IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STATE OF NEW YORK, *ex rel.*
Attorney General ELIOT SPITZER,

STATE OF MICHIGAN, *ex rel.*
Attorney General JENNIFER GRANHOLM,

STATE OF ARIZONA, *ex rel.*
Attorney General JANET NAPOLITANO,

STATE OF CALIFORNIA, *ex rel.*
Attorney General BILL LOCKYER,

DISTRICT OF COLUMBIA, *ex rel.*
Corporation Counsel ROBERT R. RIGSBY,

STATE OF IDAHO, *ex rel.*
Attorney General ALAN G. LANGE,

STATE OF INDIANA, *ex rel.*
Attorney General STEVE CARTER,

STATE OF MAINE, *ex rel.*
Attorney General G. STEVEN ROWE,

STATE OF MINNESOTA, *ex rel.*
Attorney General MIKE HATCH,

STATE OF NEW MEXICO, *ex rel.*
Attorney General PATRICIA A. MADRID,

STATE OF NORTH CAROLINA, *ex rel.*
Attorney General ROY COOPER,

STATE OF OKLAHOMA, *ex rel.*
Attorney General W.A. DREW EDMONDSON,

STATE OF UTAH, *ex rel.*
Attorney General MARK L. SHURTLEFF,

01-71835

COMPLAINT

CIVIL ACTION NO. _____

JULIAN ABELE COOK, JR.

MAGISTRATE JUDGE SCHEER

FILED
'01 MAY 14 AM 9:24

STATE OF VERMONT, *ex rel.*
Attorney General WILLIAM H. SORRELL,

STATE OF WASHINGTON, *ex rel.*
Attorney General CHRISTINE O. GREGOIRE,

STATE OF WEST VIRGINIA, *ex rel.*
Attorney General DARRELL VIVIAN McGRAW, JR.,

Plaintiffs,

v.

AVENTIS S.A.,
successor in interest to Hoechst Aktiengesellschaft

AVENTIS PHARMACEUTICALS INC.,
successor in interest to Hoechst Marion Roussel, Inc.

CARDERM CAPITAL L.P.,

ANDRX CORPORATION,

Defendants.

I.
SUMMARY

1. The States of New York, Michigan, Arizona, California, Idaho, Indiana, Maine, Minnesota, New Mexico, North Carolina, Oklahoma, Utah, Vermont, Washington and West Virginia, by and through their Attorneys General, and the District of Columbia, by and through its Corporation Counsel, (collectively "Plaintiff States" or "States") bring this action in their proprietary capacities on behalf of departments, bureaus, and agencies of state government as injured purchasers or reimbursers; and as *parens patriae* on behalf of natural persons in their collective States, and their

respective States' quasi-sovereign interests in fair competition and the health of their citizenry, and/or in their sovereign capacities; against defendants Aventis S.A., successor in interest to Hoechst Aktiengesellschaft ("Hoechst AG"), Aventis Pharmaceuticals Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc. ("HMRI"); its subsidiary Carderm Capital, L.P. ("Carderm"); and Andrx Corporation. ("Andrx") (collectively "Defendants").

2. This action seeks relief for a series of anti-competitive and illegal acts, by which Defendants sought to delay or prevent the marketing of less expensive, generic alternatives to Cardizem CD, a highly profitable, brand-name drug for treatment of chronic chest pains and high blood pressure, and prevention of heart attacks.

3. On September 15, 1997, Defendant Andrx gained preliminary Food and Drug Administration ("FDA") approval for a generic version of Cardizem CD. Such preliminary approval would have enabled Andrx to enter the market with Cartia XT, its generic version of Cardizem CD, as of July 9, 1998. Instead, on September 24, 1997, Andrx entered into a Stipulation and Agreement with HMRI (the "Agreement"), under which HMRI agreed to make quarterly payments of millions of dollars in return for Andrx's agreement to keep its generic version of Cardizem CD off the market, and to refrain from selling any other drug that was the bioequivalent of Cardizem CD. Further, the Agreement required Andrx to maintain the application it had pending before the FDA at the same time it withheld its product, the effect of which was to keep other potential generic competitors from the market. As a result of this Agreement, HMRI paid Andrx nearly $90 million and in exchange, Andrx delayed the marketing of Cartia XT for nearly a year. The market entry of other generic drugs was also obstructed and consumers were deprived of lower-priced alternatives to Cardizem CD.

4. The Agreement between HMRI and Andrx was only one manifestation of a

systematic effort by HMRI to obstruct the market entry of competitors to Cardizem CD. HMRI also sought to prevent another drug manufacturer, Biovail Corporation ("Biovail"), from selling its own generic alternative to Cardizem CD. HMRI did so by reneging on a commitment to provide Biovail with the right to use data crucial to securing speedy FDA approval of its drug. On or about July 7, 1997, shortly before it concluded its agreement with Andrx, HMRI offered to pay Biovail to delay its sale of a generic version of Cardizem CD. This offer to Biovail was strikingly similar to the agreement that Hoechst and Andrx entered to delay generic competition.

5. The Defendants' allocation of the market for Cardizem CD and its bioequivalents constituted an unreasonable restraint of trade and a violation of the Sherman Act. Moreover, by means of the Agreement and other anti-competitive acts, HMRI engaged in a conspiracy to extend its statutorily granted monopoly on Cardizem CD beyond its proper expiration, and did in fact illegally maintain its monopoly on the market for Cardizem CD and its bioequivalents. Alternatively, by means of the Agreement and other anti-competitive acts, HMRI engaged in a conspiracy to extend its monopoly on once-a-day extended release diltiazem prescription drugs, and did in fact illegally maintain its monopoly on the market for once-a-day extended release diltiazem prescription drugs.

6. As a result of this illegal conduct, Plaintiff States, and natural persons residing therein, were deprived of equally effective, cheaper generic alternatives to Cardizem CD, and instead were forced to pay the monopoly price charged by HMRI for its brand-name drug. These actions deprived Plaintiff States and their consumers of a free and fair market for pharmaceutical products, were detrimental to the health of those citizens who could not afford to pay the higher prices charged by HMRI, and resulted in higher costs to government and other payers of healthcare expenses.

