UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE LORAZEPAM & CLORAZEPATE ANTITRUST LITIGATION	**MDL Docket No. 1290** **Misc. No. 99mc0276**
This Opinion applies to: **All Actions**	

MEMORANDUM OPINION

Pending before the Court are several post-trial motions. Defendant Mylan Laboratories, Inc., Defendant Mylan Pharmaceuticals, Inc. (together, "Mylan"), Defendant Cambrex Corporation ("Cambrex"), and Defendant Gyma Laboratories of America, Inc. ("Gyma"), collectively ("Defendants"), filed the following post-trial motions: Defendants' Renewed Motion for Judgment as a Matter of Law Under Rule 50(b) [dkt. 883], Defendants' Motion for New Trial Under Rule 59(a) [dkt. 888], and Defendants' Motion for Remittur under Rule 59(e) [dkt. 890], among others. Upon careful review of the parties' motions, oppositions, replies thereto, and the entire record herein, the Court will deny the Defendants' Renewed Motion for Judgment as a Matter of Law and Defendants' Motion for a New Trial. The Court will not rule on Defendants' Motion for Remittur under Rule 59(e) at this time.[1]

[1] The Court will also reserve judgment on Plaintiffs' Joint Motion for Attorneys' Fees and Costs [dkt. 884], Plaintiffs' Motions related to treble damages [dkt. 887 & 891], and Defendants' Motion to Dismiss [dkts 910 & 911].

I. BACKGROUND[2]

After a jury trial lasting over three weeks, on June 1, 2005, the jury found for the Plaintiffs and against all Defendants on the following state law claims:[3] agreement in unreasonable restraint of trade, conspiracy in unreasonable restraint of trade, monopolization, and attempted monopolization, all in the Lorazepam active pharmaceutical ingredient ("API") market and the Lorazepam tablet market and in the Clorazepate API and tablet markets.[4] The jury awarded Plaintiff Blue Cross Blue Shield of Minnesota $1,756,096.00, Plaintiff Blue Cross Blue Shield of Massachusetts $8,430,887.00, Plaintiff Federated Mutual Insurance Company $410,878.00, and Plaintiff Health Care Services Corporation ("HCSC") $1,448,437.00 in damages.

At the center of this litigation are exclusive licensing agreements between Defendants. In November 1997, Mylan and Profarmco entered two agreements, each entitled, "Exclusive Agreement," in which Profarmco agreed to supply its Lorazepam and Clorazepate API to Mylan in exchange for an upfront payment and a share of Mylan's profits from the sale of the two drugs in the form of royalty payments. The Exclusive Agreements had a term of ten years and provided that Profarmco would not supply Lorazepam and Clorazepate API to any other generic manufacturers in the United States, but did not prohibit such sale to the branded manufacturers

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[2] For a detailed account of this case's extensive procedural history please see the following opinions in this case: 289 F.3d 98 (D.C. Cir. 2002); March 30, 2005 Mem. Op. ("S.J. Mem. Op.") [dkt. 785]; 295 F. Supp. 2d 30 (D.D.C. 2003); 202 F.R.D. 12 (D.D.C. 2001).

[3] The claims were brought under the antitrust laws of the following states: Massachusetts, Minnesota, and Illinois.

[4] Lorazepam and Clorazepate are generic prescription anti-anxiety drugs (the generic equivalents of Ativan® and Tranxene®, respectively).

or to any manufacturer outside of the United States. The Exclusive Agreements did, however, provide that Profarmco should take all steps reasonably necessary to prevent its Lorazepam and Clorazepate API that it sold outside of the United States to enter the United States. The Exclusive Agreements were terminated in December 1998 after the Federal Trade Commission ("FTC") announced its investigation of Mylan's actions.

A. The Parties

Plaintiffs Blue Cross Blue Shield ("BCBS") of Minnesota, Federated Mutual Insurance Company ("Federated"), and BCBS of Massachusetts (collectively, "BCBS Plaintiffs"), and Plaintiff HCSC are health insurance companies that are third-party payors for prescription drugs, including Lorazepam and Clorazepate, on behalf of their insureds and self-funded customers, typically employer-sponsored health plans that contract with Plaintiffs to administer claims on their behalf and pursue plan-related costs.

Defendant Mylan is a large generic drug manufacturer and distributor that markets at least 91 generic drugs, including Lorazepam and Clorazepate. Defendant Cambrex sells chemicals through its subsidiaries for, among other things, drug manufacture. Defendant Profarmco is an Italian company that is a wholly-owned subsidiary of Cambrex that manufactures and sells various APIs. Defendant Gyma sells APIs and other chemicals to the pharmaceutical industry. Gyma acts as a U.S. agent for Profarmco, buying various APIs from Profarmco and selling them to generic manufacturers in the United States. Prior to the agreements at issue in this case, Profarmco and Gyma sold Lorazepam and Clorazepate API to Mylan and its generic competitors.

