UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE PAXIL ANTITRUST LITIGATION	)	
STATE OF MARYLAND,	)	
STATE OF MICHIGAN,	)	
STATE OF NEW YORK,	)	
STATE OF WISCONSIN,	)	
STATE OF ALABAMA,	)	Master File No.
STATE OF ALASKA,	)	
STATE OF ARIZONA,	)	
STATE OF ARKANSAS,	)	
STATE OF CALIFORNIA,	)	
STATE OF COLORADO,	)	
STATE OF CONNECTICUT,	)	
STATE OF DELAWARE,	)	
DISTRICT OF COLUMBIA,	)	
STATE OF FLORIDA,	)	
STATE OF GEORGIA,	)	
STATE OF HAWAII,	)	
STATE OF IDAHO,	)	
STATE OF ILLINOIS,	)	
STATE OF INDIANA,	)	
STATE OF IOWA,	)	

STATE OF KANSAS,)
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COMMONWEALTH OF KENTUCKY,)
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STATE OF LOUISIANA,)
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STATE OF MAINE,)
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COMMONWEALTH OF MASSACHUSETTS,)
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STATE OF MINNESOTA,)
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STATE OF MISSISSIPPI,)
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STATE OF MISSOURI,)
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STATE OF MONTANA,)
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STATE OF NEBRASKA,)
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STATE OF NEVADA,)
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STATE OF NEW HAMPSHIRE,)
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STATE OF NEW MEXICO,)
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STATE OF NORTH CAROLINA,)
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STATE OF NORTH DAKOTA,)
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STATE OF OHIO,)
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STATE OF OKLAHOMA,)
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STATE OF OREGON,)
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COMMONWEALTH OF PENNSYLVANIA,)
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STATE OF RHODE ISLAND,)
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STATE OF SOUTH CAROLINA,)
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STATE OF SOUTH DAKOTA,)
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STATE OF TENNESSEE,)
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STATE OF TEXAS,)
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STATE OF UTAH,)
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STATE OF VERMONT,)
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TERRITORY OF THE VIRGIN ISLANDS,)

COMMONWEALTH OF VIRGINIA,	)
	)
STATE OF WASHINGTON,	)
	)
STATE OF WYOMING,	)
	)
Plaintiffs	)
	)
v.	)
	)
SmithKline Beecham Corporation One Franklin Plaza 16th and Race Streets Philadelphia, Pennsylvania 19102,	))))
	)
And	)
	)
SmithKline Beecham, plc One Franklin Plaza 16th and Race Streets Philadelphia, Pennsylvania 19102,	))))
	)
Defendants.	)

COMPLAINT

Plaintiffs, the States, Commonwealths and Territories, specified in the caption (collectively "Plaintiff States" or "States"), by and through their respective Attorneys General, bring this action against Defendants SmithKline Beecham, plc and SmithKline Beecham Corporation d/b/a GlaxoSmithKline, plc (collectively "GSK" or "Defendants"), to secure damages, injunctive and other equitable relief for Defendants' violations of federal and state antitrust laws, consumer protection and unfair and deceptive trade practices acts and allege as follows:

INTRODUCTION

1. Paxil® is used to treat depression, panic disorder, social anxiety disorder and obsessive compulsive disorder and is one of the most widely-prescribed prescription drugs in the United States with sales of over $2.3 billion in 2002 alone. In or around September 2003, no company marketed or distributed a generic version of Paxil® (paroxetine hydrochloride) in the United States. No generic version of Paxil® existed because the Defendants obtained approximately a dozen patents over the previous decade that effectively "evergreened" its patent monopoly and, if unchallenged, would extend their monopoly on Paxil® until 2019 -- 27 years after the expiration of the original patent. Defendants continue to pursue appeals of adverse patent decisions in hopes of further deterring generic entry. These patents are frivolous, non-novel and redundant concerning chemical properties of Paxil® and its bioequivalents that have nothing to do with the effectiveness of the drug. The sole purpose of these patent filings and suits is to protect the Defendants' monopoly profits as long as possible. Defendants have used hypertechnical patent arguments to activate the automatic stay provisions for generic drugs under the Hatch-Waxman Act. Through this frivolous litigation, Defendants have reaped millions in windfall profits for every day that they delay the onset of generic competition. With every new listed patent, Defendants manufactured an opportunity to file patent infringement suits. With each suit, Defendants automatically received a 30-month reprieve from Food and Drug Administration ("FDA") approval of generic paroxetine hydrochloride, thwarting several drugmakers that would otherwise have generic products on the market. The delay in generic competition for Paxil® has cost the Plaintiff States millions of dollars.

2. Defendants' patent filings, lawsuits and entrenchment activities, including their relabeling scheme, are part of a concerted scheme to monopolize the market for Paxil® and its generic bioequivalents.

3. Plaintiff States seek the following: a) a finding that Defendants' actions violated federal and state antitrust laws, consumer protection laws, unfair competition laws and other related state laws; b) a permanent injunction preventing Defendants from taking other actions similar to those that resulted in the improper delay in generic competition for paroxetine hydrochloride; and c) relief for injuries sustained as a result of Defendants' violations of law.

PARTIES

4. Defendant SmithKline Beecham Corporation is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, doing business as GlaxoSmithKline ("SmithKline"). Its principal place of business is at One Franklin Plaza, 16th and Race Streets, Philadelphia, PA 19102. SmithKline develops, manufactures, markets, sells and distributes pharmaceutical products, including Paxil®.

5. Defendant SmithKline Beecham, plc is a corporation organized and existing under the laws of the United Kingdom and is a corporate affiliate of SmithKline Beecham Corporation ("Beecham"). Its principal place of business within the United States is at One Franklin Plaza, 16th and Race Streets, Philadelphia, PA 19102. Both SmithKline Beecham Corporation and SmithKline Beecham, plc are hereinafter referred to as "GSK" or "Defendants." Defendants manufacture and market Paxil® throughout the United States.

6. The States bring this action by and through their Attorneys General (a) in their proprietary capacities on behalf of represented entities which may include state departments, bureaus, agencies, political subdivisions and other government entities as direct or indirect purchasers and/or as assignees of the antitrust causes of action of intermediate purchasers through which they procured or were reimbursed for such drugs or as purchasers under medical or pharmaceutical reimbursement programs, of Paxil® or any other paroxetine hydrochloride-based drug during the relevant period (hereinafter "State Governmental Entities"); and (b) in

their capacities as enforcers of federal and state law to enjoin violations, to disgorge unjust profits and to provide relief for injuries incurred in their states by securing damages and/or restitution, injunctions and other equitable remedies.

Others

7. Apotex, Inc. ("Apotex") is a corporation organized under the laws of the Dominion of Canada with its principal place of business located at 150 Signet Drive, Weston, Ontario, Canada M9L1T9. Apotex also does business as Torpharm. Apotex is engaged in the business of manufacturing and marketing pharmaceuticals and has applied to the FDA for permission to market a generic bioequivalent to Paxil®. On or about September 8, 2003, Apotex introduced the first generic Paxil® product to the market in four dosage forms.

8. Zenith Goldline Pharmaceuticals, Inc. ("Zenith") is a corporation organized under the laws of the State of Florida and maintains an office at 4400 Biscayne Boulevard, Miami, FL 33137. Zenith is engaged in the business of manufacturing and marketing pharmaceuticals and has applied to the FDA for permission to market a generic bioequivalent to Paxil®.

9. Pentech Pharmaceuticals, Inc. ("Pentech") is a corporation organized under the laws of the State of Illinois and maintains an office at 1100 Lake Cook Road, Suite 257, Buffalo Grove, IL 60089. Pentech is engaged in the business of manufacturing and marketing pharmaceuticals and has applied to the FDA for permission to market a generic bioequivalent to Paxil®.

