UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

STATE OF FLORIDA, by
ATTORNEY GENERAL ROBERT A. BUTTERWORTH,

STATE OF COLORADO, by
ATTORNEY GENERAL KEN SALAZAR,

STATE OF KANSAS, by
ATTORNEY GENERAL CARLA J. STOVALL,

Plaintiffs,

vs. **JURY TRIAL DEMANDED**

ABBOTT LABORATORIES, INC., GENEVA PHARMACEUTICALS, INC., and IVAX PHARMACEUTICALS, INC., formerly known as ZENITH GOLDLINE PHARMACEUTICALS, INC.

Defendants.
_____/

COMPLAINT

The States of Florida, Colorado and Kansas, by and through their Attorneys General ("Plaintiff States"), sue Abbott Laboratories, Inc. ("Abbott"), Geneva Pharmaceuticals, Inc. ("Geneva"), and Ivax Pharmaceuticals, Inc., formerly known as Zenith Goldline Pharmaceuticals, Inc. ("Zenith"), and allege:

NATURE OF ACTION

1. Hytrin is a brand-name drug manufactured by Abbott with the active ingredient terazosin hydrochloride. Hytrin is typically prescribed for the treatment of hypertension and benign prostatic hyperplasia ("BPH") and is a significant source of revenue for Abbott.

2. Abbott unlawfully prevented generic competition to Hytrin by engaging in a series of baseless and repetitive patent infringement suits designed to prevent generic manufacturers from marketing their version of the drug. Abbott also attempted to enforce a fraudulently obtained patent against certain generic manufacturers to further its Hytrin monopoly. When this strategy had run its course, Abbott then entered into illegal agreements wherein Abbott agreed to pay Geneva and Zenith not to market generic versions of Hytrin. Such conduct violated the antitrust laws of the United States, as well as the unfair competition and antitrust laws of the various Plaintiff States.

JURISDICTION AND VENUE

3. This Court has jurisdiction pursuant to 15 U.S.C. § 15, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1337, and 1367.

4. Venue in this district lies pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c). At all times material herein, Defendants transacted business, resided, or were otherwise found within the Southern District of Florida. Additionally, at least some of the illegal conduct described herein transpired in this judicial district, and some of the resulting consequences were felt in this judicial district as well.

5. Defendants' violations of state antitrust and/or unfair competition statutes and related state law arise from a common nucleus of operative facts and the entire action commenced by this Complaint constitutes a single case or controversy that would ordinarily be tried in a single judicial proceeding. The exercise of supplemental jurisdiction over such claims pursuant to 28 U.S.C. § 1367 would avoid unnecessary duplication, multiplicity of actions, and serve the interests of judicial economy, convenience, and fairness.

PARTIES

6. The Plaintiff States bring this action in their sovereign capacity on behalf of departments, bureaus, and agencies of state government as injured purchasers of Hytrin, and, with regard to the States of Florida and Kansas, as assignees of claims made pursuant to contracts entered into between Florida or Kansas and various purchasers of Hytrin or its generic equivalent. Plaintiff States also bring claims as reimbursers under Medicaid and other programs. The States of Florida and Kansas also bring claims on behalf of injured consumers residing in their respective states.

7. Defendant Abbott Laboratories, Inc. is an Illinois corporation with its office and principal place of business located at 100 Abbott Park Rd., Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of a broad line of health care products and services.

8. Defendant Geneva Pharmaceuticals, Inc. is a New Jersey corporation with its office and principal place of business located at 2555 W. Midway Blvd., Broomfield, Colorado 80020. Geneva is an indirect wholly owned subsidiary of Novartis Corporation which develops, manufactures and markets generic pharmaceutical products.

9. Defendant Ivax Pharmaceuticals, Inc., formerly known as Zenith Goldline Pharmaceuticals, Inc., is a Florida corporation with its office and principal place of business located at 4400 Biscayne Blvd., Miami, Florida, 33137. Zenith is engaged principally in developing, manufacturing, and marketing of generic pharmaceutical products.

FEDERAL STANDING

10. The Plaintiff States allege and seek injunctive relief against Defendants Abbott and Zenith. Additionally, the States of Florida and Kansas benefit from contractual assignments between entities who purchased Hytrin or its generic equivalent on behalf of the states. Assignment of such rights or claims as they arise from the illegal acts described herein provide Florida and Kansas an additional basis to assert federal standing to the extent that such contractual language assigns claims arising from contracts by which Florida and Kansas have purchased Hytrin or its generic equivalent.

OPERATIVE FACTS

A. Federal Regulation of Pharmaceuticals: New Drug Applications

11. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., no drug may be marketed or sold in the United States without the prior approval of the United States Food and Drug Administration ("FDA").

