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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

STATES and COMMONWEALTHS)
OF TEXAS, FLORIDA, OREGON,)
ALABAMA, ALASKA, AMERICAN)
SAMOA, ARIZONA, ARKANSAS,)
CALIFORNIA, COLORADO,)
CONNECTICUT, DELAWARE, DISTRICT)
OF COLUMBIA, GEORGIA, GUAM,)
HAWAII, IDAHO, ILLINOIS, INDIANA,)
IOWA, KANSAS, KENTUCKY, LOUISIANA,)
MAINE, MARYLAND, MASSACHUSETTS,)
MICHIGAN, MINNESOTA, MISSISSIPPI,)
MISSOURI, MONTANA, NEBRASKA,)
NEVADA, NEW HAMPSHIRE, NEW)
JERSEY, NEW MEXICO, NEW YORK,)
NORTHERN MARIANA ISLANDS,)
NORTH CAROLINA, NORTH DAKOTA,)
OHIO, OKLAHOMA, OREGON,)
PENNSYLVANIA, PUERTO RICO,)
RHODE ISLAND, SOUTH CAROLINA,)
SOUTH DAKOTA, TENNESSEE, TEXAS)
UTAH, VERMONT, VIRGIN ISLANDS,)
VIRGINIA, WASHINGTON, WEST)
VIRGINIA, WISCONSIN,)

Plaintiffs)

v.)

ORGANON USA INC. and)
AKZO NOBEL N.V.,)
Defendants)

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U.S. DISTRICT COURT
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CAUSE NUMBER: 04-5126(FSH)

COMPLAINT

Plaintiff States, the State of Alabama, Office of the Attorney General, State House, 11 South Union Street, Montgomery, AL 36130; State of Alaska, Office of the Attorney General, 1031 West Fourth Avenue, Suite 200, Anchorage, AK 99501; American Samoa, Department of Legal Affairs, American Samoa Government, Pago Pago, American Samoa 96799; State of Arizona, Attorney General of Arizona, 1275 West Washington Street, Phoenix, AZ 85007; State of Arkansas, Office of the Attorney General, 323 Center Street, Suite 200, Little Rock, AR 72201; State of California, Attorney General's Office, 455 Golden Gate Avenue, Suite 1100, San Francisco, CA 94102; State of Colorado, 1525, Sherman Street, Fifth Floor, Denver, CO 80203; State of Connecticut, 55 Elm Street, Hartford, CT 06106; District of Columbia, Office of the Attorney General, 441 4th St., NW, Suite 450N, Washington, DC 20001; State of Delaware, 820 North French Street, 5th Floor, Wilmington, DE 19801; State of Florida, Office of the Attorney General, PL-01, The Capitol, Tallahassee, FL 32399-1050; State of Georgia, Department of Law, 40 Capitol Square, S.W., Atlanta, GA 30334; Guam, Office of the Attorney General, Suite 2-200E, Judicial Center Building, 120 West O'Brien Dr., Hagatna, Guam 96910; State of Hawaii, Department of the Attorney General, 425 Queen St., Honolulu, Hawaii 96813; State of Idaho, Office of the Attorney General, Len B. Jordan Building, 650 W. State Street, Lower Level, Boise, ID 83720; State of Illinois, Office of the Attorney General, 100 West Randolph Street, Chicago, IL 60601; State of Indiana, Office of the Attorney General, 302 W. Washington, 5th Floor, Indianapolis, IN 46204; State of Iowa, Iowa Department of Justice, 2nd Floor, Hoover Office Building, Des Moines, IA 50319; State of Kansas, Office of the Attorney

General, 120 SW 10th St., 2nd Floor, Topeka, KS 66612; Commonwealth of Kentucky, Office of the Attorney General, 1024 Capital Center Drive, Frankfort, KY 40601; State of Louisiana, Louisiana Department of Justice, 1885 N. 3rd St., 4th Fl., Baton Rouge, LA 70802; State of Maine, Office of the Attorney General, 6 State House Station, Augusta, ME 04333; State of Maryland, 200 St. Paul Place, Baltimore, MD 21202; Commonwealth of Massachusetts, One Ashburton Place, Boston, MA 02108; State of Michigan, Office of the Attorney General, G. Mennen Williams Building, 525 Ottawa Street, Suite 690, Lansing, MI 48913; State of Mississippi, Office of the Attorney General, Post Office Box 22947, Jackson, MS 39225; State of Missouri, Office of the Attorney General, P. O. Box 899, Jefferson City, MO 65102; State of Montana, Office of the Attorney General, 1219 8th Ave., Helena, MT 59620; State of Nebraska, Office of the Attorney General, 2115 State Capitol, Lincoln, NE 68509; State of Nevada, Office of the Attorney General, 1000 East William St., Suite 200, Carson City, NV 89701; State of New Jersey, Office of the Attorney General, P. O. Box 086, Trenton, NJ 08625; State of New Mexico, Antitrust Unit, 111 Lomas Boulevard, NW, Albuquerque, NM 87102; State of Minnesota, Office of the Attorney General, 445 Minnesota St., Ste. 1200, St. Paul, MN 55101; State of New York, Antitrust Bureau, 120 Broadway, Suite 26-01, New York, NY 10271; State of North Carolina, P.O. Box 629, Raleigh, North Carolina 27602; State of North Dakota, Office of the Attorney General, State Capitol, 600 E. Blvd. Ave. Dept. 125, Bismarck, ND 58505-0040; Commonwealth of the Northern Mariana Islands, 2nd Fl. Hon. Juan A. Sablan Memorial Bldg., Caller Box 10007, Capitol Hill, Saipan, MP 96950; State of Ohio, Ohio Attorney General's Office, 150 East Gay St., 20th Floor, Columbus, Ohio 43215; State of Oklahoma, Office of the Attorney General, 4545 N. Lincoln Blvd., Ste. 260, Oklahoma City, Oklahoma 73105; State of Oregon, Department of Justice, Justice Building, 1162 Court Street NE, Suite 100, Salem, OR

