaintiffs allege (antitrust violation); (2) the possibility that HMRI might have been able to obtain a preliminary injunction in the patent case preventing Andrx from selling its generic drug after July 1998 (no antitrust violation); and (3) the fact that Andrx could have unilaterally refrained from going to market prior to resolution of the pending HMRI/Andrx patent infringement case so as to avoid the risk of possible damages (no antitrust violation). Defendants further argue that, because Plaintiffs would have suffered the same injury (delayed entry of the generic drug on the market and thus higher prices for a longer period of time), even without an antitrust violation (albeit under a set of

facts that contradict those Plaintiffs allege here), there is no antitrust injury as a matter of law.

Defendants' arguments are flawed. First, they ignore the standard this Court must apply to Rule 12(b)(6) motions. Second, they ignore the causation standard the Court applies when examining whether the plaintiff has shown a causal connection between an alleged antitrust violation and the injury it claims it suffered. Defendants' alternative, possible causation theories likewise ignore a basic antitrust principle that, in antitrust cases such as this, the only difference between legal and illegal conduct is the existence of an agreement to do the same thing the parties could have done unilaterally and thus legally.[16] Finally, Defendants misapply the antitrust injury test enunciated in Brunswick and its progeny and likewise misapply the Sixth Circuit precedent they rely upon to support their dismissal arguments.

c. Application of Rule 12(b)(6) Standard to Plaintiffs' Allegations

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[16]As Plaintiffs point out, it is the agreement to restrain trade that makes this an antitrust violation in the first instance. To accept Defendants' argument, the Court must also accept the argument that there can never be an antitrust violation if the antitrust defendant can posit an argument that it could have lawfully done the same thing it is accused of doing collusively. The Court finds these arguments unavailing. See Virginia Vermiculite, Ltd. v. W.R. Grace & Co., 156 F.3d 535, 539-40 (4th Cir. 1998), cert. denied, 119 S. Ct. 1458 (1999). There are many things a defendant can do unilaterally without offending the antitrust laws that it cannot do collusively. For example, consider two gas stations that have control over a large geographic market and independently price their gas in such a way that they are within a penny or so of each other. That is not an antitrust violation. However, if the two gas stations, which have a monopoly over gas in the geographic market area, agree to fix the price of gasoline, then there is an antitrust violation. The violation would meet the Brunswick criteria for antitrust injury because the claimed injury is of the type the antitrust laws were meant to discourage; agreements to fix prices. Also, the plaintiff's injury (having to pay higher, deliberately set prices) is causally related to the defendant's anticompetitive acts. The same analysis applies here.

Defendants' arguments merely present a different set of facts that support an alternative possible cause for Andrx's decision to delay going to market with its product beyond July 9, 1998 despite Plaintiffs' allegations that Andrx: (1) had the ability to do so; (2) had made representations to a court that that was what it intended to do; and (3) would have done so but for its September 1997 Agreement with Defendant HMRI to delay in exchange for tens of millions of dollars. Defendants' factual arguments do not make it any less possible that Andrx was doing as Plaintiffs allege here – not marketing its generic product and stalling the patent suit, which in turn stalled the exclusivity period under Hatch-Waxman, because HMRI was paying it $40 million a year to do just that. See Biovail Corp. Int'l, 49 F. Supp.2d at 767-68. In essence, Defendants argue that the Court must conclude that Andrx would not have marketed its generic drug prior to finally resolving the HMRI/Andrx patent litigation regardless of allegations to the contrary in Plaintiffs' complaints. The Court, however, cannot ignore that, on a Rule 12(b)(6) motion to dismiss, it must take all the Plaintiffs' well-pleaded allegations as true, and determine whether Plaintiffs have pled an antitrust injury as defined in Brunswick. The Court cannot consider facts that contradict those pled in Plaintiffs' complaints and, based on those unpled facts, conclude that Plaintiffs would have suffered the same injury with or without an antitrust violation and thus cannot plead an antitrust injury.

Despite Defendants' claims that there could have been an injunction precluding Andrx from going to market and that Andrx could have unilaterally refrained from going to market, that is not what Plaintiffs allege here. Instead, it is alleged that Andrx told the court presiding over the HMRI/Andrx patent infringement case that it expected to begin

selling its generic version of Cardizem CD as soon as it obtained FDA approval, and, "but for" the illegal HMRI/Andrx Agreement, Andrx would have done just that. This Court is required to accept those allegations as true. Dismissal under Rule 12(b)(6) is not permitted simply because Defendants can come up with a different set of facts that support an alternative possible cause for Plaintiffs' injury that does not offend antitrust law. At best, Defendants' arguments highlight disputed issues of material fact that are not to be decided at this stage of the litigation.

d. Application of Proper Causation Standard to Plaintiffs' Allegations

As to the required causal connection between Plaintiffs' alleged antitrust violation and injury suffered, the Supreme Court has observed that an antitrust plaintiff must demonstrate "*some* damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage"; and therefore "[i]t is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury under § 4 [of the Clayton Act]." Zenith Radio Corp., 395 U.S. at 114 n. 9 (emphasis added). Accord, Allied Accessories & Auto Parts Co., Inc. v. General Motors Corp., 901 F.2d 1322, 1325 (6th Cir. 1990).

Professors Areeda and Hovenkamp have likewise observed that, "[w]hile all courts demand a showing of injury-in-fact 'caused' by an antitrust violation, to require proof that the illegal conduct was the *exclusive* cause of the plaintiff's injury would effectively deny private remedies, for multiple causes always affect everyone. Accordingly, the Supreme Court has declared that the plaintiff need show only that the violation is a 'material cause'

of the claimed injury." 2 P. Areeda & H. Hovenkamp, supra, ¶ 363a at 219 (rev. ed. 1995). "It is therefore enough that the antitrust violation contributes significantly to the plaintiff's injury even if other factors amounted in the aggregate to a more substantial cause." Id. at 219-220. "Thus, a plaintiff initially obtains standing by showing that the alleged violation contributed significantly to his injury. Ultimately, of course, he must provide the jury with a reasonable basis for separating the impact of the violation from the other forces affecting him." Id. at 221.

"If there is sufficient evidence in the record to support an inference of causation between the antitrust violation and the injury suffered, the ultimate conclusion as to what that evidence proves is for the jury." Law v. Nat'l Collegiate Athletic Ass'n, 5 F. Supp. 2d 921, 927 (D. Kan. 1998) (citing Perkins v. Standard Oil Co., 395 U.S. 642, 648 (1969)). See also Rossi v. Standard Roofing, Inc., 156 F.3d 452, 483-84 (3rd Cir. 1998) (observing that, as to the causation element of antitrust injury, the plaintiff need only establish that "the defendants' illegal conduct was a material cause of [his] injury")(internal quotes and citations omitted). As the Seventh Circuit recently observed, to satisfy the second, or causation component of Brunswick,

> a § 4 plaintiff must show that its injury "flows from that which makes defendants' acts unlawful," *Brunswick*, 429 U.S. at 489 – that "but for" the alleged violation, the injuries would not have occurred. [Citations omitted]. An antitrust violation need not be the sole cause of the alleged injuries, but the plaintiff must establish, with a fair degree of certainty, that the violation was a material element of, and substantial factor in producing, the injury.

Greater Rockford Energy and Technology Corp. v. Shell Oil Co., 998 F.2d 391, 401 (7th Cir. 1993)).

Thus, the question presented here is whether, construing Plaintiffs' allegations in the light most favorable to them, the HMRI/Andrx Agreement, with its $40 million per year payments to Andrx, was a material cause of Andrx's decision to withhold its product from the market beyond the time it could have gone forward and beyond the time it had represented to another court that it intended to go forward. This Court concludes that Plaintiffs have sufficiently alleged the required causal connection between the Defendants' anticompetitive conduct and their alleged injuries.

To establish antitrust injury, Plaintiffs are not required to eliminate the hypothetical possibility that Defendant Andrx might have unilaterally delayed entry into the market even absent the HMRI/Andrx Agreement. As the Seventh Circuit recently observed in In re Brand Name Prescription Drugs Antitrust Litig., 186 F. 3d 781 (7th Cir. 1999),

> [plaintiffs] did not, . . . , as the defendant manufacturers rather absurdly argue, have to exclude all possibility that the manufacturers' price discrimination was unilateral rather than collusive. That would imply that the plaintiff in an antitrust case must prove a violation of the antitrust laws not by a preponderance of the evidence, not even by proof beyond a reasonable doubt (as indeed is required in criminal antitrust cases), but to a 100 percent certainty, since any lesser degree of certitude would leave a possibility that the defendant was innocent.

Id. at 787. Prevailing Supreme Court precedent and Sixth Circuit precedent do not support Defendants' arguments to the contrary.

e. Application of Brunswick and Its Progeny to Plaintiffs' Allegations

The Sixth Circuit, following Brunswick, applies a two-pronged test in this context, requiring the plaintiff to show "(1) that the alleged violation tends to reduce competition in some market and (2) that the plaintiff's injury would result from a decrease in that competition rather than from some other consequence of the defendant's actions."

Tennessean Truckstop, Inc. v. NTS, Inc., 875 F.2d 86, 88 (6th Cir. 1989) (quoting P. Areeda & H. Hovenkamp, supra, ¶ 334.1b at 299 (1988 Supp.)). Plaintiffs specifically allege that, as a result of the Defendants' illegal market allocation Agreement and Defendants' anticompetitive conduct, Plaintiffs and the class paid more than they would have paid for Cardizem CD absent Defendants' illegal conduct. They allege that the HMRI/Andrx Agreement eliminated generic competition and thus deprived all U.S. purchasers of the ability to buy Cardizem CD at a competitive price. This Court concludes that Plaintiffs have pled the type of injury the antitrust laws were intended to prevent and have pled an injury that flows from the conduct that makes Defendants' actions illegal.

As to the first prong of the antitrust injury test, the Supreme Court has observed that "[t]he Sherman Act was enacted to assure 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. Hovenkamp, supra, ¶ 370 at 253. Plaintiffs have sufficiently pled facts that show they satisfy the "antitrust injury" test set forth in Brunswick. No more is required. The Sixth Circuit precedent Defendants' rely upon is fully consistent with this conclusion.

f. Application of Sixth Circuit Precedent Defendants' Rely Upon

Defendants argue that under Sixth Circuit precedent, the Court must dismiss their complaints if Plaintiffs could have suffered the same injury from conduct other than that alleged in their complaints, that plausibly explains the Defendants' conduct but does not violate the antitrust laws. Defendants offer new and contradictory facts supporting alternative possible causes for Andrx's delayed entry into the market and, using those facts, argue that Plaintiffs cannot show that they would have been worse off with the alleged restraint on trade than they would have been without it and thus cannot plead antitrust injury. Defendants misconstrue and misapply the Sixth Circuit precedent they rely upon to support their dismissal arguments. See Axis, S.p.A. v Micafil, Inc., 870 F.2d 1105 (6th Cir. 1989); Hodges v. WSM, Inc., 26 F.3d 36 (6th Cir. 1994); Valley Products Co. v. Landmark, 128 F.3d 398 (6th Cir. 1997).

The Sixth Circuit determines whether "antitrust injury" has been properly pled by applying the test enunciated in Brunswick. See, e.g., Tennessee Truckstop. Contrary to Defendants' assertions here, the Sixth Circuit does not apply a more stringent "necessary predicate" test each time antitrust injury is challenged on a Rule 12(b)(6) motion. See, e.g., Re/Max Int'l, Inc., 173 F.3d at 1023. Rather, the Sixth Circuit has dismissed antitrust complaints on Rule 12(b)(6) motions when the alleged facts show that the plaintiff's antitrust injury inevitably flows, not from the alleged antitrust violation, but from an independent cause that fully accounts for the plaintiff's injury. In those circumstances, the independent cause breaks the causal connection between the alleged antitrust violation and antitrust injury thus demonstrating that the plaintiff would have necessarily suffered

the same alleged injury with or without the alleged anticompetitive conduct. See Axis, Hodges, and Valley Products. Stated in Brunswick terms, the injury flows from this independent cause, not from the alleged antitrust violation.

The Sixth Circuit has not, as Defendants urge here, dismissed an antitrust complaint 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. Defendants have not presented the Court with any decision where an antitrust complaint was dismissed based on a speculative argument that there can be no antitrust injury because the defendant could have acted other than the plaintiff alleges without offending the antitrust laws and the plaintiff would have suffered the same claimed injury. As Professors Areeda and Hovenkamp caution, "[d]enying injury when the plaintiff is no worse off than he would have been in the absence of any violation does not mean . . . that the defendant should prevail merely by asserting what he would otherwise have done." 2 P. Areeda & H. Hovenkamp, supra, ¶ 363c at 225 (emphasis added) (citing Irvin Indus., Inc. v. Goodyear Aerospace Corp., 974 F.2d 241 (2nd Cir. 1992) and observing that the Second Circuit Court of Appeals "correctly reversed" the district court's decision that there was no antitrust injury to the plaintiff and correctly refused "to base a denial of injury on speculation about what the defendant would have done had it not been acting predatorily") (emphasis added).

As discussed more fully infra, in Axis, Hodges, and Valley Products, the Sixth Circuit did not arrive at its decision that dismissal was proper by assuming the plaintiff's allegations were false and by considering contradictory facts presented by the defendants.

Rather, in those decisions, the Sixth Circuit applied Brunswick and concluded that the plaintiff had not and could not allege an antitrust injury because the injury it alleged flowed not from the alleged antitrust violation but from another independent cause that fully accounted for the plaintiff's claimed injury.

Defendants do not ground their arguments on the court's reasoning and conclusion in Axis, Hodges, and Valley Products. Instead, they focus on language that gives rise to what Defendants call the Sixth Circuit's "necessary predicate" test for establishing antitrust injury. After stating its analysis and decision, the Hodges Court, in the last paragraph of its decision, further remarked 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 pursuant to Federal Rule of Civil Procedure 12(b)(6)." Id. at 39. 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. Factually and legally, the decisions in Axis, Hodges, and Valley Products do not support dismissal of Plaintiffs' antitrust claims on a Rule 12(b)(6) motion.

As Professors Areeda and Hovenkamp have observed, "[o]n occasion, a force other than the antitrust violation fully accounts for the plaintiff's injury." 2 P. Areeda & H.

Hovenkamp, supra, ¶ 363b at 222.[17] For example, "a plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering that market in any event." Id. at 222. As an example of this principle, Professors Areeda and Hovenkamp cite the Sixth Circuit case, Axis v. Micafil, and observe that there is "no standing for [the] plaintiff who was unable to obtain a government-required license to enter the market from which the defendant allegedly excluded him." Id. at 222 n. 15. See also City of Pittsburgh v. West Penn. Power Co., 147 F.3d 256, 268-69 (3rd Cir. 1998)(where the Court observed, "it is the structure of the regulated industry, not the defendant's conduct, which creates the lack of competition -- and under these facts -- the lack of antitrust injury"). Simply put, when an independent cause fully accounts for the plaintiff's alleged antitrust injury, it breaks the causal connection between the alleged antitrust violation and the plaintiff's injury.