JURISDICTION AND VENUE

10. Subject matter jurisdiction is proper pursuant to Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4, 4C, 12 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 15c, 22 and 26, and under 28 U.S.C. §§ 1331, 1337.

11. In addition to pleading violations of federal antitrust law, the States also allege violations of state antitrust, consumer protection and/or unfair competition statutes and related state laws, as set forth below, and seek damages, civil penalties and/or equitable relief under those state laws. All claims under federal and state law are based upon a common nucleus of operative facts and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction of the non-federal claims under 28 U.S.C. § 1367(a) and under the principles of supplemental jurisdiction. Supplemental jurisdiction will avoid unnecessary duplication and multiplicity of actions and should be exercised in the interests of judicial economy, convenience and fairness.

12. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). Defendants transact business in this district. Further, the claims alleged arose, in whole or in part, in this judicial district, and a substantial portion of the affected trade and commerce described below has been carried out in this judicial district.

STATEMENT OF FACTS

A. Pioneer Drugs

13. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, a drug manufacturer must obtain approval from the United States FDA before the manufacturer may lawfully begin selling a new drug (also called a "pioneer drug") in the United States. 21 U.S.C. § 355(a). To obtain FDA approval, the manufacturer must file a New Drug Application ("NDA") demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b) or 355(j).

14. The NDA must contain, among other things, data on the composition of the drug product, including its active ingredient, the means for its manufacture and a statement of its proposed uses. An NDA must list all patents that claim the approved drug where a claim of

patent infringement could reasonably be asserted against an unauthorized manufacturer or seller of the drug. 21 U.S.C. § 355 (b) and (c).

15. A pioneer drug is typically covered by one or more patents, which grant the owner the right to exclude others from manufacturing for sale the new drug for the duration of the patent(s), including any extensions of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§ 355 *et seq.* ("Hatch-Waxman" or "Hatch-Waxman Act").

16. Once the NDA is approved and upon certification by the brand-name manufacturer that the newly-issued patent meets the listing criteria, the FDA publishes the patent information submitted by the manufacturer in a publication commonly referred to as the "Orange Book." *See* 21 U.S.C. § 355 (j) (7) (a) (iii) (formally titled, "Approved Drug Products with Therapeutic Equivalent Evaluations"). The FDA has a long-standing, publicly announced policy of accepting at face value the accuracy of patent information it receives from a patent holder and its eligibility for Orange Book filing.

17. Once approved, a new drug may be labeled, marketed and advertised only for FDA-approved uses. A pharmacist filling a prescription must fill the prescription with the drug brand specified by the physician, unless an FDA-approved generic version is available and applicable state law provides for generic substitution.

B. <u>Generic Drugs</u>

18. A generic drug is one that has been approved by the FDA as bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

19. Generic drugs are usually priced substantially below the brand-name drug. Typically, the first generic drug to be sold is priced at a percentage discount off the brand-name

drug price, and even steeper price reductions occur as additional generic versions become available.

20. A brand-name drug generally loses substantial market share to generic competition within a relatively short time after a generic is introduced to the market. Consumers covered by some form of insurance or benefit plan often switch to a generic bioequivalent and may be encouraged to do so by virtue of a lower co-payment for generics. Consumers who pay cash for prescriptions also switch from brand name to generic drugs to obtain the lower price. Medicaid purchasers are required to switch to a less-expensive generic version of a prescription drug when it becomes available.

21. A principal goal of the Hatch–Waxman Act was to facilitate generic competition by streamlining the process by which manufacturers of generic drugs receive regulatory approval to bring their products to market. Under Hatch-Waxman, a company may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j). An ANDA filer relies on the safety and efficacy data already filed with the FDA by the brand-name manufacturer. 21 U.S.C. § 355 (j) (2) (A) (I).

22. In its ANDA, a generic manufacturer generally must certify to the FDA that one of the following conditions is satisfied: (i) no patent covering the drug has been filed with the FDA ("Paragraph I Certification"); (ii) the patent for the brand-name drug has expired ("Paragraph II Certification"); (iii) the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date ("Paragraph III Certification"); or (iv) the patent for the brand-name drug is invalid or will not be infringed by the generic company's proposed product ("Paragraph IV Certification"). 21 U.S.C. § 355 (j) (2) (A) (vii).

23. Pursuant to a Paragraph III or Paragraph IV Certification, the Hatch-Waxman Act allows ANDA filers to perform all necessary testing, to submit an application for approval and to receive tentative approval before the relevant patents covering the brand-name pioneer drug expire. Upon the patents' expiration and receipt of FDA final approval, the generic drug companies may market their generic versions of the brand-name drug.

24. If the generic manufacturer submits a Paragraph IV Certification, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355 (j) (2) (A) (vii) (IV). If the patent holder fails to initiate an infringement suit within 45 days of receipt of the notice, FDA approval of the ANDA proceeds without regard to patent issues. If a patent infringement suit is brought within the 45-day window, the FDA is automatically barred from approving the ANDA until the earliest of 30 months after the patent holder's receipt of the Paragraph IV Certification, the patent expires or a final judicial determination of non-infringement. 21 U.S.C. § 355 (j) (5) (B) (iii).

C. Defendants' Anticompetitive Conduct

Defendants Made Intentional Misrepresentations to the Patent and Trade Office ("PTO") and Engaged in Sham Litigation to Obtain and Maintain an Improper Monopoly for Paxil®.

1. GSK's Unlawful Course of Conduct in Making Misrepresentations to the FDA and PTO and Filing Serial Sham Litigations.

a. The Original Expired Patent

25. On February 8, 1977, Ferrosan, a British company, obtained patent No. 4,000,196 ("the '196 patent") on a set of compounds including the drug paroxetine hydrochloride. Paroxetine is a selective serotonin reuptake inhibitor ("SSRI"). The patent abstract states: "The

invention relates to new 3-substituted 1-alkyl-4-phenylpiperkidines, being useful as antidepressant and anti-Parkinson agents, and to their production."

26. Subsequent to obtaining the '196 patent, Ferrosan succeeded in creating paroxetine hydrochloride in a crystalline form, which is the form of the drug Paxil®. The molecule created was an "anhydrate" form of the molecule, which means that the paroxetine hydrochloride does not contain a water molecule.

27. In 1980, Ferrosan licensed its paroxetine patent to GSK, who began manufacturing and testing the drug in 1981.

28. The '196 patent expired in 1992.

b. <u>GSK's NDA No. 20-031</u>

29. In March 1985, a chemist in GSK's laboratory discovered that he had produced a different polymorphic form of paroxetine, called "hemihydrate," which means that the paroxetine hydrochloride molecule does contain a water molecule. As explained below, Paxil® consists of the hemihydrate form of paroxetine, while several proposed generics would contain the anhydrate form. As FDA tentative approval of anhydrate generic forms of Paxil® illustrates, the therapeutic effects of these polymorphs is the same.

30. On or about January 26, 1988, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,721,723, titled "Anti-Depressant Crystalline Paroxetine Hydrochloride Hemihydrate ("the '723 patent"). GSK currently owns the '723 patent.

31. The '723 patent claims crystalline paroxetine hydrochloride hemihydrate and its use in treating depression.

32. GSK submitted an NDA to the FDA, which the FDA subsequently designated NDA No. 20-031, for a drug containing, as its active ingredient, paroxetine hydrochloride hemihydrate.

