

IN THE CIRCUIT COURT OF WYOMING COUNTY, WEST VIRGINIA

STATE OF WEST VIRGINIA  
*ex rel.* DARRELL V. MCGRAW, JR.,  
ATTORNEY GENERAL,

Plaintiff,

vs.

Civil Action No. \_\_\_\_\_

ABBOTT LABORATORIES and  
GENEVA PHARMACEUTICALS, INC.

Defendants.

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**COMPLAINT**

Plaintiff, the State of West Virginia (“Plaintiff” or “the State”), by and through Darrell V. McGraw, Jr., the duly elected and current Attorney General, brings this action upon information and belief, against Defendants Abbott Laboratories and Geneva Pharmaceuticals, Inc. under the antitrust and consumer protection laws of West Virginia. For its Complaint, Plaintiff alleges as follows:

**Nature of Action**

1. The State of West Virginia and its citizens and residents spend hundreds of millions of dollars each year to provide or pay for health care and other necessary services and programs on behalf of indigents, government employees, injured workers, and other eligible citizens, including payments for the prescription drug Hytrin.

2. This is a civil antitrust and consumer protection action seeking declaratory relief, injunctive relief, damages, both actual and treble, civil monetary penalties and equitable relief in

the nature of disgorgement and/or restitution for defendants' violations of West Virginia statutes proscribing unfair methods of competition and unfair trade practices and relief arising out of the unlawful efforts of Defendant Abbott Laboratories ("Abbott") to prevent the marketing of a generic version of Hytrin, a highly successful and uniquely effective brand-name drug used in the treatment of hypertension (high blood pressure) and benign prostatic hyperplasia (enlarged prostate). Those efforts include a pattern of baseless and repetitive patent litigation against potential generic competitors, including Zenith Goldline Pharmaceuticals, Inc. ("Zenith") and Defendant Geneva Pharmaceuticals, Inc. ("Geneva"), as well as an independently unlawful agreement with Geneva under which Abbott paid Geneva not to market a generic version of Hytrin. The net effect of this illegal conduct has been to deprive the persons and entities on whose behalf Plaintiff brings this action of the benefits of generic competition.

3. As a consequence of Defendants' conduct, the State spends excessive amounts for prescription costs. In addition, natural persons who are citizens and residents of the State of West Virginia have made excessive payments for prescription drugs.

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### **Jurisdiction and Venue**

4. Jurisdiction is proper in this Court pursuant to W. Va. Code § 56-3-33a, W. Va. Code § 51-2-2, and W. Va. Const. art. VIII § 6.

5. Venue is proper pursuant to W. Va. Code § 47-18-15, W. Va. Code § 46A-7-114 and W. Va. Code § 56-1-1 because Defendants transact business in Wyoming County and throughout West Virginia.

### **Parties**

6. The Plaintiff, the State of West Virginia, by and through Darrell V. McGraw, Jr., the duly elected and current Attorney General, brings this action in its sovereign capacity on behalf of its political subdivisions and public agencies and Medicaid programs of the State, as indirect purchasers of Hytrin and generic Terazosin hydrochloride against Defendants Abbott Laboratories and Geneva Pharmaceuticals, Inc. under the antitrust and consumer protection laws of West Virginia. From October 15, 1995, to the present, Plaintiff purchased Hytrin in West Virginia other than for resale and was injured by the illegal conduct alleged herein. After August 12, 1999, Plaintiff purchased generic terazosin hydrochloride in West Virginia other than for resale and was injured by the illegal conduct alleged herein. Plaintiff also brings this action in its *parens patriae* capacity on behalf of natural persons residing in West Virginia who purchased Hytrin or generic terazosin hydrochloride in West Virginia other than for resale during these same time periods.

7. Defendant Abbott Laboratories (“Abbott”) is a corporation organized and existing under the laws of the State of Illinois and having its principal place of business in Abbott Park, Illinois. Abbott is a leading U.S. pharmaceutical company and the manufacturer of several top-selling brand-name prescription drugs, including Hytrin. In 1998, Hytrin was the 33<sup>rd</sup> best-selling prescription drug in the United States by dollar volume.

8. Defendant Geneva Pharmaceuticals, Inc. (“Geneva”) is a corporation organized and existing under the laws of the State of New Jersey and having its principal place of business in Broomfield, Colorado. Geneva develops, manufactures and markets generic drugs. Geneva sought and received FDA approval to market a generic version of Hytrin and would have begun marketing that product, but for the unlawful conduct described below.

## Operative Facts

### Federal Regulation of New Pharmaceutical Products

9. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, approval by the Food and Drug Administration (“FDA”) is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a new drug application (“NDA”) with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

10. New drugs that are approved for sale by the FDA are typically protected by a patent or patents, which provide the patent owner with the exclusive right to sell that drug in the United States for the duration of the patent or patents involved, plus any extensions. Under 21 U.S.C. § 355(b)(1), a patent holder seeking FDA approval for a new drug is required to “file with the FDA the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” If the patent holder receives FDA approval and subsequently obtains an additional patent on the drug, the patent holder is required to submit the patent number and expiration date of the new patent to the FDA within 30 days after the patent is issued. 21 U.S.C. § 355(c)(2).

11. Patent information received by the FDA with respect to approved drugs is published in a book entitled “Approved Drug Products With Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book,” where it can be easily found and consulted by future FDA applicants.