97301; Commonwealth of Pennsylvania, Office of the Attorney General, 14th Floor, Strawberry Square, Harrisburg, PA 17120; Commonwealth of Puerto Rico, Department of Justice, PO Box 902192, San Juan, Puerto Rico 00902; State of Rhode Island, Office of the Attorney General, 150 South Main Street, Providence, RI 02903; State of South Carolina, Office of the Attorney General, P. O. Box 11549, Columbia, SC 29211-1549; State of Tennessee, Office of the Attorney General, 425 5th Ave. N., Nashville, TN 37243; State of Texas, Office of the Attorney General, P.O. Box 12548, Austin, TX 78711; State of Vermont, 109 State Street, Montpelier, VT 05609-1001; Territory of the Virgin Islands, Virgin Islands Department of Justice, 3438 Kronprindsens Gade, GERS Complex, 2nd floor, St. Thomas, VI 00802; Commonwealth of Virginia, Office of the Attorney General, 900 East Main St., Richmond, VA 23219; State of West Virginia, Office of the Attorney General, P. O. Box 1789, Charleston, WV 25326; State of Washington, Office of the Attorney General, 900 4th St., Ste 2000, Seattle, WA 98164; and State of Wisconsin, 17 West Main Street, Madison, WI 53707; State of Wyoming, Office of the Attorney General, 123 State Capitol, Cheyenne, WY 82002, collectively "Plaintiff States", by and through their Attorneys General, for their Complaint against Defendant Organon USA Inc., 275 Mt. Pleasant Avenue, West Orange, New Jersey, 07052 ("Organon") and Akzo Nobel N.V., Velperweg 76, 6824 BM Arnhem, The Netherlands ("Akzo"), collectively "Defendants," allege as follows:

I. INTRODUCTION

1. Remeron® is a brand name prescription drug containing mirtazapine as its active pharmaceutical ingredient. Since 1996, Remeron® has been manufactured and sold by Organon, as a medication for treating patients suffering from depression. In 2002, Organon's sales of

Remeron® in the United States totaled approximately \$400 million, making it their biggest selling drug.

2. As detailed below, Organon and its parent company, Akzo Nobel, unlawfully maintained a monopoly for mirtazapine-based prescription drug products in the United States. They did so by improperly submitting U.S. Patent No. 5,977,099 (“the ‘099 patent”) to the FDA for listing in the Orange Book for Remeron®, and by choosing to wait nearly fourteen months after the statutory deadline to submit the ‘099 to the FDA for listing in the Orange Book for Remeron®.

3. Defendants’ unlawful conduct caused the FDA to withhold final approval of applications by generic drug manufacturers to market generic mirtazapine. As a result of Organon’s illegal conduct, which blocked generic competition, consumers and governmental entities were forced to pay more for mirtazapine.

4. 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 submitting the ‘099 patent for listing in the Orange Book and from taking other actions similar to those which resulted in the improper delay in generic competition for mirtazapine; and c) relief for injuries sustained as a result of Defendants’ violations of law.

II. PARTIES

5. Defendant Organon USA Inc. is a New Jersey corporation with its principal place of business at 375 Mt. Pleasant Avenue, West Orange, New Jersey, 07052. Organon develops, manufactures, markets and distributes pharmaceutical products, including Remeron®. Organon is a subsidiary (through another subsidiary) of Akzo Nobel N.V.

6. Defendant Akzo Nobel N.V. is a Netherlands corporation with its principal place of business at Velperweg 76, 6824 BM Arnhem, The Netherlands. Akzo Nobel develops, manufactures, sells and promotes various pharmaceutical, coating and chemical products in the United States and elsewhere, directly or through its subsidiaries.

7. The States bring this action by and through their Attorneys General under statutory, equitable and/or common law authority: (a) under federal or state law, in their sovereign capacities, as representatives of, and/or as *parens patriae* on behalf of, or for the benefit of, natural persons who paid for Remeron® or any other mirtazapine product during the relevant time period; (b) as common law *parens patriae* in their sovereign capacities on behalf of their respective states' general economies; c) 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 reimbursed for such drugs, or as purchasers under medical or pharmaceutical reimbursement programs, of such drugs during the relevant time period; and/or d) for those Plaintiff States where such class actions are asserted by Attorneys General, pursuant to Rules 23 (a) and 23 (b) of the Federal Rules of Civil Procedure, on behalf of all natural persons residing in the Plaintiff States who paid for Remeron® during the relevant time period.

III. JURISDICTION AND VENUE

8. 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.

9. 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 over the non-federal claims under 28 U.S.C. § 1367(a), as well as 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.

10. 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). Organon is headquartered and transacts business in this judicial district. Further, the claims alleged arose, in whole or in part, in this district, and a substantial portion of the affected trade and commerce described below has been carried out in this district.

IV. STATEMENT OF FACTS

A. Pioneer Drugs

11. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, a drug manufacturer must obtain approval from the U.S. Food and Drug Administration ("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). In order 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).

12. 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.

13. 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 patents and any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch Waxman" or "Hatch-Waxman Act").

