

in treating depression. (Compl. ¶¶ 40-41.) On December 29, 1992, the FDA approved Defendant's New Drug Application ("NDA") for a drug containing paroxetine hydrochloride hemihydrate which Defendant markets as Paxil. (Compl. ¶¶ 42-43.) Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., once the FDA approved Defendant's NDA for Paxil, Defendant obtained a five-year statutory monopoly in the market for that drug. (Compl. ¶ 45.)

The Complaint alleges that in 1995, Defendant began to apply for patents on new anhydrous polymorphs of paroxetine hydrochloride, which patents began to issue in 1999 and which were submitted by Defendant to the FDA. (Compl. ¶ 46.) The Complaint further alleges that, once competitors of Defendant began to file Abbreviated New Drug Applications ("ANDA") for generic bioequivalents of Paxil in 1998, Defendant filed baseless patent infringement actions against those competitors, which alleged that the bioequivalent drugs infringed on the '723 Patent and the other, more recently issued patents on forms of paroxetine hydrochloride owned by Defendant. (Compl. ¶¶ 47-100.) Pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, the filing, by a branded drug patent owner, of a patent infringement suit against a generic competitor automatically blocks the FDA's approval of the competitor's ANDA for up to 30 months. (Compl. ¶¶ 38-39.) The Complaint alleges that Defendant has violated the antitrust laws by filing fourteen

baseless patent infringement actions against generic competitors in order to block FDA approval of its competitors' ANDAs and, thus, indefinitely extend its market monopoly for Paxil. (Compl. ¶ 1.) The Complaint further alleges that, because Defendant unlawfully extended its market monopoly on Paxil, the class members paid higher prices for paroxetine hydrochloride than they would have otherwise paid and that Defendant was unjustly enriched by their overpayments.

Plaintiffs have filed a motion to certify a class of persons who purchased or paid for Paxil for consumer use from January 1, 2001 to the present, and a subclass of persons who purchased or paid for Paxil for personal use in certain states from January 1, 2001 to the present. A hearing has been scheduled on Plaintiff's Motion for Class Certification for February 12, 2003. Plaintiffs have offered the opinion of Dr. Gary L. French to establish the existence of class-wide impact of Defendant's alleged violations of Section 2 of the Sherman Antitrust Act and to establish that this impact may be established by common proof and methodology.

II. DISCUSSION

To obtain class certification, Plaintiffs must meet all four requirements of Federal Rule of Civil Procedure 23(a) and at least one part of Federal Rule of Civil Procedure 23(b). Baby Neal v. Casey, 43 F.3d 48, 55 (3d Cir. 1994) (citing Wetzel v. Liberty Mutual Ins. Co., 508 F.2d 239 (3d Cir. 1975)). The four

requirements of Rule 23(a) are satisfied only if:

1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a).

Plaintiffs allege that the proposed class satisfies the requirements of Rule 23(a) and is maintainable pursuant to Rule 23(b)(2) which requires that: "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole" and Rule 23(b)(3) which requires that: "the court finds that the 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 for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(2) and (3).

Dr. French has reached the following conclusions in support of his opinion that Defendant's activity has had class-wide impact which may be established by common proof and methodology:

- a. The relevant antitrust product market in this matter is likely limited to Paxil® and its generic bioequivalents;
- b. Each member of both the proposed class

and the proposed sub-class has paid or will pay higher prices for Paxil®, regardless of whether the class member would have purchased Paxil® or a generic equivalent after January 1, 2001, than a class member would have paid absent defendant's allegedly illegal conduct;

- c. Because each class member has overpaid or will overpay for Paxil®, each class member has or will be adversely impacted or economically injured;
- d. A feasible methodology exists to calculate the aggregate overcharge damages to the indirect purchaser class;
- e. A feasible methodology exists to calculate the amount by which defendant has allegedly been unjustly enriched; and
- f. The data required to implement the methodologies to quantify the overcharge damages and the unjust enrichment damages are available from IMS America or Scott Levin, and from defendant in discovery.

(French Am. Aff. ¶ 14.)

