UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: NIFEDIPINE ANTITRUST LITIGATION	)	**Master Docket No. 03-MS-223** **MDL DOCKET NO. 1515** **ALL CASES**

MEMORANDUM OPINION
(November 21, 2007)[#136]

SAJ Distributors ("SAJ"), Stephen LaFrance Holdings, Inc. ("LaFrance"), Meijer, Inc., Meijer Distribution ("Meijer"), Rochester Drug Cooperative ("Rochester") and Independent Drug Company ("Independent")(collectively the "Sherman Act Plaintiffs") have sued the Biovail Corporation ("Biovail"), Elan Corporation ("Elan"), and Teva Pharmaceuticals ("Teva") alleging that the defendants conspired to restrain the sale of a generic hypertension drug in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Currently before the Court is the plaintiffs' motion for class certification. Upon review of the pleadings, the relevant caselaw and the parties' representations at oral arguments, plaintiffs' motion is GRANTED.

I. BACKGROUND

Adalat CC ("Adalat") is a prescription hypertension drug originally developed and marketed by the Bayer Corporation.[1] Sherman Act Plaintiffs' Second Amended Complaint ("Complaint"), ¶ 31-34. In April 1997, as the term of Bayer's patent exclusivity neared its end, Elan, a generic drug maker, filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") for a generic version of 30 mg Adalat.[2] Compl. at ¶ 37. In December 1997, Biovail, another generic drug maker, filed an ANDA for competing 30 mg and 60 mg versions. *Id* at ¶ 39. In June 1999, Elan filed an ANDA for its own 60 mg version. *Id* at ¶ 44.

Four months later, defendants entered into a marketing and distribution agreement under which Elan granted Biovail and Teva (a joint-venturer of Biovail) the exclusive right to distribute Elan's generic version of Adalat in the United States for 15 years in return for a minimum of $73.5 million (the "Agreement"). *Id* at ¶ 45. As a result, although the FDA ultimately approved Elan and Biovail's generic versions of Adalat,

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[1] In 2000, over 5.9 million prescriptions for Adalat CC were filled, making it the 70th most prescribed drug in the U.S. Compl., ¶ 35. Biovail reported that in 2000, U.S. sales for generic and branded Adalat were approximately $441 million. *Id.*

[2] A drug manufacturer who seeks to introduce a new drug must file a New Drug Application ("NDA") with the FDA. The NDA requires the submission of data on the safety and effectiveness of the drug and information on any applicable patents. When a drug manufacturer seeks to produce a generic version of a drug, the manufacturer must file an Abbreviated New Drug Application ("ANDA") with the FDA demonstrating that the generic version of the drug has the same active ingredients and is therapeutically equivalent to the pioneer drug. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv). The first generic manufacturer successfully to file an ANDA enjoys a 180-day exclusivity period during which no other generic manufacturer may market its product. *Id.* ¶ 29.

only Biovail launched the product.[3]

In June 2002, the Federal Trade Commission ("FTC") filed an administrative complaint against the defendants alleging that they had "unreasonably restrained competition" in the market for generic Adalat. *Id.* ¶ 65. As a result, the parties entered into a Consent Order with the FTC under which Elan and Biovail agreed to unwind the Agreement. *Id.* Elan subsequently sold the rights to its generic versions of 30 mg and 60 mg Adalat to Watson Pharmaceuticals, which launched the product soon after. *Id* at ¶ 69.

In March 2003, the plaintiffs, who were direct purchasers of generic Adalat, filed suit on behalf of themselves and other similarly situated purchasers, alleging that but for the Agreement, Elan and Biovail would have launched competing versions of generic Adalat and that the ensuing price competition would have driven down the price charged to the consumer. Accordingly, plaintiffs argue that the defendants artificially and illegally maintained the price of generic Adalat in violation of the Sherman Act.