Professors Areeda and Hovenkamp caution that "the defendant's reliance on supervening governmental action or other independent cause must be examined closely" to make sure that it is the supervening, independent cause, rather than the alleged illegal agreement, that gives rise to the plaintiff's antitrust injury. 2 P. Areeda & H. Hovenkamp, supra, ¶ 363b at 222 (citing Kaiser Cement Corp. v. Fishbach & Moore, 793 F.2d 1100 (9th Cir. 1986)). That is what the Sixth Circuit did in Axis, Hodges, and Valley Products.

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[17]Professors Areeda and Hovenkamp comment that "[t]his factor also helps explain some substantive antitrust doctrines. For example, lobbying the government for anticompetitive government action is not an antitrust violation because, in part, the anticompetitive impact of the government action is caused by the independent decision of the government rather than by the private party that sought such action." (referring to *Noerr-Pennington* immunity doctrine). 2 P. Areeda & H. Hovenkamp, supra, ¶ 363b at 222 n. 14.

Defendants' arguments confuse the factual circumstances presented here with those presented in Axis, Hodges, and Valley Products, where the alleged facts show that an independent cause fully accounts for the plaintiff's alleged injury and thus breaks the causal link between the alleged antitrust violation and that injury. The mere fact that Defendants can come up with additional plausible and legally permissible explanations as to why Andrx prolonged its entry into the market (albeit based on facts that contradict those alleged in the Plaintiffs' complaints) is to no avail. Dismissal under Rule 12(b)(6) is not appropriate here. As discussed infra, the decisions in Axis, Hodges, and Valley Products do not support a contrary conclusion.

i. Axis, S.p.A. v. Micafil, Inc., 870 F.2d 1105 (6th Cir. 1989).

In Axis, the court affirmed the district court's dismissal of the plaintiff's antitrust claim pursuant to a Rule 12(b)(6) motion to dismiss. Plaintiff, an Italian armature winding machine manufacturer brought antitrust claims against a Swiss manufacturer which had recently purchased two American companies that manufacture armature winding machines. Plaintiff alleged that the defendant's purchase violated the antitrust laws "because the acquisition brought about a substantial reduction of competition in the market" and caused the plaintiff to suffer "lost sales and lost profits from winding machines that it would have sold in the United States" had the defendant not made this purchase. Id. at 1106-07. The district court granted the defendant's Rule 12(b)(6) motion, finding that the plaintiff's complaint "failed to state a claim because it did not allege an 'antitrust injury'" because the plaintiff "would have suffered the same injury – exclusion from the U.S. market – if [the defendant] had not" made the challenged purchase. Id. at 1107. There was

another causal factor that fully explained the plaintiff's exclusion from the U.S. market; i.e., the plaintiff did not have access to the patents it needed to enter the U.S. market. "Thus, 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 [defendant] purchased [the American manufacturer], and they remained as great a barrier afterwards. . . . [A]ny injury that [the plaintiff] may have suffered did not flow directly from [the defendant]'s presumably unlawful act." Id. (Emphasis added).

Applying Brunswick, the Axis Court concluded that the plaintiff's injury did not "flow from" that which made the defendant's acts unlawful under the antitrust laws. It reasoned that the plaintiff's "exclusion from the United States armature winding machine market did not result from [the defendant]'s acquisition of the [American manufacturer] – the anticompetitive act. Before [the defendant] ever acquired [the American manufacturer], [the plaintiff] was shut out of the desired market by the patents" controlled by others "and by the refusal of those companies to license to [the plaintiff]." Id. at 1110.

The Axis Court observed that "[t]he single determinant of antitrust injury is whether the plaintiff has suffered an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes [a defendant's] act [ ] unlawful." Id. at 1111 (quoting Brunswick, 429 U.S. at 489). The Court affirmed the district court, finding that, even viewed in the light most favorable to the plaintiff, its complaint failed to allege an antitrust injury. Id. It observed that the plaintiff: (1) admitted in the complaint that patents controlled by others precluded its entry into the market, (2) failed to allege that the defendant violated the antitrust laws by misusing its patents or licenses, and (3) alleged

only that the defendant's acquisition of the American manufacturing companies "raised the barriers to its entry into the U.S. market" but failed to allege that the defendant "dominated the U.S. market for armature winding machines" and failed to allege "conditions under which the acquisition of patents may violate the antitrust laws and create antitrust injury for which damages may be awarded." Id. at 1111.

As Professors Areeda and Hovenkamp observe, Axis is an example of a case where "a force other than the antitrust violation fully accounts for the plaintiff's injury." 2 P. Areeda & H. Hovenkamp, supra, ¶ 363b at 222. In Axis, it was the plaintiff's inability to obtain certain patents, or a license to use those patents, that caused its alleged injury--exclusion from the relevant market. In the language of Brunswick, plaintiff's injury flowed from its inability to obtain the patents it needed to enter the relevant market; it did not flow from the defendant's alleged anticompetitive conduct. Because it did not have the necessary patents, the plaintiff would have suffered the same injury–exclusion from the relevant market–with or without the alleged antitrust violation.

In contrast, here Plaintiffs allege that "but for" the HMRI/Andrx Agreement and the millions of dollars that HMRI paid to Andrx, Andrx would have done precisely what it represented to the court presiding over the HMRI/Andrx patent infringement action that it intended to do – go to market with its generic product in July 1998 when the Hatch-Waxman 30-month waiting period expired. Unlike the facts presented in Axis, there are allegations here that Andrx's generic product did not infringe the '584 patent, thus giving rise to the inference that the patent did not present an impenetrable barrier to Andrx's July 1998 entry into the United States market for Cardizem CD and its bioequivalents.

ii. Hodges v. WSM, Inc., 26 F.3d 36 (6th Cir. 1994).

In Hodges, the plaintiffs, who operated an airport shuttle and tour service in Nashville, sued companies that owned and operated the Grand Ole Opry music radio program; the amusement park and hotel and convention center known as Opryland; and a sightseeing and tour company called Grand Ole Opry Tours, Inc. The plaintiffs alleged that these defendants violated § 1 of the Sherman Act when they unlawfully conspired with competitors in the Nashville airport shuttle and tour market. The alleged unlawful agreement was that the competitors would "refrain from transporting passengers between the airport and the Opryland complex, in exchange for defendants hiring vans and buses from these former competitors for Opryland's sightseeing tour business." Id. at 37. The plaintiffs further alleged that the defendants "policed the agreement by refusing entry onto Opryland property" to the plaintiffs and to all non-conspiring shuttle service companies. Id. Finally, the plaintiffs alleged that this illegal conspiracy caused them to lose sales of shuttle services between the Nashville airport and Opryland and thus injured the plaintiffs' "opportunity to compete in the airport shuttle transportation market." Id.

The Sixth Circuit affirmed the district court's dismissal of the plaintiffs' antitrust claims in response to the defendants' Rule 12(b)(6) motion to dismiss. The district court applied the two prong test of Brunswick and concluded that the plaintiffs' complaint failed to state a claim because it did not allege an antitrust injury. The court examined the nature of the alleged conspiracy and the plaintiffs' injury and reasoned that: (1) the plaintiffs' injury did not flow from "a decrease in competition among the allegedly conspiring shuttle operators," (2) "if the conspiracy existed, it would have benefitted [the p]laintiff by reducing its

competition to shuttle passengers from the airport to Opryland", and (3) "[i]t was Opryland's refusal to allow [the p]laintiff's vans on its property which caused [the p]laintiff's injury." Id. at 38. Agreeing with the district court's analysis, the Sixth Circuit likewise concluded that, because the alleged antitrust violation would have benefitted the plaintiffs, not injured them, the "plaintiffs were not harmed by the kind of evil contemplated by § 1 of the Sherman Act." Id. at 39. Accordingly, the plaintiffs did not, and could not, allege facts that satisfied the first prong of the Brunswick "antitrust injury" test.

As to the second prong of Brunswick, the Sixth Circuit explained, the "defendants were accused of orchestrating with former competitors a combination designed to free [the] defendants of competition." Id. at 39. The defendants allegedly agreed with these other conspiring shuttle services that the defendants would handle all shuttles from the airport to Opryland and, in exchange, the defendants would farm out tour business from Opryland to these co-conspirators. Opryland's refusal to allow the plaintiffs access to its property was not part of the alleged conspiracy. Rather, it was alleged that the defendants used the refusal as a means to police the alleged illegal agreement. Id. at 37. Accordingly, the court reasoned, the alleged "violation of the antitrust laws, a market division conspiracy to restrain competitors, was not the cause of plaintiffs' exclusion from the shuttle service market between the airport and Opryland." Id. at 39. The alleged illegal agreement did not prevent the plaintiffs from shuttling customers between the airport and Opryland. Rather, "plaintiffs' injury resulted from defendants' lawful refusal to grant plaintiffs access to their private property." Id. The alleged antitrust violation was a conspiracy to decrease competition among competitors, and the plaintiffs' alleged "injury was not an

'antitrust injury' because it did not result from any decrease in competition among shuttle operators." Id. at 39. Simply put, violation of the antitrust laws, "was not the cause of plaintiffs' exclusion from the shuttle service market between the airport and Opryland." Id. at 39. Rather, the alleged harm was caused by the defendants' denial of access to Opryland. This independent cause fully accounts for the plaintiffs' claimed injury and does not flow from the alleged antitrust violation.

The Hodges Court, as mandated under Brunswick, examined the nature of the alleged antitrust violation and the alleged antitrust injury and concluded that there could be no antitrust injury where: (1) the plaintiffs were not harmed from the kind of evil contemplated by section 1 of the Sherman Act; and (2) there was no causal connection between the harm allegedly suffered and the alleged Sherman Act violation.

In contrast, here it is alleged that Defendants conspired and agreed to keep Andrx's generic version of Cardizem CD off the market, to prolong HMRI's monopoly and to keep prices at an artificially high rate. It is further alleged that but for the Defendants' illegal conspiracy and agreement, Defendant Andrx would have done as it told the HMRI/Andrx patent court it was prepared to do; i.e., begin marketing its generic version of Cardizem CD as soon as it obtained FDA approval and the 30 month Hatch-Waxman stay period had expired – on or before July 9, 1998. Plaintiffs also allege that but for Defendants' alleged anticompetitive conduct, Plaintiffs would not have paid an artificially high price for Cardizem CD. Thus, unlike the plaintiffs in Hodges, Plaintiffs here allege facts showing that: (1) they were harmed by the kind of evil contemplated by section 1 of the Sherman

Act; and (2) their antitrust injuries "flow from" and are a direct result of the alleged antitrust violation. **iii. Valley Products Co. v. Landmark, 128 F.3d 398 (6th Cir. 1997).**

In Valley Products, the plaintiff, a manufacturer of logo-bearing hotel soaps and other hotel amenities, brought an antitrust action against a hotel franchisor and two of the plaintiff's competitors, Guest Supply, Inc. and Marietta Corp., claiming the plaintiff was the victim of an illegal tying arrangement between the defendant hotel franchisor and its franchisees. The plaintiff had been one of six approved vendors that the defendant franchisor authorized to sell logo-bearing soap and other guest amenities to its franchisees. The plaintiff and the other approved vendors had a "vendor agreement" with the defendant franchisor that allowed either party to terminate on 60 days' notice. The defendant franchisor decided to cut its number of preferred vendors down to two (Guest Supply and Marietta Corp.) and notified the plaintiff that it was terminating its vendor agreement.

After its vendor agreement was terminated, the plaintiff filed suit alleging that the defendants: (1) violated section 1 of the Sherman Act "by attempting to subject [the defendant franchisor's] franchisees to tying arrangements under which franchise rights were conditioned on purchases of logoed amenities manufactured by Guest Supply and/or Marietta"; and (2) violated section 2 of the Sherman Act "by attempting improperly to leverage the market power of the defendant manufacturers and the monopoly power that [the defendant franchisor] possessed over its franchisees' use of the [defendant franchisor's] trademarks". Id. at 401. The district court granted a Rule 12(b)(6) motion to

dismiss, finding that the plaintiff had failed to state an antitrust claim on the ground that its complaint failed to allege an antitrust injury. The Sixth Circuit affirmed.

Citing Brunswick, the Sixth Circuit observed that the plaintiff must prove antitrust injury. Id. at 402. It further observed that the Sixth Circuit bars recovery "where the asserted injury, . . . , flows directly from conduct that is not itself an antitrust violation." Id. at 403 (citing and discussing Axis and Hodges). The Valley Products Court then concluded that the plaintiff could not satisfy the Sixth Circuit requirement that the alleged antitrust violation (defendant franchisor's alleged tying arrangement with its franchisees) be a necessary predicate to the plaintiff's alleged antitrust injury (loss of logoed amenity sales). Id. at 404. The Court reasoned that the plaintiff's alleged injury – the loss of logoed amenity sales it claimed it suffered after its vendor agreement was canceled – "flowed directly from the cancellation." Id. It further observed that "the sales losses would have been suffered as a result of the cancellation whether or not [the defendant franchisor] had entered into the alleged tying arrangements with the franchisees." Id.

In Valley Products, there was no antitrust injury because the plaintiff's alleged injury flowed from the fact that the defendant franchisor terminated its vendor agreement, not from the alleged anticompetitive activity. Id. This termination was an independent cause that fully accounted for the plaintiff's claimed injury, and the termination was not itself an antitrust violation. In contrast, Plaintiffs allege that their injuries flow directly from Defendants' anticompetitive conduct. This Court cannot conclude, on a Rule 12(b)(6) motion, that an independent cause fully accounts for Plaintiffs' asserted injuries and that

Plaintiffs' alleged injuries flow directly from an independent cause that is not itself an antitrust violation.

The mere fact that Defendant Andrx can come up with other plausible and legally permissible explanations as to why it prolonged its entry into the market is to no avail. In Virginia Vermiculite, 156 F.3d at 539-40, the Fourth Circuit Court of Appeals rejected an argument similar to the one Defendants raise here. Reversing the district court's Rule 12(b)(6) dismissal of the plaintiffs' section 1 Sherman Act claims "on the ground that [the plaintiffs] failed to demonstrate a sufficient causal relationship between their alleged injury and the [defendants]' alleged violation of the antitrust laws", id. at 539, the Fourth Circuit found the district court's reasoning faulty because: (1) it failed to appreciate the Supreme Court's observations that "in antitrust cases, where the proof is largely in the hands of the alleged conspirators, dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly", id. (internal quotes and citations omitted), and (2) the district court misconstrued the nature of the plaintiffs' Sherman Act allegations and failed to appreciate that the defendant was "foreclosed from challenging causation simply on the basis that it could have achieved the same result through lawful means." Id. at 540. Accord, In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d at 787; Biovail v. Hoechst Aktiengesellschaft, 49 F. Supp. 2d at 767-78 (where the court rejected the same argument Defendants raise here, refused to dismiss plaintiff's antitrust claims under Rule 12(b)(6), and reasoned that, "while it is possible that Andrx is not marketing its generic product because it does not want to risk potential patent infringement damages, it is also *certainly* possible that Andrx is not marketing its generic product . . . because defendants

are paying it forty million dollars a year not to do so. This court simply cannot make this call on the pleadings.").

g. The Other Cases Defendants Rely Upon do not Require a Different Result.