Defendant argues that the Court should strike Dr. French's Amended Affidavit and preclude his testimony at the hearing on Plaintiff's Motion for Class Certification because his opinion does not satisfy the requirements of Federal Rule of Evidence 702. Federal Rule of Evidence 702 states as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of

reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. In determining whether expert testimony is admissible pursuant to Rule 702, the court must determine: "pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592-93 (1993). The Court must make this determination in all cases where the "testimony reflects scientific, technical, or other specialized knowledge." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141 (1999).

Under Daubert, the Court must perform the following inquiry: "First of all, the proffered 'expert' must be qualified to express an expert opinion.... Secondly, the proffered expert opinion must be reliable." In re TMI Litig., 193 F.3d 613, 664 (3d Cir. 1999). In determining the reliability of the expert testimony, the Supreme Court and the United States Court of Appeals for the Third Circuit ("Third Circuit") have provided a number of factors to offer guidance to the Court's inquiry. These factors include:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been

subjected to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 742 n. 8 (3d Cir. 1994) ("Paoli II"). This list is not exhaustive, and the inquiry under Daubert remains flexible; each factor need not be applied in every case. See, e.g., Elcock v. Kmart Corp., 233 F.3d 734, 746 (3d Cir. 2000); Schieber v. City of Philadelphia, Civ.A.No. 98-5648, 2000 U.S. Dist LEXIS 17952, at *6-7 (E.D. Pa. Dec. 13, 2000) ("These factors are non-exclusive and no one of the factors weighs more heavily than another; the approach to determining the admissibility of expert testimony is a flexible one.") (citing Daubert, 509 U.S. at 594).

Defendant argues that Dr. French's opinion, as demonstrated in his Amended Affidavit and deposition testimony, fails to satisfy the requirements of Rule 702 and Daubert because, in reaching his opinion, Dr. French ignored key facts regarding the impact of insurance coverage on injury to the class; failed to present a methodology for determining which class members have been injured by Defendant's conduct (which Defendant proposes would require a highly individualized examination of each class member's benefit

plan, buying habits, and likelihood of receiving prescriptions for Paxil); relied on an unsupported assumption that Defendant would have dropped the price of Paxil upon the entry into the market of a generic competitor; and offered no method for identifying which class members would switch to a generic form of Paxil if one were available. Defendant also argues that Dr. French's benchmark methodology for calculating aggregate damages is not reliable because there are members of the proposed class who may not have suffered any injuries and because Dr. French has not selected the benchmarks he would use to calculate damages or explained what factors he would consider in choosing benchmarks.

Dr. French's opinion need not, however, satisfy the requirements of Daubert to be admissible with respect to class certification. At this stage of the proceeding, the Court does not consider whether an expert witness's opinion would be admissible pursuant to Daubert, "the Court simply examines whether [the expert's] methodology, as proposed, will comport with the basic principles of econometric theory, will have any probative value, and will primarily use evidence that is common to all members of the proposed class." In re Polypropylene Carpet Antitrust Litigation, 996 F. Supp. 18, 26 (N.D. Ga. 1997). The United States Court of Appeals for the Second Circuit has explained that the district court's function at this stage is "not to determine whether plaintiffs had stated a cause of action or whether they

would prevail on the merits, but rather whether they had shown, based on methodology that was not fatally flawed, that the requirements of Rule 23 were met." In re Visa Check/Master Money Antitrust Litig., 280 F.3d 124, 135 (2d Cir. 2001), cert. denied 122 S. Ct. 2382 (2002); see also, In re Monosodium Glutamate Antitrust Litigation, 205 F.R.D. 229, 234-235 (D. Minn. 2001) ("Even assuming that there are problems with Dr. Beyer's methodology, however, Defendants' attack on that methodology is premature. The Daubert inquiry requires a more searching analysis than is appropriate at this preliminary stage") (citations omitted); Thomas & Thomas Rodmakers, Inc. v. Newport Adhesives and Composites, Inc., 209 F.R.D. 159, 162-63 (C.D. Ca. 2002) ("It is clear to the Court that a lower Daubert standard should be employed at this stage of the proceedings. Courts have declined to engage in a Daubert analysis at the class certification stage of an action on the ground that an inquiry into the admissibility of the proposed expert testimony under Daubert would be an inappropriate consideration of the merits of the plaintiff's claims.") (citations omitted); Midwestern Machinery v. Northwest Airlines, Inc., Civ.No. 97-1438, 2001 WL 34049897, at * 2 (D. Minn. Jan. 18, 2001) ("The application of the Daubert test, however, is somewhat limited at the stage of class certification. Daubert is helpful to the extent that it can assist the Court in preventing the entrance of methodology so apparently flawed. It would be inappropriate,