Plaintiffs have moved for class certification pursuant to Federal Rule of Civil Procedure 23 seeking to certify a class of those persons (or their assignees) who: (1) purchased 30 mg generic Adalat between March 10, 2000 and the time the effect of the

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[3] On March 10, 2000, the FDA granted final approval of Elan's 30 mg generic. *Id* at ¶ 48. The 180-day exclusivity period on Elan's 30 mg version ended on September 10, 2000. On December 4, 2000, the FDA approved Biovail's 30 mg and 60 mg versions. *Id* at ¶ 53. As a result, Biovail could have launched its 30 and 60 mg version at that time. On June 4, 2001 the 180-day exclusivity period on Biovail's 60 mg version ended. On October 26, 2001, the FDA granted final approval of Elan's 60 mg version. *Id* at ¶ 60. Accordingly, Elan could have launched its 60 mg version at that time.

unlawful conduct ended; and (2) purchased 60 mg generic Adalat between December 4, 2000 and the time the effect of the unlawful conduct ended. Compl. ¶ 16. Defendants have opposed the motion arguing that plaintiffs have failed to meet their burden under Rule 23 and that the proposed class is overinclusive.[4]

II. ANALYSIS

To obtain certification under Rule 23, the proposed class must satisfy all four prerequisites of Rule 23(a) and one of the three subsections of Rule 23(b). *Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 614 (1997); *Thomas v. Albright*, 139 F.3d 227, 233-234 (D.C.Cir.1998); *In re Vitamins Antitrust Litigation*, 209 F.R.D. 251, 256 (D.D.C. 2002). Pursuant to Rule 23(a), plaintiffs must show: (1) that the class is so numerous that joinder of all members is impracticable ("numerosity"); (2) that there are questions of law or fact common to the class ("commonality"); (3) that the claims or defenses of the representative parties are typical of the claims or defenses of the class ("typicality"); and (4) that the representative parties will fairly and adequately protect the interests of the class ("adequacy of representation"). F.R.C.P. 23(a). In order to satisfy Rule 23(b),

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[4] As to whether the proposed class is overinclusive, defendants argue that the defendants could not have introduced a competing version of 30 mg Adalat before December 4, 2000 (when the FDA granted final approval to Biovail's 30 mg version) nor a competing version of 60 mg Adalat before October 26, 2001 (when Elan's version was approved by the FDA). Plaintiffs argue in response that the defendants launched generic Adalat knowing that the Agreement would limit competition for the foreseeable future, enabling them to sell the drug at a higher price than would have been possible without the Agreement. Given the inability of the Court, at this stage in the proceedings, to evaluate the strength of plaintiffs' argument and in light of the fact that the Court can amend the class at any time prior to judgment pursuant to Rule 23(c)(1)(C), the Court declines to alter plaintiffs' proposed class.

plaintiffs must demonstrate that either: (1) that the prosecution of separate actions by or against individual members of the class would create a risk of inconsistent adjudications; (2) that the party opposing the class has acted or refused to act on grounds generally applicable to the class; or (3) that questions of law or fact common to the members of the class predominate over any questions affecting only individual members and that a class action is superior to other available methods of adjudication of the controversy ("predominance" and "superiority"). F.R.C.P. 23(b). In deciding whether to certify a class, however, courts are *not to* consider the underlying merits of the plaintiff's claim and must accept as true the allegations set forth in the complaint. *Vitamins,* 209 F.R.D. at 257; *In re Lorazepam Antitrust Litigation*, 202 F.R.D. 12, 21 (D.D.C. 2001).

A. RULE 23(a) REQUIREMENTS

Plaintiffs argue that the Rule 23(a) requirements are satisfied because: (1) at least 85 different entities purchased generic Adalat CC from the defendants and, therefore, joinder is impracticable; (2) allegations of an antitrust conspiracy predominate their complaint; (3) each potential class member's claim arises from the same alleged conspiracy; and (4) that plaintiffs can adequately represent the interests of the proposed class. The defendants agree. Accordingly, in light of the size of the proposed class, the nature of the plaintiffs claims (alleging a conspiracy to fix prices) and the uncontroverted ability of the plaintiffs to adequately represent the interests of the proposed class, the Court finds that the requirements of Rule 23(a) have been satisfied.