14. An NDA must list all patents that claim the approved drug, or that claim an approved method of using the 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 ©).

15. Once the NDA is approved, 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").

16. Pursuant to 21 U.S.C. § 355(c)(2), when a brand name drug manufacturer is issued a new patent that claims an approved drug or approved method of its use, the brand name manufacturer must submit the new patent to the FDA within 30 days of the patent's issuance. Upon certification by the brand name manufacturer that the newly-issued patent meets the listing criteria, the FDA publishes the new patent in the Orange Book. 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.

17. Once approved by the FDA, a new drug may be labeled, marketed and advertised only for the FDA-approved uses.

18. Hatch Waxman also grants the holder of an approved NDA a statutory period of exclusivity to market that drug if no drug containing the same active ingredient has previously been approved. 21 U.S.C. § 355 (c)(3)(D)(ii). This exclusivity, referred to as a “new chemical entity” (NCE) exclusivity, is separate from and runs concurrently with any patent exclusivity the NDA holder may have. Hence, if a patent holder obtains FDA approval near the end of the patent term, the NCE exclusivity can extend the branded drug’s exclusivity period.

B. Generic Drugs

19. 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.

20. Generic drugs are usually priced substantially below their brand name drug bioequivalents. 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 enter the market. The beneficiaries of this competition are prescription drug purchasers, including consumers, governmental agencies and third-party payors/reimburers.

21. A brand name drug generally loses substantial market share to generic competition within a relatively short time after a generic bioequivalent is introduced to the market. Consumers covered by insurance plans often switch from brand name to generic drugs because their insurance companies encourage their members to use generic drugs in a number of ways, including reduced co-payments. Many uninsured consumers (cash payors) switch from brand name to generic drugs in order to obtain the lower price.

22. One of Congress's principal goals in enacting 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. *See Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998). 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).

23. 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).

24. The Hatch-Waxman Act allows ANDA applicants filing Paragraph III or IV Certifications 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, the end of NCE exclusivity, and receipt of FDA final approval, the generic drug companies may market their generic versions of the brand name drug.

25. 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 forty-five days of receipt of the notice, FDA approval of the ANDA proceeds without regard to patent issues. However, if a patent infringement suit is brought within the forty-five day window, the FDA is automatically barred from approving the ANDA until thirty months after the patent holder's receipt of the Paragraph IV certification, unless the patent expires, or is held invalid or non-infringed first. 21 U.S.C. § 355(j)(5)(B)(iii).

C. Defendants' Anticompetitive Conduct

26. Mirtazapine is a chemical compound which was disclosed by U.S. Patent No. 4,062,848 (the '848 patent) as being clinically effective for treating depression. The '848 patent issued on December 13, 1977, and, following a two year extension of the patent term, expired on June 14, 1998. After that expiration date, no U.S. patent covered either mirtazapine or the use of mirtazapine to treat depression.

27. On June 14, 1996, Organon received FDA approval for an NDA to market mirtazapine as a treatment for depression. Organon began marketing mirtazapine under the brand name Remeron® shortly thereafter. The FDA approval triggered NCE exclusivity under Hatch Waxman. Because the '848 patent expired in 1998, Organon faced the prospect of generic competition beginning with the expiration of its NCE exclusivity on June 14, 2001.

28. Rather than compete with generic manufacturers, Defendants decided to take affirmative steps to block generic competition. Defendants made this decision for two reasons. First, for every day that Remeron® did not face generic competition, Defendants stood to make additional monopoly profits.

29. Second, on January 12, 2001, Organon became the holder of a newly approved NDA for Remeron SolTabs®, orally disintegrating Remeron® tablets for the treatment of

depression. Because it was not rated as AB bioequivalent to Remeron®, Remeron SolTabs® did not face the onset of generic competition in June 2001. For this reason, extending the period of exclusivity for Remeron® would allow Defendants to attempt to transfer customers (including major institutional purchasers such as state Medicaid agencies), from Remeron® to Remeron SolTab®. Defendants aggressively pursued this switching plan, using sizable financial incentives to switch institutional customers to Remeron SolTab®.

1. Defendants Improperly Listed the '099 Patent in the Orange Book

30. Defendants' attempt to block generic competition involved a patent covering the use of mirtazapine in combination with selective serotonin reuptake inhibitors ("SSRIs"), another type of anti-depressant.

31. The '099 patent issued on November 2, 1999. Defendant Akzo Nobel is identified as the assignee of the patent, and Defendant Organon is the exclusive licensee.

32. To list a patent in the Orange Book, a pioneer drug manufacturer must certify that the patent claims the drug or method of using the drug approved by the FDA, and that it is a patent with respect to which a claim of infringement could reasonably be asserted against an unlicensed person engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(b)(1).

33. The '099 patent claims a pharmaceutical composition comprising mirtazapine and one or more SSRIs, as well as a method of using this combination for the treatment of depression.

34. New combinations of previously approved drugs constitute new drugs for purposes of regulatory approval. 21 C.F.R. § 310.3(h)(2). This is the case irrespective of whether it is a single dosage unit containing both active ingredients or two separate dosage units. 21 C.F.R. § 310.3(h)(2).

35. The '099 patent requires the administration of the two separate active ingredients – mirtazapine and an SSRI – to be close enough in time such that the benefit of “the efficacious effect of the combination of the active ingredients” is not lost. For this reason, under the law, the combination of mirtazapine and an SSRI constitutes a new drug.