33. On or about December 29, 1992, the FDA approved NDA No. 20-031 for the paroxetine hydrochloride hemihydrate drug that GSK markets as Paxil® and listed the '723 patent in the Orange Book. At that time, GSK had no pending applications for any additional patents purporting to claim the drug that is the subject of NDA No. 20-031.

34. As of December 29, 1992, GSK began to enjoy a five-year statutory monopoly in the market for paroxetine hydrochloride hemihydrate by reason of the FDA's incorrect determination that the approved NDA No. 20-031 contained a new, previously unapproved active ingredient. During that five-year period, the Hatch-Waxman Act and applicable regulations barred the FDA from approving any ANDA that referenced NDA No. 20-031. Therefore, the earliest date that the FDA could have ended GSK's temporary Paxil® monopoly by approving an ANDA that referenced NDA No. 20-031 was December 29, 1997. 21 U.S.C. § 355 (j) (5) (D) (ii).

35. In May 1995, more than two years after the FDA approved NDA No. 20-031, GSK began filing patent applications with the PTO for the purportedly new *anhydrate* polymorphs of paroxetine hydrochloride, even though the same form of the drug was in the original '196 patent, which expired in 1992.

c. <u>Apotex's ANDA</u>

36. In 1998, Apotex submitted an ANDA to the FDA, which the FDA subsequently designated ANDA No. 75-356, for a paroxetine hydrochloride *anhydrate* drug, not a paroxetine hydrochloride *hemihydrate* drug (on which GSK had the '723 patent and which was referenced in NDA No. 20-031).

37. ANDA No. 75-356 contains studies that demonstrate that Apotex's paroxetine anhydrate drug was bioequivalent to the approved NDA No. 20-031 paroxetine hydrochloride hemihydrate drug.

38. Apotex addressed the '723 patent with a Paragraph IV Certification, stating that the manufacture, sale or use of Apotex's proposed paroxetine hydrochloride anhydrate drug would not infringe such patent. 21 U.S.C. § 355 (j) (2) (A) (vii) (IV).

39. Apotex was the first applicant to file an ANDA that referenced NDA No. 20-031 and contained a ParagraphIV Certification, thereby entitling it to market exclusivity on generic paroxetine hydrochloride for 180 days after either (i) Apotex began commercial marketing its paroxetine hydrochloride anhydrate drug; (ii) a court ruled that Apotex's proposed paroxetine hydrochloride anhydrate drug would not infringe the patent subject to ParagraphIV Certification; or (iii) a court ruled that such patent was invalid or unenforceable. 21 U.S.C. § 355 (j) (5) (B) (iv).

40. Apotex notified GSK of the filing of the ANDA and the reasons why the manufacture, sale or use of its proposed paroxetine hydrochloride anhydrate product did not infringe GSK's '723 patent. 21 U.S.C. § 355 (j) (2) (B) (i).

41. Apotex's Paragraph IV Certification as to the '723 patent created the requisite subject matter jurisdiction to enable GSK to file an infringement action within 45 days after receiving notice of Apotex's Paragraph IV Certification. 21 U.S.C. § 355 (j) (5) (B) (iii); 35 U.S.C. § 271 (e) (2).

42. On or about June 26, 1998, GSK sued Apotex in the United States District Court for the Northern District of Illinois for alleged infringement of the '723 patent, pursuant to 21 U.S.C. § 355 (j) (5) (B) (iii) and 35 U.S.C. § 271 (e) (w) (the "First Illinois Action").

43. When it filed the First Illinois Action, GSK knew that such suit was baseless because Apotex was proposing the manufacture, sale or use of its paroxetine hydrochloride *anhydrate* product, a product that is prior art for the '723 patent.

44. In addition to being baseless, the First Illinois Action was intended to thwart potential generic competitors. The mere filing of the First Illinois Action triggered a statutory 30-month statutory stay—until December 2000—on FDA approval of Apotex's ANDA No. 75-356. 21 U.S.C. § 355 (j) (5) (B) (iii).

45. In April of 2005, the Federal Circuit Court of Appeals ruled that Apotex's generic product did infringe the '723 patent; however, claim 1 (crystalline paroxetine hydrochloride hemihydrate) of the '723 patent is invalid because it is anticipated by the prior art. *SmithKline Beecham Corp. v. Apotex*, 403 F.3d 1331, 1334 (Fed. Cir. 2005). The court noted that the anhydrate product manufactured by Apotex would contain the same molecule as covered by the '196 patent which expired in 1992. "The '196 patent suffices as an anticipatory prior art reference if it discloses in an enabling manner the production of PHC hemihydrate." *Id.* at 1344.

46. Although the product manufactured by Apotex infringes on the '723 patent the court held that there was "clear and convincing evidence that production of PHC anhydrate inherently results in at least trace amounts of PHC hemihydrate...the '196 patent inherently anticipates claim 1 of the '723 patent." *Id.* at 1345.

d. <u>GSK Continues to Stockpile Patents</u>

47. GSK further defrauded the FDA by submitting two newly-issued patents for purportedly new *anhydrate* forms of paroxetine hydrochloride, which GSK referenced to the '723 patent.

48. Specifically, on or about February 16, 1999, the PTO issued U.S. Patent No. 5,872,132, titled "Form of Paroxetine Hydrochloride Anhydrate" ("the '132 Form C patent"). GSK currently owns the '132 Form C patent.

49. The '132 Form C patent claims a particular, allegedly new crystalline form of paroxetine hydrochloride *anhydrate* designated in the patent as Form C.

50. Additionally, on or about May 4, 1999, the PTO issued U.S. Patent No. 5,900,423, titled "Form of Paroxetine Hydrochloride Anydrate" ("the '423 Form A patent"). GSK currently owns the '423 Form A patent.

51. The '423 Form A patent claims a second, allegedly new *anhydrate* crystalline form of paroxetine hydrochloride.

52. Neither the '132 Form C patent nor the '423 Form A patent claims that the paroxetine hydrochloride *hemihydrate* drug for which GSK submitted NDA No. 20-031 and which the FDA approved in 1992. Nonetheless, GSK submitted the '132 Form C patent and the '423 Form A patent as related to NDA No. 20-031, and the FDA, in fact, listed the two patents as related in the Orange Book. Neither patent claims the drug for which GSK submitted NDA No. 20-031, *i.e.*, paroxetine hydrochloride hemihydrate,"in violation of the Hatch-Waxman Act and its regulation." 21 U.S.C. § 355 (b) (1); 21 C.F.R. § 314.53 (b).

53. Moreover, when GSK submitted the '132 Form C patent and the '423 Form A patent to the FDA, GSK knew that it was making false representations to the FDA, since Apotex, and not GSK, had performed (and submitted with its ANDA) the clinical trial work necessary to enable the FDA to approve a paroxetine hydrochloride *anhydrate* drug for marketing to the American public. Indeed, before it wrongfully submitted the patents to the FDA, GSK had never sought FDA approval for *any* anhydrate form of paroxetine hydrochloride and could not market an anhydrate form.

54. After the FDA listed the '132 patent and the '423 patent with NDA No. 20-031, Apotex was forced to file Paragraph IV Certifications as to the '132 patent and the '423 patent. In addition, Apotex notified GSK of such certifications.

55. Thereafter, with the knowledge that its listing in the Orange Book was improper, on or about August 26, 1999, GSK filed a new patent infringement action against Apotex in the

United States District Court for the Eastern District of Pennsylvania, asserting technical infringement of the '423 Form A patent ("the First Pennsylvania Action"). The First Pennsylvania Action was objectively baseless and was solely intended to keep generic paroxetine hydrochloride off the market. It did just that, as the filing of the litigation extended GSK's monopoly another 30 months pursuant to the Hatch-Waxman Act.