B. The Pharmaceutical Industry

1. The Supply Chain

Mylan, and other generic drug manufacturers, sell their products to wholesalers and retail pharmacies. The pharmacies sell the generic drugs to consumers, and then seek reimbursements for costs beyond the consumer's co-payment or co-insurance payment from the consumer's insurance company, such as Plaintiffs. BCBS Plaintiffs contract with what is known as a pharmacy benefit manager ("PBM"), who in turn contracts directly with the pharmacies. Plaintiff HCSC contracts directly with the pharmacies. Thus, the pharmacies generally bill the PBMs, who in turn bill the insurance companies. The amount Plaintiffs pay for a prescription reimbursement varies, and is set by formulas with many fluctuating variables in their contracts with the PBMs or directly with the pharmacies.

2. Regulatory Framework

Prior to selling prescription drugs in the United States, a manufacturer must obtain approval from the Food and Drug Administration ("FDA"). Manufacturers of generic drugs can expedite the approval process by filing an Abbreviated New Drug Application ("ANDA"), which relies on the data filed with the FDA concerning the bioequivalent pioneer drug. The ANDA process can take from several months to up to two years. All ANDA applications must reference the API provider that has already been approved by the FDA to supply API for the relevant drug. To obtain FDA approval to sell API, the API manufacturer must file a Drug Master File ("DMF") with the FDA. Different drug manufacturers may reference the DMF of the same API producer in their ANDAs. Further, when a generic drug manufacturer wants to use a new API producer that it did not originally gain approval to use, it must file a supplemental ANDA that

references that API supplier's DMF and test results using the new supplier's API. This approval process can take up to one year.

II. DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER RULE 50(B)

A. Legal Standard

A Rule 50(b) motion "should not be granted unless the evidence, together with all inferences that can reasonably be drawn therefrom, is so one-sided that reasonable jurors could not disagree on the verdict." *Elam v. C & P Telephone Co.*, 609 F. Supp. 938, 940 (D.D.C. 1984) (internal citations omitted).

The Court must grant a motion for judgment as a matter of law if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. Pro. 50(a); *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). If reasonable minds could disagree about the import of the evidence, judgment as a matter of law is inappropriate. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 250–51 (1986). When making its decision, the court should review all of the evidence in the record. *Reeves*, 530 U.S. at 150. In doing so, however, the court must draw all reasonable inferences in favor of the non-moving parties, and it may not make credibility determinations or weigh the evidence. *Id.* (citing *Lytle* v. *Household Mfg., Inc.,* 494 U.S. 545, 554 (1990)); *Continental Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 696, n. 6 (1962); *Thomas v. Mineta*, 310 F. Supp. 2d 198, 203 (D.D.C. 2004); *Nyman v. Chairman, Federal Deposit Insurance Corp.*, 1997 WL 243222, *2 (D.D.C. 1997). Thus, although the court should review the record as a whole, it must disregard

all evidence favorable to the movant that the jury was not required to believe. *Reeves*, 530 U.S. at 151. That is, the court must give credence to the evidence favoring the non-moving party as well as that evidence supporting the movant that was uncontradicted and unimpeached. *Id*. (internal citations omitted).

B. Agreement in Unreasonable Restraint of Trade

Plaintiffs' first claim against Defendants is that they entered agreements that unreasonably restrained trade, in violation of Illinois, Massachusetts and Minnesota antitrust laws. *See generally* 740 Ill. Comp. Stat. Ann. § 10/7 (2004); Mass. Gen. Laws ch. 93A §2(a) (2004); Minn. Stat. § 325D.49 (2004).[5] To prevail on this claim, Plaintiffs were required to show by a preponderance of the evidence that: (i) the Defendants entered into an agreement; (ii) the agreement unreasonably restrained trade in an appropriately defined relevant market; (iii) the restraint of trade affected commerce in the relevant states as to relevant Plaintiffs; and (iv) Plaintiffs were injured in their business or property because of Defendants' conduct.

1. Unreasonable Restraint of Trade

Here, there was no dispute that Defendants entered into an agreement. Defendants' primary contention is that the evidence at trial did not show that their agreements unreasonably restrained trade. To prove that the restraint of trade was unreasonable, Plaintiffs had to prove by a preponderance of the evidence (a) what the relevant market is; (b) Defendants' actions had a

[5] Illinois, Massachusetts, and Minnesota all look to federal antitrust law for guidance in interpreting their own state antitrust laws. 740 Ill. Comp. Stat. Ann. § 10/11 (2004); Mass. Gen. Laws ch. 93A §2(b); *Ciardi v. F. Hoffman-LaRoche Ltd.*, 762 N.E.2d 303, 309 (Mass. 2002); *Howard v. Minnesota Timberwolves Basketball Ltd. P'ship*, 636 N.W.2d 551, 556 (Minn. Ct. App. 2001).

substantially harmful effect on overall competition in that relevant market, for example, by raising prices or reducing output; and (c) the harmful effect on competition outweighed any beneficial effect on competition. *See e.g., Business Elects. Corp. V. Sharpe Elects. Corp.,* 485 U.S. 717, 723 (1988). In the context of exclusive agreements, as the jury was instructed, such agreements are considered unreasonable restraints of trade when a significant fraction of buyers or sellers are foreclosed from the market for a non-transitory period of time. *See e.g., Tampa Elect. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327-28 (1961); *Geneva v. Barr Labs.,* 386 F.3d 485, 508 (2d Cir. 2004).