12. A pioneer drug manufacturer that seeks approval for the marketing and sale of new brand name drugs files a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355(b). During the NDA application process, the manufacturer must successfully demonstrate that the new drug is both safe and effective. It is both rigorous and expensive to prosecute an NDA, and many applications are never approved.

13. NDA subject drugs are typically protected by one or more patents. Such patents grant patent owners the legal right to preclude others from making, using, offering for sale or selling the drug within the United States for the duration of the patents. Such patents also preclude the importation of the protected drug into the United States.

14. As part of its NDA application, the pioneer drug manufacturer is required to file with the FDA the patent number of any patent which claims the NDA subject drug or claims a method of using such drug, if a claim of patent infringement could reasonably be asserted against another party by the patent owner. *See* 15 U.S.C. § 355(b)(1).

15. The FDA accepts patent information submitted by the NDA holder as true. *See* 21 CFR § 314.53(f).

16. Upon approval of the NDA, the subject drug will be listed in the Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book"). The Orange Book identifies all patents asserted by the NDA holder which either claim the approved drug or claim a method of using such drug.

17. Should additional patents relevant to the subject drug issue after the NDA filing date, the pioneer manufacturer is required to supplement its NDA within 30 days of the date the patent is issued. *See* 21 U.S.C. §355(c)(2).

18. In 1984, the Federal Circuit held that the manufacture, use, or sale of a patented invention was an act of infringement, even if it was done for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. *See Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, *cert. denied*, 469 U.S. 856, 105 S.Ct. 183, 83 L. Ed.2d 117 (1984).

19. Following that decision, generic manufacturers planning to compete with a patentee faced an enormous hurdle. They could no longer prepare for regulatory approval of generic drugs prior to the expiration of any patent claiming the subject drug or claiming a method of its use. The unintended result of the *Roche* decision was that the monopoly granted to the patent holder would be extended *de facto* throughout the generic drugs approval process.

20. To ameliorate this situation, and to ease and streamline the approval and marketing of generic drugs, Congress enacted several changes to the Federal Food, Drug, and Cosmetic Act through the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman"). *See* 98 Stat. 1585, 21 U.S.C. § 355; *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S.Ct. 2683, 2691, 110 L.Ed 2d 605 (1990).

B. Federal Regulation of Pharmaceuticals: Abbreviated New Drug Applications

21. Generic drugs are pharmaceuticals that are bioequivalent to the brand-name drug marketed by a pioneer manufacturer: comparable to the brand-name in dosage, form, strength, route of administration, quality, performance characteristics and intended use.

22. A generic drug is typically sold at a substantial discount off the price of the brand-name drug. When a generic version of a drug is available, insurance and other health plans frequently require a pharmacist to automatically substitute the generic version for a name-brand drug unless the physician's prescription specifically states in the prescription that the name-brand must be dispensed. States that purchase such drugs frequently have similar policies or practices, and benefit from generic competition through lower drug prices.

23. Under Hatch-Waxman, the prospective generic manufacturer may gain expedited FDA approval by filing what is termed an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j).

24. An ANDA streamlines and substantially shortens the approval process for generic drugs because the generic manufacturer may rely on the safety and efficacy data contained in the pioneer manufacturer's NDA already on file with the FDA.

25. Hatch-Waxman permits generic manufacturers intending to supply a generic to the market to conduct tests and develop information necessary to apply for regulatory approval *prior* to the expiration of any applicable patent.

26. Each ANDA applicant is required to formally certify to the FDA that one of the following conditions is satisfied: the brand name manufacturer has not filed patent information with the FDA ("Paragraph I certification"); the patent or patents filed in the Orange Book have expired ("Paragraph II certification"); the patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of patent expiration ("Paragraph III certification"); or that the patent is invalid or not infringed by the generic manufacturer's product ("Paragraph IV certification").

27. If the ANDA applicant makes a Paragraph IV certification, it must notify both the holder of the approved NDA and the owner of the patent(s) that the Paragraph IV certification has been made. The notification must include the factual and legal basis upon which the ANDA applicant asserts that the listed patent is invalid or will not be infringed.

28. Notification of the Paragraph IV certification gives rise to an artificial cause of action for infringement through the legal fiction that the Paragraph IV certification itself infringes the patent. Upon receipt of the required notice, the patent holder or the NDA holder may sue the ANDA applicant for patent infringement within forty five (45) days from receipt of Paragraph IV notice. *See* 21 U.S.C. § 355(j)(5)(B)(ii).

29. If the 45-day period elapses without an infringement action, the FDA is free to proceed with the ANDA approval process and the generic manufacturer will be entitled to market its product as soon as it receives final FDA approval. *See id.*

30. However, if a patent infringement suit is filed against the ANDA applicant within the 45-day period, the FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final judicial determination of non-infringement or invalidity in the lawsuit; or (iii) the expiration of a 30-month period commencing upon receipt of the Paragraph IV certification notice.