36. For method-of-use patents, the NDA holder may submit for inclusion in the Orange Book only those patents that claim indications or other conditions of use of the pending or approved NDA. 21 C.F.R. § 341.53. In this regard, a brand name company is required to certify to the FDA that the patents submitted by it to the FDA claim the formulation, composition, and/or method of using the drug product that is the subject of the approved or pending NDA. 21 C.F.R. § 314.53(c). The FDA accepts this certification as true without conducting an independent review.

37. Defendants have never filed with the FDA an NDA seeking approval to market a combination product containing mirtazapine and an SSRI, nor have Defendants ever filed a Supplemental NDA to market Remeron® for use in combination with an SSRI. For this reason, the '099 patent covers neither the FDA-approved mirtazapine drug product nor an FDA-approved use of mirtazapine.

38. In January 2001, Defendants submitted information and a supporting declaration to the FDA certifying that the '099 patent met the statutory and FDA requirements for Orange Book listing knowing that the '099 patent 1) did not cover the FDA-approved Remeron® product, which contains mirtazapine as its only active ingredient, and 2) did not cover an FDA-approved method of using mirtazapine.

39. Defendants' submission of the '099 patent to the FDA for listing in the Orange Book with the knowledge that neither the drug product nor the use claimed in the '099 patent had been approved by the FDA constituted a fraudulent misrepresentation.

40. Defendants' actions caused the '099 patent to be listed in the Orange Book.

41. After a generic competitor challenged the accuracy of the '099 patent information submitted by Defendants, the FDA sent a letter to Defendants requesting confirmation that the '099 patent was properly listed for Remeron®. In its letter, dated March 13, 2002, the FDA informed Defendants that it could not list a patent for an unapproved use in the Orange Book.

42. On April 8, 2002, Defendants responded in writing to the FDA's inquiry by confirming, without explanation, that the '099 patent was properly listed under both the relevant statute and FDA regulations. The FDA, consistent with its ministerial role with respect to the listing of patents in the Orange Book, did not review the propriety of Defendants' confirmation and retained the '099 patent listing in the Orange Book.

43. Defendants' April 8, 2002 letter to the FDA constituted a fraudulent misrepresentation.

44. Defendants' actions caused the '099 patent to continue to be listed in the Orange Book.

45. Teva Pharmaceuticals USA, Inc. ("Teva") and Mylan Pharmaceuticals, Inc. ("Mylan") both filed ANDAs for generic mirtazapine in February 2001. Both generic manufacturers sought FDA approval to market mirtazapine as a single drug treatment for depression, not as a new drug combination therapy for use of mirtazapine with an SSRI. Teva and Mylan both intended to and were prepared to enter the mirtazapine market when they received final approval from the FDA.

46. For the reasons discussed in paragraphs 33-44 above, in listing the '099 patent in the Orange Book, Defendants knowingly violated the Orange Book listing requirements. Because the '099 patent should not have been listed in the Orange Book, by filing suit against Mylan and Teva pursuant to the Hatch-Waxman Act, Defendants impermissibly obtained a stay of the FDA approving Mylan and Teva's ANDAs. In so doing, Defendants improperly delayed generic competition and extended their Remeron® monopoly.

2. Defendants Impermissibly Delayed Listing the '099 Patent in the Orange Book

47. Under Hatch Waxman, a generic drug manufacturer is permitted to submit to the FDA an ANDA containing a Paragraph IV certification after four years of NCE exclusivity. 21 U.S.C. § 355(j)(5)(D)(ii). If a generic drug manufacturer is unable to submit a Paragraph IV certification with its ANDA, it is barred from filing its ANDA with the FDA until five years of NCE exclusivity have passed. A generic manufacturer cannot file an ANDA containing a Paragraph IV certification with the FDA unless there is a patent listed in the Orange Book for the Paragraph IV certification to challenge. Thus, if a pioneer drug manufacturer intentionally delays listing a patent in the Orange Book, it can block generic drug manufacturers from filing ANDAs with the FDA until either it ultimately chooses to list the patent in the Orange Book or the five-year period of Hatch-Waxman exclusivity expires.

48. The Hatch-Waxman Act requires that any patents issued after the approval of an NDA which claim the pioneer drug must be submitted to the FDA for listing in the Orange Book within 30 days of being issued. 21 U.S.C. § 355(c)(2).

49. The '099 patent should have been listed in the Orange Book, if at all, by December 2, 1999. Defendants did not submit the patent for listing in the Orange Book until January 31, 2001, a delay of almost fourteen months.

50. By early 1999, generic drug manufacturers including Mylan and Teva had begun developing generic versions of mirtazapine in anticipation of filing ANDAs upon expiration of Organon's NCE exclusivity.

51. Anticipating the onset of generic competition, Defendants were seeking strategies to prolong their exclusivity for Remeron®. In December 2000, one of Defendants' employees learned from a news article that Bristol-Myers Squibb Co. ("BMS") had obtained an additional 30 months exclusivity for BuSpar® by listing a patent in the Orange Book, despite the fact that the patent in question was, in the words of this employee, "very questionable."

52. Reading about BMS' success in keeping generics off the market prompted Defendants to attempt to identify an existing patent that could be filed in the Orange Book to extend Defendants' Remeron® exclusivity period. Within weeks, Defendants identified the '099 patent and on January 31, 2001, Organon submitted the '099 patent for listing in the Orange Book.

53. On February 13, 2001, the FDA listed the '099 patent in the Orange Book. Approximately two weeks later, on February 28, 2001, Mylan filed an ANDA with the FDA for various dosage levels of mirtazapine. On February 29, 2001, Teva filed an ANDA with the FDA for various dosages of mirtazapine. Defendants subsequently filed suit against Mylan and Teva. By so doing, Defendants prevented FDA approval of these companies' ANDAs.