7. By this action, the States seek: 1) monetary relief to remedy and compensate them, and consumers residing therein, for the injuries they sustained as a result of Defendants' anti-competitive acts; and 2) equitable relief and civil penalties, including disgorgement of profits, to prevent Defendants from engaging in similar improper conduct in the future, and to restore the integrity of the marketplace.

II.
JURISDICTION AND VENUE

8. This Complaint, which alleges violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, is filed under, and jurisdiction is conferred upon this Court by, Section 4 of the Clayton Act, 15 U.S.C. § 15, and Section 16 of the Clayton Act, 15 U.S.C. § 26.

9. The Complaint also alleges violations of state antitrust, unfair competition and/or consumer protection statutes and related state laws. This Court has jurisdiction over those claims under 28 U.S.C. § 1367, and under the principles of supplemental jurisdiction. The federal and state law claims arise from a common nucleus of operative facts, and the entire suit commenced by this Complaint constitutes a single action which would ordinarily be tried in one judicial proceeding. The exercise of supplemental jurisdiction would avoid duplication and a multiplicity of actions, and should be exercised in the interests of judicial economy, convenience and fairness.

10. Venue in this district is proper under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). At all times relevant to this action, Defendants transacted business, did business, or were found in the Eastern District of Michigan. The claims alleged also arose, in part, in this judicial district.

III.
THE PARTIES

11. The States, by and through their Attorneys General, bring this action in their proprietary capacities on behalf of departments, bureaus, and agencies of state government as injured purchasers or reimbursers under Medicaid and other programs; as *parens patriae* on behalf of natural persons in their collective States; and on behalf of their respective States' quasi-sovereign interests in fair competition and the health of their citizenry.

12. Defendant Aventis S.A. is a French corporation with its office and principal place of business in Strasbourg, France. Aventis S.A. was formed in December 1999, following the merger of Hoechst AG, a German corporation, and Rhone-Poulenc, S.A, a French corporation. Aventis S.A. owns approximately 97 percent of the outstanding shares of Hoechst A.G.

13. Defendant Aventis Pharmaceuticals Inc. is a Delaware corporation with its office and principal place of business in Parsippany, New Jersey ("Aventis"). Aventis is an indirect, wholly owned subsidiary of Aventis S.A. Until the merger of Hoechst A.G. and Rhone-Poulenc, S.A, Aventis was known as HMRI, which was an indirect, wholly owned subsidiary of Hoechst A.G. Aventis is, and HMRI was, responsible for, among other things, developing, distributing, advertising and selling Cardizem CD throughout the United States. On information and belief, Aventis does business throughout the United States, and is the successor in interest to HMRI in all respects.

14. Defendant Carderm Capital L.P. ("Carderm") is a Delaware limited partnership having its office and principal place of business at Richmond House, 12 Par-la-Ville Road, Hamilton, Bermuda. Carderm was directly or indirectly owned or controlled by HMRI. On information and belief, Carderm is now directly or indirectly owned or controlled by Aventis. Carderm holds the patents covering Cardizem CD and licensed them to HMRI. On information and belief, the patents on

Cardizem CD held by Carderm are now licensed to Aventis.

15. Defendant Andrx Corporation is a Delaware corporation with its office and principal place of business at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida 33314. Andrx develops, manufactures and markets controlled-release drugs. Andrx does business throughout the United States through its distribution subsidiary, Anda Generics, which sells generic drugs to independent pharmacies and regional drug chains. Andrx developed a generic bioequivalent of Cardizem CD, called Cartia XT, which was fully approved by the FDA for sale in the United States in June 1999.

IV.
ANTICOMPETITIVE CONDUCT

A. The Statutory Regime for Entry of Generic Drugs

16. A generic drug is a pharmaceutical product comparable to a brand-name drug in dosage, form, strength, route of administration, quality, performance characteristics and intended use. It is typically sold, however, at a substantial discount from the brand-name drug's price. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an AB rating.

17. Cardizem CD is available in the United States only by prescription written by a physician. When a prescription is written for a brand-name drug such as Cardizem, a pharmacist can fill the prescription only by dispensing either the brand-name drug or its AB rated generic.

18. Under most insurance plans, a pharmacist will substitute an AB rated generic version of a prescribed brand-name drug, when available, unless the physician has indicated "DAW" or "dispense as written" on the prescription. Similarly, many State agencies for which Plaintiffs seek to recover damages and other monetary relief have policies or practices which allow, or require, that

they purchase cheaper, bioequivalent, generic alternatives to brand-name drugs when they are available, or set a maximum allowable cost ("MAC") price which reflects the less expensive generic product prices.

19. In order for Cardizem CD or its generic equivalent products to be eligible for utilization under state Medicaid programs, the manufacturer must enter a rebate agreement either directly with the State or with the United States Secretary of Health and Human Services, acting on behalf of the State. HMRI has entered such a contract which, upon information and belief, is substantially similar in form to the contract attached as Appendix A.

20. Upon information and belief, HMRI has agreed under the contract, "to calculate and□make a Rebate Payment to each State Medicaid Agency for [HMRI's] Covered Outpatient Drugs [including Cardizem CD] paid for by the State Medicaid Agency during a quarter." Appendix A, paragraph II(a). Andrx and other manufacturers of generic versions of Cardizem CD have entered similar contracts. Under these contracts, each state directly invoices the manufacturer based upon the number of units paid for by the state in each calendar quarter.

21. The total cost to a State Medicaid agency for the utilization of Cardizem CD or its generic equivalents is a function of a reimbursement amount paid by the State to pharmacies where the drug was dispensed minus the contractually agreed rebate payment, which is invoiced by the State Medicaid Agency directly to the manufacturer. To the extent that Defendants' illegal activities have increased this total cost, State Medicaid agencies are injured in their business or property as set forth in 15 U.S.C. § 15.