31. This process must be repeated for each patent listed in the Orange Book regardless of when the patent was submitted for listing. Thus, each time a new patent is listed in the Orange Book, the holder of the NDA is afforded an opportunity to delay approval of a generic competitor for up to 30 months simply by filing suit for infringement.

32. As a reward for successfully negotiating the regulatory minefield, Hatch-Waxman makes the first ANDA applicant filing a Paragraph IV certification eligible for a 180-day period during which no other generic ANDAs for the same drug may be finally approved by the FDA ("180-day Exclusivity Period"). This period does not commence until the earlier of (i) the date the generic drug is first commercially marketed or (ii) a court enters final judgment that the patents subject to the Paragraph IV Certification are invalid or not infringed. Thus, if approval of the first filed ANDA with a Paragraph IV certification is delayed by the suit provisions of Hatch-Waxman, all other similar ANDAs may be delayed.

C. Abbott's Hytrin Product

33. Hytrin, manufactured and marketed by Abbott, is the brand name of a drug whose active ingredient is terazosin hydrochloride. Terazosin hydrochloride is an alpha-1-selective adrenoceptor blocking agent used in the treatment of hypertension and benign prostatic hyperplasia. Hypertension and benign prostatic hyperplasia are chronic conditions that afflict millions of Americans, including many senior citizens.

34. Abbott introduced Hytrin tablets on or about August 7, 1987. Hytrin capsules were introduced in 1995. Until Geneva introduced its generic version of Hytrin on or about August 13, 1999, Abbott's product was the only terazosin hydrochloride product sold in the United States.

35. Abbott is the owner of at least seven (7) patents claiming terazosin hydrochloride or a method of using terazosin hydrochloride. These 7 patents are:

a. The "'894 patent" - Abbott was issued U.S. Patent No. 4,026,894 on or about May 31, 1977. The '894 patent claims a genus of chemicals including terazosin hydrochloride and expired on or about May 31, 1994.

b. The "'097 patent" - Abbott was issued U.S. Patent No. 4,112,097 on or about September 5, 1978. The '097 patent claims a pharmaceutical composition containing terazosin hydrochloride, as well as a method of treating hypertension by the administration of terazosin hydrochloride. Under the terms of the Uruguay Round Agreements Act ("URAA") - extending the life of patents in force June 8, 1995 to the greater of seventeen years from the date of issue or twenty years from the application filing date - the '097 patent expired on or about October 14, 1995.

c. The "'532 patent" - Abbott was issued U.S. Patent No. 4,251,532 on or about February 17, 1981. The '532 patent claims the dihydrate of the hydrochloride salt of terazosin ("terazosin hydrochloride dihydrate"), a form of terazosin hydrochloride used to produce Hytrin. The '532 patent expired on or about February 17, 2000.

d. The "'176 patent" - Abbott was issued U.S. Patent No. 5,212,176 on or about May 18, 1993. The '176 patent claims the R(+) enantiomer of terazosin hydrochloride dihydrate. The terazosin hydrochloride molecule possesses a chiral center, and can therefore exist in two

mirror-image forms, R ("right-handed") and S ("left-handed"). This patent claims a terazosin product that is substantially free of the left-handed form. The '176 patent did not claim Hytrin or a method of using Hytrin, and Abbott only requested the FDA include it in the Orange Book after a generic manufacturer developed a competing product.

e. The "'615 patent" - Abbott was issued U.S. Patent No. 5,294,615 on or about March 15, 1994. The '615 patent claims an anhydrous crystalline polymorph of terazosin hydrochloride commonly referred to as Form II. Because the '615 patent did not claim Hytrin or a method of using Hytrin, Abbott only requested the FDA include it in the Orange Book after a generic manufacturer developed a competing product.

f. The "'095 patent" - Abbott was issued U.S. Patent No. 5,412,095 on or about May 2, 1995. The '095 patent claims an anhydrous crystalline polymorph of terazosin hydrochloride commonly referred to as Form III. Because the '095 patent did not claim Hytrin or a method of using Hytrin, Abbott only requested the FDA include it in the Orange Book after a generic manufacturer developed a competing product.

g. The "'207 patent" - Abbott was issued U.S. Patent No. 5,504,207 on or about April 2, 1996. The '207 patent claims an anhydrous crystalline polymorph of terazosin hydrochloride commonly referred to as Form IV. Because the '207 patent did not claim Hytrin or a method of using Hytrin, Abbott only requested the FDA include it in the Orange Book after a generic manufacturer developed a competing product.