however, for a court to look beyond the methodology and critique the prospective results of its application to a complete set of data. A party and its experts should not be expected to have fully evaluated all data at the preliminary stage of class certification.") (citations omitted). The Court finds, accordingly, that Dr. French's opinion, as presented in his Amended Affidavit and testimony, need not satisfy a full Daubert examination at this stage of the litigation. In determining whether Dr. French's Amended Affidavit should be stricken and his testimony precluded, in connection with Plaintiff's Motion for Class Certification, the Court will examine whether Dr. French has identified a generally accepted methodology for determining impact which is applicable to the class, whether this methodology uses evidence common to all class members, and whether his opinion has probative value. See In re Polypropylene Carpet Antitrust Litig., 996 F. Supp. at 26; In re Visa Check/Master Money Antitrust Litig., 280 F.3d at 135.

Dr. French opines that Defendant's prevention of the sale of generic bioequivalents to Paxil resulted in the following common impact to members of the nationwide end-payer class and the indirect purchaser sub-class:

29. Based on the above descriptions of pricing in the pharmaceutical industry and the literature on the impact of generic entry into pharmaceutical markets, the impact on members of the nationwide end-payer class and the indirect purchaser sub-class can be explained.

Both classes include consumers and TPPs [Third Party Payers] which [sic] pay for Paxil®. Consumers in both classes also include individuals who would have switched from Paxil® to generic paroxetine hydrochloride, as well as individuals who would have continued to use Paxil® even after the introduction of generics. The large price differential between Paxil® and even Apotex's first generic would have provided a powerful economic incentive for Paxil® users to switch to the generic. In addition, formulary management by TPPs, as well as state laws requiring, encouraging, or allowing switching without a new prescription, also mean that most Paxil® users would have switched to the generics.

30. In the absence of SmithKline's patent infringement lawsuits against Apotex and other generic drug manufacturers, first Apotex and then others would have introduced bioequivalents to Paxil®. . . .

31. In the absence of SmithKline's allegedly illegal conduct, Apotex would have entered the market for paroxetine hydrochloride on or about January 1, 2001, with prices to direct purchasers (i.e., wholesalers and large chain retailers) significantly lower than SmithKline's Paxil® prices to the same direct purchasers. Given the highly competitive nature of wholesale and retail markets for pharmaceutical products, much, if not all, of the savings wholesale and retail markets would have achieved by purchasing from Apotex would have been passed through to consumers and TPPs. All those who would have switched to generic paroxetine hydrochloride were obviously adversely affected because SmithKline's conduct deprived them of the opportunity to have purchased substantially lower priced generics in place of Paxil®.

32. Even those class members who would have continued to purchase Paxil® after generic entry in January 2001 have also been economically injured, although to a lesser extent. As explained above, current

manufacturers of brand-name drugs lower their prices, or at least do not increase them as much, when competitive generics are introduced. Thus, in all likelihood, SmithKline would have lowered its prices for Paxil® or not increased them as much in response to actual or impending generic entry in order to limit the sales it would have lost to Apotex initially and to all generic manufacturers eventually. Because SmithKline's patent lawsuits have allowed it to avoid generic competition and the need to restrain its Paxil® prices, it has not restrained them. Thus even those class members who would have remained loyal purchasers of Paxil® after generic availability in January 2001 have also been adversely impacted by paying higher Paxil® prices than would have existed absent delayed generic entry.

(French Am. Aff. ¶¶ 30-32.) At his deposition, Dr. French based these conclusions upon economic literature and the fact that the entry of generic competitors into the markets for other brand name drugs has resulted in similar effects. He also stated that he would need to have additional information obtained through merits discovery to determine whether Defendant would lower its price in response to generic entry into the market. (French Dep. at 140-165.)