Defendants first contend that in this case a significant number of competitors were not foreclosed from the Lorazepam and Clorazepate markets for a non-transitory period of time, and thus their motion should be granted. Defendants argue that the evidence adduced at trial was insufficient to show that Mylan's competitors were denied access to API and frozen out of the Lorazepam and Clorazepate markets for a non-transitory period of time. According to Defendants, the evidence at trial showed that Mylan's competitors, including the brand companies, were not affected by the agreements, that two new competitors entered the Lorazepam market subsequent to the execution of the agreements, that the existing competitors in both markets never left, and that any concerns about disruption to API supply were short-lived and resolved. Defendants argue that Plaintiffs never showed there was a shortage of API and that Mylan's competitors were never foreclosed from either the Lorazepam or Clorazepate tablet markets.

Defendants' argument is based on their position that the relevant markets are Lorazepam and Clorazepate tablet markets, including the brand competitors in each of these, and contend

that Plaintiffs themselves acknowledged this conclusion during trial. Plaintiffs contend the appropriate markets are the *generic* Lorazepam and Clorazepate tablet markets. The relevant market is defined as all products "reasonably interchangeable by consumers for the same purposes," because the ability of consumers to switch to a substitute restrains a firm's ability to raise prices above the competitive level. *United States v. E.I. duPont de Nemours*, 351 U.S. 377, 395 (1956). The fact that products are just functionally interchangeable does not compel a finding that they belong in the same market. *See e.g., United States v. Archer-Daniels-Midland Co.,* 866 F.2d 242, 246 (8th Cir. 1988) (finding that sugar and high fructose corn syrup, though functionally interchangeable, were not part of single, relevant product market due to price differentials). The definition of a product market also relies on a fact-intensive inquiry that considers factors such as recognition of the market as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Indeed, the purpose of defining the relevant market is to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output. *See Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2004) (finding generic's pricing at fifty percent of brand indicative of distinct customer group with brand allegiance and/or high risk sensitivity that was unwilling to switch from known brand even in face of discounted alternative); S.J. Mem. Op. at 13.

While there was conflicting evidence concerning the market definition presented at trial, Plaintiffs are correct that there was sufficient evidence from which a reasonable jury could conclude that the relevant antitrust market was comprised of only generic manufacturers. First,

many witnesses from the generic industry agreed that they do not consider the brand price in setting their own prices. *See* Trial Tr. vol. 6 at 19, 26, May 10, 2005 Afternoon (Dr. Stern) (stating that brand prices do not discipline generic prices); Trial Tr. vol. 4 at 32, May 6, 2005 Morning (Stupar) (Mylan's Director of Purchasing stating, "Brand was a different market in my eyes."); Pl. Ex. 5101 at 22:22-23:05 (Puskar Deposition). Second, both Plaintiffs' experts and industry participants viewed generics as competing in a different market than the branded manufacturers. *See e.g.,* Trial Tr. vol. 15 at 93, May 23, 2005 Afternoon (Walsh) (Mylan sales representative stating, "the brands and the generics don't compete really"); Trial Tr. vol. 6 at 19, May 10, 2005 Afternoon (Dr. Stern) (Plaintiffs' expert on pharmaceutical industry and managed care); *see generally* Trial Testimony of Dr. Saha (Plaintiffs' economic expert). Finally, Plaintiffs' expert Dr. Stern also noted that as well as other differences, brand and generic drugs tend to have different consumer bases and that the two are promoted and marketed very differently. *See* Trial Tr. vol. 6 at 23-24, May 10, 2005 Afternoon at 23-24. Therefore, there was sufficient evidence for a reasonable jury to conclude that the relevant antitrust markets were generic Lorazepam tablet manufacturers and generic Clorazepate tablet manufacturers, respectively.

Given the evidence concerning relevant antitrust markets, the Court now turns to whether there was sufficient evidence for a reasonable jury to decide that a substantial portion of the markets were foreclosed. The central question is whether after the Exclusive Agreements were signed Mylan's competitors were able to meaningfully compete or whether they were foreclosed from the market.