56. In response to these events, on or about February 3, 2000, Apotex sought administrative relief by filing a Citizen Petition (the "Petition") with the FDA. In the Petition, Apotex noted that "if an NDA holder is permitted, as GSK did here, to list for an indefinite and extended future period any new patents that issue," generic manufacturers such as Apotex face "exposure to multiple lawsuits, serial stays of FDA approval, loss of generic exclusivity periods and virtually no guarantee of market entry even if the original 'pioneer' patent has expired."

57. On or about June 27, 2000, the PTO issued to GSK U.S. Patent No. 6,080,759 ("the '759 patent") for an invention titled "Paroxetine Hydrochloride Form A."

58. The '759 patent claims, *inter alia,* a paroxetine hydrochloride anhydrate Form A made according to a certain process and a process for making paroxetine hydrochloride anhydrate Form A.

59. GSK submitted the '759 patent for listing in the Orange Book in connection with NDA No. 20-031.

60. On or about September 5, 2000, the PTO issued U.S. Patent No. 6,113,944 ("the '944 patent") to GSK, for an invention titled "Paroxetine Tablets and Process to Prepare Them."

61. The '944 patent claims, *inter alia,* a pharmaceutical composition in tablet form containing paroxetine hydrochloride, produced on a commercial scale by a defined process.

62. GSK submitted the '944 patent for listing in the Orange Book in connection with the NDA No. 20-031.

63. Apotex filed a paragraph IV Certification claiming that the '759 patent is invalid, unenforceable and will not be infringed by Apotex's proposed generic bioequivalent. Apotex also notified GSK of its position that, *inter alia,* "the '759 patent was not properly listed with the [FDA], because GSK filed patent information with the FDA prior to approval of its NDA No. 20-031, because GSK did not apply for or procure issuance of the '759 patent until long after approval of the NDA, because the '759 patent does not claim the drug for which GSK obtained FDA approval and because information on process patents may not be submitted to [the] FDA."

64. Similarly, with respect to the '944 patent, Apotex filed and served a Paragraph IV Certification. In that certification, Apotex pointed out that GSK procured the patent by making fraudulent misrepresentations to and concealing material facts from the PTO. Apotex claimed that the '944 patent was invalid and would not be infringed by Apotex's proposed generic product. Further, Apotex noted that the '944 patent was improperly submitted to the FDA for listing in the Orange Book because "SmithKline filed patent information with the FDA prior to approval of its NDA No. 20-031; because SmithKline did not apply for or procure the issuance of the '944 patent until long after approval of the NDA and because Torpharm's [Apotex's] ANDA was filed prior to the '944 patent's issuance and listing in the Orange Book." Lastly, the drug for which GSK sought and received FDA approval on or about December 29, 1992, was made using a different formulation process. Apotex claimed that any patent litigation over the '944 patent would be sham litigation because the patent was invalid, unenforceable, procured by fraud on the PTO and listed in the Orange Book as a result of a fraud on the FDA.

65. Upon receiving the foregoing Paragraph IV Certifications, GSK continued its pattern of filing baseless litigation intended to keep generic paroxetine hydrochloride off the market. For example, on or about September 27, 2000, GSK filed another patent infringement action against Apotex in the United States District Court for the Eastern District of Pennsylvania

(the "Second Pennsylvania Action"). Although the Second Pennsylvania Action was based upon an invalid patent that GSK improperly caused to be listed by the FDA in the Orange Book, GSK filed it to keep its monopoly stranglehold on the Paxil® market and to prevent its competitors from providing a generic form of the drug to the public.

66. Similarly, on or about January 11, 2001, after receiving the Paragraph IV Certification with respect to the '944 patent, GSK again sued Apotex for patent infringement, again in the Eastern District of Pennsylvania (the "Third Pennsylvania Action"). As set forth in Apotex's Paragraph IV Certification, the Third Pennsylvania Action was and is objectively baseless and its sole purpose was to prevent FDA consideration of Apotex's ANDA for an additional 30 months.

2. Serial Fraud and Sham Litigation

67. GSK's pattern of fraud on the FDA and its filing of serial sham litigation has not been confined to Apotex.

a. Litigation Against Zenith

68. Zenith filed with the FDA ANDA No. 75-691 for paroxetine hydrochloride tablets and included a Paragraph IV Certification with respect to the '723 patent, the '132 Form C patent, the '423 Form A patent and U.S. Patent No. 5,789,449 ("the '449 patent").

69. On or about February 3, 2000, GSK received a letter from Zenith, dated February 1, 2000, and sent by certified mail, purporting to be a Notice of Certification under Section 505 (j) (2) (B) of the Hatch-Waxman Act, 21 U.S.C. § 355 (j) (2) (B) (i) and (ii). This letter alleges that the product for which Zenith sought approval is paroxetine hydrochloride. This letter further alleges that the paroxetine hydrochloride tablets do not infringe on the '723, '132, '423 or '449 patents, nor use the methods claimed by the '449 patent.

70. Specifically, Zenith advised GSK that, with respect to the '723 patent, the paroxetine hydrochloride sought to be marketed by Zenith are not in hemihydrate form. Regarding the '132 patent, Zenith explained how its paroxetine hydrochloride does not infringe on any of the patent's two claims. Finally, with respect to the '423 patent, Zenith noted that it has no intention of marketing the product as claimed by the '423 patent nor use the methods claimed by the '449 patent.

71. Despite its knowledge that the proposed paroxetine hydrochloride did not infringe on the '723, '132, '423 or '449 patents, on or about March 16, 2000, GSK filed patent litigation against Zenith in the Eastern District of Pennsylvania (the "Fourth Pennsylvania Action"), claiming infringement of the '723, '132, '423 and '449 patents. For the reasons described above, such litigation was objectively baseless and intended to block Zenith from selling its generic for at least 30 months.

72. As a result, GSK improperly maintained its monopoly over the Paxil® market.

b. <u>Litigation Against Pentech</u>

73. Pentech filed an ANDA with the FDA for paroxetine hydrochloride capsules and included a Paragraph IV Certification.

74. On or about May 11, 2000, GSK filed patent infringement litigation against Pentech in the Northern District of Illinois (the "Second Illinois Action") with respect to the '723 and '132 patents. For the reasons stated above, such litigation was baseless and intended to prevent prospective generic competition.

75. In April 2003, Pentech settled its litigation with GSK. In exchange for the dismissal, which was submitted under seal, Pentech negotiated the right to distribute GSK-manufactured Paxil® in Puerto Rico immediately, and could sell the licensed product throughout the United States but only when Apotex launched its generic product. "The deal represents a

new type of arrangement between brand and generic firms, the effect of which is to reduce the value of first-to-file exclusivity." The Pink Sheet, *Paxil Authorized Generic: Par Gets Puerto Rico Now, States Later*, April 21, 2003; GSK thereby reduced the viability of generic entry by stripping Apotex of the 180-day exclusivity period.

c. <u>Litigation Against Geneva</u>

76. Geneva filed with the FDA ANDA No. 75-566 for paroxetine hydrochloride tablets and included a Paragraph IV Certification.

77. On or about May 17, 1999, GSK received a letter from Geneva, dated May 13, 1999, and sent by certified mail, labeled as a Patent Certification Notice under Section 505 (j) (2) (B) of the Hatch-Waxman Act, 21 U.S.C. § 355 (j) (2) (B) (i) and (ii). According to this notification, the paroxetine hydrochloride for which Geneva sought approval does not infringe on the '723 or the '132 patents. The letter further stated that the claims of the '723 and '132 patents are invalid and unenforceable.