Defendants' reliance on City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3rd Cir. 1998) is likewise misplaced. In that case, the plaintiff City asserted antitrust claims against the defendant power companies "alleging that the two companies entered into a premerger agreement in restraint of trade and that their proposed merger would substantially lessen competition or tend to create a monopoly" and limit the City's ability to choose to buy power from one company over the other. Id. at 258. The Court affirmed the district court's dismissal of the plaintiff's complaint, pursuant to Rule 12(b)(6), reasoning that the plaintiff failed to state an antitrust claim because "any injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three [parties] were actors." Id. at 265. Central to the Court's decision were the alleged facts that the defendant power companies were never competitors, "the regulatory scheme mandated that they not compete;" and that any attempts to compete "were no more than attempts, with no assurance that competition would be permitted." Id. Thus, the Court concluded, the City's alleged injury, "[t]he purported lessening of competition", "was not caused by the premerger agreement and proposed merger" of defendant power companies." Id. at 266. Rather, "the City's inability to choose to buy from either [defendant power company] . . . is an injury visited upon it by the regulated nature of the utility services, not caused by an agreement between [defendant power companies] to withdraw [one of the company]'s application to be able to

compete." Id. The defendant power company needed regulatory approval before it could compete, it did not have that approval, it never competed and thus "any injury to the City did not result from a lessening of competition." Id. The Third Circuit, agreeing with the district court, observed that "it is the structure of the regulated industry, not the defendants' conduct, which creates the lack of competition – and under these facts – the lack of standing." Id. at 269. The Court went on to observe that "[t]he very essence of our ruling is that the advent of deregulation will likely remove the break in the causal chain so that future utility arrangements in the free market atmosphere may well pass muster for purposes of standing under the antitrust laws." Id. at 269. With the current statutory and regulatory scheme in place, however, the Court concluded that "the City cannot establish the necessary antitrust injury and causal connection between the alleged antitrust violation and its injury." Id.

The District Court for the District of Columbia recently reached a similar conclusion in a case pending between Andrx and Biovail Corporation International, a Canadian corporation and competitor of Defendants Andrx and HMRI. In Andrx Pharm., Inc. v. Friedman, 83 F. Supp. 2d 179 (D. D.C. 2000), the court concluded that Biovail's alleged antitrust injury – delayed sales and profits for its generic version of Cardizem CD – did not flow from the HMRI/Andrx Agreement but from two other independent causes: (1) the FDA had not yet approved Biovail's ANDA for its generic version of Cardizem CD; and (2) the "troublesome" statutory scheme (the Hatch-Waxman Amendments) that prohibits Biovail from "marketing a drug until the first ANDA recipient goes to market, and which places no restrictions on when, or even whether, that applicant must go to market." Id. at 185.

Unlike the City in City of Pittsburgh and Biovail in Andrx Pharm. v. Friedman, Plaintiffs here allege an antitrust injury – having to pay an artificially high price – that flows directly from the alleged antitrust violation, the September 1997 HMRI/Andrx Agreement. The Hatch-Waxman Amendments did not prohibit Andrx from going to market with its generic product on July 9, 1998. Defendant Andrx not only had the unfettered right to do so, Plaintiffs allege that it represented to the court presiding over the HMRI/Andrx patent infringement action that that was what it intended to do. It is further alleged that but for HMRI's promise to pay it tens of millions of dollars to delay, Andrx would have gone to market on July 9, 1998. Even though the Hatch-Waxman Amendments may authorize very specific unilateral conduct and a specific, limited restraint of trade, they do not authorize agreements to restrain trade.

h. Conclusion

Unlike the plaintiffs in Axis, Hodges, Valley Products, and City of Pittsburgh, Plaintiffs here have alleged an injury that flows directly from the Defendants' anticompetitive acts. These allegations must be taken as true. That Defendants can come up with contrary facts to support their alternative hypothesis about what Defendant Andrx could have done so as to not offend the antitrust laws is irrelevant. As the Seventh Circuit recently observed in In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d at 787, to require Plaintiffs to "exclude all possibility that the manufacturers' price discrimination was unilateral rather than collusive" would impermissibly require an antitrust plaintiff to "prove a violation of the antitrust laws . . . to a 100 percent certainty, since any lesser degree of certitude would leave a possibility that the defendant was innocent." Defendants'

arguments here that Plaintiffs "must plead a coherent factual basis to conclude the injury they allege would not have occurred in the absence of the HMRI/Andrx Agreement" likewise requires Plaintiffs to "exclude all possibility" that Defendant Andrx's conduct was unilateral rather than collusive, and likewise impermissibly requires an antitrust plaintiff to not only prove but to plead facts that would allow the Court, on a Rule 12(b)(6) motion, to determine to a 100 percent certainty that there was no antitrust injury. Accordingly, Defendants' motions to dismiss based on Plaintiffs' inability to plead the fact of antitrust injury are DENIED.

C. Preemption/Exemption of Plaintiffs' Claims

Issues: Whether the Hatch-Waxman Amendments (1) Preempt Plaintiffs' State Law Claims; and (2) Provide an Implied Exemption from the Sherman Act Plaintiffs' Antitrust Claims?

1. Preemption of State Law Plaintiffs' claims

In Gustafson v. City of Lake Angelus, 76 F.3d 778 (6th Cir. 1996), the Sixth Circuit observed that:

> Preemption is predicated on congressional intent. . . . A statute may be construed as preemptive under three circumstances. First, Congress, in enacting a federal statute, may express a clear intent to preempt state law. Second, absent express preemption, federal law may have an implied preemptive effect if Congress revealed this intent by "occupying the field" of regulation. There is implied preemption when there is a scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it or because the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. There is a third type of preemption when state law actually conflicts with federal law. Such conflict occurs where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Id. at 782-83 (internal quotes and citations omitted). Defendants argue here that there is preemption under the second and third set of circumstances. This Court disagrees.

Defendants first argue that Plaintiffs' state law claims are preempted because Congress has so pervasively regulated this particular intersection of patent law, pharmaceutical regulation, and antitrust law that a clear intent to occupy the field can be inferred. Focusing as it must on congressional intent, this Court examines Defendants' evidence of pervasiveness and its argument that the Hatch-Waxman Amendments preclude enforcement of Plaintiffs' state law claims.

Defendants assert that the Hatch-Waxman Amendments were intended to expedite the availability of lower-priced generic drugs by encouraging drug manufacturers to develop generic forms of brand-name drugs (180 day exclusivity period for the first to file an application) while preserving the brand-name drug manufacturer's protections under the patent laws (30 month suspension of FDA approval of the first filer's application for approval of its generic version of the patented drug if the patent holder timely files a patent infringement action against the generic drug manufacturer). Without evidence of congressional intent or analysis of the state laws at issue here, Defendants conclude without support that Congress intended to so occupy the field of prescription drug development so as to preclude enforcement of Plaintiffs' state law claims. The fact that the Hatch-Waxman Amendments set out a statutory scheme designed to encourage drug manufacturers to develop generic forms of brand-name drugs that do not infringe the brand-name drug manufacturer's patents, and the fact that the FDA has adopted regulations to enforce the Hatch-Waxman statutory scheme, does not convince the Court

that Congress left no room for Plaintiffs' state law claims or that Plaintiffs' state law claims address the same subject matter addressed in the Hatch-Waxman Amendments or the FDA regulations relating to enforcement of those Amendments. Defendants have not convinced the Court that the state laws at issue impinge in any way on the federal government's "established scheme" in this area of federal law. The cases Defendants rely upon do nothing to advance their position that permitting Plaintiffs to bring their state law claims against Defendants would frustrate Congress' intent to bring the subject areas of law under a uniform set of federal regulations.

Defendants next argue that Plaintiffs' state law claims are preempted because compliance with both the state laws and the Hatch-Waxman Amendments is impossible. Specifically, Defendants argue that Plaintiffs' state law claims are preempted because the state laws would render illegal the very conduct Congress approved in the Hatch-Waxman Amendments. Defendants' arguments are without merit.

As Plaintiffs correctly point out, there is nothing in the language of the Hatch-Waxman Amendments or their legislative history that prohibited Defendant Andrx from bringing its generic product to market in July 1998. If it had done so, there would be no violation of the state laws at issue here. Moreover, if Defendant Andrx had unilaterally decided not to market its generic product until resolution of the HMRI/Andrx patent infringement action, there would be no state law violations. However, there is nothing in the language of the Act or its legislative history that impliedly authorizes a patent-holder, like Defendant HMRI, to contract with and pay a generic drug competitor, like Defendant Andrx, to delay its entry into the market beyond the time the statute permits it to go to

market so as to artificially inflate the price at which the patented brand-name drug is sold. That is what Plaintiffs are alleging here. See Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1072 (D.C. Cir. 1998) (observing that the statutory scheme creates an unfortunate opportunity for illegal anticompetitive conduct, "the first applicant could even collude with the original patent-holder to prolong their litigation, and thereby keep the second applicant's drug off the market indefinitely");[18] Mylan Pharm., Inc. v. Shalala, ___ F.3d ___, 2000 WL 424204, *17 (D. D.C. 2000) (same)[19]; Biovail Corp. Int'l, 49 F. Supp.

[18]In Mova, the court concluded "that the FDA exceeded its statutory authority in imposing a successful-defense requirement as a prerequisite to the invocation of the 180-day exclusivity rule by a first applicant" because that requirement was "inconsistent with the statutory text and structure," and was "not justified by a need to protect the essential function of the statute or a clear congressional intent." 140 F.3d at 1076. The FDA's successful-defense requirement impermissibly: (1) allowed later applicants to obtain FDA approval for their generic drugs and to begin marketing these drugs even though the first ANDA applicant has not yet obtained the benefits of the 180-day exclusivity period; and (2) wrote the commercial marketing trigger out of the Hatch-Waxman Act. Id. at 1069-70.

[19]At issue in Mylan Pharm., was the underlying patent infringement litigation between the patent-holder of a patent covering the drug tamoxifen and Barr Laboratories, a generic maker of tamoxifen who had filed an ANDA with a Paragraph IV certification. The United States District Court for the Southern District of New York had held that the tamoxifen patent was invalid. 2000 WL 424204 at *3. The patent holder then appealed, but the matter settled before there was any substantive review by the Federal Circuit. The Settlement Agreement "was expressly conditioned on Barr's agreement to abandon its challenge to the validity of [the patent holder]'s patent. Barr would abandon its challenge by amending its Paragraph IV certified ANDA back to a Paragraph III certified ANDA" and, as a result, "Barr's ANDA was no longer eligible for approval until after August 20, 2002, the date that [the patent holder]'s tamoxifen patent was scheduled to expire." Id. at *4. "After settling the case but during the pendency of the appeal" the parties jointly asked the appellate court to vacate the district court decision and to remand the case with instructions to dismiss the case without prejudice. The Federal Circuit issued a short order granting the parties' request. Id. at *4. Subsequently, at Barr's request, the FDA granted Barr's petition to preserve its right to the 180-day exclusivity period provided under Hatch-Waxman and thus preserved its right "to exclude all other generic makers of tamoxifen." Id. at *6.

2d at 768 (observing that Biovail was alleging "that defendants are taking advantage of the exclusivity period in an anticompetitive manner"; that "it could be said that the Andrx Agreement falls squarely within what the court in Mova speculated would be an abuse of the statute"; and further observing that in Woods Exploration & Producing Co. v. Aluminum Co. of Am., 438 F.2d 1286, 1303 (5th Cir. 1971), the court had held "that actions taken to 'subvert' a regulatory scheme 'for anticompetitive purposes' are subject to the antitrust laws"). See also A. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?", 39 IDEA: J. L. & Tech. 389 (1999) where the author criticizes the ease with which the Hatch-Waxman statutory scheme and its original goals can be and have been subverted, citing the facts of this multidistrict litigation and the HMRI/Andrx Agreement as an example. As the author observes:

Subsequently, two other generic manufacturers of tamoxifen, Mylan Pharmaceuticals, Inc. and Pharachemie, B.V., brought the instant suit asserting that the FDA's decision to grant Barr's request violated the Hatch-Waxman Amendments and the FDA's own regulations. The Mylan Pharm. Court agreed and concluded that the FDA had exceeded its statutory authority under the Hatch-Waxman Amendments when the FDA: (1) "gave no effect to the [United States District Court for the] Southern District [of New York] decision that determined that Barr had not infringed [the patent-holder]'s patent and [thus determined] that Barr was entitled to 180 days of marketing exclusivity"; and (2) "determined that Barr was the first Paragraph IV ANDA applicant and thus, was entitled to exclusivity, despite the fact that first-filer Barr's application had not contained a Paragraph IV certification since 1993. Id. at *12. The Mylan Pharm. Court construed the statutory language "a decision of a court", discerned "clear congressional intent that the draftsmen intended 'a decision of the court' to mean all court decisions, whether subsequently vacated, settled, appealed or otherwise mooted", id. at *15, and held that it "unambiguously" applied "to cover a district court decision subsequently appealed and vacated pursuant to a settlement during the pendency of the appeal." Id. at *18. The court further observed that "Hatch-Waxman [was] intended to provide an incentive for drug companies to explore new drugs, not a market 'windfall' for crafty, albeit industrious, market players." Id. at 17.

> [t]he likelihood that a patent challenge will result in an actual judgment that triggers the 180-day exclusive period is, in fact, very small. Of the approximately two dozen or more patent challenges filed since 1984, only a handful have resulted in an actual judgment after a full trial. . . . The vast majority of patent challenges have resulted in a settlement involving either a cash payment to the challenger in exchange for an agreement to forego the challenge or the grant of a deferred license; i.e., a license which would allow the generic challenger to begin competition on an agreed-upon date before the actual expiration of the patent, typically six months or more. In a pending case involving a sustained release version of diltiazem, the patent owner (Hoechst-Roussel) is paying the challenger (Andrx) the sum of $10 million per quarter to refrain from entering the market unless and until a final judgment is entered in pending litigation even though more than thirty months have lapsed and Andrx is free to enter the market under its approved ANDA.

Id. at 416-17 (emphasis added).

Plaintiffs have alleged here that Defendants, a patent holder and the first generic applicant, agreed that the patent holder (HMRI) would pay the first generic applicant (Andrx) a portion of its monopoly profits (tens of millions of dollars) to delay marketing its FDA-approved generic drug beyond July 9, 1998 and beyond the time it represented to another court that it intended to begin marketing its generic drug. Such collusive conduct falls outside the parameters of the Hatch-Waxman Amendments yet falls squarely within the parameters of the state and federal laws that give rise to Plaintiffs' claims. The Court is satisfied that Plaintiffs may well be able to show that although Defendants fully complied with the Hatch-Waxman Amendments, they have unfairly restricted competition and thus are liable under the state and federal claims asserted in Plaintiffs' complaints.