a. Generic Lorazepam Tablet Market

The evidence at trial showed that prior to the execution of the Exclusive Agreements, the following generic manufacturers produced Lorazepam tablets: Mylan, Watson Pharmaceuticals, Inc. ("Watson"), and Purepac Pharmaceuticals ("Purepac"). *See generally* Trial Tr. vol. 6, May 10, 2005 Afternoon (Dr. Stern). Watson generally obtained its Lorzaepam API from Profarmco through its U.S. agent Gyma. *See* Trial Tr. vol. 10, at 13-16, 18, May 16, 2005 Afternoon (Beidman) (Purchasing Clerk at Watson). In November/December 1997, subsequent to the signing of the Exclusive Agreements, Watson was unable to get its order of Lorazepam API from Gyma. Trial Tr. vol. 10 at 16, May 16, 2005 Afternoon (Beidman). In December of 1997, Watson then tried to obtain Lorazepam API from SST Corporation ("SST"), the U.S. agent for Fabbrica Italiana Sintetici ("FIS"), to no avail. Trial Tr. vol. 10 at 19, May 16, 2005 Afternoon (Beidman). SST stated that because Watson had not ordered API from them in some time, and because FIS had not been producing Lorazepam API for Watson, that they could not supply Watson, and that they were uncertain of when they would be able to supply them again. *Id*. At this point Watson had to turn to the only other active Lorazepam API manufacturer - Technochemie GmBH ("Technochemie"). However, Technochemie was not listed in Watson's ANDA and thus to use their API Watson had to go through the process of getting them qualified by the FDA, which would take about a year and a half. *See* Trial Tr. vol. 10, May 16, 2005 Afternoon at 20 (Beidman). During this time period, Watson continued its attempts to get Lorazepam API from SST unsuccessfully, and when they finally did get a price, they viewed it as prohibitively high ($75,000/kilo). *Id.* at 21; Trial Tr. vol. 10 at 10, May 16, 2005 Afternoon (Chow) (Watson Vice-President, Operations); Pl. Ex. 1885. As a result, Watson was not able to

get Lorazepam API until 1999 when Technochemie finally got qualified. As a result of not having enough raw material, Watson not only had to drop some of its Lorazepam customers, it also had to raise its prices near Mylan's level in order to sustain its remaining Lorazepam tablet inventory. *See e.g.,* Trial Tr. vol. 10 at 34, May 16, 2005 Afternoon (Wilkinson) (Watson Chief Operations Officer); *Id*. at 8 (Chow); *Id.* at 27, 32 (Hartman) (Watson, Director of Sales & Marketing). *See also* Pl. Ex. 2232 (Watson letter dated 2/16/98 to customers). The anecdotal testimony cited above was also confirmed by Plaintiffs' economic expert Dr. Saha and pharmaceutical industry expert Dr. Stern. From the evidence presented at trial, it is clear that a reasonable jury could find that Watson's ability to compete in the Lorazepam tablet market was substantially impacted and they were foreclosed from the market for a substantial period of time due to the Exclusive Agreements.

Plaintiffs also presented sufficient evidence concerning the foreclosure of Purepac from the Lorazepam tablet market such that a reasonable jury could find Purepac was foreclosed from meaningfully competing in the market. Prior to the Exclusive Agreements, Purepac purchased its Lorazepam API from Profarmco's U.S. agent Gyma as it was the only API provider qualified in its ANDA. Trial Tr. vol. 10 at 37, May 16, 2005 Afternoon (Fox) (Purepac Purchasing Manager). After the Exclusive Agreements went into effect, Purepac was in dire need of Lorazepam API in order to continue its production, so Purepac contacted FIS, but was informed in February 1998 that FIS did not have enough capacity to sell to Purepac. Pl. Ex. 1659 (Purepac letter to FIS dated 1/22/98); Pl. Ex. 1643 (Purepac internal email). Purepac also tried to get Lorazepam API from Sanofi, but was unable to do so. Trial Tr. vol. 10 at 43, May 16, 2005 Afternoon (Fox). Further in March 1998, Purepac had to inform its customers that it was

suspending the supply of Lorazepam tablets and would not be accepting new customers and would be increasing prices on the remaining supply of the tablets. Pl. Ex. 1072 (Purepac letter to customers dated 3/3/98). Purepac tried to launch a new supply in September 1998 but was thwarted by regulatory issues relating to testing its new sample API from FIS. Thus, Purepac was not really able to get back into the market until 1999. *See* Trial Tr. vol. 10 at 45-46, May 16, 2005 Afternoon (Fox). Purepac's foreclosure from the market was also confirmed by Plaintiffs' two experts. From the evidence presented at trial, it is clear that a reasonable jury could find that Purepac's ability to compete in the Lorazepam tablet market was substantially impacted and they were foreclosed from the market for a substantial period of time due to the Exclusive Agreements.

Defendants cite evidence concerning Watson's inventory of Lorazepam tablets and Watson's option to purchase Lorazepam API from SST, Purepac's sales to one customer in 1998 as well as Purepac's purchase of some Profarmco API through another European company. Defendants also argue that Lederele, Wyeth's authorized generic, was able to enter into the Lorazepam tablet market at this time and had no problems obtaining Lorazepam API from Wyeth. Defendants also point to evidence presented at trial concerning Geneva's re-entry into the Lorazepam generic tablet market and that Geneva was able to obtain its API needs from FIS. Defendants argue this evidence shows as a matter of law that the Lorazepam tablet market was not foreclosed. While Geneva was ultimately able to re-enter the market, it had to purchase API at an extremely high price and had issues fully supplying its customers' needs. *See* Pl. Ex. 5106 at 62, 176-78 (Deposition of Bruce Basarb). Geneva also had problems using the API it obtained from FIS for some technical reasons. *See* Pl. Ex. 302 (6/17/98 letter from SST to Geneva).