78. With regard to the '723 patent, Geneva pointed out that the products for which it sought approval contain a different active ingredient, *i.e.*, anhydrate paroxetine hydrochloride, while "[a]ll claims of the '723 patent are limited to crystalline paroxetine hydrochloride *hemihydrate,* its compositions, its uses or its manufacture." In addition, Geneva asserted that the invention claimed in the '723 patent was *not* a pioneer invention.

79. Regarding the '132 patent, Geneva stated that the anhydrate paroxetine hydrochloride in the Geneva product is different from the anhydrate paroxetine hydrochloride claimed in the '132 patent because of vast differences in the melting point claims of the two products. For these and other reasons, Geneva asserted that "the manufacture, use or sale of the Geneva Products will not infringe, or induce or contribute to infringement of, any valid claim of the '132 patent, either literally or under the Doctrine of Equivalents."

80. Despite its knowledge of these facts, on or about June 9, 1999, GSK filed patent infringement litigation against Geneva in the Eastern District of Pennsylvania (the "Fifth Pennsylvania Action") with respect to the '723 and '132 patents. For the reasons stated above, such litigation was and is objectively baseless and brought by GSK for the purpose of extending its monopoly of the Paxil® market.

81. On or about October 5, 2000, Geneva sent to GSK notice of its Paragraph IV Certifications with respect to the U.S. Patent No. 6,063,927 ("the '927 patent") and the '759 patent, which Geneva claimed are invalid and/or unenforceable. According to Geneva, the '927 patent covers paroxetine methanesulfonate, while the Geneva products comprise paroxetine hydrochloride and do not involve paroxetine methanesulfonate in any step of the preparation process.

82. As to the '759 patent, Geneva's Certification letter asserted that information material to GSK's patent was not submitted to the PTO and that two of the claims of the '759 patent were invalid.

83. Despite knowledge of these facts, including its omissions of material facts to the PTO, on or about November 22, 2000, GSK filed another patent infringement suit against Geneva in the Eastern District of Pennsylvania with respect to the '759 and '944 patents (the "Sixth Pennsylvania Action"). For the reasons stated above, the Sixth Pennsylvania Action was objectively baseless and its sole purpose was to impede the introduction of a generic competitor for another 30 months.

84. By filing such litigation, GSK has effectively blocked Geneva from selling its generic for at least 30 months, and, as a result, GSK has and continued to improperly maintain its monopoly over the Paxil® market.

d. Litigation Against Alphapharm

85. Alphapharm filed with the FDA ANDA No. 75-716, for paroxetine hydrochloride tablets and included a Paragraph IV Certification.

86. Alphapharm sent notices of the Paragraph IV Certification to GSK on or about January 11, 2001, in accordance with Section 505 (j) (2) (b) of the Hatch-Waxman Act, 21 U.S.C. § 355 (j) (2) (B) (i) and (ii). As explained in this notice, the '723 patent is inapplicable and cannot be infringed because Alphapharm's product is paroxetine hydrochloride *anhydrate.* The '449 patent is invalid because its claims regarding the function of the drug were known prior to any invention by GSK. According to Alphapharm, its product would not infringe the '132 patent because of differences in melting points and because Alphapharm's product contains an ingredient not covered by the '132 patent. In addition, Alphapharm claimed that the '423 patent is invalid because the form of paroxetine hydrochloride claimed was disclosed as early as May 1987 (which, Alphapharm alleged, GSK must have been concealed from the PTO when GSK sought the patent). Alphapharm pointed out that, in contrast to the '927 patent, its product does not contain paroxetine methane sulfonate. Therefore, the '927 patent would not be infringed by Alphapharm's product. Finally, Alphapharm noted that its paroxetine hydrochloride product has materially different ingredients than the drug covered by the '759 patent. Similarly, the synthesis of the paroxetine hydrochloride anhydrate of Alphapharm is different than, and thus not covered by, the claims of the '759 patent.

87. Despite the knowledge of these facts, on or about March 1, 2001, GSK filed patent infringement litigation against Alphapharm in the Eastern District of Pennsylvania (the "Seventh Pennsylvania Action") with respect to the '723, '132, '759 and '423 patents. For the reasons stated above, the Seventh Pennsylvania Action was and is objectively baseless and intended to thwart the ability of GSK's competitors to enter the marketplace with generic Paxil®.

88. By filing such litigation, GSK has effectively blocked Alphapharm from selling its generic for at least 30 months, and, as a result, GSK has and will continue to improperly maintain its monopoly over the Paxil® market and prevent the public from reaping the substantial benefits of generic competition.

89. On or about May 18, 2001, Alphapharm sent notice to GSK of its Paragraph IV Certifications with respect to the '449 patents, which Alphapharm claimed are invalid and/or unenforceable. As to the '449 patent, Alphapharm's certification letter asserted that the use of the product to treat depression would not violate the '449 patent because the use of a recognized re-uptake blocker has been employed to treat depression and is prior art to the '449 patent.

90. Despite knowledge of these facts, including its omissions of material facts to the PTO, on or about November 15, 2002, GSK filed another patent infringement suit against Alphapharm in the Eastern District of Pennsylvania with respect to the '449 patent ("The Eighth Pennsylvania Action"). For the reasons stated above, the Eighth Pennsylvania Action was objectively baseless and its sole purpose was to impede the introduction of a generic competitor for another 30 months.

91. By filing such litigation, GSK effectively blocked Alphapharm from selling its generic for at least 30 months, and, as a result, GSK continued to improperly maintain its monopoly over the Paxil® market.

3. GSK Delists Three Paxil® Patents

92. On or about July 1, 2003, GSK announced that it had asked the FDA to delist U.S. Patent No. 6,172,233 ("the '233 patent"), '759 and '927 patents from the Orange Book. These patents, if they had gone unchallenged, would have extended GSK's Paxil® monopoly to 2019.

93. The delisting of the '233 patent removed the final 30-month stay on approval of Apotex's ANDA. On September 8, 2003, Apotex brought its generic product to market, in four dosage strengths.

RELEVANT MARKET

94. The relevant product market is the manufacture and sale of paroxetine hydrochloride-based prescription drugs. The relevant geographic market is the United States, including its Commonwealths, territories and protectorates, as a whole.

95. The only seller of prescription drugs containing paroxetine hydrochloride in the United States could impose a significant, non-transitory price increase without losing sales sufficient to render the price increase unprofitable, as demonstrated by the Defendants' ability to charge supracompetitive prices for paroxetine hydrochloride during the period in which Paxil® lacked generic competition.

96. Once a physician writes a prescription for a brand-name drug such as Paxil®, that prescription defines and limits the alternatives to the drug named or its AB-rated generic equivalent. Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug. As explained on one generic manufacturer's web page:

> The majority of states use the FDA's "AB" rating of therapeutic substitution as the foundation for generic substitution, either by permitted substitution based on the FDA's Orange Book listing or by using the FDA's "AB" rating as the basis for a cursory administrative approval. A total of 39 states permit substitution of generic products while 11 states mandate generic substitution.
>
> http://www.barrlabs.com/pages/faqcon.htm.

97. Until approximately September 8, 2003, Defendants were the sole manufacturers and sellers of prescription drugs containing paroxetine hydrochloride in the United States. Their share of the Relevant Market was 100%.

TRADE AND COMMERCE

98. Throughout the relevant period, Paxil® was sold throughout the United States. Paxil® and paroxetine hydrochloride were transported across state lines and sold in each of the Plaintiff States.

99. Defendants' activities, including manufacturing, marketing, distributing and selling Paxil® and paroxetine hydrochloride were in the regular, continuous and substantial flow of interstate commerce, and have had, and continue to have, a substantial effect upon interstate commerce.