B. RULE 23(b) REQUIREMENTS

Plaintiffs contend that subsection (3) of Rule 23(b) is satisfied in this case. They argue, in essence, that a common nucleus of anti-competitive conduct is at the center of the proposed class members claims and, therefore, common issues of law and fact predominate. *See* F.R.C.P. 23(b)(3). Moreover, plaintiffs contend, as required under subsection (3), that a class action is a superior method of adjudicating the potential class members' claims. Defendants have opposed plaintiffs' contentions arguing that individualized, rather than common issues of fact, predominate. For the following reasons, the Court agrees with the plaintiffs.

1. Predominance

There is, of course, no bright line test for determining whether common questions of law or fact predominate. *Vitamins,* 209 F.R.D. at 262; *Lorazepam*, 202 F.R.D. at 29. Rather, the predominance requirement is generally satisfied "when there exists generalized evidence which proves or disproves an element [of plaintiff's claim] on a simultaneous, class-wide basis, since such proof obviates the need to examine each class member's individual position." *Lorazepam*, 202 F.R.D. at 29 *quoting In re Potash Antitrust Litigation,* 159 F.R.D. 682 (D.Minn. 1995). In order to make such a determination, the Court must consider the substantive elements of the plaintiff's claims and the type of proof plaintiff intends to proffer to establish them. *Vitamins,* 209 F.R.D. at 256.

Here, plaintiffs have alleged that defendants conspired to fix the price of generic Adalat in violation of Section 1 of the Sherman Act. Accordingly, they must prove: (1) that there was a conspiracy to fix the price of generic Adalat; (2) that plaintiffs were injured as a result; and (3) the amount of that injury. *Vitamins,* 209 F.R.D. at 257; *Lorazepam,* 202 F.R.D. at 29. The issue of predominance, in this case, turns on whether there is sufficient common evidence of a resulting injury and the amount of that injury.[5] There is!

a. Common Issues of Causation

In order to demonstrate that common evidence exists to prove class-wide impact or injury, plaintiffs do not need to prove that every class member was actually injured. *Lorazepam,* 202 F.R.D. at 29. Instead, plaintiffs need only present a "colorable method by which they intend to prove impact on a predominantly common basis," *Vitamins,* 209 F.R.D. at 257; *see also Lorazepam,* 202 F.R.D. at 29; *In re Cardizem CD Antitrust Litigation,* 200 F.R.D. 297 (E.D.Mich. 2001), and the Court, in reaching its decision, must refrain from either deciding the merits of the plaintiff's claims or indulging in a duel "between opposing experts." *Cardizem,* 200 F.R.D at 311; *see also Vitamins,* 209 F.R.D. at 257. Plaintiffs have met this requirement here.

First, as to plaintiffs' contention that defendants' conduct had the effect of

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[5] The defendants do not challenge plaintiffs predominance claim with respect to the element of whether a conspiracy existed between the parties. That there was an agreement between them, of course, is undisputed. Whether it constituted a "conspiracy," however, is an issue common to all prospective plaintiffs.

artificially maintaining the *average* price of generic and branded Adalat, they apparently assume that any direct purchaser of Adalat during the relevant period was injured by the allegedly anti-competitive conduct. Indeed, plaintiffs have offered, in support of these assertions, the expert opinion of Dr. Jeffrey Leitzinger, an economist who has studied the structure of the pharmaceutical industry and the price effects of generic drugs on brand drug markets. Leitzinger Decl., p. 1-2. Based on his research, Dr. Leitzinger has opined that, in this case, class-wide injury (the fact of the artificially inflated price charged to class members) can be proven by: (1) government and academic studies that conclude, in general, that the entry of additional generic competitors drives down the price of generic and branded pharmaceuticals[6]; (2) the defendants' testimony and internal projections that the entry of a second generic would lead to lower prices[7]; and (3) evidence that the entry

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[6] According to Dr. Leitzinger, an extensive body of research has shown that, in general, generic competition reduces the costs of drugs sold by manufacturers. Leitzinger Decl., p. 15-18. Because the first generic entrant is granted a six month exclusivity period, the price of the first generic drug in the market is typically lower than the branded drug, but the amount of the drop in price is limited. *Id.* Once the exclusivity period ends, however, and additional generic competitors enter the market, the price of the generic and branded drug fall rapidly towards incremental costs. *Id.*