22. The entry of a generic drug into the market can significantly lower the costs incurred

by consumers of the brand-name drug. The first generic competitor usually prices its product approximately 20% lower than the equivalent brand-name drug, while subsequent generic entrants can cause the price of the initial generic offering to fall as much as 80%. The manufacturer of the brand-name drug will typically suffer a substantial decline in its market share immediately after generic alternatives are made available to purchasers. Third party payers, such as government prescription drug assistance programs, also often charge a lower consumer co-payment on purchases of generic drugs than they do for the drugs' brand-name equivalents.

23. Before a drug may be marketed in the United States, the manufacturer must obtain FDA approval. To streamline the approval process, and thereby encourage the development of cheaper, generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"). Under the Hatch-Waxman Act, a prospective generic entrant may gain FDA approval by filing an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA filer must certify that, as of market entry, the generic drug will not infringe any patent for an existing drug listed in *Approved Drugs with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," a compendium of such patents maintained by the FDA. 21 U.S.C. §355(j)(2)(A)(vii). The ANDA filer may certify that patent information on the brand-name drug has not been filed, or that such patent has expired, or that the generic will not be marketed until the date on which such patent will expire. Alternatively, the ANDA filer may make a "Paragraph IV Certification," by which the applicant asserts that the brand-name patent is invalid, or not infringed. 21 U.S.C. §355(j)(2)(A)(vii)(IV). The applicant must provide notice of its Paragraph IV Certification to the maker of the brand-name drug.

24. To provide an impetus to challenge patents and/or design around them, the Act entitles the first Paragraph IV certified ANDA filer to a 180-day period of marketing exclusivity (the "Exclusivity Period"), during which the FDA may not grant final approval to any other generic manufacturer's ANDA regarding the same brand-name drug. The Exclusivity Period does not begin to run until either the first applicant enters the market with its product, or a court enters a final judgment that the patent(s) subject to the Paragraph IV Certification are invalid or not infringed.

25. The Act also makes the filing of a Paragraph IV Certification an "artificial act of infringement" for purposes of patent law. 34 U.S.C. § 271(e)(2). If the patent holder commences an infringement action within 45 days of receiving the Paragraph IV Certification, FDA approval is automatically stayed until the earlier of (i) the expiration of the relevant patent, (ii) 30 months from the date of receipt of the Paragraph IV certification, or (iii) a final judicial determination of non-infringement or invalidity of the patent. If the 45-day period elapses without an infringement action, final FDA approval is not contingent on, and will not be delayed by, any subsequently filed patent infringement action.

B. HMRI's Acquisition and Maintenance of its Exclusive Hold on Cardizem CD.

26. Cardizem CD is prescribed for the treatment of chronic chest pains and high blood pressure, and for the prevention of heart attacks. Once prescribed, Cardizem CD is generally taken by a patient for years.

27. The active ingredient in Cardizem CD is diltiazem hydrochloride ("diltiazem"). The United States patent on diltiazem expired in November 1992. However, prior to the expiration of the patent on diltiazem, Carderm made a patent application claiming the Cardizem CD dissolution profile, which is the amount of diltiazem released into the blood over a specific period of time. The

application claimed that 0-45% of the total diltiazem in Cardizem CD was released within 18 hours of ingestion, and not less than 45% was released over a 24 hour period, as measured in a hydrochloric acid test (the "dissolution profile"). On November 28, 1995 the U.S. Patent and Trademark Office issued United States Patent No. 5,470,584 ("the 584 patent") to Carderm, which licensed it to HMRI. However, the 584 patent did not in any way extend the patent on the active ingredient, diltiazem, which came "off patent" in 1992 and is in the public domain. Accordingly, since the patent expired diltiazem has been in the public domain.

28. Diltiazem-based drugs have been available for treatment of hypertension as early as 1982, but the immediate release formulations of the first diltiazem drugs required that patients take three or four doses per day. As a result, the incidence of non-compliance was high, and users often suffered from side effects caused by undesirable fluctuations of diltiazem in the blood. Cardizem CD, however, uses a delay-release formulation, and therefore need be taken only once per day.

29. Cardizem CD's single administration of diltiazem over the course of a day is based on a sustained release delivery and absorption method claimed in United States patent no. 5,002,776 (the "776 patent") and United States patent no. 4,894,240 (the "240 patent") (collectively termed the "controlled absorption formulation patents"). Marion Merrell Dow Corporation ("MMD") and Carderm were the licensees of the controlled absorption formulation patents.

30. When it was introduced in 1992, Cardizem CD immediately captured a substantial share of the market. Through 1999, Cardizem CD dominated the once-a-day diltiazem prescription market, with sales in the United States of over $700 million in each of 1996 and 1997, and a market share of almost 80%. During this period, Cardizem CD was the largest revenue producer for HMRI.

As a result, there was intense pressure on HMRI's management to delay market entry by generic competitors of Cardizem CD until HMRI produced another drug which generated comparable profits.

31. Cardizem CD was first developed and manufactured by Marion Merrell Dow Corporation ("MMD")MMD. HMRI initially obtained the rights to another once-daily diltiazem-based drug known as Tiazac, via a Rights and Supply Agreement with Biovail.

32. MMD brought an action against HMRI and Biovail, alleging that Tiazac infringed its patent for Cardizem CD. At first, HMRI contested the suit. But in June 1995, HMRI purchased MMD from its parent, Dow Chemical Corporation, thereby acquiring the right to market Cardizem CD. It then terminated the joint venture with Biovail.

33. Biovail responded by suing HMRI and Carderm for breach of contract and antitrust violations. The parties eventually settled the suit and, as part of the settlement, HMRI entered into a broad covenant not to sue Biovail for actions related to diltiazem-based drugs.