MARKET EFFECTS

100. Defendants' illegal conduct had the purpose or effect of, or the tendency or capacity to, unreasonably restrain and injure competition by preventing the entry of generic paroxetine hydrochloride.

101. Absent Defendants' anticompetitive conduct, at least one generic competitor would have begun marketing a generic version of paroxetine hydrochloride well before September 2003.

102. If a generic competitor had been able to enter the Relevant Market and compete with Defendants, the State Governmental Entities (as payors, purchasers, and reimbursers) would have been free to substitute -- and would have substituted -- a lower-priced generic for the higher-priced brand-name drug.

103. By preventing generic competitors from entering the market, Defendants deprived Plaintiff States of the competition that the federal and state antitrust laws, consumer protection laws and/or unfair competition statutes and related state laws are designed to promote, preserve and protect.

INJURY

104. But for Defendants' anticompetitive acts, the State Governmental Entities would have been able to purchase a generic paroxetine hydrochloride product at a far lower price than the monopoly prices maintained by Defendants and beginning at an earlier time.

105. As a direct and proximate result of the unlawful conduct alleged above, Plaintiff States, including their State Governmental Entities, were not able to purchase or pay reimbursements for purchases of paroxetine hydrochloride products at prices determined by free and open competition, and, consequently, have been injured in their business and property in that, *inter alia*, they have paid more and continue to pay more for paroxetine hydrochloride products than they would have paid in a free and open competitive market.

106. As a direct and proximate result of the unlawful conduct alleged above, Defendants have unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits.

ALLEGATIONS UNDER FEDERAL LAW

COUNT I
(Violations of Section 2 of the Sherman Act)

107. Plaintiff States repeat each and every preceding allegation as if fully set forth herein.

108. At all relevant times, Defendants maintained monopoly power in the Relevant Market.

109. As described above, Defendants knowingly and willfully engaged in conduct designed to unlawfully obtain and extend their monopoly power in the Relevant Market. These actions included, among others, (i) intentionally submitting false patent information to the FDA; (ii) intentionally submitting fraudulent statements to, and omitting material facts from, the PTO;

(iii) prosecuting baseless, sham patent litigation against the generic manufacturers; and (iv) maintaining sham defenses to the counterclaims by the generic manufacturers.

110. Defendants' Infringement Actions were objectively baseless due to, *inter alia*, the nature of the anhydrate product, which by definition would not infringe on the '723 patent and, therefore, constituted sham litigation. Further, the purpose of Defendants' notification in bringing the actions was to directly interfere with the ability of the generic manufacturers to market less expensive generic versions of Paxil® to compete with the brand-name product.

111. Defendants illegally created and maintained monopoly power in the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

112. Defendants' conduct in unlawfully obtaining and maintaining a monopoly in the market for Paxil® and paroxetine hydrochloride injured the Plaintiff States in their business or property. Plaintiff States, including State Governmental Entities, were deprived of the ability to purchase less expensive, generic versions of Paxil® and paid higher prices for paroxetine hydrochloride-based products than they would have paid, absent Defendants' unlawful conduct.

113. Defendants' anticompetitive and unlawful conduct alleged herein has injured competition in the Relevant Market by obtaining and maintaining their power to exclude competitors, reduce output, charge monopoly prices, reap monopoly profits and otherwise thwart competition in the Relevant Market.

COUNT II
(Unjust Enrichment)

114. Plaintiff States repeat each and every preceding allegation as if fully set forth herein.

115. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts include improperly listing their

patents in the Orange Book; submitting fraudulent misrepresentations to and concealing material facts from the PTO; filing and pursuing baseless patent infringement actions and maintaining baseless defenses to counterclaims at the expense of the Plaintiff States.

116. The overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Paxil® are the direct and proximate result of Defendants' unlawful practices.

117. The financial benefits derived by Defendants rightfully belong in substantial part to the Plaintiff States.

118. It would be inequitable and unjust for Defendants to be permitted to retain any of the unlawful proceeds resulting from their fraudulent, illegal, and inequitable conduct.

119. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff States, including State Government Entities.

SUPPLEMENTAL STATE LAW CLAIMS

120. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Plaintiff States, as set forth below.

121. Plaintiff States seek damages, multiple damages, treble damages and other damages as permitted by state law for their injuries caused by these violations pursuant to federal and state law as set forth below. Plaintiff States also seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through the use of the invalid patents is unlawful. Plaintiff States further seek equitable and injunctive relief to correct for the anti-

competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants and other relief so as to assure that similar conduct does not occur in the future.

122. Plaintiff State of Alabama repeats and realleges each and every allegation contained in paragraphs 1 through 119.

123. Defendants' acts violate, and/or Plaintiff State of Alabama is entitled to relief under, the Alabama Deceptive Trade Practices Act, § 8-19-1, *et seq.*, Code of Alabama 1975. Section 8-19-11, Code of Alabama 1975 provides for civil penalties and reasonable attorney fees.

124. Plaintiff State of Alaska repeats and realleges each and every allegation contained in paragraphs 1 through 119.

125. Defendants' acts violate, and Plaintiff State of Alaska is entitled to relief under, the AS 45.50.471 *et seq.* and AS 45.50.562 *et seq.*

126. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 119.

127. Defendants' acts violate, and Plaintiff State of Arizona is entitled to relief under, the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. Section 44-1401 *et seq.*

128. Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 119.

129. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief under, the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.* and the Arkansas Unfair Practices Act, Ark. Code Ann. §§ 4-75-201, *et. seq*, 4-75-301, *et. seq.*

130. Plaintiff State of California repeats and realleges each and every allegation contained in paragraphs 1 through 119.

131. Defendants' acts violate, and Plaintiff State of California is entitled to relief under, the Cartwright Act, Business and Professions Code section 16700, *et. seq.*, and the California Unfair Competition Act, Bus. & Prof. Code section 17200, *et. seq.*

132. Plaintiff State of Colorado repeats and realleges each and every allegation contained in paragraphs 1 through 119.

133. Defendants' acts violate, and Plaintiff State of Colorado is entitled to relief under, the Colorado Antitrust Act of 1992, § 6-4-101, *et seq.*, Colo. Rev. Stat.

134. Plaintiff State of Connecticut repeats and realleges each and every allegation contained in paragraphs 1 through 119.

135. Defendants' acts violate, and Plaintiff State of Connecticut is entitled to relief under, the Connecticut Antitrust Act, Conn. Gen. Stat § 35-24 *et seq.*, and the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a *et seq.*

136. Plaintiff State of Delaware repeats and realleges each and every allegation contained in paragraphs 1 through 119.

137. Defendants' acts violate, and/or Plaintiff State of Delaware is entitled to relief under, the Delaware Antitrust Act, 6 *Del.C.* § 2101 *et seq.*, the Delaware Consumer Fraud Act, 6 *Del.C.* § 2511 *et seq.*, and the Uniform Deceptive Trade Practices Act, 6 *Del.C.* § 2511 *et seq.*

138. Plaintiff District of Columbia repeats and realleges each and every allegation contained in paragraphs 1 through 119.

139. Defendants' acts violate, and Plaintiff District of Columbia is entitled to relief under, the District of Columbia Antitrust Act, D.C. Code §§ 28-4501 *et seq.*

140. Plaintiff State of Florida repeats and realleges each and every allegation contained in paragraphs 1 through 119.

141. Defendants' acts violate, and Plaintiff State of Florida is entitled to relief under, the Florida Antitrust Act of 1980, § 542.15 Florida Statutes, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, § 501.201 Florida Statutes, *et seq.*

142. Plaintiff State of Georgia repeats and realleges each and every allegation contained in paragraphs 1 through 119.

143. Defendants' acts violate, and/or Plaintiff State of Georgia is entitled to relief under, the O.C.G.A., § 13-8-2 and Ga. Const. Art. III, § VI, para. V (1983).