54. On December 18, 2002, this Court granted summary judgment to Mylan and Teva. *Organon, Inc. v. Teva Pharm., Inc.*, 244 F. Supp. 2d 370 (D.N.J. 2002). In its decision, this Court found that there was no evidence that the generic manufacturers intended to induce infringement of the '099 patent.

55. On information and belief, if Defendants had listed the '099 patent in a timely manner, Teva, Mylan, and potentially other generic drug manufacturers, would have filed ANDAs containing Paragraph IV certifications approximately eight months earlier. Had the '099 patent been timely listed, Defendants would have either filed suit against Teva, Mylan and (potentially) other generic manufacturers by July 30, 2000, or they would have forfeited their right to an automatic 30-month stay under the Hatch-Waxman Act. If Defendants had filed suit by July 30, 2000, any lawsuits would have been resolved well before December 18, 2002.

56. Defendants' actions violated the 30-day statutory filing requirement and prevented generic mirtazapine entry, delaying competition in the market for Remeron® for the period between May 2002 and January 2003. Organon's late listing of the '099 patent delayed generic competitors' ability to file mirtazapine ANDAs by approximately eight months.

57. Patents constitute valuable intellectual property for pharmaceutical companies, including Defendants. In order to protect their property, pharmaceutical companies, including Defendants, have systems in place to keep track of their patents. Pharmaceutical companies that sell prescription drugs in the United States, including Defendants, are also closely attuned to FDA regulatory procedures and requirements.

58. Defendants' delay in listing the '099 patent in the Orange Book with the FDA was intentional. In the alternative, this delay was the result of willful negligence. Defendants' delayed listing of the '099 patent in the Orange Book allowed them impermissibly to extend their Remeron® monopoly.

V. RELEVANT MARKETS

59. The relevant product market is the manufacture and sale of prescription drugs containing mirtazapine. The relevant geographic market is the United States.

60. As the only seller of prescription drugs containing mirtazapine in the United States, Organon could impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Organon's ability to charge supracompetitive prices for mirtazapine during the period in which Remeron® lacked generic competition.

61. A material change in the price of mirtazapine relative to that of other antidepressants would not induce patients to change to another antidepressant, e.g. from an antidepressant that works for them to one that does not, or from an antidepressant that does not have adverse side effects for them for one that does.

62. Until 2003, Organon was the sole manufacturer and seller of prescription drugs containing mirtazapine in the United States. Its share of the relevant market was 100%.

VI. TRADE AND COMMERCE

63. Throughout the period alleged, Defendants' activities, including manufacturing, marketing, distributing and selling mirtazapine-based prescription drugs were in the regular, continuous and substantial flow of interstate commerce, and have had and continue to have a substantial effect upon interstate commerce.

64. Defendants' businesses involve a substantial and continuous flow of commodities and payments in interstate commerce.

VII. MARKET EFFECTS

65. The Defendants' acts and practices had the purpose or effect of, or the tendency or capacity to, unreasonably restrain and injure competition by preventing the entry of generic mirtazapine.

66. Absent Defendants' anticompetitive conduct, at least one generic competitor would have begun marketing a generic version of mirtazapine well before January 2003.

67. Had a generic competitor been able to enter the relevant market and compete with Organon, consumers and state entities (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.

68. By preventing generic competitors from entering the market, Defendants deprived Plaintiff States and their consumers of the benefits 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.

VIII. INJURY

69. But for Defendants' anticompetitive acts, consumers and state agencies would have been able to purchase a generic mirtazapine product at a far lower price than the monopoly prices maintained by Defendants, and beginning at an earlier time.

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

71. As a direct and proximate result of the unlawful conduct alleged above, consumers were not and are not able to purchase mirtazapine products at prices determined by free and open competition, and consequently have been injured in their business or property in

that, *inter alia*, they have paid more and continue to pay more for mirtazapine products than they would have paid in a free and open competitive market.

72. As a direct and proximate result of the unlawful conduct alleged above, the general economies of the States have sustained injury, and are threatened with further injury to their business and property unless the Defendants are enjoined from their unlawful conduct.

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

IX. CLASS ACTION ALLEGATIONS

74. For those Plaintiff States where such class actions are asserted by Attorneys General, this action is brought pursuant to Rules 23 (a) and 23 (b) of the Federal Rules of Civil Procedure, on behalf of the following Class: all natural persons residing in the Plaintiff States who paid for Remeron® during the relevant time period.

75. Excluded from the Class are Defendants and their respective subsidiaries and affiliates, all federal governmental entities, agencies and instrumentalities, and all persons or entities that purchased Remeron® for purposes of resale.

76. There are thousands of members in the above-described class. Their exact number and identities are currently unknown to Plaintiff States.

77. Questions of law and fact are common to the Class, including but not limited to the following:

(I) Whether Defendants have unlawfully monopolized the market for Remeron® and its generic equivalents;

- (ii) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Remeron® and its generic equivalents;
- (iii) Whether Defendants through their monopolization have caused the prices of Remeron® to be maintained at supracompetitive levels;
- (iv) Whether Defendants wrongfully listed the '099 patent in the Orange Book;
- (v) Whether Defendants wrongfully delayed listing the '099 patent in the Orange Book;
- (vi) Whether the Class suffered and continued to suffer antitrust injury; and
- (vii) Whether Defendants were and continue to be unjustly enriched to the detriment of the Class, entitling Plaintiff States and the Class to disgorgement of all monies resulting therefrom.