D. <u>The Threat of Generic Terazosin Hydrochloride</u>

36. Geneva filed its ANDA covering the tablet form of terazosin hydrochloride on or about January 12, 1993. It was the first to do so. Other ANDAs from other generic drug

manufacturers quickly followed. The only patents Abbott had submitted to the FDA for listing in the Orange Book at the time Geneva filed its ANDA were the '894, '097 and '532 patents.

37. Geneva made a Paragraph III certification as to the '894 and '097 patents, and made a Paragraph IV certification as to the '532 patent because its generic version of Hytrin was based on an anhydrous form of terazosin hydrochloride, not the dihydrous (two water molecules) form covered by the '532 patent.

38. Nevertheless, Abbott sued Geneva for infringement of the '532 patent in February of 1993. Following a voluntary dismissal of that case in November that year, Geneva faced no patent impediment to FDA approval of its generic terazosin hydrochloride other than the '097 patent, set to expire October 14, 1995.

39. Faced with this threat, Abbott began a course of conduct which exploited the provisions for the 30-month stay found in Hatch-Waxman in order to block generic entry by both Geneva and other ANDA filers, thus preserving its Hytrin monopoly.

The '615 Patent

40. Abbott applied for issuance of the '615 patent on or about April 29, 1993, more than three months after Geneva had filed its ANDA for generic terazosin hydrochloride.

41. Pursuant to 21 U.S.C. § 355(c)(2), Abbott had thirty (30) days from issuance of the patent to provide the patent information to the FDA and have the patent listed in the Orange Book. Abbott did not in fact provide the FDA the required patent information until April 25, 1995.

42. Knowing that it had forfeited its right to sue under Hatch-Waxman by failing to list the '615 patent, Abbott nevertheless sued Geneva in the Northern District of Illinois for infringement of the '615 patent on or about September 15, 1994, invoking the 30 month Hatch-

Waxman stay. Following assurances that Geneva would not use any form of terazosin that was covered by patent protection *at that time,* Abbott voluntarily dismissed the suit on or about July 17, 1995.

43. Abbott sued Zenith for infringing the '615 patent as well. Zenith had filed its Hytrin ANDA on or about June 2, 1994 and also certified to Paragraph IV with respect to the '532 patent. No certification to the '615 was made as the patent had never been listed in the Orange Book.

44. On or about March 15, 1994, the district court dismissed Abbott's action against Zenith because the '615 patent was not listed in the Orange Book. Abbott responded by listing the patent in the Orange Book – well after the statutorily imposed deadline – and filing suit against Zenith again, once more invoking the Hatch-Waxman 30 month stay against any FDA approval of generic Hytrin. The action was dismissed for Abbott's late listing of the '615 patent on or about September 28, 1995. *See Abbott Lab. v. Zenith Lab., Inc.*, 934 F.Supp 925 (N.D. Ill. Sept 28, 1995).

The '097 Patent

45. Following the voluntary dismissal of its '615 infringement action against Geneva on or about July 17, 1995, once again, the only hurdle to FDA approval of Geneva's ANDA was the expiration of the '097 patent, set to expire October 14, 1995. Less than three months of life remained to Abbott's Hytrin monopoly.

46. However, following the adoption of the Uruguay Round Agreements Act ("URAA"), Abbott intentionally misrepresented to the FDA that the new expiration date of the '097 patent, as extended by the URAA, was January 21, 1997.

47. The FDA subsequently published the false date of expiration in the Orange Book and instructed all ANDA applicants to amend their ANDAs reflecting this change. Geneva responded by amending its application to reflect a Paragraph IV certification with respect to the '097 patent on or about October 5, 1995.

48. Despite knowing that its '097 patent had in fact expired, Abbott sued Geneva for infringement of the '097 patent on or about November 16, 1995. The action was later consolidated with a similar action filed against Novopharm Ltd. ("Novopharm").

49. On or about March 14, 1996, the district court found that the '097 patent had in fact expired on October 14, 1995, and, amending the resulting order on April 9, 1996, ordered Abbott to de-list the expired '097 patent from the Orange Book. The district court was affirmed by the Federal Circuit on January 14, 1997. *See Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305 (Fed. Cir. 1997).

The '207 Patent

50. Following Geneva's victory over Abbott in the '097 patent litigation, the FDA would have been free to approve ANDAs on file with the agency had Abbott not used the delay caused by that litigation to secure another illegitimate patent - the '207 patent.

51. In its application for the '207 patent, Abbott admitted to the Patent and Trademark Office that Form IV had been sold commercially more than one year prior to its application, but represented that its patent should be granted because neither of the purchasers of the drug - Geneva and its suppliers, Todogawa and Byron - knew that they were selling Form IV. Without such a representation, Abbott would not have been able to receive the '207 patent due to the restrictions present in the statutory on-sale bar found at 35 U.S.C. § 102(b).