34. The FTC launched an investigation into HMRI's purchase of MMD, which was ultimately settled by consent order. To rectify the anticompetitive effects of the merger, the order specifically directed HMRI to provide Biovail with a right of reference for the toxicology data that MMD had submitted to the FDA in support of its initial New Drug Application ("NDA") for Cardizem. Toxicology data demonstrates a drug's safety and efficacy, and is normally quite time consuming and expensive to generate. By compelling HMRI to authorize use of its toxicology data as support for any NDA filed by Biovail for a diltiazem-based product, the FTC effectively allowed Biovail to market a generic version of Cardizem CD by filing an NDA, rather than an ANDA. Normally, FDA approval of an ANDA is much faster than of an NDA, but with the right of reference, Biovail's NDA could have been approved as quickly as an ANDA. Further, use of an NDA would

mean that Biovail's generic drug application would not be subject to the Hatch-Waxman ANDA regulations, including the "artificial act of infringement" claim based on notice of Paragraph IV certification, the statutory 30 month stay or the Exclusivity Period rules.

35. In accordance with the consent order, HMRI sent a letter to the FDA on December 18, 1995, advising the agency that Biovail was entitled to reference toxicology data from its Cardizem NDA, and any supplemental NDAs "related to that product." The FDA subsequently confirmed to Biovail that the right of reference granted by HMRI was broad enough to cover "all future NDA submissions involving diltiazem-based drug products that Biovail might file."

36. HMRI did not, however, abide by its promise to the FTC, or the representations set forth in its letter to the FDA. Instead, on July 11, 1996, HMRI informed the FDA by letter that the right of reference granted to Biovail by HMRI extended only to Tiazac, and that Biovail could not use the right of reference for other diltiazem-based products, including Cardizem CD. Neither Biovail nor the FTC were informed by HMRI that it had chosen to reinterpret its obligations under the consent order and retreat from its earlier position.

37. Biovail did not learn of HMRI's revised stance until informed of it by the FDA by letter dated November 8, 1996. At the time, Biovail had been planning to file both an ANDA and an NDA for its version of Cardizem CD. Once HMRI reneged on the commitment it had given the FTC, Biovail could not seek approval via an NDA without compiling its own toxicology data, which would have required the expenditure of substantial funds and entailed significant delay.

38. In June 1997, Biovail filed an ANDA for a generic version of Cardizem CD. (The first filer, Andrx, had filed its ANDA for a generic equivalent of Cardizem CD on September 22, 1995, over one and one half years earlier.) On August 1, 1997, just prior to the end of the forty-five

day period during which HMRI could delay the generic product's entry by filing suit. HMRI contacted Biovail and initiated a series of meetings in which HMRI sought to forestall Biovail's sale of a generic competitor to Cardizem CD.

39. During these meetings, HMRI offered to pay Biovail a substantial sum of money in exchange for Biovail's agreement to delay the marketing of its generic competitor to Cardizem CD. In addition, HMRI promised that it would provide Biovail with a lucrative license to "develop" and sell one of its other drugs, Probucol. On information and belief, it was intended that this "license" agreement to develop Probucol would contain no development milestones or targets and would have been a non-refundable payment by HMRI to Biovail, even if Biovail did nothing to develop Probucol. HMRI also insisted, as part of their agreement, that Biovail not contact Andrx, the first filer and holder of the rights to the Exclusivity Period for a generic Cardizem CD. HMRI refused, however, to grant Biovail the right of reference which would have allowed the FDA to grant final approval of Biovail's generic alternative to Cardizem CD by means of an NDA, and the parties failed to reach agreement.

40. Because HMRI had previously entered into a covenant not to sue Biovail, it did not bring an infringement action against Biovail. Nonetheless, because Biovail's ANDA was subordinate to Andrx's rights as the first filer of an ANDA, the entry of Biovail's generic alternative to Cardizem CD was delayed by the terms of the market division agreement entered into by HMRI and Andrx, the details of which are set forth below.

C. The Competitive Threat by Andrx

41. In August 1995, prior to filing its ANDA and Paragraph IV Certification for a generic version of Cardizem CD, Andrx gave samples of its product to HMRI so that HMRI could test

Andrx's version and confirm that it did not infringe the patents claiming Cardizem CD. Andrx shared its samples with HMRI with the hope of avoiding infringement litigation. In addition, Andrx filed a patent application with the United States Patent & Trademark Office (the "US PTO") on March 24,1995 claiming its diltiazem controlled release formulation. On October 22, 1996, the US PTO issued United States Patent No. 5,567,441 to Andrx.

42. On September 22, 1995, Andrx became the first manufacturer to file a Paragraph IV Certified ANDA for a generic alternative to Cardizem CD with the FDA.

43. After filing its ANDA with the FDA, Andrx notified HMRI of its Paragraph IV Certification, which stated that the Andrx product did not infringe any unexpired patents listed in the Orange Book concerning Cardizem CD.

44. Two months after Andrx filed its ANDA, on November 28, 1995 the US PTO issued United States Patent No. 5,470,584 (the "584 patent") to HMRI's subsidiary, Carderm was granted the 584 patent on the 0-45% over 18 hours dissolution profile for Cardizem CD. The 584 patent claimed a dissolution rate from 0-45% of total diltiazem released after 18 hours and not less than 45% of total diltiazem released after 24 hours. The 584 patent was immediately listed by HMRI in the Orange Book as covering Cardizem CD.

45. On information and belief, the 584 patent was prosecuted and listed solely to give HMRI a basis for initiating sham litigation to delay and exclude Andrx and other generic manufacturers from competing with Cardizem CD. On information and belief, the Andrx product did not infringe on the 584 patent.

46. On January 31, 1996, HMRI and Carderm filed a patent infringement suit against

Andrx in the United States District Court for the Southern District of Florida, claiming that Andrx's generic product would infringe the 584 patent. The filing of the suit triggered the 30-month Hatch-Waxman Act waiting period, during which the FDA could not finally approve Andrx's product for marketing, unless the patent suit was fully resolved.