[7] Dr. Leitzinger reviewed the testimony of Paul Krauthauser, Teva's Director of Product Marketing, who averred that Teva generally expects prices to fall when additional generics enter the market. Leitzinger Decl., p. 19. He also considered the testimony of Anne Payne, Teva's Director of Market Research and Analysis who testified that Teva's standard computer model of he generic market predicted that the price of generic Adalat would fall with the entry of a second generic competitor. *Id* at p. 18-19. Dr. Leitzinger also reviewed the testimony of Steven Thornton, an Elan executive, who testified before the FTC that second generics generally drive down the price of a particular drug, as well as Elan documents that predicted a significant fall in price for generic Adalat after the entry of a second generic. *Id* at p. 19-20. Finally, Dr. Leitzinger considered the testimony of Biovail's Chief Financial Officer, who testified that he generally expected the price of a generic to fall when additional competitors enter the market. *Id*

of Watson's generic version of Adalat in August 2002 led to lower prices.[8] *Id* at 7.

Not surprisingly, defendants have opposed plaintiffs' predominance argument on this causation issue on the grounds that the price paid by individual class members during the relevant period varied widely and that for some purchasers, the price of Adalat rose after the Agreement was unwound (indicating that the alleged anti-competitive conduct had no impact on the price of Adalat). Moreover, defendants contend that plaintiffs have failed to consider external factors (i.e. the introduction of Procardia XL, an identical hypertension drug, during the same period) that might have led to changes in the average price of Adalat. Finally, defendants argue that the time frame studied by plaintiffs expert skewed the report's results.[9] Unfortunately, defendants' arguments, at this point in the case, are premature.

Plaintiffs, at this stage in the proceedings, need only demonstrate a *colorable* method by which they intend to prove class-wide impact. *Vitamins,* 209 F.R.D. at 264. Although defendants argue that plaintiffs' approach to proving that impact is hopelessly flawed, plaintiffs have offered, nonetheless, a means of proving the anti-competitive

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at p. 20.

[8] According to Dr. Leitzinger's research, in August 2002 (before Watson entered the market) the average net price of generic Adalat to class members was $.54 per 30 mg tablet. Leitzinger Decl., p. 21. In 2003 (after Watson had introduced its generic version), the price had fallen to approximately $.41 per tablet. Moreover, the price of Bayer's branded 30 mg Adalat fell from $.97 per tablet in 2001 to $.74 per tablet in 2003. *Id.* According to Dr. Leitzinger, prices for 60mg generic and branded Adalat likewise fell. *Id* at 22.

[9] Defendants have offered the expert opinion of Dr. Ramsey Shehadeh in order to rebut Dr. Leitzinger's methodology and conclusions.

impact of defendants' conduct that is reasonable and well established[10] in the following respects.

First, plaintiffs' expert has relied on numerous academic and government studies that conclude that the introduction of a second generic drug will lead to increased price competition. Although defendants argue that certain studies dispute this contention, the Court, at this stage in the proceedings, will not choose between dueling studies. The fact that plaintiffs can point to significant scholarship in this area in support of their claims is sufficient. Second, the defendants' testimony (supported by their internal projections) that they expected that the entry of a second generic version of Adalat into the market would drive down prices is powerful and compelling. Certainly, the Court has no reason, at this point, to doubt the accuracy of these projections; particularly as they are based on the defendants' experience in the marketplace and echo the conclusions drawn in the academic literature.