52. Upon information and belief, Abbott's representation was knowingly false because Abbott was aware that both Geneva and its suppliers did in fact know that the form of terazosin being sold prior to Abbott's application was Form IV.

53. In the alternative, Abbott willfully and deliberately failed to inquire whether Geneva and/or its suppliers knew that the form of terazosin being sold more than one year prior to the '207 patent application was Form IV. Notwithstanding its failure to inquire, Abbott nonetheless made an affirmative representation to the Patent and Trademark office that Geneva and its suppliers in fact did not know that the form of Terazosin being sold was Form IV in order to ensure that the '207 patent would issue.

54. Despite this knowledge of this misrepresentation – and the resulting invalidity of the '207 patent - Abbott amended its NDA to include the '207 patent in early 1996. As required, the FDA listed that patent in the Orange Book and requested that ANDA filers amend their applications.

55. In April 1996, Geneva filed a Paragraph IV Certification with the FDA alleging that neither its generic terazosin hydrochloride tablet nor its generic capsule product would infringe the '207 patent because the form of the drug covered by the '207 patent (Form IV) had been commercially sold more than one year prior to the date Abbott applied for the patent and thus, the patent was invalid due to the statutory on-sale bar.

56. Despite knowing that its '207 patent was invalid due to the on-sale bar, and despite knowing that the patent was obtained by fraud, Abbott again sued Geneva for infringement of the '207 patent on or about June 4, 1996. For reasons unknown, Abbott's suit limited its infringement claim to Geneva's tablet product. When Abbott made no claim against

Geneva's capsule product within the 45 day period provided by Hatch-Waxman, the FDA approval process was free to proceed without impediment.

57. Zenith adopted another approach. Instead of certifying to the '207 patent, Zenith filed a complaint against Abbott in the United States District Court for the District of New Jersey seeking a declaration that Abbott's submission of the '097 patent, the '615 patent, the '176 patent, the '095 patent and the '207 patent for listing in the Orange Book were improper, and for an injunction to de-list the patents.

58. On August 7, 1996, the New Jersey District Court denied Abbott's motion to dismiss, and on or about August 20, 1996, Abbott filed its answer as well as counterclaims against Zenith alleging infringement of the '615, '097, and '207 patents. On October 2, 1997, the court denied Zenith's motion seeking a preliminary injunction against Abbott's listing of the questioned patents in the Orange Book. Zenith appealed this order and continued to pursue this litigation until it entered its illegal agreement with Abbott, described below.

59. Throughout 1995, 1996, and 1997, Zenith consistently took the position that its generic product did not infringe any valid patent owned by Abbott, and that, but for Abbott's unlawful patent listings, it would have entered the market with a generic version of Hytrin on or about July 8, 1997.

60. At the time Abbott entered into its illegal agreements with Geneva and Zenith, Geneva was not entitled to 180 days of exclusivity because it had not "successfully defended" the patent infringement action brought by Abbott. Because Geneva had not yet satisfied the "successful defense" requirement, applications by other ANDA filers would have been approved by the FDA without regard to Geneva's status as the "first filer."

E. Abbott and Geneva's Illegal Agreement

61. Despite the on-going '207 patent litigation against its tablet product, Geneva pushed ahead in 1997 and early 1998 with plans to bring its capsule product to market because it knew that final FDA approval to market the capsule product could come at anytime.

62. Preparations to launch the capsule product proceeded on all fronts: the manufacturing team sought to validate the terazosin hydrochloride capsule manufacturing process; the purchasing department instructed its supplier to manufacture commercial quantities of the terazosin hydrochloride active ingredient; sales and marketing personnel contacted customers to inform them of the impending launch and to enter into distribution contracts for the product; and the legal staff busily prepared to oppose any further effort by Abbott to block Geneva's entry.

63. On March 30, 1998, final FDA approval to market terazosin hydrochloride capsules was granted. Geneva was thus free to begin sales of its generic capsule product.

64. That same day, Geneva contacted Abbott and announced that it would launch its generic terazosin hydrochloride capsules unless it was paid by Abbott not to enter the market.

65. Abbott, forecasting that entry of generic terazosin hydrochloride would eliminate over $185 million in Hytrin sales within six months, quickly came to the bargaining table. By April 1, 1998, a deal was in place.

66. Abbott and Geneva agreed that Geneva would not enter the Hytrin market with any generic terazosin hydrochloride product - capsule or tablet - until the earlier of: (i) resolution of the patent infringement litigation involving Geneva's terazosin hydrochloride tablets product, *including review by the Supreme Court of the United States*; or (ii) entry of another generic

terazosin hydrochloride product. Geneva further agreed not to transfer, assign, or relinquish its right to a 180-day exclusivity period.