47. On April 4, 1996, Andrx amended its ANDA to increase the dissolution rate of its generic product to 55% over 18 hours ("Andrx's Amended ANDA"), thereby making its product even more distinct from Cardizem CD. The increased dissolution rate specified by Andrx was within the dissolution range that Carderm had specifically canceled from its application for the '584 patent. Andrx gave notice of this change to HMRI, which nonetheless persisted with its infringement litigation.

48. On information and belief, the change in the dissolution profile precluded HMRI from having a realistic expectation of success in the infringement suit. On information and belief, HMRI maintained its infringement action against Andrx with the intent of delaying the market entry of a generic competitor.

49. During the pendency of Andrx's Amended ANDA, a third generic manufacturer, Purepac, filed its ANDA in January 1997. HMRI responded by commencing a patent infringement action against Purepac, which stayed FDA approval of Purepac's product until July 1999.

50. During the first half of 1997, Andrx readied Cartia XT for sale. Andrx ordered machines, produced initial batches of product, prepared marketing materials and hired new employees. Simultaneously, Andrx officials began to discuss with their counterparts at HMRI the possibility of entering into an agreement under which Andrx would postpone the marketing of its generic equivalent to Cardizem CD.

51. On September 17, 1997, the FDA gave preliminary approval to Andrx's Amended ANDA for its generic version of Cardizem CD. Such approval meant that on July 8, 1998 (or sooner, if the patent case was resolved), Andrx would be free to enter the market. Upon information and belief, Andrx fully intended to market its product as soon as it was legally permitted to do so, unless it could secure an agreement with HMRI, by which HMRI would compensate it for refraining from selling its generic alternative to Cardizem CD. But for the agreement with HMRI, Andrx would have begun marketing its generic version of Cardizem CD on or shortly after July 8,1998.

D. HMRI and Andrx's Illegal Agreement

52. On September 24, 1997, one week after Andrx received preliminary FDA approval for its amended ANDA, HMRI and Andrx entered into the HMRI/Andrx Stipulation and Agreement (the "Agreement" or "the HMRI-Andrx Agreement").

53. The Agreement delayed the appearance of a generic competitor to Cardizem CD, guaranteed that HMRI would maintain its 100% share of the market for Cardizem CD and its AB-rated bioequivalents, and effectively insured HMRI's continued dominance over the once-a-day diltiazem prescription drug market. Under the Agreement, Andrx promised not to sell a generic version of Cardizem CD, regardless of whether its product infringed HMRI's patent, unless Andrx obtained a license from HMRI under terms specified in the Agreement, or HMRI provided Andrx with notice that it intended to license Cardizem CD to a third party. The Agreement was to last until the entry of a final judgment in the patent litigation.

54. In addition to withholding its product from the market, Andrx agreed to diligently prosecute its ANDA, so as to preserve its right to the Exclusivity Period, and not to relinquish any right to which it was entitled thereunder during the pendency of the Agreement, including selling or

transferring its right to the Exclusivity Period. Since the Exclusivity Period would not begin to run until Andrx actually entered the market or the patent lawsuit was resolved, the Agreement effectively blocked any other manufacturer from selling a generic version of Cardizem CD. Indeed, the sole benefit HMRI received from these contractual terms was to shield Cardizem CD from competition from other potential generic entrants. On information and belief, in or about July 1998, there was at least one generic manufacturer who was prepared to purchase Andrx's rights as first filer and enter the market with a generic version of Cardizem CD, and who made an offer to Andrx to that effect.

55. HMRI paid heavily to maintain its monopoly in this profitable market. Pursuant to the Agreement, HMRI was obligated to start making quarterly "interim payments" to Andrx of $10 million each as of July 9, 1998, the day after Andrx otherwise could have entered the market. The payments would not terminate until the patent case reached final resolution, including all appeals. If Andrx won the case, HMRI had to pay Andrx an additional $60 million per year from July 9, 1998 until the date that the final judgement became effective, bringing Andrx's total payments to $100 million per year of delayed entry. If Andrx lost the patent suit, the Agreement would still provide Andrx with a licensing option.

56. The Agreement specifically did not settle the patent litigation, and was not presented to the court handling that case. Indeed, the Agreement required the parties to keep its terms a secret, and stated explicitly that it was never to be filed in any court proceeding.

57. In September 1998, Andrx filed a supplement to its ANDA, specifying a 65% dissolution profile for its product. This amendment further undermined the already remote possibility that HMRI's infringement action against Andrx would be successful.

58. On June 9, 1999, following the commencement of private antitrust litigation based on the Agreement, HMRI and Andrx announced that they had agreed to settle their patent suit. They claimed that the settlement had been made possible by Andrx's ANDA amendments, and its concomitant reformulation of its generic version of Cardizem CD. At the time of settlement, HMRI paid Andrx an additional $50,700,000, bringing its total payments to Andrx to $89,830,000.

59. On June 23, 1999, Andrx began marketing Cartia XT, its generic alternative to Cardizem CD. Cartia XT sold for approximately 10% less than Cardizem CD. Within six months, HMRI's share of the market for Cardizem CD and its AB-rated bioequivalents dropped to approximately 50%.

60. Because of HMRI's Agreement with Andrx, and the resulting delay in Andrx's entry into the market, Andrx's Exclusivity Period did not finally expire until December, 1999.

61. In July 1999, generic drug manufacturer Purepac received final FDA approval for its generic version of Cardizem It settled its patent litigation with HMRI by entering into a licensing agreement, which permitted Purepac to sell its generic alternative. However, Purepac could not come to market until December 1999, when Andrx's Exclusivity Period expired.

62. In October, 1999, the FDA approved Biovail's ANDA for its generic version of Cardizem CD. Biovail also could not sell its product at that time, because of the bottleneck created by Andrx's exclusive right to market a generic version of Cardizem CD.

63. Once all three generic competitors to Cardizem CD reached the market, HMRI's market share plummeted to 30%. The prices of the generic drugs also fell, until they were available at 60% less than the brand-name price.