The FDA has recently observed that agreements and arrangements between a patent holding drug company and a first-to-apply generic drug company, "may contribute to delayed generic competition by forestalling the beginning, or triggering, of the 180-day

exclusivity period." 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 21 C.F.R. Part 314, Proposed Rules, Dept. of Health & Human Serv., F.D.A., 64 Fed. Reg. 42873 at 42874-75 (August 6, 1999). Accordingly, such agreements, can subvert "Congress's central goal" underlying its passage of the Hatch-Waxman Amendments; i.e., "to bring generic drugs on the market as rapidly as possible." Mova, 140 F.3d at 1068. To cure this problem, the FDA has recently announced proposed rule changes to the regulations that place a time limit on when the first-filed ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period provided under the Hatch-Waxman Amendments; a "use it or lose it" triggering period is proposed. The FDA explains the problem and proposed remedial regulations as follows.

> The Hatch-Waxman Amendments benefit consumers by bringing lower priced generic versions of previously approved drugs to market, while simultaneously promoting new drug innovation through the restoration of patent life lost during regulatory proceedings. The award of a 180-day period of market exclusivity for certain ANDA applicants with paragraph IV certifications was designed to maintain this balance by rewarding generic firms for their willingness to challenge unenforceable and invalid innovator patents, or design noninfringing drug products. Recently, however, this balance has been upset and generic competition impeded, in part through the establishment of certain licensing agreements or other commercial arrangements between generic and innovator companies.
>
> Under current regulatory provisions, the first generic applicant to file a substantially complete ANDA with a paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company. The result may be, notwithstanding the intent of the Hatch-Waxman Amendments, rewards are directed to generic companies for hindering rather than speeding generic competition. A necessary condition for such arrangements is that the economic gains to the innovator from delaying generic competition exceed the potential economic gains to the generic applicant from the 180 days of market exclusivity. Such instances are becoming more frequent because a successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an

> innovator firm. Under such circumstances, it can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments.
>
> FDA's proposal to establish a 180-day triggering period addresses this problem in several ways. In most cases, the first generic applicant with a paragraph IV certification would lose its claim to 180-day exclusivity if it withheld its drug product from the market, or failed to obtain a favorable court decision, for more than 180 days after the tentative approval of a subsequent generic applicant for the same drug product. Also, a subsequent generic applicant could not be blocked from marketing its drug product for longer than, at most, 1 year from when it received tentative approval (the 180-day triggering period plus the 180-day exclusivity period). As a result, the potential economic losses to consumers from the increased unavailability of lower priced generic products would be reduced significantly.
>
> Moreover, decreasing the length of time that these commercial arrangements could block generic competition lessens the market incentive for entering into such agreements. Limiting the period during which an agreement between an innovator and the first generic ANDA applicant with a paragraph IV certification could block generic competition provides less incentive, and therefore makes it less likely, that an innovator and a generic company would enter into such an agreement. Consequently, consumers would benefit because commercial arrangements to block generic competition would be not only less damaging, but would be less likely to occur.

64 Fed. Reg. at 42882-83 (emphasis added). The Bureau of Competition and of Policy Planning of the Federal Trade Commission ("FTC") published comments supporting the proposed rule and suggesting that "the FDA consider a requirement that both patent litigation settlement agreements (either full or partial settlements) between branded companies and ANDA applicants and agreements related to the filing of an ANDA by a potential applicant be filed confidentially with the agency in a timely manner and be accessible to federal antitrust authorities on a non-public basis so that the antitrust

agencies can be made aware of any anticompetitive issues involved with such settlements." In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications: "Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission", Docket No. 85N-0214 at 1, 5-6 (November 4, 1999).

2. The Hatch-Waxman Amendments Do Not Provide an Implied Exemption from Plaintiffs' Antitrust Claims

"[T]he courts often say that [antitrust] immunity is not lightly to be implied, unless 'necessary to make the [regulatory] Act work.'" 1A P. Areeda & H. Hovenkamp, supra,¶ 243a1 at 36 (quoting Silver v. New York Stock Exchange, 373 U.S. 341, 357 (1963)). See also United States v. Nat'l Ass'n of Sec. Dealers, Inc., 422 U.S. 694, 719-720 (1975) (observing that "implied antitrust immunity is not favored, and can be justified only by a convincing showing of clear repugnancy between the antitrust laws and the regulatory system" at issue). Defendants have not demonstrated such a "clear repugnancy" between the antitrust laws and the Hatch-Waxman Amendments and have not supplied this Court with any decision so holding. Because the Hatch-Waxman Amendments neither require nor approve of agreements between competitors to keep a product off the market, Defendants arguments for antitrust immunity are to no avail.

The fact that the Hatch-Waxman Amendments permit Defendant Andrx to unilaterally do what it cannot do collusively does not serve to immunize Defendants' conduct from the antitrust laws. As Professors Areeda and Hovenkamp observe, "[w]here a statute conveys no express immunity and leaves acts open to private discretion, antitrust law will be

applied to define the limits of private behavior." 1A P. Areeda & H. Hovenkamp, supra, ¶ 243a2 at 37. These commentators caution that, "courts should not conclude too quickly that antitrust jurisdiction is ousted merely by virtue of the existence of a federal regulatory scheme." Id. ¶ 244a at 66. "Antitrust is presumptively relevant whenever the conduct being challenged was engaged in by a private party and not mandated or adequately reviewed by the federal agency." Id. Here, the challenged conduct was engaged in by private parties, was not mandated by the Hatch-Waxman Act, and was not adequately reviewed by any federal agency.

As the Sherman Act Plaintiffs point out, no court has held that the sixteen year old Hatch-Waxman Amendments provide immunity from the antitrust laws or have repealed the Sherman Act, and Defendants have not persuaded this Court that it should be the first to do so. Moreover, this Court agrees with Plaintiffs' argument that both the FDA and the FTC's actions and comments discussed above clarify that neither agency considers that the regulatory scheme of the Hatch-Waxman Amendments conflicts with, or is inconsistent with, existing antitrust laws. Contrary to Defendants' arguments, the Hatch-Waxman Amendments are not clearly repugnant to the antitrust laws and thus do not provide an implied exemption from antitrust law.

D. FTC Consent Decree

Issue: Do Plaintiffs' Claims Require This Court to Enforce a FTC Consent Decree

The Hoechst Defendants argue Plaintiffs' state law claims cannot be based on their allegations that the Hoechst Defendants violated an FTC Consent Decree because

Plaintiffs lack standing to collaterally enforce the Decree or to even have this Court construe its terms. The FTC Consent Decree required Defendant Hoechst AG to provide Biovail with a limited right to rely on certain toxicology data that had been filed in support of Cardizem CD in order to assist Biovail in gaining approval for its Tiazac product – a generic version of Cardizem CD. Defendants assert that Plaintiffs' state law claims require the Court to construe the provisions of the Consent Decree and to conclude that Defendants violated that Decree. They further assert that, because Plaintiffs are neither parties to nor intended beneficiaries of the Consent Decree, they have no express enforcement rights under the Decree and thus lack standing to ask this Court to construe and enforce its provisions. Defendants cite Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723 (1975) and its progeny in support of their arguments.

State Law Plaintiffs respond that: (1) this Court, in its October 14, 1999 Mem. Op. and Order, has already observed that State Law Plaintiffs' claims do not seek to have the Consent Decree enforced and do not require the Court to construe or apply the Federal Consent Decree and thus Defendants should not be allowed to relitigate this matter; and (2) even if this Court were to allow the issue to be relitigated, it should adopt the reasoning in Biovail Corp., Int'l v. Hoechst Atkiengesellschaft, 49 F. Supp. 2d 750, 762-66 (D. N.J. 1999) and similarly reject Defendants arguments. The Court agrees with Plaintiffs on both points.

This Court has observed that the State Law Plaintiffs' substantive claims arise under state law, not federal law, and that Plaintiffs' allegations regarding the FTC Consent Decree are merely evidence of the Plaintiffs' state law claims. This Court further observed

that Plaintiffs' claims do not require it to interpret the FTC Consent Decree, and the cases Defendants relied upon failed to support their position to the contrary. Unlike the circumstances in the cited cases, State Law Plaintiffs do not seek to overturn the FTC Consent Decree, nor do they challenge its appropriateness. Rather, they use the Hoechst Defendants' conduct in connection with that FTC Consent Decree as evidence in support of their state law claims. See In re Cardizem CD Antitrust Litig., 99-md-1278, Mem. Op. and Order at 36-37 (E.D. Mich. October 14, 1999).

In their amended consolidated complaint, State Law Plaintiffs likewise do not seek enforcement of the FTC Consent Decree and in no way threaten the FTC's enforcement of that Decree, either by inconsistent interpretations or otherwise.[20] The cases Defendants rely upon in their motions to dismiss fail to support their position to the contrary.[21]

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[20]Plaintiffs confirmed at the hearing on this matter that they intend to use the Hoechst Defendants' conduct in connection with the FTC Consent Decree as evidence in support of their state law claims and not as the basis for a separate cause of action. See 4/18/00 Hrg. Transcript at 81.

[21]See Golden v. Nat'l Finance Adjusters, 555 F. Supp. 42, 47 (E.D. Mich. 1982) (dismissing the plaintiffs' declaratory judgment action and observing that "[p]laintiffs have failed to show how an interpretation of a consent decree between the government and defendant, which plaintiffs cannot enforce against defendant, presents a justiciable controversy to this Court"); S.E.C. v. Prudential Securities, Inc., 136 F.3d 153, 156-160 (D.C. Cir. 1998) (affirming the denial of a motion, brought by a group of investors, to intervene in an ongoing enforcement proceeding against a securities seller because these investors were third parties to the subject Consent Decree, were not the intended beneficiaries of that Consent Decree, had no legally protected interest in enforcing the Consent Decree, and thus had no right to intervene in proceedings to enforce it); Rafferty v. NYNEX Corp., 60 F.3d 844, 849 (D.C. Cir. 1995) (holding that the plaintiff could not sue to uphold a consent decree between the government and the parent company of his employer and observing that "[u]nless a government consent decree stipulates that it may be enforced by a third party beneficiary, only the parties to the decree can seek enforcement of it"); Beckett v. Air Line Pilots Ass'n, 995 F.2d 280, 288-89 (D.C. Cir. 1993) (observing that incidental third party beneficiaries cannot sue to enforce a consent

State Law Plaintiffs' claims here do not depend upon a finding that the Biovail FTC Consent Decree was breached and do not seek enforcement of that Decree. As recently observed by the District Court for the District of New Jersey in Biovail, although Biovail lacked standing to enforce the FTC Consent Decree, "this does not mean that defendants' behavior with respect to the FTC Decree cannot be considered, along with all the other allegations, as support of Biovail's antitrust claims. Biovail's standing to enforce the consent decree is distinct from its standing to maintain an antitrust claim." Biovail, 49 F. Supp. 2d at 764-65. The same analysis applies here. Plaintiffs do not seek to enforce the FTC Decree, and thus the Court may consider allegations in their complaint about activity in connection with that FTC Decree.

E. Challenges to State Law Plaintiffs' Claims

1. Wisconsin and Tennessee – Intrastate versus Interstate Commerce Issue

Issue: Whether Plaintiffs are required to allege conduct affecting intrastate as opposed to interstate commerce to state claims under the relevant Wisconsin and Tennessee statutes?

Defendants argue that the Wisconsin Plaintiffs (Albert Eirich and United Wisconsin Services, Inc.) and the Tennessee Plaintiffs (Eugenia Wynne Sams and Larry S. Sizemore) have failed to state a claim for relief because the Wisconsin antitrust statute and the Tennessee antitrust and consumer fraud statutes apply to intrastate, as opposed to interstate, commerce. Plaintiffs respond that Defendants make too much of the interstate/intrastate dichotomy. Citing a recent Seventh Circuit decision, Plaintiffs assert

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decree).

that Defendants' narrow interpretation of the Wisconsin and Tennessee statutes would render them a virtual nullity. See In re Brand Name Prescription Drugs Antitrust Litig., 123 F.3d 599, 612-13 (7th Cir. 1997) (observing that to narrowly limit the reach of Alabama's antitrust statute to wholly intrastate commerce would render it "a dead letter because there are virtually no sales, in Alabama or anywhere else in the United States, that are intrastate in *that* sense").

a. Claims under Wisconsin Law

Defendants HMRI and Andrx argue that the Wisconsin Supreme Court has long held that the state's antitrust statute applies to anticompetitive conduct that affects intrastate as opposed to interstate commerce. See Andrx Br. at 44 (Wisconsin antitrust statute applies "solely to transactions involving wholly intrastate commerce"). Plaintiffs respond that Defendants' arguments focus on legislative intent in 1893 and ignore the effect of more recent 1980 amendments, including one that permits indirect purchasers, like Plaintiffs here, standing to bring private antitrust actions. Plaintiffs urge this Court to adopt the reasoning in Emergency One, Inc. v. Waterous Co., Inc., 23 F. Supp. 2d 959, 969 (E.D. Wis. 1998) (where the court considered the Wisconsin antitrust statute at issue here, found that the Wisconsin's courts have recognized that the antitrust statute had some applicability to interstate transactions, and concluded that an adverse effects standard; i.e., one that recognizes claims against persons doing business in interstate commerce where the alleged unlawful anticompetitive activity significantly and adversely affects the trade and economic competition within the state, was "consistent with both Wisconsin precedent and judicial interpretation of the scope of federal antitrust law.")

In Emergency One, the court conducted a thorough review of the Wisconsin courts' interpretation of that state's antitrust statute and observed that, with the possible exception of the initial 1914 decision in Pulp Wood Co. v. Green Bay Paper & Fiber Co., 157 Wis. 604, 147 N.W. 1058 (1914), the remainder of the decisions in the "oft-cited string of precedent" supporting the intrastate versus interstate commerce dichotomy do not "for the most part" "examine the scope of state antitrust law with respect to specific allegations of interstate commerce, and thus none sheds much light on where or how the line should be drawn in a case like the one before [it]." Emergency One, 23 F. Supp. 2d at 962. Based on its review of relevant Wisconsin decisions, the court concluded that "[r]ote reliance on the 'intrastate as distinguished from interstate,' Pulp Wood to Grams line of precedent to dismiss state antitrust claims with any interstate aspect is . . . misplaced and inconsistent with Wisconsin precedent." Id. at 966.