144. Plaintiff State of Hawaii repeats and realleges each and every allegation contained in paragraphs 1 through 119.

145. Defendants' acts violate, and Plaintiff State of Hawaii is entitled to relief under, the Haw. Rev. Stat. Chapter 480, Monopolies; Restraint of Trade, §§ 480-1 *et seq.*

146. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 119.

147. Defendants' acts violate, and Plaintiff State of Idaho is entitled to relief under, the Idaho Competition Act, Idaho Code §§ 48-101 *et seq.*

148. Plaintiff State of Illinois repeats and realleges each and every allegation contained in paragraphs 1 through 119.

149. Defendants' acts violate, and Plaintiff State of Illinois is entitled to relief under, the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, including without limitation 740 ILCS 10/3(3).

150. Plaintiff State of Indiana repeats and realleges each and every allegation contained in paragraphs 1 through 119.

151. Defendants' acts violate, and Plaintiff State of Indiana is entitled to relief under, the Indiana Code § 24-1-1-1, *et seq.*

152. Plaintiff State of Iowa repeats and realleges each and every allegation contained in paragraphs 1 through 119.

153. Defendants' acts violate, and Plaintiff State of Iowa is entitled to relief under, the Iowa Competition Act, Iowa Code sections 553, *et seq.*, the Iowa Consumer Fraud Act, Iowa Code section 714.16, and Iowa common law.

154. Plaintiff State of Kansas repeats and realleges each and every allegation contained in paragraphs 1 through 119.

155. Defendants' acts violate, and Plaintiff State of Kansas is entitled to relief under, the laws of the State of Kansas, including, without limitation: the Kansas Restraint of Trade Act, Kansas Statutes Annotated 50-101 *et seq.* and its predecessor; the Kansas Consumer Protection Act, Kansas Statutes Annotated 50-101 *et seq.* and its predecessor, the common laws of Kansas including, without limitation: the common law of fraud, unconscionable acts or practices, deceptive acts and practices, unfair methods of competition, and unjust enrichment.

156. Plaintiff Commonwealth of Kentucky repeats and realleges each and every allegation contained in paragraphs 1 through 119.

157. Defendants' acts violate, and Plaintiff Commonwealth of Kentucky is entitled to relief under, the Kentucky Antitrust Law, KRS 367.175, the Kentucky Consumer Protection Act KRS 367.110 *et seq.*, and the common law of Kentucky.

158. Plaintiff State of Louisiana repeats and realleges each and every allegation contained in paragraphs 1 through 119.

159. Defendants' acts violate, and Plaintiff State of Louisiana is entitled to relief under, the LSA R.S. 51:122 *et seq.*; 51:1401 *et seq.*

160. Plaintiff State of Maine repeats and realleges each and every allegation contained in paragraphs 1 through 119.

161. Defendants' acts violate, and Plaintiff State of Maine is entitled to relief under, the Monopolies and Profiteering law, 10 M.R.S.A. § 1102, and its Unfair Trade Practices Act, 5 M.R.S.A. § 207.

162. Plaintiff State of Maryland repeats and realleges each and every allegation contained in paragraphs 1 through 119.

163. Defendants' acts violate, and Plaintiff State of Maryland is entitled to relief under, the Maryland Antitrust Act, Md. Com. Law Code Ann. § 11-201, *et seq.* (2000).

164. Plaintiff Commonwealth of Massachusetts repeats and realleges each and every allegation contained in paragraphs 1 through 119.

165. Defendants' acts violate, and Plaintiff Commonwealth of Massachusetts is entitled to relief under, the Massachusetts Consumer Protection Act, G.L. c. 93A sec. 2 (a) *et seq.*

166. Plaintiff State of Michigan repeats and realleges each and every allegation contained in paragraphs 1 through 119.

167. Defendants' acts violate, and Plaintiff State of Michigan is entitled to relief under, the Michigan Antitrust Reform Act, Mich. Comp. Laws Ann. § 445.771 *et seq.*, the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901 *et seq.*, and the common law of Michigan.

168. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 119.

169. Defendants' acts violate, and Plaintiff State of Minnesota is entitled to relief under, the Minnesota Antitrust Law of 1971, Minn. Stat. § 325 D.49-66, Minn. Stat. § 8.31, and the common law of Minnesota.

170. Plaintiff State of Mississippi repeats and realleges each and every allegation contained in paragraphs 1 through 119.

171. Defendants' acts violate, and Plaintiff State of Mississippi is entitled to relief under, its Consumer Protection Act found at Miss. Code Ann. § 75-24-1, *et seq*. (1972), as amended) and its Antitrust Act found at Miss. Code Ann. § 75-21-1, *et seq.* (1972, as amended).

172. Plaintiff State of Missouri repeats and realleges each and every allegation contained in paragraphs 1 through 119.

173. Defendants' acts violate, and Plaintiff State of Missouri is entitled to relief under, the Missouri Merchandising Practices Act, Mo. Rev. Stat. Section 407.010 *et seq.*, the Missouri Antitrust Law, Mo. Rev. Stat. Section 416.011 *et seq.* and the common law of Missouri.

174. Plaintiff State of Montana repeats and realleges each and every allegation contained in paragraphs 1 through 119.

175. Defendants' acts violate, and Plaintiff State of Montana is entitled to relief under, Mont. Code Ann. § 30-14-205.

176. Plaintiff State of Nebraska repeats and realleges each and every allegation contained in paragraphs 1 through 119.

177. Defendants' acts violate, and Plaintiff State of Nebraska is entitled to relief under, the Unlawful Restraint on Trade, Neb.Rev.Stat. sec. 59-801, *et seq*. (Reissue 2004), Consumer Protection Act, Neb.Rev.Stat. sec. 59-1601 *et seq*. (Reissue 2004), Uniform Deceptive Trade Practices Act, sec. 87-301 *et seq*. (Reissue 1999, Cum Supp 2004).

178. Plaintiff State of Nevada repeats and realleges each and every allegation contained in paragraphs 1 through 119.

179. Defendants' acts violate, and Plaintiff State of Nevada is entitled to relief under, the Nevada Unfair Trade Practice Act, Nev. Rev. Stat. § 598A.010, *et seq.*

180. Plaintiff State of New Hampshire repeats and realleges each and every allegation contained in paragraphs 1 through 119.

181. Defendants' acts violate, and Plaintiff State of New Hampshire is entitled to relief under, the New Hampshire Rev. Stat. Ann. 356:2, *et seq*. Michie Butterworth, 1995 & Supp. 2004.

182. Plaintiff State of New Jersey repeats and realleges each and every allegation contained in paragraphs 1 through 119.

183. Defendants' acts violate, and Plaintiff State of New Jersey is entitled to relief under, the New Jersey Antitrust Act, N.J.S.A. 56:9-1, *et seq*.

184. Plaintiff State of New Mexico repeats and realleges each and every allegation contained in paragraphs 1 through 119.

185. Defendants' acts violate, and Plaintiff State of New Mexico is entitled to relief under, the New Mexico Antitrust Act, § 57-1-1 *et seq.*, NMSA 1978, and the New Mexico Unfair Practices Act, § 57-12-1 *et seq.*, NMSA 1978.

186. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 119.

187. Defendants' acts violate, and Plaintiff State of New York is entitled to relief under, the N.Y. Gen. Bus. Law §§ 340-347, and constitute fraudulent or illegal acts under N.Y. Exec. Law § 63(12) and deceptive acts under N.Y. Gen. Bus. Law § 349.