Finally, Dr. Leitzinger's calculations that the average price of Adalat fell after the introduction of Watson's generic versions of 30 and 60mg Adalat, are neither clearly erroneous nor misleading. Although defendants argue that Dr. Leitzinger's methodology ignored individual variations in price and that sales data shows that the price paid by

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[10] Indeed, courts have repeatedly accepted the use of: (1) government and academic studies; (2) internal projections; and (3) empirical sales data, to prove class-wide impact. *See e.g. In re Relafen Antitrust Litigation,* 218 F.R.D. 337 (D.Mass. 2003); *J.B.D.L Corp. v. Wyeth-Ayerst Labs, Inc.,* 225 F.R.D. 208 (S.D.Oh. 2003); *In re Cardizem CD Antitrust Litigation,* 200 F.R.D. 297 (E.D. Mich. 2001).

some customers rose after the introduction of Watson's generic, the Court can find no fault in Dr. Leitzinger's calculations of *aggregate* changes in price. Although a jury may ultimately find defendants' methodology (i.e. calculating price change on an individualized rather than aggregate basis) more compelling, that determination is for the finder of fact. Indeed, "courts have found common impact in cases alleging price-fixing despite individual negotiations, varied purchase methods and different amounts, prices, and types of products purchased." *Vitamins,* 209 F.R.D. at 266.[11] Accordingly, the Court finds that plaintiffs have offered a sufficient colorable method of proving class-wide impact with common evidence as to the issue of causation.

b. Common Issues of Damages

As to whether common issues of damages predominate, the Court need only assess whether "methods are available to prove damages on a class-wide basis." *Vitamins,* 209 F.R.D. at 268. As a result, plaintiffs do not need to provide a precise damage formula, nor do they need to take into account or eliminate individual variations in damages. *Id*; *see also Potash,* 159 F.R.D. at 697; *Jack Faucett Assoc. v. American Tel. & Tel.*, slip op. 1983 WL 4601, * 3 (D.D.C. Mar. 18, 1983) ("[w]hile the quantum of damages for each plaintiff may be different, that fact alone is insufficient to introduce a predominant

[11] Furthermore, evidence of increased price competition after Watson's entry into the market serves only as a rough estimate of the effect of the Agreement. Given that the Agreement delayed the introduction of a second generic by two years and presumably allowed defendants to entrench their position in the market, the effect of Watson's introduction of a generic version is relevant, but certainly not identical to the effect of increased competition during the time the Agreement was in place.

noncommon question."). Instead, plaintiffs need only show that "the proposed methods are [not] so insubstantial as to amount to no method at all." *Potash,* 159 F.R.D. at 697.

Here, plaintiffs argue that damages can be shown by calculating the "but for" price of Adalat (i.e. what the price of Adalat would have been if Biovail and Elan had introduced competing generic versions) and then calculating the amount plaintiffs were overcharged based on actual sales and price data. Although defendants argue that individualized calculations of damages are more appropriate, plaintiffs need only demonstrate that a viable methodology is available, not that their methodology is the best or most accurate. Accordingly, as plaintiffs have offered a reasonable approach to calculating damages (certainly more than "no method" at all), the Court finds that plaintiffs have established that common issues of damages predominate.

2. Superiority

As noted earlier, plaintiffs must also demonstrate under Rule 23(b)(3) that a class action is "superior to other available methods for the fair and efficient adjudication of the controversy." F.R.C.P. 23(b)(3). Indeed, Courts in this district have noted that certification is appropriate in cases in which a class action "would promote judicial efficiency and uniformity of decision as to persons similarly situated." *Vitamins,* 209 F.R.D. at 270 .

Here, plaintiffs argue that it would be inefficient to force each class member to prove the same nucleus of operative facts in dozens of separate trials. Moreover,

plaintiffs argues that some claims may be so small as to make litigation unfeasible. I agree as to both.

Defendants' counter argument that the proposed class is made up of sophisticated purchasers, each with large claims and many of whom will likely want to control the prosecution of their claims is insufficient. Class members who want to prosecute their own claims can opt out of the proposed class. By contrast, aggregating these claims in a single action greatly furthers the interests of judicial economy. Accordingly, the Court finds that a class action is the superior method of adjudicating this controversy.

III. CONCLUSION

Therefore, for the reasons noted above, the Court finds that plaintiffs have satisfied the requirements of Rule 23. Accordingly, plaintiffs' motion for class certification is GRANTED.

RICHARD J. LEON
United States District Judge