Ultimately, the court concluded that an adverse effects standard was "consistent with both Wisconsin precedent and judicial interpretations of the scope of federal antitrust law" and that it "comports with the legislative intent" of Wisconsin's antitrust law. Id. at 969.[22] Accord K-S Pharmacies, Inc. v. Abbott Laboratories, No. 94-CV-2384, Mem. Decision and Order (Cir. Ct. Dane County, Wisconsin, Sept. 5, 1995), Slip Op. at 17-18. In K-S Pharmacies, the plaintiffs, independent pharmacies, brought a Wisconsin antitrust action

[22]Contrary to Defendants' arguments here, the Emergency One Court's discussion of Wisconsin law, its prediction as to what standard the Wisconsin Supreme Court would adopt, and its application of that standard to the facts presented in the case were essential to its determination and thus are not properly dismissed as mere dictum. See Black's Law Dictionary at 454 (West 1990) ("*Dicta* are opinions of a judge which do not embody the resolution or determination of the court, and made without argument, or full consideration of the point, are not the professed deliberate determinations of the judge himself.")

against 27 drug manufacturers and wholesalers alleging that they had engaged in a conspiracy to restrain trade. Rejecting the same arguments Defendants raise here, the court observed that "[t]he Wisconsin antitrust statute applies to illegal conspiracies that are alleged to have restrained trade in Wisconsin." Slip Op. at 18. (citing State v. Allied Chemical & Dye Corp., 9 Wis.2d 290, 101 N.W.2d 133 (1960)). The court further observed that, although the "state antitrust statute applies to intrastate commerce", this "does not necessarily mean that all acts violative of the statute must occur in-state. Cases limiting the scope of the statute to intrastate commerce do not limit it to intrastate conspiracy." Id. This Court agrees with the reasoning in Emergency One and likewise concludes that the Wisconsin antitrust statute applies to illegal conspiracies that are alleged to have restrained trade in Wisconsin. Construing the allegations in Plaintiffs' complaint in the light most favorable to them, this Court further concludes that the Wisconsin Plaintiffs have alleged conduct that significantly and adversely affected trade and commerce in that state and thus state a claim for relief under Wis. Stats. § 133.03.

b. Claims under Tennessee Law

Tennessee Plaintiffs allege violations of the Tennessee Trade Practices Act, Tenn. Code § 47-25-101 *et seq.*, and the Tennessee Consumer Protection Act, Tenn. Code § 47-18-104. Defendant Andrx argues that both these statutes apply only to transactions that are intrastate in character. Defendant HMRI similarly argues that the Tennessee laws apply only to transactions that are wholly or predominantly intrastate in character. See Blake v. Abbott Labs, Inc., 1996-1 Trade Cases (CCH) ¶ 71,369, 1996 WL 134947 at *4-5, *7 (Tenn. App. March 27, 1996). See also Dzik &. Dzik, P.C. v. Vision

Serv. Plan, 1989 WL 3082 (Tenn. App. Jan. 20, 1989); Lynch Display Corp. v. Nat'l Souvenir Ctr., Inc., 640 S.W.2d 837 (Tenn. App. 1982); Valley Products Co., Inc. v. Landmark, 877 F. Supp. 1087 (W.D. Tenn. 1994), aff'd, 128 F.3d 398 (6th Cir. 1997); FTC v. Mylan Laboratories, Inc., 62 F. Supp. 2d 25 (D. D.C. 1999). In essence, Defendants argue that, because Plaintiffs' consolidated complaint alleges anticompetitive activity and restraints of trade occurring in several jurisdictions, the Tennessee Plaintiffs cannot possibly claim that the alleged restraints of trade in Tennessee predominantly affect Tennessee's intrastate commerce, as opposed to their "predominantly" affecting interstate commerce, and thus the Tennessee Plaintiffs cannot possibly state a claim for relief under Tennessee's antitrust and consumer protection statutes.

Plaintiffs respond that Defendants read the Tennessee statutes too narrowly as evidenced by the plain language of Tennessee's antitrust statute and the Tennessee Supreme Court's decisions construing this statute. Plaintiffs assert that the Tennessee antitrust and consumer protection statutes are not limited to transactions that are wholly or predominantly intrastate in character. Rather, they allow Tennessee to regulate anticompetitive conduct occurring outside the state but having more than an incidental effect on Tennessee's intrastate commerce; i.e., situations like that alleged here where anticompetitive conduct may have occurred outside the state but results in a prescription drug product intentionally coming to rest within Tennessee and causing injury to Tennessee citizens who have purchased the product in Tennessee at artificially inflated prices as a result of Defendants' anticompetitive conduct. The Court agrees with Plaintiffs.

In Standard Oil Co. v. State, 117 Tenn. 618, 100 S.W. 705 (1907), the Tennessee

Supreme Court observed that articles of commerce "which had been imported from other states and countries, [and] commingled with the common mass of property in this state" were "intended to be included with the provisions" of Tennessee's antitrust statute. Id. at 711. Otherwise, the Court observed, "commerce, in the vast amount of valuable property of foreign production and manufacture that was then and is now in this state, would be wholly unprotected from the abuses legislated against." Id. Accord Jo Ann Forman, Inc. v. Nat'l Council on Compensation Ins., Inc., 13 S.W.3d 365, 373 (Tenn. App. 1999) (observing that "it is clear that Tennessee Code Annotated section 47-25-101, in express terms, applies to articles of foreign and domestic origin").

The Standard Oil Court further observed that "[a] combination affecting interstate commerce is none the less a violation of the federal anti-trust statute and punishable under it because the agreement made incidentally affects interstate commerce; and the same rule will apply to combinations made in violations of the statute of the state upon the same subject where interstate commerce is incidentally affected. If it were otherwise, neither the federal nor the state laws could be enforced in any case." Standard Oil, 100 S.W. at 712. Accordingly, as the courts have subsequently observed, to state a claim under Tennessee's antitrust statute, "the dispute need not be exclusively intrastate" but "it must more than incidentally affect intrastate commerce." Valley Products, 877 F. Supp. at 1095 (citing Lynch, 640 S.W.2d at 840). Contrary to Defendants' arguments, the Tennessee statutes at issue here are not limited to anticompetitive conspiracies that are hatched and implemented solely or predominantly in Tennessee; they do not apply "only to transactions that are intrastate in character." (Andrx Br. at 43). To the extent the decisions in Lynch,

Blake, Dzik & Dzik, and Mylan Lab. hold otherwise, this Court finds them to be wrongly decided.

This Court predicts that the Tennessee Supreme Court, if presented with the issue, would disagree with Defendants. The mere fact that there are allegations that Cardizem CD was sold in other states as well as Tennessee, or that the anticompetitive conspiracy was hatched and implemented in other states as well as Tennessee, does not mean that Tennessee Plaintiffs, who allege they purchased Cardizem CD in Tennessee at artificially inflated prices as a result of Defendants' anticompetitive conduct, are precluded from asserting a claim under Tennessee's antitrust and consumer protection laws. Rather, the Tennessee Supreme Court would find that a cognizable claim for relief under Tennessee's antitrust statute is stated when the alleged facts show that an illegal combination or agreement more than incidentally affects Tennessee's intrastate commerce.[23] It would hold that the Tennessee antitrust statute applies to illegal conspiracies alleged to have restrained trade in Tennessee. See Standard Oil Co. v. State, 100 S.W. 705 (Tenn. S. Ct. 1907).

Construing the allegations in Plaintiffs' complaint in the light most favorable to them, this Court concludes that Plaintiffs have alleged claims cognizable under the laws of Tennessee. They have alleged facts showing that the Defendants' collusive and

[23]See Meridan Mutual Ins. Co. v. Kellman, 197 F.3d 1178, 1181 (6th Cir. 1999) ("In construing questions of state law, the federal court must apply state law in accordance with the controlling decisions of the highest court of the state. If the state's highest court has not addressed the issue, the federal court must attempt to ascertain how that court would rule if it were faced with the issue. . . . A federal court should not disregard the decisions of intermediate appellate state courts unless it is convinced by other persuasive data that the highest court of the state would decide otherwise") (internal citations omitted).

anticompetitive conduct restrained trade in Tennessee; i.e., that the named Tennessee Plaintiffs paid artificially inflated prices for Cardizem CD they purchased in Tennessee and were thus injured as a result of Defendants' collusive and anticompetitive conduct in restraint of trade in that state. See Blake, 1996 WL 13497.[24]

2. Unjust Enrichment Claims

Issue: Have Plaintiffs stated a claim for unjust enrichment?

State Law Plaintiffs allege claims for unjust enrichment under the common law of the following states: Alabama, California, District of Columbia, Illinois, Michigan, Minnesota, New York, North Carolina, Tennessee and Wisconsin. Each claim is premised upon allegations that: (1) the "Hoechst Defendants have benefitted from overcharges they have been able to levy for Cardizem CD, resulting from acts alleged in this Complaint, and

[24]In Blake, the Tennessee Court of Appeals disregarded the interstate/intrastate dichotomy and concluded that the plaintiff's complaint stated a claim under Tennessee's antitrust and consumer protection laws and thus would not be dismissed because it alleged facts that gave rise to the inference that the challenged conduct affected Tennessee's intrastate commerce; i.e., allegations that out-of-state manufacturers of infant formula had "conspired to fix prices and did fix prices of baby formula" and thus injured Tennessee consumers who were "grossly overcharged" for formula purchased in the State of Tennessee at "artificially high and non-competitive" prices. Id. at **1, 3, 4-5. The court based its decision upon the well-established principle of Tennessee law that "once a product was imported into the state from other states or countries and became commingled with the common mass of property in [Tennessee], it is no longer an article of interstate commerce. 'It is well settled that commerce in such imported articles may be regulated by state legislation.'" Id. at *5 (quoting the Tennessee Supreme Court's decision in State ex rel Cates v. Standard Oil Co. of Kentucky, 120 Tenn. 86, 110 S.W. 565, 580 (1908), aff'd sub nom, Standard Oil Co. of Kentucky v. Tennessee, 217 U.S. 413 (1910)). The decision in Blake was also guided by the principle that, on a Rule 12 motion to dismiss, the court is required to accept the allegations of the complaint as true and to construe the complaint in the plaintiff's favor. Blake, 1996 WL 13497 at *4. The same analysis and result apply here.

resulting in overpayments by plaintiffs and the class for Cardizem CD"; (2) "Defendant Andrx has benefitted from the acts alleged in this Complaint to the extent of the payments ($89,830,000) it has received under the Hoechst-Andrx Agreement. . . [and] [t]he funds for such payments by the Hoechst Defendants derived from plaintiffs' and the class' overpayments for Cardizem CD"; (3) "Plaintiffs and the class have conferred upon both the Hoechst Defendants and Andrx an economic benefit in the nature of profits resulting from unlawful overcharges, to plaintiffs' and the class' economic detriment"; (4) "[t]he economic benefit of overcharges obtained by supra-competitive prices is a direct and proximate cause of the defendants' anticompetitive behavior restricting competition as set forth above"; (5) "[t]he benefit held by the Hoechst Defendants and Andrx rightfully belongs to plaintiffs and the class, as plaintiffs and the class paid these anticompetitive sums to defendants during the class period, when the Hoechst Defendants, and later Andrx, used anticompetitive measures to block generic entry into the market"; (6) "[i]t would be inequitable for Andrx to be permitted to retain any of the proceeds of the Hoechst-Andrx Agreement"; and (7) "[i]t would be inequitable for the Hoechst Defendants to be permitted to retain any of the plaintiffs' and the class' overpayments for Cardizem CD derived from their unfair and unconscionable methods, acts and trade practices, including, but not limited to, the Hoechst-Andrx Agreement and the acts alleged herein, designed to prevent introduction by Biovail and others of generic bioequivalents to Cardizem CD." See State Law Plfs' Am. Complt. at 46-47. See also State Law Plfs' Am. Complt. at 53-54, 58-59, 60-61, 65-66, 70-71, 74-75, 80-81, 87-88, and 92-93.

Defendants seek dismissal of State Law Plaintiffs' unjust enrichment claims, arguing that they fail to state a common law claim under the law of any state based on principles of unjust enrichment. Specifically, Defendants argue that Plaintiffs cannot state a common law unjust enrichment claim because: (1) Plaintiffs' unjust enrichment claims are dependent upon the allegations supporting their state law antitrust claims and thus suffer from the same flaws that preclude Plaintiffs from stating an antitrust claim; (2) they do not and cannot allege that they bestowed a benefit directly on Defendants; (3) they do not and cannot allege that privity exists between Plaintiffs and Defendants; and (4) to the extent they succeed on their statutory claims, Plaintiffs have an adequate remedy at law. Defendants' arguments lack merit. Construing the allegations in Plaintiffs' complaint as true and in the light most favorable to Plaintiffs, this Court concludes that State Law Plaintiffs' common law claims of unjust enrichment survive Defendants' motions to dismiss.

The first of Defendants' arguments fails to read Plaintiffs' complaint in the light most favorable to Plaintiffs and confuses Plaintiffs' right to recover an equitable remedy under a common law claim based upon principles of unjust enrichment with its right to recover a remedy at law for an alleged violation of a state's antitrust laws. The authority Defendants rely upon fails to support their position that the success of Plaintiffs' common law unjust enrichment claims necessarily depends upon the success of their statutory claims. To the contrary, the courts often award equitable remedies under common law claims for unjust enrichment in circumstances where claims based upon contract or other state law violations prove unsuccessful. See e.g., Watts v. Watts, 137 Wis.2d 506, 530, 405 N.W.2d 303, 313 (1987) ("[A] claim of unjust enrichment does not arise out of an

agreement entered into by the parties. Rather, an action for recovery based upon unjust enrichment is grounded on the moral principle that one who has received a benefit has a duty to make restitution where retaining such a benefit would be unjust."). Accord Acton Constr. Co. v. State, 383 N.W.2d 416, 417 (Minn. App. 1986); Paschall's Inc. v. Dozier, 219 Tenn. 45, 57-58, 407 S.W.2d 150, 155-56 (1966).