Defendant contends that Dr. French's assumption that all class members were damaged by Defendant's conduct because the price of Paxil would drop after generic entry into the market is baseless. Defendant relies on the opinion of its own expert, Dr. Richard T. Rapp, that it does not intend to drop the price of Paxil, or raise it more slowly than otherwise, after the entry of a generic

bioequivalent into the market. Dr. Rapp bases his opinion on a review of Defendant's business plans and the testimony of its personnel. (Rapp Rpt. at 18.) He also concludes that Defendant's intention is consistent with economic theory. (Rapp Rpt. at 19.) Dr. French maintains that Dr. Rapp's criticisms of his opinions are "unfounded and/or inappropriate." (French Reply Aff. ¶ 3.) The fact that Dr. Rapp and Dr. French disagree about whether Defendant would reduce the price of Paxil, or raise the price more slowly, after the entry of generic competitors, is not sufficient reason to strike Dr. French's affidavit or disallow his testimony at the class certification hearing, as, at this stage of the litigation, the Court "may not weigh conflicting expert evidence or engage in statistical dueling of experts." In re Visa Check/Master Money Antitrust Litig., 280 F.3d at 135 (citation omitted).

Defendant also argues that the aggregate method of calculating damages proposed by Dr. French is inappropriate in this case because there is an unknown percentage of class members who have not been injured. Defendant suggests that there are four classes of class members who were not injured by its conduct: (1) class members whose insurance plans provide the same co-pay for brand name and generic drugs; (2) class members whose benefit plans have different co-pays for generic and brand name drugs but who would not have switched to a generic version of Paxil (Dr. French estimated that 20-50% of consumers stay with the brand name drug

after a generic enters the market); (3) class members who pay cash but would not switch to a generic version of Paxil; and (4) class members who would not be prescribed Paxil after generic entry into the market because of a decrease in promotional efforts by Defendant. Defendant relies on Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154 (3d Cir. 2001), in which the Third Circuit affirmed the denial of class certification in a Section 10(b) securities case in which individual issues regarding whether class members suffered economic losses from the manner in which their trades were transacted predominated over issues common to the class. The Third Circuit found, in Newton, that “[t]he ability to calculate the aggregate amount of damages does not absolve plaintiffs from the duty to prove each investor was harmed by the defendants’ practice.” Id. at 188. In Newton, class certification was denied because “[d]etermining which class members were economically harmed would require an individual analysis into each trade and its alternatives. The individual questions, therefore, are overpowering.” Id. at 89. Defendant argues that, like in Newton, an unknown, but substantial, number of class members in this case have not been injured and, therefore, Dr. French’s attempt to calculate damages on a class-wide basis would not help the Court in determining whether to certify the class.

The issue presently before the Court, however, is not whether each of the millions of sales of Paxil to indirect purchasers

during the proposed class period resulted in damage to each individual indirect purchaser, but whether Dr. French has a sufficient basis for opining that the class members suffered a common impact from Defendant's alleged attempts to indefinitely prolong its monopoly power in the market for paroxetine hydrochloride. Dr. French's opinion has not been offered in support of an assessment of individual damages but, rather, to assist the Court in determining, for purposes of class certification, whether there exists common evidence available to the class as a whole with respect to the issue of class-wide impact of Defendant's allegedly anti-competitive activity. "In order to show impact is susceptible to class-wide proof, Plaintiffs are not required to show that the fact of injury actually exists for each class member." In re Cardizem CD Antitrust Litig., 200 F.R.D. 297, 307 (E.D. Mich. 2001). If Plaintiffs are able to establish the existence of generalized evidence "which will prove or disprove this injury element on a simultaneous class-wide basis, then there is no need to examine each class members' individual circumstance as Defendant claims. Such an examination will relate to the quantum of damages; not the fact of the injury." Id. (citation omitted). Therefore, the Court cannot find that the possibility that some class members may not have been damaged by Defendant's alleged anticompetitive activity means that Dr. French's opinion would not be probative of any of the issues before the Court with

respect to Plaintiff's Motion for Class Certification.

Defendant also argues that Dr. French's benchmark damages calculation methodology is flawed because he has not specifically stated the percentage of class members who would switch to a generic form of Paxil and because he does not identify all of the benchmarks he would use in estimating damages. (Def.'s Mem. at 15-17.) Dr. French describes his methodology in his Amended Affidavit as follows:

37. The damages to class members equal the sum of the overcharges they have and will pay from January 1, 2001 until such time as generic manufacturers are allowed to sell generic paroxetine hydrochloride and establish their market shares. Such damages would be calculated by applying an overcharge percentage or amount per unit to the dollar or unit volume of purchases by class members. The overcharge amount or percentage can be determined by comparing actual Paxil® prices to the lower Paxil® and generic retail and TPP prices that would have existed since January 1, 2001. The physical or dollar volumes of Paxil® purchases since January 1, 2001 can be obtained from SmithKline and then forecast to the end of the damage period. The proportions of such Paxil® volumes that would have been transferred to generics because of switching can also be determined. All of these estimates and calculations can be made by using a competitive benchmark, which is a well accepted practice in antitrust cases.