78. Plaintiff States' claims are typical of the Class because Plaintiff States and all members of the Class were injured and continue to be injured in the same manner by Defendants' unlawful, anticompetitive and inequitable methods, acts and practices, *i.e.*, they have paid supracompetitive and artificially high prices for Remeron® and will continue to be forced to do so until the markets for Remeron® and its generic equivalents are competitive and prices reach competitive levels.

79. Plaintiff States will fully and adequately protect the interest of all members of the Class. Plaintiff States are experienced in antitrust litigation, including class action litigation. Plaintiff States have no interests which are adverse to or in conflict with those of the Class.

80. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

81. For those Plaintiff States bringing this as a class action, a class action is equivalent or superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all consumer purchasers of Remeron® and its generic equivalents would be impracticable. The Class is readily definable and prosecution as a class action will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual complex litigation.

82. Defendants have acted, or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief, and/or corresponding declaratory relief with respect to the Class as a whole.

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

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

84. At all relevant times, Defendants possessed monopoly power in the relevant market.

85. Defendants' actions and omissions with regard to their actions before the FDA constitute an impermissible attempt to extend unlawfully their monopoly over mirtazapine. These actions included, among others, the following: 1) fraudulently inducing the FDA to list Organon's '099 patent in the Orange Book; and 2) improperly delaying the submission of the '099 patent for listing in the Orange Book, even if it was properly listed. Defendants' actions before the FDA, and the subsequent filing of suits against generic manufacturers under the Hatch-Waxman Act, constituted illegal maintenance of their monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT II
(Unjust Enrichment)

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

87. Defendants have benefitted from the supracompetitive and artificially inflated prices and monopoly profits on their sale of Remeron® resulting from their unlawful and inequitable conduct.

88. Defendants' financial benefits resulting from their unlawful and inequitable conduct resulted from and are economically traceable to overpayments for Remeron® by consumers and Plaintiff States.

89. Plaintiff States and consumers have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of the States and consumers.

90. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Remeron® is a direct and proximate result of Defendants' unlawful practices.

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

92. 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.

93. 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 and consumers.

COUNT III
(Violations of State Law)

94. Plaintiff State of Alabama repeats each and every preceding allegation as if fully set forth herein.

95. Defendants' acts violate, and 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.

96. Plaintiff State of Alaska repeats each and every preceding allegation as if fully set forth herein.

97. Defendants' acts violate, and Plaintiff State of Alaska is entitled to relief under, AS 45.50.471(a), AS 45.50.495, AS 45.50.501, AS 45.50.551, and AS 45.50.562-.596.

98. Plaintiff American Samoa repeats each and every preceding allegation as if fully set forth herein.

99. Defendants' acts violate, and Plaintiff American Samoa is entitled to relief under, American Samoa Code §§ 27.0401 - 27.0403.

100. Plaintiff State of Arizona repeats each and every preceding allegation as if fully set forth herein.

101. Defendants' acts violate, and Plaintiff State of Arizona is entitled to relief under, Arizona's Uniform State Antitrust Act, A.R.S. §§ 44-1401 *et seq.*

102. Plaintiff State of Arkansas repeats each and every preceding allegation as if fully set forth herein.

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

104. Plaintiff State of California repeats each and every preceding allegation as if fully set forth herein.

105. Defendants' acts violate, and Plaintiff State of California is entitled to relief under, The Cartwright Act, California Business & Professions Code sections 16720 *et seq.*, and the Unfair Practices Act, California Business & Professions Code sections 17200 *et seq.*

106. Plaintiff State of Colorado repeats each and every preceding allegation as if fully set forth herein.

107. 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.

108. Plaintiff State of Connecticut repeats each and every preceding allegation as if fully set forth herein.

109. 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.*

110. Plaintiff State of Delaware repeats each and every preceding allegation as if fully set forth herein.

112. Defendants' acts violate, and 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.* § 2101 *et seq.*, the Delaware Consumer Fraud Act, 6 *Del.C.* § 2511 *et seq.*, and the Uniform Deceptive Trade Practices Act, 6 *Del.C.* § 2531 *et seq.*

113. Plaintiff District of Columbia repeats each and every preceding allegation as if fully set forth herein.

114. Defendants' acts violate, and Plaintiff District of Columbia is entitled to relief under, the District of Columbia Antitrust Act, D.C. Code, 2001 Ed. § 28-4501 *et seq.*, including, without limitation, D.C. Code, 2001 Ed. § 28-4507.

115. Plaintiff State of Florida repeats each and every preceding allegation as if fully set forth herein.

116. 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.*

117. Plaintiff State of Georgia repeats each and every preceding allegation as if fully set forth herein.

118. Defendants' acts violate, and Plaintiff State of Georgia is entitled to relief under, O.C.G.A. § 13-8-2 and Ga. Const. Art. III, §VI 5 (1983).

119. Plaintiff Territory of Guam repeats each and every preceding allegation as if fully set forth herein.

120. Defendants' acts violate, and Plaintiff Territory of Guam is entitled to relief under the Deceptive Trade Practice – Consumer Protection Act, Chapter 32 of Title 5 of the Guam Code Annotated, §§ 32102 *et seq.* and under Chapter 69 of Title 9 (unlawful to restrain or monopolize trade or commerce) of the Guam Code Annotated §§ 69.10 *et seq.*

121. Plaintiff State of Hawaii repeats each and every preceding allegation as if fully set forth herein.

122. Defendants' acts violate, and Plaintiff State of Hawaii is entitled to relief under, Haw Rev. Stat. § 480-2, §480-4, and §480-9.