67. In consideration for this concession, Abbott agreed to pay Geneva $4.5 million per month in non-refundable payments until the district court rendered its decision in the patent infringement dispute.

68. Abbott and Geneva further agreed that if the district court declared the '207 patent invalid, or that Geneva's product would not infringe, Abbott would pay the $4.5 million monthly payments into escrow, the funds payable to the party prevailing on appeal.

69. In or around August of 1998, after appellate decisions quashed the "successful defense" requirement, the FDA granted to Geneva the 180 exclusivity period because it had been the first to file a terazosin hydrochloride ANDA. Because this entitlement would not be triggered until Geneva began to sell its capsule product, after August 1998, no other generic manufacturer could receive final FDA approval while this agreement was in place.

70. On September 1, 1998, the district court agreed with Geneva that the statutory on-sale bar of 35 U.S.C. § 102(b) rendered the'207 patent invalid. This decision was affirmed July 1, 1999. *See Abbott Laboratories v. Geneva Pharmaceuticals, Inc., et. al.*, 182 F.3d 1315 (Fed. Cir. 1999).

71. Under the agreement, Geneva would not enter the market until Abbott's petition for certiorari to the Supreme Court was disposed of. However, because of an investigation by the Federal Trade Commission into the agreement recited herein, Abbott and Geneva cancelled the agreement allowing generic Hytrin to enter the market on or about August 13, 1999.

F. <u>Abbott and Zenith's Illegal Agreement</u>

72. On or about March 31, 1998, Abbott and Zenith entered an agreement wherein

Abbott agreed to pay Zenith $6 million per quarter beginning July 15, 1998 in exchange for Zenith's agreement not to market its generic version of Hytrin until the expiration of the '532 patent – despite the fact that Abbott had never challenged Zenith's Paragraph IV certification that its product would not infringe the '532 patent.

G. Abbott's Unilateral Illegal Conduct

73. The agreement with Geneva was a concession by Abbott that its litigation strategy had run its course and could no longer guarantee that generic Hytrin would be kept from the market. However, that concession said nothing about the overall success of the strategy.

74. Between February of 1993 and April of 1998, Abbott filed no fewer than seventeen (17) lawsuits based on four (4) separate patents against the incipient generic competition. Abbott failed to win a single one of these suits but succeeded in manipulating the Hatch-Waxman provisions so that the FDA could not approve a Hytrin ANDA until March of 1998.

75. Abbott's purpose in filing these suits was to use the litigation process as an anti-competitive weapon. Abbott knew that the patents upon which it based these actions were invalid and that such actions could not succeed on their merits. Abbott's infringement actions were therefore mere sham designed to exclude generic competition from the Hytrin market.

76. Each of the 17 patent infringement suits was objectively baseless in the sense that no reasonable litigant could realistically have expected to succeed on the merits. Each of the suits was brought without regard to the merits and for the purpose of injuring a market rival.

TRADE AND COMMERCE

77. During the relevant period, Hytrin was sold throughout the United States. Hytrin was transported across state lines and sold in each of the Plaintiff States**.** The unlawful activities of Defendants alleged in this Complaint have occurred in and have had a substantial effect upon interstate commerce.

RELEVANT MARKET

78. The relevant product market is the manufacture and sale of prescription drugs containing terazosin hydrochloride as an active ingredient (Hytrin and its FDA-approved, AB-rated bioequivalents).

79. The relevant geographic market is the United States.

80. At all times prior to August 13, 1999, Abbott maintained a 100% monopoly share of the relevant market.

ANTICOMPETITIVE EFFECTS OF DEFENDANTS ILLEGAL CONDUCT

81. Defendants' conduct had the purpose and effect of unreasonably and illegally restraining competition and injuring competition by preventing entry of competing products into the relevant market.

82. As a direct and proximate result of the illegal conduct alleged above, the Plaintiff States, as well as consumers residing in the Plaintiff States, were unable to purchase a generic version of Hytrin when they would have otherwise been able to do so. But for the illegal conduct alleged above, the Plaintiff States and consumers residing in the Plaintiff States would have been able to purchase generic Hytrin at a substantial discount from the name-brand drug.

83. Additionally, but for the illegal conduct alleged above, the Plaintiff States and

consumers residing in the Plaintiff States would have been able to purchase name brand Hytrin at a substantially discounted price.

84. As a direct and proximate result of the unlawful conduct alleged above, Abbott has unjustly profited by extending its monopoly share of the market for terazosin hydrochloride pharmaceuticals for a period of time exceeding that to which it was lawfully entitled.

85. As a direct and proximate result of the unlawful conduct alleged above, Geneva has unjustly profited by receiving payments made pursuant to an illegal and unreasonable agreement in restraint of trade, and thus shared in Abbott's illegal monopoly profit.