While the Defendants challenge the jury's conclusion, the Court cannot find that the evidence presented on this issue is one-sided such that no reasonable jury could find that a substantial number of competitors were foreclosed from the market and that therefore the Exclusive Agreements unreasonably restrained trade in the Lorazepam tablet market.

b. Generic Clorazepate Market

Prior to the execution of the Exclusive Agreements, in the Clorazepate market, the major generic manufacturers included Mylan and Watson, with Mylan possessing a larger market share. Trial Tr. vol. 6, May 10, 2005 Afternoon (Dr. Stern); Trial Tr. vol. 8 at 47, May 12, 2005 Morning (Dr. Saha). Both Mylan and Watson were supplied with their Clorazepate API by Profarmco prior to the Exclusive Agreements. Trial Tr. vol. 8 at 31, May 12, 2005 Morning (Dr. Saha).

After the Exclusive Agreements were signed, Watson could no longer obtain its Clorazepate API from Profarmco. *See* Trial Tr. vol. 10 at 15-16, May 16, 2005 Afternoon (Beideman); Trial Tr. vol. 8 at 32, May 12, 2005 Morning (Dr. Saha). As a result, in December 1997, Watson tried to get Clorazepate API from FIS, but found that they were no longer producing it. Trial Tr. vol. 10 at 19, May 16, 2005 Afternoon (Beideman). As a result of their inability to obtain Clorazepate API, Watson had to put its Clorazepate on backorder. *See* Pl. Ex. 1785 (Watson internal email). *See also* Pl. Ex. 1806 (Internal Watson memorandum stating "All contracts on Clorazepate will be terminated"); Pl. Ex. 2232 (Feb. 16, 1998 Watson letter to customers). In order to sustain their inventory, Watson had to raise its Clorazepate tablets prices to match Mylan.

Although Watson did try to obtain Clorazepate API from Abbott, the brand manufacturer,

it decided not to as it would have had to qualify Abbott API on its ANDA, and did not want to wait the necessary 18 to 24 months. Trial Tr. vol. 10 at 21, May 16, 2005 Afternoon (Beideman). Defendants argue that because in June 1998 Watson became an authorized generic of Abbott and was able to sell Abbott's finished Clorazepate tablets, it was not foreclosed from the Clorazepate tablet market. While there was evidence presented regarding Watson's relationship with Abbott, the Court does not find that, taking all the inferences in favor of the non-movants, here the Plaintiffs, the evidence was so one-sided that a reasonable jury could only find that a substantial portion of the market was not foreclosed from the Clorazepate tablet market.

2. Causation

To prevail on their claim of unreasonable restraint of trade, Plaintiffs needed to show that there was a "direct relationship between the claimed injury and the alleged anticompetitive conduct." *In re Lorazepam and Clorazepate Antitrust Litig.*, 295 F. Supp. 2d at 38. Defendants argue that at trial Plaintiffs did not produce sufficient evidence to show a direct relationship between their alleged injury and Defendants actions. Defendants argue that neither Mylan, nor the other Defendants, had any part in negotiating the reimbursement rates Plaintiffs pay their PBMs or directly to the pharmacies. Defendants point to evidence indicating that the reimbursement rates set between Plaintiffs and PBMs or pharmacies are set in one of three ways and that Plaintiffs never explained which of the three methodologies were used in instances where they alleged damages. Defendants argue that Plaintiffs did not establish at trial that their damages were in any way related to Mylan's action - that Plaintiffs could not establish any nexus between their damages and Mylan's prices.

Plaintiffs argue that the evidence presented at trial, including Defendants' admissions and

economic expert testimony, did establish that Defendants' activities directly led to their increased reimbursements for Lorazepam and Clorazepate. It was established at trial that the generic manufacturers, including Mylan, do influence the average wholesale price ("AWP"), even though they do not publish it, which is then used in one of the reimbursement formulas between Plaintiffs and PBMs. *See* Trial Tr. vol. 6 at 88, May 10, 2005 Morning (Dr. Stern); Trial Tr. vol. 6 at 33, May 10, 2005 Afternoon (Dr. Stern); Trial Tr. vol. 12 at 81, May 18, 2005 Morning (Jackson). Generally, a higher AWP means a higher reimbursement cost for insurers like Plaintiffs. *See e.g.,* Trial Tr. vol. 6 at 23, May 10, 2005 Morning (Krinke) (Mylan's Director of Trade Relations and Government Affairs). Another reimbursement formula involves the "maximum allowable cost," or "MAC," which is generally set based on the AWP. See Trial Tr. vol. 7 at 34, May 11, 2005 Morning (Dr. Stern). Mylan increased its wholesale prices and its AWP, and thus, according to Plaintiffs, directly contributed to an increase in Plaintiffs' reimbursements for Lorazepam and Clorazepate.