123. Plaintiff State of Idaho repeats each and every preceding allegation as if fully set forth herein.

124. Defendants' acts violate, and Plaintiff State of Idaho is entitled to relief under, the Idaho Competition Act, Idaho Code §§ 48-101 *et seq.*, and the Idaho Consumer Protection Act, Idaho Code §§ 48-601 *et seq.*

125. Plaintiff State of Illinois repeats each and every preceding allegation as if fully set forth herein.

126. 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).

127. Plaintiff State of Indiana repeats each and every preceding allegation as if fully set forth herein.

128. Defendants' acts violate, and Plaintiff State of Indiana is entitled to relief under, Ind. Code §§ 24-1-1-1, 24-1-2-1, 24-5-0.5-3 and Ind. Code 24-5-0.5-4(c)(2).

129. Plaintiff State of Iowa repeats each and every preceding allegation as if fully set forth herein.

130. Defendants' acts violate, and Plaintiff State of Iowa is entitled to relief under, the laws of the State of Iowa, alleging violations of the Iowa Competition Act, Iowa Code sections 553 *et seq.*, the Iowa Consumer Fraud Act, Iowa Code section 714.16, and a claim for unjust enrichment under Iowa common law.

131. Plaintiff State of Kansas repeats each and every preceding allegation as if fully set forth herein.

132. 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.

133. Plaintiff Commonwealth of Kentucky repeats each and every preceding allegation as if fully set forth herein.

134. 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.

135. Plaintiff State of Louisiana repeats each and every preceding allegation as if fully set forth herein.

136. Defendants' acts violate, and Plaintiff State of Louisiana is entitled to relief under, the Louisiana Antitrust Act, La. R.S. 51: 121, *et seq.* and La. R.S. 51:1401, *et seq.*

137. Plaintiff State of Maine repeats each and every preceding allegation as if fully set forth herein.

138. Defendants' acts violate, and Plaintiff State of Maine is entitled to relief under, the Maine Monopolies and Profiteering Law, 10 MRSA § 1102, and the Maine Unfair Trade Practices Act, 5 MRSA § 207.

139. Plaintiff State of Northern Mariana Islands repeats each and every preceding allegation as if fully set forth herein.

140. Defendants' acts violate, and Plaintiff State of Northern Mariana Islands is entitled to relief under, 4 N. Mar. I. Code §§ 5101 *et seq.*

141. Plaintiff State of Maryland repeats each and every preceding allegation as if fully set forth herein.

142. 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).

143. Plaintiff Commonwealth of Massachusetts repeats each and every preceding allegation as if fully set forth herein.

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

145. Plaintiff State of Michigan repeats each and every preceding allegation as if fully set forth herein.

146. Defendants' acts violate, and Plaintiff State of Michigan is entitled to relief under, the Michigan Antitrust Reform Act, Mich. Comp. Laws Ann. § 445.776 *et seq.*, the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901 *et seq.*, the common law of Michigan, and Mich. Comp. Laws Ann. § 14.28 and § 14.201.

147. Plaintiff State of Minnesota repeats each and every preceding allegation as if fully set forth herein.

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

149. Plaintiff State of Mississippi repeats each and every preceding allegation as if fully set forth herein.

150. 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).

151. Plaintiff State of Missouri repeats each and every preceding allegation as if fully set forth herein.

152. 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.

153. Plaintiff State of Montana repeats each and every preceding allegation as if fully set forth herein.

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

155. Plaintiff State of Nebraska repeats each and every preceding allegation as if fully set forth herein.

156. Defendants' acts violate, and Plaintiff State of Nebraska is entitled to relief under, Neb. Rev. Stat. §§ 59-801 & 59-831 and §§ 59-1601 & 59-1623 (1998), Neb. Rev. Stat. §§ 59-801 *et seq.* (1998, Cum. Supp. 2002), and Rev. Stat. §§ 59-1601 *et seq.* (1998, Cum. Supp. 2002).

157. Plaintiff State of Nevada repeats each and every preceding allegation as if fully set forth herein.

158. Defendants' acts violate, and Plaintiff State of Nevada is entitled to relief under, Nev. Rev. Stat. § 598A.010 *et seq.* Specifically, but without limitation, Nev. Rev. § 598A.060.

159. Plaintiff State of New Hampshire repeats each and every preceding allegation as if fully set forth herein.

160. Defendants' acts violate, and Plaintiff State of New Hampshire is entitled to relief under, N.H. Rev. Stat. Ann. §356.

161. Plaintiff State of New Jersey repeats each and every preceding allegation as if fully set forth herein.

162. Defendants' acts violate, and Plaintiff State of New Jersey is entitled to relief under, New Jersey Antitrust Act, Title 59 Ch. 9, N.J. Stat. Ann. 56:9-1 *et seq.*

163. Plaintiff State of New Mexico repeats each and every preceding allegation as if fully set forth herein.

164. Defendants' acts violate, and Plaintiff State of New Mexico is entitled to relief under, New Mexico Antitrust Act, Section 57-1-1 *et seq.*, N.M.S.A.1978 and New Mexico Unfair Practices Act, Section 57-12-1 *et seq.*, N.M.S.A. 1978.

165. Plaintiff State of New York repeats each and every preceding allegation as if fully set forth herein.

166. Defendants' acts violate, and Plaintiff State of New York is entitled to relief under, New York General Business Law §§ 340-347, 349 and also constitute fraudulent or illegal acts under New York Exec. Law § 63(12).