86. As a direct and proximate result of the unlawful conduct alleged above, Zenith has unjustly profited by receiving payments made pursuant to an illegal and unreasonable agreement in restraint of trade, and thus shared in Abbott's illegal monopoly profit.

COUNT I – CONSPIRACY IN RESTRAINT OF TRADE
(INJUNCTIVE RELIEF ONLY)

Plaintiff States repeat and reallege each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein. This claim is asserted against Defendants Abbott and Zenith.

87. Beginning in or around February of 1993 and continuing through at least April of 1998, Abbott filed and prosecuted no fewer than seventeen (17) lawsuits based on four (4) separate patents against the incipient generic competition. Each of these lawsuits was objectively baseless, was without merit, and Abbott failed to win a single one of the cases in brought against its potential competitors. However, Abbott did succeed in manipulating the Hatch-Waxman provisions so that the FDA could not approve a competitor's Hytrin ANDA until March of 1998, and the purpose and effect of filing such suits was to eliminate competition in the

relevant market and to monopolize the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

88. Beginning on or about March 31, 1998, and continuing until a date unknown, Abbott and Zenith entered into a continuing illegal contract, combination or conspiracy, the purpose and effect of which was to eliminate competition in the relevant market and to allocate the relevant market between them in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

89. The agreement described above did not reasonably accomplish any pro-competitive objective of the Defendants. Moreover, any justification put forward to defend said agreement does not and cannot outweigh the anticompetitive effects of the agreements.

90. Defendants' agreement has caused and continues to cause substantial harm to the economies of Florida, Colorado and Kansas. Plaintiff States are entitled to injunctive relief under Section 16 of the Clayton Act in their common-law capacity as *parens patriae* to prevent and redress continuing injury to their citizens.

91. Plaintiff States hereby request an injunction requiring Abbott:

a. cease and desist from engaging in any future pattern or practice of sham litigation involving any pharmaceutical product for which Abbott is the NDA holder with the FDA;

b. give notice to the Plaintiff States of any patent infringement action brought against an ANDA holder pursuant to 21 U.S.C. § 355(j)(5)(B)(ii) and for which Abbott is the NDA holder for any pharmaceutical product for a period of ten (10) years from the date this injunction is entered;

c. provide the Plaintiff States, upon the request of any or all of the Plaintiff States and within ten (10) days, copies of any pleadings or other non-privileged filings relating to any

patent infringement action subject to the notice provision of Paragraph 86b, *above*, for a period of ten (10) years from the date this injunction is entered.

92. Plaintiff States hereby request an injunction requiring Zenith to cease and desist from entering into any agreement with any brand-name pharmaceutical manufacturer whereby Zenith agrees not to market a generic pharmaceutical product.

COUNT II – CONSPIRACY IN RESTRAINT OF TRADE

Plaintiff States repeat and reallege each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein. This claim is asserted against Geneva and Abbott.

93. Beginning on or about April 1, 1998, and continuing until at least August 13, 1999, Abbott and Geneva executed and agreed to participate in a continuing illegal contract, combination, or conspiracy, the purpose and effect of which was to eliminate competition in the relevant market and to allocate the relevant market between them in violation of Section 1 of the Sherman Act, 15 U.S.C. §1.

94. The agreement between Abbott and Geneva was anticompetitive and a *per se* violation of the antitrust laws. *See In re Terazosin Hydrochloride Antitrust Litigation*, No. 99-MDL-1371 (S.D. Fla. Dec. 13, 2000) (order granting Plaintiffs' Motion for Partial Summary Judgment).

95. But for Defendants' antitrust violations, Geneva would have entered the market with a generic version of Hytrin prior to August 13, 1999, and other generic manufacturers would have entered the market earlier than they actually entered. Plaintiff States and/or their assignors have been injured by Defendants' antitrust violations and have been forced to pay higher prices for Hytrin and its generic equivalent than would have been paid in the absence of Defendants' illegal conspiracy.

COUNT III – CONSPIRACY IN RESTRAINT OF TRADE

Plaintiff States repeat and reallege each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein. This claim is asserted against Zenith and Abbott.

96. Beginning on or about March 31, 1998, and continuing until a date unknown, Abbott and Zenith executed and agreed to participate in a continuing illegal contract, combination, or conspiracy, the purpose and effect of which was to eliminate competition in the relevant market and to allocate the relevant market between them in violation of Section 1 of the Sherman Act, 15 U.S.C. §1.

97. The agreement between Abbott and Zenith was anticompetitive and a *per se* violation of the antitrust laws. *See In re Terazosin Hydrochloride Antitrust Litigation,* No. 99-MDL-1371 (S.D. Fla. Dec. 13, 2000) (order granting Plaintiffs' Motion for Partial Summary Judgment).