Defendants point to testimony during trial disputing the manufacturers' relationship to the AWP and testimony that the PBMs establish the MAC independently. While Defendants are correct in pointing to testimony related to the establishment of AWPs and MACs and the variables involved in setting a MAC, the Court does not find that the evidence on this issue was so one-sided that a reasonable jury could find only for Defendants. As stated, Plaintiffs also provided evidence connecting Defendants' actions to Plaintiffs' damages and the Court cannot grant Defendants' renewed motion for judgment as a matter of law based on this argument.

C. Monopolization

In order to prevail on the count of monopolization, Plaintiffs needed to show by a preponderance of the evidence that: (i) Defendants possessed monopoly power in a relevant market; (ii) Defendants willfully acquired or maintained that power through restrictive or exclusionary conduct; (iii) Defendants' activities occurred in or affected trade or commerce in the relevant states for the relevant Plaintiffs; and (iv) that Plaintiffs were injured in their business or property because of Defendants' restrictive or exclusionary conduct. *See United States v. Grinnell Corp.,* 384 U.S. 563, 570-71 (1966). Defendants argue that the evidence did not show that Defendants possessed monopoly power in the relevant markets, nor did it show that they willfully acquired or maintained that power through exclusionary conduct.

1. Monopoly Power

Monopoly power is the power to control prices and exclude competition in the relevant antitrust market. A firm is generally considered to have monopoly power if it can profitably raise prices substantially above the competitive level for a non-transitory period of time. Factors to consider in determining the existence of monopoly power include the following: the trend in the firm's market share, the number and size of the firm's competitors, the history of entry and exit from the relevant market, and whether the firm could maintain supracompetitive prices for a non-transitory period of time. *See e.g., Int'l Distrib. Ctr., Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 792 (2d Cir. 1987). Defendants first contend that the evidence presented at trial did not support the finding that Mylan had monopoly power in the Lorazepam and Clorazepate tablet markets. As stated above, Plaintiffs presented sufficient evidence at trial such that a reasonable jury could find that the relevant markets for antitrust purposes were the generic Lorazepam and Clorazepate

tablet markets, respectively**.** Defendants state that the evidence showed that Mylan's market share in both markets went up slightly in 1998, and then fell because of its price increases. Defendants also point to evidence that there was no exit from either market at the relevant time period and that new entry occurred in the Lorazepam market. Defendants argue that prices were driven by competition and that Mylan did not have the ability to exclude any competitors from either market. For all of these reasons, Defendants posit that Mylan did not have monopoly power.

There was evidence presented at trial of various firms exiting the relevant markets after the Exclusive Agreements were signed. *See supra* Section II.B.1. As discussed, there was sufficient evidence at trial to establish that many of Mylan's competitors were foreclosed from the generic Lorazepam and Clorazepate tablet markets, increasing Mylan's market share. There was also a great deal of expert testimony presented at trial confirming that Mylan did indeed have monopoly power, an expert opinion based on a number of factors including, but not limited to, the number of firms in the relevant markets and the barriers to entry into these markets. *See generally* Trial Testimony of Dr. Saha. Furthermore, there was a great deal of evidence presented concerning Mylan's extremely high price increases on Lorazepam and Clorazepate tablets and the fact that Mylan was able to gain market share during these prices increases. This type of evidence is sufficient to lead a reasonable jury to infer that Mylan did indeed have monopoly power.

Given the evidence presented at trial, and making all inferences favorable to the non-moving party, Plaintiffs, the Court cannot find that the jury's finding was not supported by the evidence. The evidence was not so one-sided as to result in only one conclusion.

2. Willful Acquisition/Maintenance of Monopoly Power Through Exclusionary Conduct

Monopoly power in and of itself is not illegal. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). To be violative of the antitrust laws, a firm must have willfully acquired or maintained its monopoly power through exclusionary conduct. *Id*. Defendants argue, similar to their argument as to the unreasonable restraint of trade claim, that because their agreements did not foreclose substantial competition, Plaintiffs' monopolization claims must fail as a matter of law. For the reasons discussed above, there was evidence presented at trial regarding the foreclosure of competition as a result of the Defendants' agreements. The Court cannot find that based on such evidence that no reasonable jury could find that competition in the relevant markets were foreclosed, and therefore that Defendants willfully acquired monopoly power through exclusionary conduct.

D. Attempted Monopolization

In order to prove their claim of attempted monopolization, Plaintiffs needed to prove that: (i) Defendants engaged in exclusionary conduct; (ii) Defendants had a specific intent to achieve monopoly power in a relevant market; (iii) there was a dangerous probability that Defendants would achieve the goal of monopoly power in the relevant market; (iv) Defendants' conduct occurred in or affected trade or commerce in the relevant states for the relevant Plaintiffs; and (v) Plaintiffs were injured in their business or property by Defendants' exclusionary act. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Defendants argue the evidence did not show they engaged in exclusionary conduct or that there was a dangerous probability of achieving monopoly power. As discussed above, the Court finds there was sufficient evidence

such that a reasonable jury could find that Defendants did engage in exclusionary conduct and had monopoly power, and thus it was not unreasonable for the jury to conclude that Defendants did attempt to monopolize the generic Lorazepam and Clorazepate tablet markets.