188 Plaintiff State of North Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 119.

189. Defendants' acts violate, and Plaintiff State of North Carolina is entitled to relief under, the N.C. Gen. Stat. §§ 75-1, 75-1.1, 75-2 and 75-2.1.

190. Plaintiff State of North Dakota repeats and realleges each and every allegation contained in paragraphs 1 through 119.

191. Defendants' acts violate, and Plaintiff State of North Dakota is entitled to relief under, the North Dakota State Antitrust Act, N.D.C.C. § 51-08. 1-01 *et seq.*, and North Dakota's Consumer Protection Act, N.D.C.C. § 51-15-01, *et seq.*

192. Plaintiff State of Ohio repeats and realleges each and every allegation contained in paragraphs 1 through 119.

193. Defendants' acts violate, and Plaintiff State of Ohio is entitled to relief under, the Ohio's Antitrust Law, Ohio Revised Code §§ 109.81 and 1331.01, *et seq.*, and the common law of Ohio.

194. Plaintiff State of Oklahoma repeats and realleges each and every allegation contained in paragraphs 1 through 119.

195. Defendants' acts violate, and Plaintiff State of Oklahoma is entitled to relief under, the Oklahoma Antitrust Reform Act, 79 O.S. § 201 et seq., and the Oklahoma Consumer Protection Act, 15 O.S. § 751, *et seq.*

196. Plaintiff State of Oregon repeats and realleges each and every allegation contained in paragraphs 1 through 119.

197. Defendants' acts violate, and Plaintiff State of Oregon is entitled to relief under, the Oregon Antitrust Act, ORS 646.705, *et seq.*

198. Plaintiff State of Pennsylvania repeats and realleges each and every allegation contained in paragraphs 1 through 119.

199. Defendants' acts violate, and Plaintiff Commonwealth of Pennsylvania is entitled to relief under, the Pennsylvania common law doctrines against monopolies and unjust enrichment, proceeding under 71 Pennsylvania Statutes Annotated § 732-204(c).

200. Plaintiff Commonwealth of Puerto Rico repeats and realleges each and every allegation contained in paragraphs 1 through 119.

201. Defendants' acts violate, and Commonwealth of Puerto Rico is entitled to relief under, the Commonwealth of Puerto Rico, Monopolies and Restraint, Act No. 77 as amended, June25, 1964, 10 laws P.R. Ann. § 257 *et seq.*

202. Plaintiff State of Rhode Island repeats and realleges each and every allegation contained in paragraphs 1 through 119.

203. Defendants' acts violate, and Plaintiff State of Rhode Island is entitled to relief under, Rhode Island common law doctrines against fraudulent misrepresentation and unjust enrichment, the Rhode Island Deceptive Trade Practices Act, R.I. Gen.Laws Chapter 6-13.1, and the Rhode Island Antitrust Act, R.I.Gen Laws Chapter 6-36.

204. Plaintiff State of South Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 119.

205. Defendants' acts violate, and Plaintiff State of South Carolina is entitled to relief under, the South Carolina Unfair Trade Practices Act - Sections 39-5-10 *et seq.*

206. Plaintiff State of South Dakota repeats and realleges each and every allegation contained in paragraphs 1 through 119.

207. Defendants' acts violate, and Plaintiff State of South Dakota is entitled to relief under, S.D. Codified Laws ch. 37-1.

208. Plaintiff State of Tennessee repeats and realleges each and every allegation contained in paragraphs 1 through 119.

209. Defendants' acts violate, and Plaintiff State of Tennessee is entitled to relief under, Tenn. Code Ann. § 8-6-109, § 47-18-101 *et seq*. (The Tennessee Consumer Protection Act of 1977), Code Ann. § 47-18-108, Tenn. Code Ann. § 47-18-106, Tenn. Code Ann. §§ 8-6--109 and 47-18-101 *et seq*.

210. Plaintiff State of Texas repeats and realleges each and every allegation contained in paragraphs 1 through 119.

211. Defendants' acts violate, and Plaintiff State of Texas is entitled to relief under, the Texas Free Enterprise and Antitrust Act, Texas Business and Commerce Code § 15.01, *et seq.*

212. Plaintiff State of Utah repeats and realleges each and every allegation contained in paragraphs 1 through 119.

213. Defendants' acts violate, and Plaintiff State of Utah is entitled to relief under, the Utah Antitrust Act, Utah Code Ann. § 76-10-911 *et seq.* and the common law of Utah.

214. Plaintiff State of Vermont repeats and realleges each and every allegation contained in paragraphs 1 through 119.

215. Defendants' acts violate, and Plaintiff State of Vermont is entitled to relief under, the Vermont Consumer Fraud Act, 9 V.S.A. Sec. 2451 *et seq.*

216. Plaintiff Territory of the Virgin Islands repeats and realleges each and every allegation contained in paragraphs 1 through 119.

217. Defendants' acts violate, and Plaintiff Territory of the Virgin Islands is entitled to relief under, Title 3, Chapter 8, Section 114 of the Virgin Islands Code.

218. Plaintiff Commonwealth of Virginia repeats and realleges each and every allegation contained in paragraphs 1 through 119.

219. Defendants' acts violate, and Plaintiff Commonwealth of Virginia is entitled to relief under, the Virginia Antitrust Act, § 59.1-9.1, *et seq.*, Va. Code Ann. 2001.

220. Plaintiff State of Washington repeats and realleges each and every allegation contained in paragraphs 1 through 119.

221. Defendants' acts violate, and Plaintiff State of Washington is entitled to relief under, Wash. Rev. Code 19.86 RCW.

222. Plaintiff State of Wisconsin repeats and realleges each and every allegation contained in paragraph 1 through 119.

223. Defendants' acts violate, and Plaintiff State of Wisconsin is entitled to relief under, Wis. Stat. § 133.03 and Wis. Stat. §§ 133.16-18.

224. Plaintiff State of Wyoming repeats and realleges each and every allegation contained in paragraph 1 through 119.

225. Defendants' acts violate, and Plaintiff State of Wyoming is entitled to relief under, (I) Wyoming's "Discrimination" statutes as set out by Wyo. Stat. §§ 40-4-101 through 123 and (ii) portions of the "Wyoming Consumer Protection Act" as set out by Wyo. Stat. §§ 40-12-101 through 114.

RELIEF REQUESTED

Accordingly, the Plaintiff States pray that this Court:

226. Adjudge and decree that Defendants engaged in conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

227. Adjudge and decree that Defendants engaged in conduct in violation of the state statutes and state laws set forth in this Complaint;

228. Enjoin and restrain, pursuant to federal and state law, Defendants, their affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and employees and all other persons acting or claiming to act on their behalf or in concert with them from engaging in any conduct and from adopting any practice, plan, program or device having a similar purpose or effect to the anticompetitive actions set forth above;

229. Award the Plaintiff States all damages sustained by and permitted to be recovered by the States (as direct purchasers, assignees of direct purchasers or as indirect purchasers) and

for all additional damages, penalties and other monetary relief provided by applicable law, including treble damages;

230. Award Plaintiff States such other equitable relief, including, but not limited to, restitution and disgorgement, as the Court finds necessary to redress Defendants' violations of federal and state law;

231. Award to each Plaintiff State the maximum civil penalties allowed by law; and

232. Directing such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff States demand a trial by jury.

DATED: March 27, 2006

Respectfully submitted,

PLAINTIFF STATES

COMMONWEALTH OF PENNSYLVANIA
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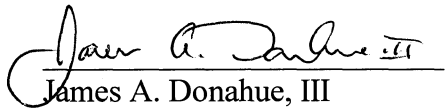

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