64. On June 6, 2000, Federal District Court Judge Nancy Edmunds issued a Memorandum Opinion and Order Granting Plaintiffs' Motion for Partial Summary Judgment, which ruled that Defendants' September 24, 1997 Agreement constituted a *per se* violation of Section One of the Sherman Act. *In Re: Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, (E.D. Mich. 2000).

V.
RELEVANT MARKET

65. A relevant product market for assessing Defendants' anticompetitive acts is the market for Cardizem CD and its FDA-approved, AB-rated, bioequivalents. Under FDA regulations, once a physician prescribes Cardizem CD, the patient may only purchase that drug or its AB-rated bioequivalent. Other once-a-day diltiazem medications cannot be substituted by the pharmacist or consumer without a new prescription. Thus, from the perspective of consumers, the prescribing practices of their physicians limit consumers' purchasing options to the prescribed brand-name drug, and its approved AB-rated generic alternatives, if any.

66. Until the entry of Cartia XT, HMRI had an absolute monopoly in this market.

67. Alternatively, a relevant product market for assessing Defendants' anticompetitive acts is the market for once-a-day extended release diltiazem prescription drugs. Neither other forms of diltiazem, nor other medications for treatment of hypertension and prevention of heart attacks, effectively compete with once-a-day diltiazem.

68. Until the entry of Cartia XT, HMRI had an effective monopoly in this market.

69. The relevant geographic market is the United States.

VI.
INTERSTATE COMMERCE

70. At all times relevant to this Complaint, HMRI and its successor Aventis have participated in the market for Cardizem CD and its FDA-approved, AB-rated, bioequivalents, or alternatively, the market for once-a-day diltiazem prescription drugs in the United States. At all times relevant to this Complaint, Defendant Andrx either prepared to, or did in fact, participate in this market.

71. The activities of the Defendants, including manufacturing, marketing, distributing and selling pharmaceutical products, were in the regular, continuous and substantial flow of interstate commerce and have had and continue to have a substantial effect on interstate commerce.

VII.
EFFECTS OF DEFENDANTS' ILLEGAL CONDUCT

72. The Defendants' acts and practices had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition within each State and throughout the United States, by:

(a) depriving direct and indirect purchasers of Cardizem CD of less expensive, comparable, generic alternatives;

(b) maintaining the monopoly price of Cardizem CD for pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, consumers, and others who purchased Cardizem CD, but who would otherwise have purchased a generic alternative, if one were available;

(c) delaying the establishment of MAC prices and restricting the negotiation of larger discounts or rebates for both Cardizem CD and its generic alternatives;

(d) depriving consumers of the benefits of competition among generic pharmaceutical manufacturers and delaying the entry of new competitors;

(e) depriving consumers of access to needed pharmaceuticals, and thereby injuring their health; and

(f) injuring the States' economies, by engaging in collusive behavior that distorted the process of free and open competition.

73. Many of the injured purchasers, including bureaus, agencies and departments of state governments, purchase generic drugs, when they are available, as a matter of policy or practice. Defendants' anticompetitive acts deprived these purchasers of the ability to implement such policies or practices, and to select a cheaper alternative to Cardizem CD or to obtain Cardizem CD less expensively.

74. The Defendants' acts and practices had the purpose or effect, or the tendency or capacity, and did unjustly enrich the Defendants.

VIII.
INJURY

75. As a direct and proximate result of the unlawful conduct alleged above, from July 1998 through June 1999, the States and consumers residing therein were not able to purchase a generic version of Cardizem CD, and they have consequently been injured in their business and property in that, *inter alia*, they have paid more for once-a-day diltiazem prescription drugs than they would have paid but for HMRI's and Andrx's anti-competitive practices, because they were unable to purchase generic alternatives to Cardizem CD that would have been available but for Defendants' acts.

76. As a direct and proximate result of the unlawful conduct alleged above, consumers in the Plaintiff States paid, and continue to pay, higher prices for Cardizem CD and/or the generic versions of Cardizem CD now available, because of the delay caused by HMRI's and Andrx's anti-competitive conduct, and its effect on generic price decreases, larger discounts and larger rebates that inevitably appear upon the entry of multiple generic competitors.

77. As a direct and proximate result of the unlawful conduct alleged above, the States have sustained injury, and are threatened with further injury unless the Defendants are enjoined from engaging in similar unlawful conduct in the future. The States do not have an adequate remedy at law for such conduct.

78. As a direct and proximate result of the unlawful conduct alleged above, HMRI has unjustly profited by maintaining a higher share of the market for once-a-day diltiazem than it would have enjoyed absent its anti-competitive acts, and by maintaining a 100% share of the market for Cardizem CD and its AB-rated bioequivalents. Andrx has unjustly profited by receiving payments pursuant to an illegal and unreasonable agreement in restraint of trade, and by delaying competition from other generic entrants.

IX.
FIRST CLAIM FOR RELIEF
VIOLATION OF SECTION 1
OF THE SHERMAN ACT

79. The States repeat and reallege paragraphs 1 through 78.

80. From September 1997 until June 1999, Defendants engaged in a continuing combination, conspiracy, and arrangement in unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

81. The combination, conspiracy, and arrangement consisted of an agreement between and among HMRI and Andrx to allocate to HMRI the market for Cardizem CD and its AB-rated bioequivalents, or alternatively, the market for once-a-day extended release diltiazem prescription drugs, by keeping Cardizem CD free from generic competition from July 1998 through June 1999, and further delaying the entry of other generic competitors thereafter. In return for postponing its own entry, and thereby delaying all generic entry into the market, Andrx received nearly $90 million from HMRI. This combination, conspiracy, arrangement and agreement was in violation of Section 1 of the Sherman Act.

82. By delaying entry of generic versions of Cardizem CD, HMRI denied consumers access to less expensive, medically equivalent alternatives to its product, thus causing consumers, government agencies and others who purchase or reimburse others for the purchase of Cardizem CD to pay more than they would have under natural conditions of competition in the absence of such illegal restraints of trade. The restraint also impeded the establishment of larger discounts, rebates or other price caps which would have resulted in lower prices for Cardizem CD and/or its generic alternatives.