Rather than allegations and proof of the elements necessary for its antitrust claims, Plaintiffs' common law claims for unjust enrichment depend upon allegations and proof that "'the defendant has unjustly retained a benefit to the plaintiff's detriment, and that the defendant's retention of the benefit violates the fundamental principles of justice, equity, and good conscience.'" Peddinghaus v. Peddinghaus, 295 Ill. App. 3d 943, 948, 692 N.E.2d 1221, 1225 (Ill. App. 1998) (quoting HPI Health Care Services, Inc. v. Mt. Vernon Hospital, Inc., 131 Ill. 2d 145, 160, 545 N.E.2d 672 (1989)). See also Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Chipetine, 221 A.D.2d 284, 286, 634 N.Y.S.2d 469, 471 (N.Y. App. Div. 1995) (where the New York court observed that a cause of action for unjust enrichment "requires the court to determine whether it is against equity and good conscience to permit defendant to retain what is sought to be recovered") (internal quotes and citation omitted); Management Computer Services, Inc. v. Hawkins, Ash, Baptie & Co., 206 Wis.2d 158, 557 N.W.2d 67, 79-80 (1996) (where the Wisconsin court observed that a cause of action "for recovery based upon unjust enrichment is grounded on the moral principle that one who has received a benefit has a duty to make restitution where retaining such a benefit would be unjust")(internal quotes and citations omitted); Booher v. Frue, 86 N.C. App. 390, 393-94, 358 S.E.2d 127, 129 (N.C. App. 1987) (where the court

observed that North Carolina law distinguishes between damages recovery and restitution recovery; the damage award is designed to compensate a plaintiff for her loss whereas "[t]he principle of restitution is to deprive the defendant of benefits that in equity and good conscience he ought not to keep . . . even though plaintiff may have suffered no demonstrable losses") (internal quotes and citations omitted), aff'd, 321 N.C. 590, 364 S.E.2d 141 (1988); Foshee v. General Tele. Co. of the Southeast, 295 Ala. 70, 322 So.2d 715, 717 (1975) (where the Alabama Supreme Court observed that "[t]he essence of the theories of unjust enrichment or money had and received is that facts can be proved which show that defendant holds money which in equity and good conscience belongs to plaintiff . . . . Thus, in order to prevail under these theories of law, a plaintiff must show that the defendant is legally or equitably obligated to pay money to plaintiff") (emphasis added); Paschall's, Inc. v. Dozier, 219 Tenn. 45, 57, 407 S.W.2d 150, 155 (1966) ("The most significant requirement for a recovery . . . is that the enrichment to the defendant be unjust"); Acton Constr. Co. v. State, 383 N.W.2d 416, 417 (Minn. App. 1986) (where the Minnesota court observed that recovery for unjust enrichment "is governed by principles of equity"); Hollowell v. Career Decisions, Inc., 100 Mich. App. 561, 570, 298 N.W.2d 915, 920 (1980) ("The essential elements of such a claim are (1) receipt of a benefit by the defendant from the plaintiff and (2) which benefit it is inequitable that the defendant retain"); Emerine v. Yancey, 680 A.2d 1380, 1383 (D.C. Ct. of App. 1996) ("To recover on a theory of unjust enrichment, . . . the plaintiff must show that [the defendant] was unjustly enriched at his expense and that the circumstances were such that in good conscience [the defendant] should make restitution") (internal quotes and citations omitted);

Lectrodryer v. SeoulBank, 77 Cal. App. 4th 723, 91 Cal. Rptr. 2d 881, 883 (Cal. App. 2000) (where the court identified the elements of an unjust enrichment claim under California law as: "receipt of a benefit and unjust retention of the benefit at the expense of another" and concluded that the defendant bank "was unjustly enriched when it retained for itself the funds [a commercial customer] used to purchase the [subject] letter of credit for the purpose of paying [the customer's supplier]").

Likewise unpersuasive are Defendants' arguments that Plaintiff must allege, as an essential element of their unjust enrichment claims, facts showing that they directly conferred a benefit on both HMRI and Andrx and facts showing that privity exists between Plaintiffs and Defendants. The decisions Defendants rely upon do not support the argument that either privity or a directly conferred benefit is an essential element of an unjust enrichment claim under the state common laws at issue here.

As to the lack of privity, the decisions Defendants rely upon do not support its position and at least one refutes, rather than supports, the argument that privity between parties is required to state a common law claim for unjust enrichment. See Paschall's Inc., 407 S.W.2d at 154 (observing that "[i]t is well established that want of privity between parties is no obstacle to recovery"). See also Schiff v. Am. Ass'n of Retired Persons, 697 A.2d 1193, 1194 (D.C. App. 1997) ("[T]here can be no claim for unjust enrichment when an express contract exists between the parties.").

Similarly, the authority Defendants' rely upon fail to support their broad claim that Plaintiffs cannot state a common law claim for unjust enrichment unless they allege facts showing that they conferred a benefit directly upon each of the Defendants. Rather,

careful examination of the cited authority shows that the courts dismiss such claims only where the plaintiffs fail to allege facts showing that they have bestowed some sort of benefit upon the defendant that the defendant ought not keep in equity and good conscience. See Rapaport v. United States Dep't of Treasury, 59 F.3d 212, 218 (D.C. Cir. 1995) (where the court observed that unjust enrichment cannot be found where the plaintiff has failed to show that the defendant has been enriched or why that enrichment is unjust). "[T]he fundamental characteristic of unjust enrichment is 'that the defendant has been unjustly enriched by receiving something . . . that properly belongs to the plaintiff [, thereby] forcing restoration to the plaintiff.'" Id. at 217 (quoting Dobbs, Law of Remedies § 4.1(2)). As the Rapaport Court observed, the typical elements of a cause of action for unjust enrichment are: "(1) the plaintiff conferred a benefit upon the defendant; (2) the defendant accepted and retained the benefit; and (3) it would be unjust for the defendant not to pay the plaintiff the value of the benefit." Id. Plaintiffs here have alleged that they conferred a benefit, in the form of overpayments and increased profits, on Defendants, that Defendants accepted that benefit and that it would be unjust under the alleged circumstances for Defendants to retain that benefit.

Contrary to Defendants' argument, there is no additional requirement that a benefit flow solely from Plaintiffs to Defendants. The courts do not define "benefit" as narrowly as Defendants urge. As the Alabama Supreme Court observed, "[w]henever one person adds to the other's advantage in any form, whether by increasing his holdings or saving him from expense or loss, he has conferred a benefit upon the other." Opelika Production Credit Ass'n, Inc. v. Lamb, 361 So.2d 95, 99 (1978) (citing Restatement, Restitution, §

1(b); Sullivan, "The Concept of Benefit in the Law of Quasi-Contract," 64 Geo. L. J. 1 (1975)). Whether or not the benefit is directly conferred on the defendant is not the critical inquiry; rather, the plaintiff must show that his detriment and the defendant's benefit are related and flow from the challenged conduct. Id. Defendants' arguments, that the connection between Plaintiffs alleged overpayments for Cardizem CD and the benefits Defendants obtained as a result of those overpayments is too tenuous, raise factual questions and refute Defendants' claim that Plaintiffs can prove no set of facts allowing it to state a common law claim for unjust enrichment.[25]

F. Personal Jurisdiction Over Defendant Hoechst AG in Tennessee and Minnesota

Issue: Do Tennessee and Minnesota Plaintiffs have Personal Jurisdiction over Defendant Hoechst AG?

a. Standard of Review

Plaintiffs, "as the party seeking assertion of *in personam* jurisdiction, bear[] the burden of showing that such jurisdiction exists." CompuServe, Inc. v. Patterson, 89 F.3d 1257, 1261-62 (6th Cir. 1996). "When, however, a district court rules on a jurisdictional motion to dismiss made pursuant to Federal Rule of Civil Procedure 12(b)(2) without conducting an evidentiary hearing, the court must consider the pleadings and affidavits in a light most favorable to the plaintiff". Id. at 1262. Thus, "[t]o defeat such a motion, a party

[25]Defendant HMRI also argues that Plaintiffs' unjust enrichment claims must be dismissed because Plaintiffs have not alleged that they lack an adequate remedy at law. Plaintiffs' ability to plead in the alternative renders this argument moot.

in [Plaintiffs'] position need only make a prima facie showing of jurisdiction." Id. (citing Theunissen v. Matthews, 935 F.2d 1454, 1458 (6th Cir. 1991)).

"Furthermore, a court disposing of a 12(b)(2) motion does not weigh the controverting assertions of the party seeking dismissal, . . ., because we want to prevent non-resident defendants from regularly avoiding personal jurisdiction simply by filing an affidavit denying all jurisdictional facts. Dismissal in this procedural posture is proper only if all the specific facts which the plaintiff . . . alleges collectively fail to state a prima facie case for jurisdiction." Id. (internal quotes and citations omitted) (emphasis added). Accord Dean v. Motel 6 Operating L.P., 134 F.3d 1269, 1272 (6th Cir. 1998) (where the court observed, under similar procedural circumstances, that the district court "should not have considered any controverting evidence submitted by [defendant]").

b. Parties' Arguments

Defendant Hoechst Aktiengesellschaft ("Hoechst AG"), a German holding company with its principal place of business located in Frankfurt am Main, Federal Republic of Germany, argues that the Minnesota and Tennessee courts lack personal jurisdiction over it because it has no presence in those states or any connection with them whatsoever. In support of its 12(b)(2) motion to dismiss for lack of personal jurisdiction, Defendant Hoechst AG submits three affidavits in which Hoechst AG denies many of the jurisdictional facts asserted in Plaintiffs' complaint. Specifically, it is averred that Hoechst AG: (1) has absolutely no presence in or connection with the state of Minnesota or Tennessee; (2) markets no products for sale in Minnesota, Tennessee or elsewhere in the United States; and (3) the contacts of its subsidiary HMRI in Minnesota and Tennessee cannot be

imputed to it. Hoechst AG avers that it and HMRI are separate and distinct corporations, there is no co-mingling of funds, HMRI's board of directors is separate and distinct from Hoechst AG's Management Board and Supervisory Board, it does not direct the day-to-day business operations of HMRI, it is not a party to the September 24, 1997 Hoechst/Andrx Agreement, and neither its Management Board or Supervisory Board considered, approved, or authorized that September 24, 1997 agreement.

The Vice President and General Counsel for HMRI further avers that "Hoechst AG neither participated in nor directed activities by HMRI to clarify the scope of the right of reference" provided on Biovail's behalf pursuant to the subject FTC consent decree. See Stratemeier Declaration ¶ 5. The Vice President and General Patent Counsel for HMRI also avers that the patents developed by HMRI are owned in the name of HMRI or Carderm Capital L.P. and not in the name of Hoechst AG; and that the decision to file the patent infringement action was made solely by the management of HMRI and Carderm without consultation with Hoechst AG. See Street Declaration ¶¶ 2, 3. See also Kuhlhorn Declaration ¶ 29 where Hoechst AG counsel avers that Hoechst AG has no rights or interest in the patent which is the subject of the patent infringement action brought by HMRI against Andrx.

It is further averred that the capital stock of HMRI is held by two companies (HMR Pharma, Inc., a Delaware corporation, and Hoechst Marion Roussel S.A., a French corporation). These two companies are wholly-owned subsidiaries of Hoechst Marion Roussel AG, a German corporation, which in turn is wholly-owned by Hoechst AG.

Rhone-Poulence S.A. (now Aventis)

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Hoechst AG
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Hoechst Marion Roussel AG
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HMR Pharma, Inc. Hoechst Marion Roussel S.A.
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Hoechst Marion Roussel, Inc. (HMRI)

In light of the denial of jurisdictional facts asserted in its supporting affidavits, Hoechst AG argues that the Minnesota and Tennessee courts lack personal jurisdiction over it and thus the Minnesota and Tennessee Plaintiffs' claims against it must be dismissed.

Plaintiffs respond that they have sufficiently alleged facts that establish a prima facie case of personal jurisdiction over Hoechst AG in the states of Minnesota and Tennessee. Specifically, Plaintiffs allege facts supporting their claim that Hoechst AG: (1) conspired with Andrx and HMRI to delay the entry of generic versions of Cardizem CD into the United States market, to allow HMRI prolonged enjoyment of its monopoly in the $700-million-plus annual United States market for Cardizem CD and its generic bioequivalents, and to allow HMRI the prolonged ability to fix the price of Cardizem CD at supra-competitive prices; (2) engaged, along with the other Defendants, in a continuing pattern of unlawful anticompetitive conduct in furtherance of their conspiracy to prevent competition in the Cardizem CD market in the United States; and (3) has enriched itself at the expense of Plaintiffs by sharing in profits derived from overcharges for Cardizem CD. Plaintiffs further allege that Hoechst AG: (1) has securities traded publicly throughout the United States; (2) conducts extensive business throughout the United States through its wholly owned

U.S. subsidiaries, including HMRI; (3) through HMRI, regularly transacts business throughout every state in the United States, including promotion, marketing and sale of Cardizem CD and other prescription drugs; (4) controls the board of directors and business operations of HMRI, including its pharmaceutical business in the United States; (5) representatives had ultimate decision-making authority for all decisions relevant to allegations in Plaintiffs' complaint; (6) representatives met with Biovail's executives on a Sunday in August 1997 offering Biovail a bribe of at least $20 million cash from Hoechst AG not to market a generic version of Cardizem CD before January 2000, telling Biovail that Hoechst AG, a public company, had represented to its shareholders that it believed it would not encounter generic competition before 2000, and threatening Biovail with a lawsuit for patent infringement, notwithstanding a prior covenant not to sue, if it filed an NDA for a generic version of Cardizem CD, (7) received samples of Andrx's generic version of Cardizem CD in August of 1995 so it could perform tests and confirm there was no infringement of patents claiming Cardizem CD; and (8) pursued the Andrx patent infringement action solely to indefinitely delay and prevent entry of generic versions of Cardizem CD in the United States market. See Coordinated Amended Complaint at ¶¶ 3, 6, 7,10, 13, 14, 40, 43, 57, 61, 69, 71, 74, 75, 76, 78, 83, 85, 86-95, 98-104, 127-131, 135-136.

Construing the allegations in Plaintiffs' complaint in the light most favorable to them and not considering any controverting evidence submitted by Defendant Hoechst AG, the Court concludes that the Minnesota and Tennessee Plaintiffs have made out a prima facie case of personal jurisdiction. See CompuServe, 89 F.3d at 1263.

c. Analysis

1. General Principles

In a diversity case such as this, state law is considered when determining whether personal jurisdiction exists as to a defendant. Theunissen, 935 F.2d at 1459. Thus, Tennessee's and Minnesota's long arm statutes will apply here. Determination whether personal jurisdiction exists over Defendant Hoechst AG typically involves a two-step inquiry: (1) whether the exercise of jurisdiction offends the Tennessee and Minnesota's long-arm statutes; and (2) whether the exercise of jurisdiction is consistent with the due process clause of the Fourteenth Amendment. Because the Tennessee and Minnesota Courts have held that the long-arm statutes of their respective states extend personal jurisdiction to the maximum limit allowed under the due process clause, the state requirements are satisfied if due process requirements are satisfied. See Northrup King Co. v. Compania Productora Semillas Algodoneras Selectas, S.A., 51 F.3d 1383, 1387 (8th Cir. 1995) (applying Minnesota law);[26] Masada Inv. Corp. v. Allen, 697 S.W.2d 332, 334 (Tenn. 1985).[27] Accordingly, the single issue presented here is whether personal

[26]Minnesota's long-arm statute, Minn. Stat. § 543.19 (1990), permits personal jurisdiction over nonresident foreign corporations that transact any business within the state or that "[c]ommits any act outside Minnesota causing injury . . . in Minnesota" in a cause of action arising from such acts. Minn. Stat. §§ 543.19(b), (d).

[27]Tennessee's long-arm statute, Tenn. Code Ann. § 20-2-223(a)(1), (4) (1997), permits personal jurisdiction over "a person who acts directly or indirectly, as to a claim for relief arising from the person's" "transacting any business" in Tennessee or causing "tortious injury" in Tennessee "by an act or omission outside this state of the person who regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered," in

jurisdiction over Hoechst AG comports with the requirements of due process. See Dean, 134 F.3d at 1273.

"To exercise personal jurisdiction over a defendant, the defendant must have had minimum contacts with the forum state so that the exercise of jurisdiction would comport with 'traditional notions of fair play and substantial justice.'" Theunissen, 935 F.2d at 1459 (quoting International Shoe Co. v. State of Washington, 326 U.S. 310, 316 (1945)).[28] The Court considers three criteria when determining whether a nonresident defendant has had sufficient contacts to support personal jurisdiction:

> First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences caused by the defendant must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

So. Mach. Co. v. Mohasco Indus., Inc., 401 F.2d 374, 381 (6th Cir. 1968).