E. Conclusion

For the reasons stated above, after making all favorable inferences for the Plaintiffs, and examining the entire record, the Court denies Defendants' Renewed Motion for Judgment as a matter of law because the evidence in the record was not so one-sided such that a reasonable jury could find only for Defendants.

III. DEFENDANTS' MOTION FOR A NEW TRIAL UNDER RULE 59(A)

In this motion, Defendants argue they are entitled to a new trial under Rule 59(a) for two main reasons: Plaintiffs' counsel's conduct during trial and improper instruction of the jury. Under Rule 59(a) of the Federal Rules of Civil Procedure, a new trial may be granted in a case that had a jury trial for "any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States." The decision to grant or deny such a motion lies within the sound discretion of the court. *See e.g., Grogan v. General Maint. Co.,* 763 F.2d 444, 448 (D.C. Cir. 1985); *Machesney v. Larry Bruni, M.D., P.C.,* 905 F. Supp. 1122, 1130 (D.D.C. 1995). To preserve the function of the jury, new trials should not be granted unless "a solid basis for doing so" exists. *Warren v. Thompson*, 224 F.R.D. 236, 239 (D.D.C. 2004) (internal citations and quotations omitted). Further, such a motion should be granted only when the court is convinced that the jury verdict was a "seriously erroneous result" and where denial of

the motion will result in a "clear miscarriage of justice." *Id*. (internal citations and quotations omitted). Generally, a new trial may only be granted when a manifest error of law or fact is presented. Further, the standard for granting a new trial is not whether minor evidentiary errors were made. *See, e.g.*, *Nyman v. Chairman, Fed. Deposit Ins. Corp.*, 1997 WL 243222, *3 (D.D.C. 1997).

A. Plaintiffs' Counsel's Alleged Conduct

Defendants first argue that Plaintiffs' counsel improperly used his peremptory challenges to exclude jurors on racial grounds. Clearly, such use of peremptory challenges is prohibited by the Fourteenth Amendment. *See Edmundson v. Leesville Concrete Co., Inc.,* 500 U.S. 614, 628-29 (1991); *Batson v. Kentucky*, 476 U.S. 79, 86-87 (1986). Defendants argue Plaintiffs' counsel improperly used all six of his peremptory challenges to exclude only white panelists from the jury. In determining whether a party's use of peremptory challenges has violated the Constitution, the Court first examines whether the challenging party has made out a prima facie case of discrimination, then whether the challenged party has offered a race-neutral reason for its use of its peremptory challenges, and then whether the challenged party's race-neutral reason is pretextual and whether the challenging party has shown purposeful discrimination. *See Purkett v. Elem*, 514 U.S. 765, 767-68 (1995); *Hernandez v. New York*, 500 U.S. 352, 360 (1991); *Batson*, 476 U.S. at 96-97. Defendants state that the fact that Plaintiffs used all six of their peremptory challenges to exclude white panelists provides their prima facie case of

discrimination. Defendants also argue that it is clear that Plaintiffs' non-discriminatory reasons[6] are pre-textual, when the non-stricken black panelists' qualifications and information are examined.

The Court already rejected Defendants' initial *Batson* challenge and found that Plaintiffs' challenges were not race-based, finding the selections were more related to economics and education. *See* Trial Tr. vol. 2 at 87, May 4, 2005 Morning. Revisiting the transcript and the juror information does not incline this Court to reverse its prior decision. Defendants have not shown purposeful discrimination and the Court does not believe Plaintiffs' non-discriminatory reasons were pretextual. Plaintiffs' use of peremptory strikes does not support Defendants' motion for a new trial.

Defendants also argue that Plaintiffs' counsel improperly argued facts not in evidence in a manner highly prejudicial to Defendants. Defendants argue that Plaintiffs' counsel's statements at trial, especially during closing statements, were so prejudicial that no instruction from the Court could have cured them. Specifically, Defendants point to comments from Plaintiffs' counsel including comments that allegedly implied collusion among Defendants when there was no evidence to support such statements, comments implying Mylan purged its records despite documents being excluded for use at trial by the Court, and that Defendants would engage in the same behavior as was at issue at trial if the jury found for them despite the fact that

[6] These included: (i) panelist's association with business journal and husband's experience as an antitrust attorney; (ii) panelist was a lobbyist for American Steel and could be too probusiness; (iii) panelist works for Department of Commerce and had concerns about his economic impact statement; (iv) panelist who showed some bias against insurance companies and had some economic experience and knowledge; (v) panelist had friend working at Defendants' law firm and felt he might favor business; and (vi) panelist was policy analyst for GAO and made comments indicating she might be pro-Defendants in this case.

Defendants have signed an FTC Consent Decree. Defendants also argue Plaintiffs prejudicially asked the jury to step in the shoes of the Plaintiffs and encouraged jury nullification, which should not have been allowed as it likely inflamed the passions of the jury. Plaintiffs deny many of Defendants' allegations in their opposition. Defendants raised similar arguments in arguing for a mistrial on May 26, 2005 when the jury was deliberating. The Court denied that request, noting Defendants' concerns but also noting that Defendants easily could have requested a curative instruction earlier that would have helped the situation. While Plaintiff's counsel was occasionally admonished at trial and the Court did have concerns about some of the statements made by Plaintiff's counsel, the Court does not find that cumulatively these incidents were manifest errors that justify a new trial, especially in light of the instructions that were given to the jury concerning what they may or may not consider in their deliberations.