38. Generally in situations involving overcharges, the determination of the extent to which prices were higher than they would have been in the absence of anticompetitive activities, the shares of the market the various sellers would have had absent the anticompetitive conduct, and other circumstances that would have existed but for

the wrongdoing is done by means of a competitive benchmark. There are well established approaches or typical benchmarks for determining the characteristics of the "but-for" world. One benchmark consists of a comparable market not affected by the anticompetitive activity. Another would be the market in which the anticompetitive conduct occurred, but in a period of time either before or after the effects of the conduct.

39. Either of these standard benchmarks might be employed to calculate damages in this case. If, before trial, generic manufacturers are able to introduce generic paroxetine hydrochloride and begin establishing their market positions, then an after-period benchmark would be created. A number of comparable markets could also serve as benchmarks for calculating damages. These markets reflect the price and market share effects of generic entry on brand-name drugs over time.

(French Am. Aff. ¶¶ 37-39.) Dr. French also opined that benchmarks could be obtained from data provided by Defendant with respect to its own sales and marketing forecasts and material which can be obtained from outside data sources IMS America or Scott Levin. (French Am. Aff. ¶¶ 40-41, French Dep. at 21-23.) He further states that Defendant currently prepares similar studies of comparable markets for use in market forecasting:

40. In her 30(b)(6) deposition, Ms. Bonnie Rossello, who has had product management responsibilities for Paxil® for many years, essentially explained how the experience of one product or group of products can be employed to predict or forecast what another product might do in its market. She did not refer to the other products as competitive

benchmarks, but rather described them as "market analogs" and indicated that the Marketing Analytics department of GlaxoSmithKline has historically developed and continually develops market analogs by which to forecast the sales, prices, and market shares of GlaxoSmithKline products. Moreover, exhibits to Ms. Rossello's deposition illustrate the decline in sales or market shares of brand-name drugs when generics were introduced. Thus, defendant's own documents provide considerable insight into which other pharmaceutical markets could serve as competitive benchmarks in calculating damages.

(French Am. Aff. ¶ 40, footnotes omitted.)

The two benchmarks proposed by Dr. French for calculating damages in this case, (1) a comparable market not affected by anticompetitive activity and (2) the market in which the anticompetitive activity occurred in a period of time either before or after the effects of the conduct (French Am. Aff. ¶ 38), are standard methods for proving damages in an antitrust case. Park v. El Paso Board of Realtors, 764 F.2d 1058, 1068 (5th Cir. 1985) ("Generally, an antitrust plaintiff can prove lost profits by two methods: (1) the before and after method, which involves comparing records of profits earned by the plaintiff prior to the impact of the violation with those subsequent to it; and (2) the yardstick test, which consists of studies of the profits of firms closely comparable to plaintiff's.") (citations omitted). Moreover, Plaintiffs are not required to have chosen one particular method for calculating damages, or a particular benchmark product, or to have determined the exact percentage of consumers who would have

switched to generic paroxetine hydrochloride, at this stage in the litigation. In re Linerboard Antitrust Litigation, 203 F.R.D. 197, 217 (E.D. Pa. 2001), aff'd, 305 F.3d 145 (3d Cir. 2002) (determining that plaintiffs are not required "to have selected a particular econometric model for demonstrating impact (or proving damages) at the class certification stage."). Dr. French has, therefore, demonstrated the existence of evidence common to the class which can be utilized to determine the appropriate benchmark.

The Court finds that Dr. French has identified a generally accepted methodology for calculating impact in an antitrust suit and that Dr. French proposes the use of evidence common to the class to determine impact and damages in the nature of overcharges or unjust enrichment on a class-wide basis. The Court further finds that Dr. French's opinion has probative value with respect to class certification. Accordingly, Defendant's Motion is denied.

An appropriate order follows.