To determine the first factor, purposeful availment of the privilege of acting in the forum or causing a consequence in the forum, "[i]t is the 'quality' of such contacts . . . that

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Tennessee. The statute further provides for jurisdiction over a person who "contracts to supply services or things" in Tennessee. § 20-2-223(a)(2).

Tennessee's long arm statute, Tenn. Code Ann. §§ 20-2-214(a)(1), (2) and (5), permits personal jurisdiction over non-resident foreign corporations "as to any action or claim for relief arising from" the "transaction of any business within the state", or "[a]ny tortious act or omission within" Tennessee, or "[e]ntry into a contract for . . . materials to be furnished in" Tennessee.

[28]Under the Fourteenth Amendment, the due process requirement serves two functions: (1) it protects the defendant against the burden of litigating in a distant or inconvenient forum; and (2) it ensures that the states do not reach out beyond the limits imposed on them as coequal sovereigns. Handley v. Indiana & Michigan Electric Co., 732 F.2d 1265, 1271 (6th Cir. 1984).

determines whether they constitute purposeful availment." Reynolds v. Int'l Amateur Athletic Fed'n, 23 F.2d 1110, 1119 (6th Cir. 1994). Physical presence in the forum state, however, is not required. Id. at 1264. The Sixth Circuit has observed that,

> [p]hysical presence of an agent is not necessary . . . for the transaction of business in a state. The soliciting of insurance by mail, the transmission of radio broadcasts into a state, and the sending of magazines and newspapers into a state to be sold there by independent contractors are all accomplished without the physical presence of an agent; yet all have been held to constitute the transaction of business in a state.

Id. (quoting Mohasco Indus., 401 F.2d at 382 (footnotes omitted)).

As to the second "arising under" factor, "[a]n action will be deemed not to have arisen from the defendant's contacts with the forum state only when they are unrelated to the operative facts of the controversy." Creech v. Roberts, 908 F.2d 75, 80 (6th Cir. 1990). Finally, as to the third factor, this Court has observed that when the first two factors of the Southern Machine test have been satisfied, "only the unusual case will not satisfy the third factor of a 'substantial enough connection with the forum to make the exercise of jurisdiction reasonable.'" General Motors Corp. v. Ignacio Lopez de Arriortua, 948 F. Supp. 656, 644 (E.D. Mich. 1996) (quoting Creech, 908 F.2d at 80).

Consistent with Supreme Court precedent, the Sixth Circuit recently observed that "the confluence of the increasing nationalization of commerce and modern transportation and communication," have resulted in a "relaxation of the limits that the Due Process Clause imposes on courts' jurisdiction." CompuServe, 89 F.3d at 1362 (internal quotes and citations omitted). "Simply stated, there is less perceived need today for the federal constitution to protect defendants from 'inconvenient litigation,' because all but the most

remote forums are easily accessible for the pursuit of both business and litigation." Id. Accordingly, "the due process rights of a defendant should be the courts' primary concern where personal jurisdiction is at issue." Id. (citing Insur. Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee, 456 U.S. 694, 702 n. 10 (1982)).

2. Application Here

Plaintiffs allege here that Defendant Hoechst AG took actions that constitute the transaction of business in the states of Minnesota and Tennessee and took part in actions that caused an injury or consequence in those states; i.e., they allege that Hoechst AG controls the board of directors and business operations of HMRI, including its pharmaceutical business in the United States; that part of that pharmaceutical business in the United States includes the sale and distribution of Cardizem CD to consumers in Minnesota and Tennessee; that Plaintiffs in Minnesota and Tennessee were consumers of Cardizem CD; that these Minnesota and Tennessee Plaintiffs suffered an injury in the nature of overcharges paid for Cardizem CD as a result of Defendant Hoechst AG conspiracy, along with the other Defendants, to restrain trade, reduce competition and to fix prices;[29] and that Defendant Hoechst AG profited from overcharges paid by the Minnesota and Tennessee Plaintiffs. Construing these allegations in the light most favorable to the Plaintiffs and not considering any controverting evidence submitted by

[29]Plaintiffs persuasively argue that antitrust injuries, by their nature, involve infliction of tortious injury, Chrysler Corp. v. Fedders Corp., 643 F.2d 1229, 1236 (6th Cir. 1981); Weinstein v. Norman M. Morris Corp., 432 F. Supp. 337, 344 (E.D. Mich. 1977), and that the courts have long recognized that "the place of injury from a price-fixing conspiracy is the place of sale, since the consumer is injured at the time he pays the artificially inflated price." In re Mid-Atlantic Toyota Antitrust Litig., 525 F. Supp. 1265, 1274 (D. Md. 1981).

Hoechst AG, this Court concludes that those allegations show: Hoechst AG has purposefully availed itself of the privilege of conducting business in all states, including Minnesota and Tennessee; that Hoechst AG authorized distribution of Cardizem CD in Minnesota and Tennessee; that it caused injury in those states; that it shared in profits generated by sales of Cardizem CD in those states; that the cause of action arises from Hoechst AG's contacts with these states because they are related to the operative facts of the controversy; and the consequences caused by Hoechst AG's contacts have a substantial enough connection with these states to make the exercise of jurisdiction over Hoechst AG reasonable. See Tobin v. Astra Pharm. Prod., Inc., 993 F.2d 528, 543-44 (6th Cir. 1993) (holding that a Dutch drug manufacturer was subject to personal jurisdiction in Kentucky, even though it did not directly engage in the sale of the drug in the United States, because the defendant drug company had obtained FDA approval for the subject drug and "made a *deliberate decision* to market [the subject drug] in all 50 states, including . . . the forum state" and rejecting an argument similar to the one Hoechst AG raises here; i.e., that defendant did "nothing in particular to purposefully avail itself of the Kentucky market as distinguished from any other state, by reasoning that acceptance of that argument would allow a foreign corporation to improperly "insulate itself from liability in each of the 50 states simply by using an independent national distributor to market its products") (emphasis in original). See also In re Telectronics Paging Sys., Inc., 953 F. Supp. 909 (S.D. Ohio 1997) (concluding that personal jurisdiction over Australian parent companies was appropriate in a multidistrict product liability action because the parent corporations had approved large capital expenditures of their Delaware subsidiaries, the

CEO's of the subsidiaries reported directly to the parent corporations, there was centralized banking, the parents occasionally guaranteed obligations for the subsidiaries, the parents' representatives attended meetings with FDA officials regarding the subject product, and the parent corporations would not be burdened by defending in the United States). Accordingly, this Court concludes that Plaintiffs have made a prima facie showing of jurisdiction and thus denies Hoechst AG's 12(b)(2) motion to dismiss.[30]

G. Whether Plaintiffs Have Failed to State an Antitrust Claim That Allows the Reasonableness of the Alleged Restraint of Trade to be Analyzed Under Either a Per Se or Rule of Reason Analysis

"The essential elements of a violation of Section 1 of the Sherman Act are: 1) a contract, combination or conspiracy; 2) affecting interstate commerce; 3) which imposes an 'unreasonable' restraint on trade." White & White, Inc. v. Am. Hosp. Supply Co., 723 F.2d 495, 504 (6th Cir. 1983). Courts use two methods of analysis, the *per se* rule and the rule of reason, to determine "whether restraints of trade unreasonably restrict competition." United States v. Cooperative Theatres of Ohio, Inc., 845 F.2d 1367, 1370 (6th Cir. 1988).

State Law Plaintiffs, the Sherman Act Class Plaintiffs, and the Individual CVS and Rite Aid Sherman Act Plaintiffs allege antitrust claims and further assert that the reasonableness of the alleged restraint of trade may be analyzed under either a *per se* or rule of reason analysis. Individual Kroger Sherman Act Plaintiffs allege a section 1, Sherman Act violation under a *per se* analysis, but do not allege a section 1, Sherman Act violation under a rule of reason analysis. Defendants argue that Plaintiffs' antitrust claims

[30]In light of this decision, it is unnecessary for the Court to address whether Plaintiffs have established a prima facie showing of jurisdiction under a conspiracy theory of jurisdiction.

must be dismissed because they fail to state an antitrust violation that can be analyzed under either a *per se* or rule of reason analysis. Specifically, Defendants argue that: (1) the HRMI/Andrx Agreement is not susceptible to a *per se* analysis because it is not between actual or potential horizontal competitors and is not the type of agreement that has previously received *per se* treatment; and (2) it is not actionable under a rule of reason analysis because: a) it is reasonable as a matter of law; and b) Plaintiffs have not pled the relevant market and market power. This Court disagrees with Defendants.

1. Per Se Analysis

As to the per se analysis, the Supreme Court has observed that "[c]ertain agreements, such as horizontal price fixing and market allocation, are thought so inherently anti-competitive that each is illegal *per se* without inquiry into the harm it has actually caused." Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984). See also Arizona v. Maricopa County Medical Soc., 457 U.S. 332 (1982) (horizontal price-fixing arrangement); and Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) (per curium) (horizontal market allocation agreement); Cooperative Theatres, 845 F.2d 1367 (6th Cir. 1988) (horizontal agreements to allocate markets among competitors). Accordingly, "[i]n those horizontal price-fixing [and market allocation] cases where the *per se* rule applies, the only inquiry is whether there was an agreement to restrain trade, since the unreasonableness of the restraint is conclusively presumed regardless of whether the rule of reason would lead to a different result." Re/Max Int'l, 900 F. Supp. at 148 n. 8 (citing Arizona v. Maricopa County Medical Soc'y, 457 U.S. at 344). The Sixth Circuit has observed that "'horizontal' restraints – that is, agreements among competitors at the same

level of the market structure – are particularly suspect because they typically serve no purpose other than to stifle competition." Betkerur, M.D. v. Aultman Hosp. Ass'n, 78 F. 3d 1079, 1092 (6th Cir. 1996).

Defendants argue that, despite Plaintiffs' characterization of the HMRI/Andrx Agreement as a horizontal price fixing agreement, the reasonableness of this alleged restraint of trade cannot be analyzed under a per se analysis because: (1) it is not the type of agreement that warrants *per se* treatment; (2) it has nothing to do with the pricing of Cardizem CD; and (3) it is not between actual or potential horizontal competitors. Defendants' arguments lack merit. They ignore Plaintiffs' allegations that: (1) the HMRI/Andrx Agreement is also a horizontal market allocation agreement; (2) that its terms affect the price of Cardizem CD; (3) the federal courts have consistently held that the per se rule applies to both horizontal price-fixing and market allocation agreements; and (4) that the Agreement is between actual or potential horizontal competitors.

Only Defendant's third argument requires further discussion. Defendants do not dispute that they perform at the same level of the market structure or that they are currently competitors in the U.S. market for Cardizem CD or its generic bioequivalents. Rather, Andrx asserts that it was not an actual competitor and cannot be considered a potential competitor of HMRI's in the relevant market during the relevant time period because if it had attempted to compete it might have been found liable for infringing HMRI's patent. This Court finds Andrx's argument unpersuasive.

First, Andrx's argument ignores the allegations in Plaintiffs' complaints and the reasonable inferences to be drawn from those allegations; i.e., but for the HMRI/Andrx

Agreement: (1) Andrx would have begun marketing its generic version of Cardizem CD on or shortly after July 9, 1998; (2) Andrx would have done as it had represented to the court presiding over the HMRI/Andrx patent case – begun marketing and selling its generic version of Cardizem CD on or shortly after July 9, 1998 and not wait until after the HMRI/Andrx patent case was finally resolved on appeal; (3) HMRI would not have paid Andrx millions of dollars to stay off the market if it was not reasonably probable that Andrx would enter the market on or shortly after July 9, 1998; and (4) the entry of other generic products -- those manufactured by Biovail and Faulding (which had received tentative FDA approval for its product on or about October 26, 1998) -- would not have been delayed as long as they were as a result of Defendants' anticompetitive conduct. Construing these allegations in the light most favorable to Plaintiffs and taking them as true, the Court finds that these allegations support an inference that, but for the HMRI/Andrx Agreement, the pending HMRI/Andrx patent action would not have eliminated Andrx as a potential competitor of HMRI. See Palmer v. BRG of Georgia, Inc., 498 U.S. at 49-50 (where the Supreme Court held that a horizontal market allocation agreement is illegal per se "regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other.") These allegations likewise support an inference that, during the relevant time period, Andrx and HMRI were actual competitors; i.e., during Andrx's enjoyment of the 180-day exclusivity period. Contrary to Andrx's arguments here, the allegations in Plaintiffs' complaints support rather than contradict its characterization of the HMRI/Andrx Agreement as a horizontal market allocation or price-fixing agreement that is to be analyzed under a *per se* analysis.

This Court is not persuaded by Andrx's legal arguments that, at least until HMRI's patent infringement claims against it had been finally resolved, the HMRI/Andrx Agreement cannot be characterized as a horizontal agreement between actual or potential competitors. Defendant's reliance on dicta in a footnote in B. Braun Med., Inc. v. Abbott Lab., Inc., 124 F.3d 1419, 1427 n. 4 (Fed. Cir. 1997) and on the U.S. Justice Department and the Federal Trade Commission's Antitrust Guidelines for the Licensing of Intellectual Property, §§ 3.1, 3.3 n. 14, and 3.3 Example 5 (1995) is misplaced.

At issue in B. Braun Med. were use restrictions that the plaintiff patent holder had placed on its patented product, "a reflux valve that attaches to an intravenous (IV) line and permits injection or aspiration of fluids by means of a needleless syringe." Id. at 1421. Unlike HMRI and Andrx here, the plaintiff and defendant in B. Braun Med. were in a buyer/seller relationship. The defendant purchased patented valves from the plaintiff after agreeing to comply with the plaintiff's use restriction; i.e., that the valve be used only on certain IVs.

Ultimately, the defendant had another company develop a substitute valve. The plaintiff then sued both companies for patent infringement. The defendants "denied infringement, challenged validity and asserted the equitable defenses of patent misuse, estoppel and implied license." Id. at 1422. The dispute went to trial, and a jury found that the plaintiff had "misused its patent, was equitably estopped from asserting its patent, and that, in any event," there was no infringement of the plaintiff's patent. Id. at 1421. On appeal, the Federal Circuit Court of Appeals affirmed in part, reversed in part, and vacated

in part. Relevant here, the court concluded that "the district court erred with respect to its treatment of equitable estoppel and patent misuse." Id.

In the footnote in B. Braun Med., upon which Defendant relies, the Court discussed the defendant's argument on appeal that the plaintiff's use restrictions "constitute a horizontal restraint that violates the antitrust laws per se." Id. at 1427 n. 4. The Court only briefly addressed the issue "in the event that it is reached on remand" and concluded that the relationship between the plaintiff and the defendant was that of seller and buyer and thus, because they were not horizontal competitors with regard to the plaintiff's restricted sale of its patented product, the plaintiff's use restrictions could not be considered a horizontal restraint that violates the antitrust laws per se. Rather, the plaintiff's sale to the defendant purchaser "is akin to a vertical restraint, which . . . should be analyzed under the rule of reason." Id.