X.
SECOND CLAIM FOR RELIEF
MONOPOLIZATION OF THE MARKET FOR CARDIZEM CD AND ITS BIOEQUIVALENTS, OR ALTERNATIVELY, THE MARKET FOR ONCE-A-DAY DILTIAZEM PRESCRIPTION DRUGS, IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT.

83. The States repeat and reallege paragraphs 1 through 78.

84. HMRI has engaged in exclusionary, anti-competitive conduct designed to prevent

competition on the merits between HMRI and its generic competitors, including but not limited to: a) the formation of an illegal agreement with Defendant Andrx; and b) engaging in various efforts intended to prevent or induce Biovail to refrain from marketing a generic alternative to Cardizem CD. These Acts were intended to and did allow HMRI to maintain its monopoly power in the market for Cardizem CD and its AB-rated bioequivalents, or alternatively, in the market for once-a-day diltiazem prescription drugs, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XI.

THIRD CLAIM FOR RELIEF
ATTEMPTED MONOPOLIZATION OF THE MARKET FOR CARDIZEM CD AND ITS BIOEQUIVALENTS, OR ALTERNATIVELY, THE MARKET FOR ONCE-A-DAY DILTIAZEM PRESCRIPTION DRUGS IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

85. The States repeat and reallege paragraphs 1 through 78.

86. HMRI engaged in a course of exclusionary conduct in order to obtain or maintain its monopoly over the markets for once-a-day diltiazem and for Cardizem CD and its AB-rated bioequivalents including: a) the formation of an illegal agreement with Defendant Andrx; and b) engaging in various efforts intended to prevent or induce Biovail to refrain from marketing a generic alternative to Cardizem CD.

87. At all relevant times, HMRI acted with a specific intent to monopolize, and to destroy competition in the market for Cardizem CD and its AB-rated bioequivalents, or alternatively in the market for once-a-day diltiazem prescription drugs, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

88. At the time HMRI engaged in these acts, it had a dangerous probability of succeeding

in obtaining or maintaining a monopoly on the sale of Cardizem CD and its AB-rated bioequivalents and alternatively on the sale of once-a-day diltiazem prescription drugs.

XII.

SUPPLEMENTAL STATE LAW CLAIMS

89. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 78.

90. Defendants' acts violate New York General Business Law §§ 340-347, and constitute fraudulent or illegal acts under New York Executive Law § 63(12) and deceptive acts under New York General Business Law § 349.

91. Plaintiff State of Michigan repeats and realleges each and every allegation contained in Paragraphs1 through 78.

92. Defendants' acts violate the Michigan Antitrust Reform Act MCL 445.771 *et seq.* Specifically, but without limitation, Michigan is entitled to redress pursuant to MCL 445.777 and MCL 445.778.

93. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 78.

94. Defendants' acts violate the Arizona Uniform State Antitrust Act, A.R.S. § 44-1401 *et seq.* Specifically, but without limitation, Defendants' practices are in violation of A.R.S. §§ 44-1402 and 44-1403.

95. Plaintiff State of California repeats and realleges each and every allegation contained in Paragraphs 1 through 78.

96. Defendants' acts violate California's Cartwright Act, Cal. Bus. & Prof. Code §§16720 *et seq.* and California's Unfair Competition Act, Cal. Bus. & Prof. Code §§17200 *et seq.*

97. Plaintiff District of Columbia repeats and realleges each and every allegation contained in Paragraphs 1 through 88.

98. Defendants' acts were in violation of the District of Columbia Antitrust Act, specifically D.C. Code §§ 28-4502 and 28-4503. The laws of the District of Columbia are included in the term "state law" as used in this complaint.

99. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 78 .

100. Defendants' acts violate the Idaho Competition Act, Idaho Code § 48-101 *et seq.* (2000 Supp.) Specifically, but without limitation, Defendants' acts violate Idaho Code §§ 48-104 and 48-105 (2000 Supp.).

101. Plaintiff State of Indiana repeats and realleges each and every allegation contained in paragraphs 1 through 78 .

102. Defendants' acts violate the Indiana Code §§ 24-1-1-1, 24-1-2-1, and 24-1-3-1.

103. Plaintiff State of Maine repeats and realleges each and every allegation contained in paragraphs 1 through 78.

104. Defendants' acts violate the Maine "mini-Sherman Act," 10 M.R.S.A. §1101 *et seq.*, and the Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A *et seq.*

105. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 78.

106. Defendants' acts violate the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66.

107. Plaintiff State of New Mexico repeats and realleges each and every allegation contained in paragraphs 1 through 78.

108. Defendants' acts violate the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1, *et seq.* NMSA (1978) and the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1 *et seq.* (1978).

109. Plaintiff State of North Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 78.

110. Defendants' acts violate N.C. Gen. Stat. §§ 75-1 *et seq.*

111. Plaintiff State of Oklahoma repeats and realleges each and every allegation contained in paragraphs 1 through 78.

112. Defendants' acts violate the Oklahoma Antitrust Reform Act , 79 O.S. § 201 *et seq.* (1998) and the Oklahoma Consumer Protection Act ("OCPA"), 15 O.S. § 751 *et seq.*

113. Plaintiff State of Utah repeats and realleges each and every allegation contained in paragraphs 1 through 78.

114. Defendants' acts violate the Utah Antitrust Act, Utah Code Ann. §§ 76-10-911 through 76-10-926 (1999 Replacement, as amended) and the common law of Utah. Specifically, but without limitation, Defendants' acts violate Utah Code Annotated § 76-10-914(1) and § 76-10-914(2).

115. Plaintiff State of Vermont repeats and realleges each and every allegation contained in Paragraphs1 through 78.

116. Defendants' acts violate the Vermont Consumer Fraud Act, 9 Vermont Statutes Annotated Chapter 63, and the common law of Vermont. Specifically, but without limitation, the aforementioned practices violate 9 V.S.A. §2453.