98. But for Defendants' antitrust violations, Zenith would have entered the market with a generic version of Hytrin in 1998. Plaintiff States and/or their assignors have been injured by Defendants' antitrust violations and have been forced to pay higher prices for Hytrin and its generic equivalent than would have been paid in the absence of Defendants' illegal conspiracy.

COUNT IV - MONOPOLIZATION

Plaintiff States repeat and reallege each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein. This claim is asserted solely against Abbott.

99. Abbott engaged in exclusionary, anticompetitive conduct designed to prevent competition on the merits between Abbott and its generic competitors to the drug Hytrin. This conduct included the formation of an illegal agreement with Defendants Geneva and Zenith

recited above, as well as engaging in repeated prosecution of patent actions against generic manufacturers based on patents that Abbott knew to be invalid such that these actions amounted to nothing more than sham litigation. This conduct was calculated to illegally maintain Abbott's monopoly over the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

100. But for Abbott's illegal monopolization, generic manufacturers would have entered the market with generic versions of Hytrin as early as 1996. Plaintiff States and/or their assignors have been injured by Abbott's antitrust violations and have been forced to pay higher prices for Hytrin and its generic equivalent than would have been paid in the absence of those violations.

COUNT V - ATTEMPTED MONOPOLIZATION

Plaintiff States repeat and reallege each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein. This claim is asserted solely against Abbott.

101. Abbott engaged, with a dangerous probability of success, in a course of exclusionary, anticompetitive conduct designed to prevent competition on the merits between Abbott and its generic competitors to the drug Hytrin. This conduct included the formation of an illegal agreements with Defendants Geneva and Zenith, as well engaging in repeated prosecution of baseless patent actions against generic manufacturers such that these actions amounted to nothing more than sham litigation. This conduct was calculated to illegally maintain Abbott's monopoly over the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

102. At all relevant times, Abbott acted with the specific intent to monopolize the relevant market, and to destroy competition in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

103. But for Abbott's illegal attempted monopolization, generic manufacturers would have entered the market with generic versions of Hytrin as early as 1996. Plaintiff States and/or their assignors have been injured by Abbott's antitrust violations and have been forced to pay higher prices for Hytrin and its generic equivalent than would have been paid in the absence of those violations.

COUNT VI - VIII SUPPLEMENTAL STATE LAW CLAIMS

Plaintiff States repeat and reallege each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein.

104. Defendants' actions described herein constitute unfair or deceptive trade practices substantially affecting trade or commerce in Florida in violation of the Florida Deceptive and Unfair Trade Practices Act, § 501.201, *Florida Statutes, et seq*., as well as the Florida Antitrust Act of 1980, §542.18, *Florida Statutes, et seq*.

105. Defendants' actions described herein were and are in violation Kansas Restraint of Trade Act, *Kansas Statutes Annotated* 50-101 *et seq.* and the Kansas Consumer Protection Act *Kansas Statutes Annotated* 50-623 *et seq*.

106. Defendants' actions described herein were and are in violation of the Colorado Antitrust Act of 1992, § 6-4-104 and -105, *Colo. Rev. Stat.*.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff States respectfully pray this Court:

1. 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;

2. Adjudge and decree that Defendants have engaged in conduct in violation of the state statutes enumerated herein;

3. Enjoin and restrain, pursuant to federal and state law, Defendants Abbott and Zenith, their affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and employees thereof, 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 anticompetitive actions, and as further requested in Count I, *above*;

4. Disgorge Defendants of all unjust enrichment received as a result of their illegal conduct;

5. Enter judgment for the Plaintiff States awarding three (3) times the amount of damages sustained by the Plaintiff States and their respective agencies for direct purchases of Hytrin and its generic equivalents within the damages period;

6. Enter judgment for the Plaintiff States awarding damages sustained by the Plaintiff States and their respective agencies for direct purchases of Hytrin and its generic equivalents within the damages period in such manner consistent with the laws of each State;

7. Enter judgment for the States of Florida and Kansas awarding three (3) times the amount of damages sustained by injured consumers who were indirect purchases of Hytrin and its generic equivalents within the damages period;

8. Enter judgment for the States of Florida and Kansas awarding the amount of damages sustained by injured consumers who were indirect purchases of Hytrin and its generic equivalents within the damages period where such recovery is authorized by state law;

9. Enter judgment for the State of Kansas awarding the amount paid in full consideration or sum paid for the goods;

10. Enter judgment for the Plaintiff States fining Defendants the maximum civil penalties allowable under the laws of each State;

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

12. Grant such other relief as is just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff States demand a trial by jury of all issues so triable.

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