Andrx's reliance on the U. S. Justice Department and the Federal Trade Commission's Antitrust Guidelines for the Licensing of Intellectual Property, §§ 3.1, 3.3 n. 14, and 3.3 Example 5 (1995) is likewise misplaced. The Guidelines as a whole, as well as the cited sections and example, address intellectual property licensing arrangements and the licensor/licensee relationship in particular, not the relationship alleged in Plaintiffs' complaints.[31] Here there is no alleged licensor/licensee relationship between

[31]Section 3.3 of the Guidelines provides that: "antitrust analysis of intellectual property licensing arrangements examines whether the relationship among the parties to the arrangement is primarily horizontal or vertical in nature, or whether it has substantial aspects of both." It further provides that, "[f]or analytical purposes, the Agencies ordinarily will treat a relationship between a licensor and its licensee, . . . , as horizontal when they would have been actual or likely potential competitors in a relevant market in the absence of a license."

HMRI/Andrx as the HMRI/Andrx Agreement provides only an option to obtain a license under certain circumstances and that option was never exercised. None of the cited text or examples from the Guidelines address the question presented here; i.e., whether, in the absence of a licensor/licensee relationship, and in the face of contested infringement claims, and in the face of an agreement between a brand-name and a generic drug manufacturer where the generic manufacturer agrees to stay off the market beyond the time it claimed it was prepared to enter the market in exchange for payments of tens of millions of dollars, these drug manufacturers can be considered actual or potential horizontal competitors.

Defendants' reliance on Guidelines § 3.1 n. 14 is similarly misplaced. Footnote 14 provides that "[a] firm will be treated as a likely potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the licensing arrangement." Defendant Andrx relies on this footnote and argues that it cannot be considered a likely potential competitor because, despite Plaintiffs' allegations to the contrary and despite its statement to the contrary in the HMRI/Andrx patent infringement litigation, its entry in the marketplace was not reasonably probable in the absence of a license agreement. Andrx's argument lacks merit because: (1) it assumes facts that contradict those asserted by Plaintiffs in their complaints; (2) it assumes that the HMRI/Andrx relationship can be compared with that of a licensor/licensee; (3) it ignores the fact that Andrx supplemented its ANDA, changing its dissolution profile specification, and thus strengthened its defense against HMRI's infringement claims; and (4) ignores the reasonable inference that HMRI

would not have paid Andrx millions of dollars to stay off the market beyond July 9, 1998 if it was not reasonably probable that Andrx would enter the market without a licensing arrangement with HMRI. Accordingly, Defendants' motions to dismiss as to this issue are DENIED.

2. Rule of Reason Analysis

To establish a Section 1 antitrust claim that is susceptible to analysis under the rule of reason, the plaintiff must show that:

> the defendants contracted, combined or conspired among each other, that the combination or conspiracy produced adverse, anti-competitive effects within relevant product and geographic markets, that the objects of and conduct pursuant to that contract or conspiracy were illegal and that the plaintiff was injured as a proximate result of that conspiracy.

Re/Max Int'l v. Realty One, Inc., 900 F. Supp. at 149 (quoting Davis-Watkins Co. v. Serv. Merchandise, 686 F.2d 1190, 1195-96 (6th Cir. 1982)).

Andrx first argues that Plaintiffs cannot state an antitrust claim that is susceptible to analysis under the rule of reason because the HMRI/Andrx Agreement is reasonable as a matter of law. In support of its argument, Andrx asserts that the Court should: (1) construe the Agreement in a manner that contradicts the allegations in Plaintiffs' complaints and take judicial notice of what could have occurred, but did not in fact occur, had HMRI obtained a preliminary injunction in the HMRI/Andrx patent litigation and then lost its patent case; (2) conclude, contrary to the allegations in Plaintiffs' complaints, that the HMRI/Andrx Agreement was Andrx's only reasonable response to HMRI's pending patent case; and (3) conclude, contrary to the allegations in Plaintiffs' complaints, that Plaintiffs' harm was caused by the Hatch-Waxman Amendments and not by any anti-

competitive conduct on the part of Andrx. Andrx's arguments are patently flawed because they disregard the standard this Court must apply to Rule 12(b)(6) motions to dismiss.

Andrx further argues that Plaintiffs cannot state an antitrust claim that is susceptible to analysis under the rule of reason because their complaints fail to allege a relevant market or market power. Although Andrx acknowledges that "[m]arket definition often involves consideration of factual issues", it asserts that dismissal is proper here because Plaintiffs have failed to allege "any facts that could properly define a relevant market." Andrx Br. at 32. Specifically, Andrx asserts that: (1) Plaintiffs have failed to adequately reference the rule of reasonable interchangeability when making allegations regarding the relevant market; and (2) improperly limit the relevant market to a single brand. Plaintiffs respond that their allegation of the relevant market is sufficient to survive Defendant's Rule 12(b)(6) motion to dismiss; i.e., the market for Cardizem CD and its FDA-approved AB-rated bioequivalents in the United States. See State Law Plfs. Complt. ¶ 133; Sherman Act Class Plfs. Complt. ¶ 65; CVS Complt. ¶ 26. This Court agrees with Plaintiffs.

As observed by the Sixth Circuit, when "'considering what is the relevant market for determining the control of price and competition, no more definitive rule can be declared than that commodities reasonably interchangeable by consumers for the same purposes make up that 'part of the trade or commerce' monopolization of which may be illegal.'" Tarrant Serv. Agency, Inc. v. Am. Standard, Inc., 12 F.3d 609, 614 (6th Cir. 1993) (emphasis added) (quoting United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956)). Thus, relevant markets are to be judged from the consumers' perspective, and they include not only "products or services that are reasonably interchangeable with"

the defendant's product, but also products or services that are "identical to" the defendant's product. See Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, 185 F.3d 606, 622 (6th Cir. 1999).

State Law Plaintiffs allege that the relevant product and geographic market is the one for Cardizem CD and its FDA-approved AB-rated generic bioequivalents in the United States. As to "reasonable interchangeability", Plaintiffs allege that, due to FDA regulations, once a physician prescribes Cardizem CD, a consumer patient may only purchase Cardizem CD or its FDA-approved AB-rated bioequivalent. Plaintiffs further allege that prior to June 23, 1999, when Andrx's Cartia XT was introduced into the market, HMRI's Cardizem CD comprised a 100% share of the U.S. market for Cardizem CD and its generic bioequivalents. See State Law Plfs. Complt. ¶¶ 133-34. Thus, the physician's prescribing practices and the FDA approval barriers define the relevant market. Accordingly, no heart patient who entered a U.S. pharmacy with a physician's prescription for Cardizem CD could obtain any drug other than Cardizem CD prior to June 23, 1999 when Andrx began shipping Cartia XT. See Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc., 93 F.3d 511, 513 (8th Cir. 1996) (where the Court observed that "[p]harmacists may freely substitute among AB drugs, but only a prescribing physician may substitute one BC drug for another").[32] Contrary to Andrx's arguments, a single brand of

[32]The Sherman Act Class Plaintiffs similarly allege that the relevant market is the U.S. market for Cardizem CD and its generic equivalents (¶ 65), and that prior to June 23, 1999, HMRI had a 100% share of the U.S. market for Cardizem CD and its generic bioequivalents (¶¶ 3, 4, 48, 48, 66). Individual Sherman Act Plaintiffs CVS Meridian and Rite Aid likewise allege that the relevant market is the U.S. market for Cardizem CD and its bioequivalents (¶ 26).

a product can constitute a relevant market for antitrust purposes. See Eastman Kodak Co. v. Image Technical Serv., Inc., 504 U.S. 451, 481-82 (1992) (where the Supreme Court rejected an argument similar to Defendants and observed that "[t]he relevant market for antitrust purposes is determined by the choices available to [the consumer]").

Construing the allegations in Plaintiffs' complaints in the light most favorable to them and construing all the allegations as true, this Court concludes that State Law, Sherman Act Class, and Independent CVS and Rite Aid Sherman Act Plaintiffs have adequately pled a relevant market with regard to their antitrust claims.[33] The determination whether there are additional products that are "reasonably" interchangeable with Cardizem CD involves questions of fact not properly addressed in a Rule 12(b)(6) motion to dismiss. "The proper market definition in this case can be determined only after a factual inquiry into the 'commercial realities' faced by consumers." Eastman Kodak, 504 U.S. at 482. Accordingly, Defendant's motion is DENIED.

IV. Conclusion

For the foregoing reasons, this Court **DENIES**: (1) Defendant Hoechst AG's motion to dismiss the Minnesota action (Aetna U.S. Healthcare, No. 99-73329) for lack of personal jurisdiction and failure to state a claim; (2) Defendant Hoechst AG's motion to dismiss the Tennessee action (Larry S. Sizemore, No. 99-73345) for lack of personal jurisdiction and

[33] The Individual Kroger Sherman Act Plaintiffs do not allege a relevant market nor do they allege that Defendants' Sherman Act violation can be analyzed under a rule of reason analysis. Rather, they allege that the violation is susceptible to per se analysis and under that analysis it isn't necessary to make allegations regarding the relevant market. As discussed above, this Court has determined that these Plaintiffs have sufficiently alleged facts that allow their antitrust claims to be analyzed under a per se rule.

failure to state a claim; (3) Defendant HMRI's motion to dismiss the Sherman Act Class Plaintiffs' Amended Complaint (Louisiana Wholesale, No. 99-73259, and Duane Reade, No. 99-73870); (4) Defendant HMRI's motion to dismiss Sherman Act Individual Plaintiffs' Amended Complaint (Kroger, et al., No. 99-73735); (5) Defendant HMRI's motion to dismiss Sherman Act Individual Plaintiffs' Complaint (CVS Meridian and Rite Aid Corp., No. 99-75036); (6) Defendant HMRI's motion to dismiss State Law Plaintiffs' Coordinated First Amended Complaints (Nos. 99-75070, 99-73422, 99-73412, 99-73871, 99-74262, 99-73667, 98-74043, 99-73239, 99-73845, 99-73713, 99-74377, 99-73190, 99-73345, 99-73981, and 99-73666); (7) Defendant Andrx's motion to dismiss the Coordinated "Indirect Purchaser" Complaints (Nos. 98-74043, 99-75070, 99-73422, 99-73412, 99-73871, 99-74262, 99-73239, 99-73667, 99-73845, 99-73713, 99-74377, 99-73190, 99-73345, 99-73981, and 99-73666); and (8) Defendant Andrx's motion to dismiss the Consolidated "Direct Purchaser" Complaint and the two additional "Direct Purchaser" Complaints (Nos. 99-73870, 99-73259, 99-73735, and 99-75036).

/s/
Nancy G. Edmunds
U.S. District Judge

Dated: May 11, 2000

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE: CARDIZEM CD ANTITRUST LITIGATION,

Master File No. 99-md-1278
MDL No. 1278

THIS DOCUMENT RELATES TO:
ALL ACTIONS,

Honorable Nancy G. Edmunds

_____/

REVISED ORDER NO. 12
CORRECTING TYPOGRAPHICAL ERROR IN
MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS' MOTIONS TO DISMISS

The Court issued Order No. 12, Memorandum Opinion and Order Denying Defendants' Motions to Dismiss on May 11, 2000. The Court issues this Revised Order No. 12 with corrected pages 44 and 45. The only change corrects a typographical error, the deletion, on page 44, of the first sentence following the heading "v. Conclusion." The paragraph should read:

"The Court is convinced that interim agreements, like the HMRI/Andrx Agreement here, that restrain trade through private rather than governmental conduct are subject to antitrust liability and are not entitled to immunity under the *Noerr-Pennington* doctrine. A final, private settlement that would resolve the HMRI/Andrx patent infringement litigation by entering into a market allocation agreement like the one alleged here would not enjoy

Noerr-Pennington immunity and neither should the Defendants "interim" Agreement that accomplishes the same anticompetitive results."

Revised pages 44 and 45 are attached.

SO ORDERED.

/s/
Nancy G. Edmunds
U.S. District Judge

Dated: May 16, 2000

themselves and a class consisting of an estimated 40 million consumers of [the] defendants' tobacco products". Id. at 1203. The plaintiffs alleged, *inter alia*, that, as a result of the settlement agreement, the defendants had violated federal antitrust laws when they unlawfully "agreed to raise tobacco prices in order to pay the costs of the settlement." Id. The court dismissed the plaintiffs' section 1 Sherman Act claim, finding that "the *Noerr-Pennington* doctrine and the *Illinois Brick* indirect purchaser rule preclude recovery". Id. at 1205. As to the *Noerr-Pennington* doctrine, the court found "that the actions of [the] defendants in negotiating and executing" the Master Settlement Agreement fell "within the recognition that *Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose". Id. at 1206-07 (internal quotes and citations omitted). The Hise court then concluded that "the concerted effort by [the] defendants to influence public officials, i.e., the states' Attorneys General, to accept a settlement in exchange for dismissing the numerous lawsuits pending against defendants is among the activities protected by the *Noerr-Pennington* doctrine." Id. at 1207.

Unlike Hise, in this case the HMRI/Andrx Agreement is not a result of negotiations with a state attorney general or any government official, and therefore, unlike the Master Settlement Agreement in Hise, it cannot be considered as conduct incidental to litigation with a governmental entity.

v. Conclusion

The Court is convinced that interim agreements, like the HMRI/Andrx Agreement here, that restrain trade through private rather than governmental conduct are subject to

antitrust liability and are not entitled to immunity under the *Noerr-Pennington* doctrine. A final, private settlement that would resolve the HMRI/Andrx patent infringement litigation by entering into a market allocation agreement like the one alleged here would not enjoy *Noerr-Pennington* immunity and neither should the Defendants "interim" Agreement that accomplishes the same anticompetitive results.

2. Adequacy of Plaintiffs' Pleading that the HMRI/Andrx Patent Infringement Action is a Sham

In light of the above analysis, the Court may consider whether the HMRI/Andrx Agreement is subject to antitrust liability independent of any decision that the HMRI/Andrx patent infringement litigation was a sham.[10] State Law Plaintiffs, however, have asserted an additional reason for opposing Defendants' arguments that they have failed to sufficiently allege facts showing that HMRI's initiation and continued prosecution of the HMRI/Andrx patent litigation was both objectively baseless and brought for anticompetitive purposes; i.e., a sham. These Plaintiffs argue that, but for HMRI's initiation of the sham patent infringement action, the 30 month Hatch-Waxman period would not have gone into effect and generic versions of Cardizem CD would have entered the market much sooner than the July, 1998 date when that 30-month period expired. Accordingly, the following is

[10]The Individual Sherman Act Plaintiffs' complaints allege no facts supporting an argument that the HMRI/Andrx patent litigation was a sham. This is not an omission by the Plaintiffs. Rather, these Plaintiffs argue that there is no need to make any such allegations in order to state a claim under section 1 of the Sherman Act. Plaintiffs are correct.