117. Plaintiff State of Washington repeats and realleges each and every allegation contained in Paragraphs1 through 78.

118. Defendants' acts violate Wash. Rev.Code 19.86.010 *et seq.*

119. Plaintiff State of West Virginia repeats and realleges each and every allegation contained in paragraphs 1 through 78.

120. Defendants' acts violate the West Virginia Antitrust Act, W.Va. Code § 47-18-1 *et seq.* and the West Virginia Consumer Credit and Protection Act, W.Va. Code § 46A-1-101 *et seq.*

XIII.
RELIEF REQUESTED

Accordingly, the Plaintiff States request judgment as follows:

121. Adjudge and decree that Defendants have engaged in conduct in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

122. Adjudge and decree that Defendants have engaged in conduct in violation of the state statutes enumerated in Paragraphs 89 to 120;

123. Enjoin and restrain, pursuant to federal and state law, the 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, contract, combination or conspiracy, and from adopting or following any practice, plan, program or device having a similar purpose or effect to the anti-competitive actions set forth above;

124. Enter judgment for the Plaintiff States and award all other available equitable relief, including, but not limited to, restitution and disgorgement, as the Court finds necessary to redress Defendants' violations of state and federal law and/or the unjust enrichment of the Defendants;

125. Enter judgment for the Plaintiff States for three (3) times the amount of damages sustained by the States as purchasers or assignees of purchasers of Cardizem CD, as allowed by federal law;

126. Enter judgment for the Plaintiff States of California, Maine, Minnesota, New Mexico, New York, North Carolina, Vermont, and West Virginia against Defendants, jointly and severally, for three (3) times the amount of damages sustained by the Plaintiff States and their agencies (including medical reimbursement programs) as purchasers or assignees of purchasers of Cardizem CD, as allowed by state law;

127. Enter judgment for the Plaintiff States of Arizona, Michigan, Oklahoma, Utah, and Washington, and for the District of Columbia, against Defendants, jointly and severally, for the amount of damages sustained by the States and their agencies (including medical reimbursement programs) as purchasers or assignees of purchasers of Cardizem CD, as allowed by state law;

128. Enter judgment for the Plaintiff States of Arizona, California, Maine, Michigan, Minnesota, New Mexico, New York, North Carolina, Vermont, and Washington, and for the District of Columbia, against Defendants, jointly and severally, and award damages sustained by the States,

their agencies, and the entities and persons they represent or on whose behalf this suit is brought. for indirect purchases of Cardizem CD, to the full extent permitted by state law;

129. Enter judgment for the States of Arizona, California, Idaho, Maine, Michigan, Minnesota, New Mexico, New York, North Carolina, Utah, Vermont, Washington, and West Virginia against Defendants for the maximum civil penalties permitted by state law;

130. Award each State the costs of this action, including reasonable attorneys' fees, and, where applicable, expert fees; and

131. Grant such other and further relief as may be just and proper.

XIV.
JURY TRIAL DEMAND

Plaintiffs demand trial by jury pursuant to Rule 38(b) of the Federal Rules of Civil Procedure on all issues triable of right by a jury.

Respectfully Submitted,

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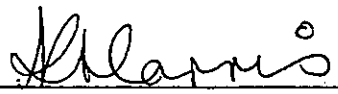

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Exhibit A

Enclosure A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f) "Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(g) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(h) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(i) "Health Care Financing Administration (HCFA)" means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by HCFA as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by HCFA.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete

11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) "Quarter" means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with HCFA's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, HCFA shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify HCFA and for HCFA to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by HCFA will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations
Family and Children's Health Programs Group
Division of Benefits, Coverage and Payment
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to HCFA concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The HCFA address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to HCFA at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate HCFA official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:_____

Title: Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations
Health Care Financing Administration
Department of Health and Human Services

Date: _____

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____

JS 44
(REV. 3/99)

CIVIL COVER SHEET

01-71835

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
States of New York, Michigan, Arizona, California, Idaho, Indiana, Maine, Minnesota, New Mexico, North Carolina, Oklahoma, Utah, Vermont, Washington, West Virginia and the District of Columbia

DEFENDANTS
Aventis S.A., Aventis Pharmaceuticals Inc., Gardenn Capital L.P. and Andrx Corporation

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF New York
(EXCEPT IN U.S. PLAINTIFF CASES)

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(C) ATTORNEYS (FIRM NAME, ADDRESS AND TELEPHONE NUMBER)
See Attached list

ATTORNEYS (IF KNOWN)

MAGISTRATE JUDGE SCHEER

II. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Equipment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury—Med. Malpractice
- ☐ 365 Personal Injury—Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

HABEAS CORPUS
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure Of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant
- ☐ 871 IRS — Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☒ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (CITE THE US CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUES UNLESS DIVERSITY)

Restraint of Trade, Monopolization and Attempted Monopolization under 15 U.S.C. Sections 1 and 2, as well as various state law claims.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23

DEMAND $Over $100 million

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ YES ☐ NO

VIII. RELATED CASE(S) IF ANY (See instructions)

JUDGE Honorable Nancy G. Edmunds DOCKET NUMBER MDL #1278

DATE May 14, 2001

SIGNATURE OF ATTORNEY OF RECORD Paul F Novak

FOR OFFICE USE ONLY

RECEIPT _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

PURSUANT TO LOCAL RULE 83.11

1. Is this a case that has been previously dismissed? ☐ Yes ☑ No

If yes, give the following information:

Court: _____

Case No.: _____

Judge: _____

2. Other than stated above, are there any pending or previously discontinued or dismissed companion cases in this or any other court, including state court? (Companion cases are matters in which it appears substantially similar evidence will be offered or the same or related parties are present and the cases arise out of the same transaction or occurrence.) ☐ Yes ☐ No

If yes, give the following information:

Court: several cases are consolidated.

Case No.: in MDL. 12.78

Judge: _____

Notes:

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