167. Plaintiff State of North Carolina repeats each and every preceding allegation as if fully set forth herein.

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

169. Plaintiff State of North Dakota repeats each and every preceding allegation as if fully set forth herein.

170. Defendants' acts violate, and Plaintiff State of North Dakota is entitled to relief under, the North Dakota State Antitrust Act, N.D.C.C. Sec. 51-08.1-01 *et seq.*, and North Dakota's Consumer Protection Act, N.D.C.C. Sec. 51-15-01, *et seq.*

171. Plaintiff State of Ohio repeats each and every preceding allegation as if fully set forth herein.

172. Defendants' acts violate, and Plaintiff State of Ohio is entitled to relief under, Ohio's Antitrust Law, Ohio Revised Code, §§ 109.81 and 1331.01, *et seq.*, §§ 1345.02 and 1345.03 of Ohio's Consumer Sales Practices Act, Ohio Rev. Code §§ 1345.01, *et seq.*, and the common law of Ohio.

173. Plaintiff State of Oklahoma repeats each and every preceding allegation as if fully set forth herein.

174. 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.*

175. Plaintiff State of Oregon repeats each and every preceding allegation as if fully set forth herein.

176. Defendants' act violates, and Plaintiff State of Oregon is entitled to relief under, the Oregon Antitrust Act, ORS 646.705, *et seq.*

177. Plaintiff Commonwealth of Pennsylvania repeats each and every preceding allegation as if fully set forth herein.

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

179. Plaintiff Commonwealth of Puerto Rico each and every preceding allegation as if fully set forth herein.

180. Defendants' acts violate, and Plaintiff Commonwealth of Puerto Rico is entitled to relief under, Act No. 77 of June 25, 1964, "Act to Prohibit Monopolistic Practice and Protect Fair and Free Competition in Trade and Commerce", 10 P.R. Laws Ann. §§ 257-276, and Act No. 118 of June 25, 1971, "Class Suit for Consumers of Goods and Services", 32 P.R. Laws Ann. §§ 3341-3344. The laws of the Commonwealth of Puerto Rico are included in the term "state law" as used in this complaint.

181. Plaintiff State of Rhode Island repeats each and every preceding allegation as if fully set forth herein.

182. Defendants' acts violate, and Plaintiff State of Rhode Island is entitled to relief under, Rhode Island General Laws Chapter 6-36.

183. Plaintiff State of South Carolina repeats each and every preceding allegation as if fully set forth herein.

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

185. Plaintiff State of South Dakota repeats each and every preceding allegation as if fully set forth herein.

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

187. Plaintiff State of Tennessee repeats each and every preceding allegation as if fully set forth herein.

188. 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.*

189. Plaintiff State of Texas repeats each and every preceding allegation as if fully set forth herein.

190. Defendants' acts violate, and Plaintiff State of Texas is entitled to relief under, Texas Business and Commerce Code § 15.01 *et seq.*

191. Plaintiff State of Utah repeats each and every preceding allegation as if fully set forth herein.

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

193. Plaintiff State of Vermont repeats each and every preceding allegation as if fully set forth herein.

194. Defendants' acts violate, and Plaintiff State of Vermont is entitled to relief under, the Vermont Consumer Fraud Act, 9 Vermont Statutes Annotated, Chapter 63, and the common law of Vermont.

195. Plaintiff Territory of the United States Virgin Islands repeats each and every preceding allegation as if fully set forth herein.

196. Defendants' acts violate, and Plaintiff Territory of the United States Virgin Islands is entitled to relief under, Territory of the United States Virgin Islands Code of Laws 11 V.I.C. §§ 1503 & 1507, *et seq.*

197. Plaintiff Commonwealth of Virginia repeats each and every preceding allegation as if fully set forth herein.

198. 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. Sections 59.1-9.15(a) and 59.1-9.11 provide for civil penalties and reasonable attorney fees.

199. Plaintiff State of Washington repeats each and every preceding allegation as if fully set forth herein.

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

201. Plaintiff State of West Virginia repeats each and every preceding allegation as if fully set forth herein.

202. Defendants' acts violate and Plaintiff State of West Virginia is entitled to relief under the West Virginia Antitrust Act, W. Va. Code § 47-18-1 *et seq.*

203. Plaintiff State of Wisconsin repeats each and every preceding allegation as if fully set forth herein.

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

205. Plaintiff State of Wyoming repeats each and every preceding allegation as if fully set forth herein.

206. 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 States demand judgment as follows:

1. Adjudging and decreeing that Defendants engaged in conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.
2. Adjudging and decreeing that Defendants engaged in conduct in violation of the state statutes enumerated in Section X of this Complaint;
3. Awarding the Plaintiff States all damages sustained by the States (as direct purchasers, assignees of direct purchasers, or as indirect purchasers), on behalf of their consumers, and for all additional damages, penalties and other monetary relief provided by applicable law, including treble damages;
4. Awarding the Plaintiff States injunctive relief to prevent Defendants in the future from engaging in conduct similar to the improper conduct they used to block generic competition for Remeron®;
5. Awarding 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;
6. Awarding each Plaintiff State its costs of this action, including reasonable attorneys' fees

and costs, and where applicable, expert fees; and

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

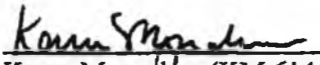
JURY TRIAL DEMAND

Plaintiff States demands a trial by jury.

Dated: October 20th, 2004

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