B. Jury Instructions

Defendants argue that several instructions given to the jury on the law were improper, and as such a new trial should be granted. The standard for determining whether an erroneous jury instruction mandates a new trial is the general harmless error standard. *See Williams v. United States Elevator Corp.*, 920 F.2d 1019, 1022 (D.C. Cir. 1990). Defendants argue that taken together the erroneous instructions raise a substantial possibility that the jury's verdict was based on an improper legal theory, and thus require reversal. *See United States v. Lemire*, 720 F.2d 1327, 1343 (D.C. Cir. 1983).

The first instruction Defendants challenge is that related to relevant markets. Defendants argue that Plaintiffs' counsel admitted at trial that the market was both brand and generic tablet

manufacturers and thus the jury did not need to be instructed. Such a statement did not constitute a judicial statement and as discussed the jury was presented with conflicting evidence on the issue of market definition and had sufficient evidence to reasonably find that the relevant antitrust markets were generic Lorazepam and Clorazepate tablets, respectively.

Defendants then argue that even if the instruction regarding market definition was appropriate, the jury should have also been asked to consider supply substitutability in deciding the relevant antitrust market. Defendants posit that if the jury were given that instruction, it is likely that they would have included brands in the market because the brands could easily shift to manufacture generic tablets, as evidenced by the brands' generic authorization agreements. Defendants argue that the branded companies did compete even if the market includes only generic tablets, through the authorized generics Lederele and Watson. The Court cannot find that such an additional instruction would result in a different outcome because as discussed above, even considering the evidence about Lederele and Watson's participation in the markets, there was still sufficient evidence for a reasonable jury to find substantial foreclosure of the relevant markets.

The second jury instruction Defendants challenge relates to market foreclosure. While the Court did instruct the jury that to find substantial foreclosure the foreclosure had to be for a non-transitory period of time, Defendants state that the Court should have defined "non-transitory" as more than one year, citing *Williamsburg Wax Museum v. Historic Figures, Inc.*, 810 F.2d 243, 252 (D.C. Cir. 1987). Defendants argue the jury's question during deliberations about non-transitory period of time indicate juror confusion and indicate that a precise definition should have been provided in the jury instructions. The Court already considered the

Williamsburg Wax decision in crafting the jury instructions and responding to the juror note. Further, as the Court has stated Defendants' reading of *Williamsburg Wax* does not exactly stand for the proposition Defendants cite it for and does not control in this situation. *See* S.J. Mem. Op at 21-22; Trial Tr. vol. 19 at 3, May 27, 2005 Morning. The Court does not find that not giving this additional instruction sought by Defendants was in error.

The third jury instruction Defendants challenge is that the jurors should have been instructed that price increases alone do not constitute antitrust violations. Defendants argue that Plaintiffs overemphasized evidence concerning price increases and that the jury needed an instruction to know that unilateral price increases in and of themselves do not constitute exclusionary behavior. The Court disagrees with Defendants' argument and finds that there was sufficient language in the instructions to ensure that the jury would not find that price increases alone were antitrust violations. *See* Trial Tr. vol. 18 at 71-72, May 26, 2005 (jury instruction regarding price increases). The Court cannot find that the lack of the specific instruction requested by Defendants was a manifest error of law.

Fourth, Defendants challenge the Court's instruction regarding damages calculations. Defendants argue that the jury instructions were contradictory and that it was unclear that Plaintiffs' damages should be limited to the excess reimbursement they paid that can be attributed to Defendants' actions. The Court's instruction to the jury on damages was that "the damage amount in this case is the amount by which the plaintiffs - prices plaintiffs actually paid exceeded the price they would have paid if there was no antitrust violation." Trial Tr. vol. 18 at 69, May 26, 2005. This "but for" test is appropriate in this case and the Court gave a further instruction to make clear for the jury that damages should be apportioned to account only for

Defendants' anticompetitive actions, and that any additional excess paid by Plaintiffs that was not a result of Defendants' actions should not be included. *Id.* at 72. The Court does not find these instructions to be contradictory and does not find that they were a manifest error of law.

C. Conclusion

Even taken together, the alleged errors of law cited by Defendants in support for a new trial are not sufficient to meet their burden to show that there was a clearly erroneous result or that denying such a motion would result in a clear miscarriage of justice. At best, Defendants cite minor evidentiary issues, none of which, even cumulatively justify the grant of a new trial.

IV. CONCLUSION

For the foregoing reasons, the Court denies Defendants' Renewed Motion for Judgment as a Matter of Law and Defendants' Motion for a New Trial Under Rule 59(a). An appropriate order accompanies this memorandum opinion.

December 20, 2006 /s/
Thomas F. Hogan
Chief Judge