12. Generic drugs are drugs which the FDA has found to be bioequivalent to brand name drugs. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generics continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 15% of the price of the brand-name drug and have captured as much as 90% of the brand-name drug's pre-generic sales.

13. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Pharmacies in West Virginia are required by statute, W Va. Code § 30-5-12b, to substitute generic equivalents for prescribed patent medications except in limited circumstances permitted by statute. State law requires substitution of generic drugs for brand-name drugs in order to lower health care costs.

#### **Abbreviated New Drug Applications and Generic Drugs**

14. Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments to the Food and Drug Act, a drug manufacturer may seek expedited FDA approval to market a generic version of a patented brand-name drug by filing an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug. Congress's principal purpose in enacting the Hatch-Waxman

Amendments was “to bring generic drugs onto the market as rapidly as possible.” *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

15. An applicant filing an ANDA for a generic version of a brand-name drug must certify to the FDA that one of the following conditions is satisfied:

1. the brand-name manufacturer has not filed patent information with the FDA (a “Paragraph I certification”);

2. the patent or patents have expired (a “Paragraph II certification”);

3. the patent will expire on a particular future date and the generic manufacturer does not seek to market its generic product before that date (a “Paragraph III certification”); or

4. the patent is invalid and/or will not be infringed by the generic manufacturer’s product (a “Paragraph IV certification”).

21 U.S.C. § 355(j)(2)(A)(vii).

16. If the generic manufacturer makes a Paragraph IV certification, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. The patent owner, upon receiving a Paragraph IV certification from an ANDA applicant, is given a statutory period of forty-five days in which to initiate a patent infringement action against the applicant. If no action is initiated within 45 days, FDA approval of the generic proceeds without regard to patent issues. However, if a patent infringement lawsuit is brought within the 45-day window, FDA approval of the generic drug is automatically postponed until the earliest of: (i) the expiration of the patent; (ii) thirty months from the patent holder’s receipt

of the Paragraph IV certification; or (iii) a final judicial determination of non-infringement from which no appeal can be or has been taken. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(e).

18. The Hatch-Waxman Amendments and the federal regulations that implement them do not give the FDA authority to resolve issues of patent law. The FDA is required to accept as true patent information it obtains from patent holders, such as patent expiration dates, and to withhold its approval of new generic drugs whenever the patent holder presents a litigated dispute (whether genuine or not) regarding the validity or infringement of a patent. If an unscrupulous patent holder is willing to provide false information to the FDA or to file frivolous patent infringement actions in order to delay the onset of generic competition, the FDA is powerless to stop it.

19. Under 21 U.S.C. § 355(j)(5)(B)(iv), the first applicant to submit an ANDA with a paragraph IV certification for a generic version of a brand-name drug will receive a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA. The 180-day period begins when the first ANDA applicant either begins selling the generic drug or obtains a final judgment of non-infringement in a patent infringement action, whichever occurs first. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without competition from other generic manufacturers. By the same token, if the patent holder is able to delay the events which trigger the start of the 180-day period of exclusivity, so that the period never begins to run, it can delay indefinitely the entry of all generic competitors.

### **Terazosin Hydrochloride-based Prescription Drugs**

20. Hytrin, a form of terazosin hydrochloride, belongs to a group of drugs known as “alpha blockers,” which are used for the treatment of hypertension and other diseases. Although Hytrin is used to treat hypertension, it is marketed today primarily as a treatment for benign prostatic hyperplasia (enlarged prostate). Both hypertension and benign prostatic hyperplasia are chronic conditions that affect millions of Americans, many of whom are senior citizens.

21. The pioneer new drug in the United States containing terazosin hydrochloride as its active ingredient for treating hypertension and benign prostatic hyperplasia was Hytrin, manufactured by Defendant Abbott.

22. Abbott has received a number of patents for terazosin hydrochloride, both alone and in combination with other substances. In 1977, Abbott received U.S. Patent No. 4,026,894 (the “894 patent”), covering the compound terazosin hydrochloride itself. That patent expired on or about May 31, 1994. In 1978, Abbott received U.S. Patent No. 4,112,097 (the “097 patent”), covering a pharmaceutical composition containing terazosin hydrochloride, as well as a method of treating hypertension by the administration of terazosin hydrochloride. The 097 patent expired on October 14, 1995.

23. The 894 and 097 patents are the only patents broad enough to prevent any generic version of Hytrin from coming to market. Both patents had expired by October 1995. By late 1995, a generic manufacturer could and would have begun marketing a generic version of Hytrin if it had not been prevented from doing so by Abbott’s unlawful efforts to extend its patent monopoly beyond the expiration of the patents on which its monopoly was based.

24. In 1981, Abbott was issued U.S. Patent No. 4,251,532 (the “532 patent”), covering terazosin hydrochloride dihydrate, which is the specific chemical compound marketed



as Hytrin. On August 7, 1987, Abbott received FDA approval to market Hytrin in the United States, and Abbott began marketing terazosin hydrochloride dihydrate as Hytrin shortly thereafter. The 532 patent expired on February 17, 2000. Other patents which Abbott claims are applicable to Hytrin include U.S. Patents No. 5,294,615 (the “615 patent”); No. 5,212,176 (the “176 patent”); No. 5,412,095 (the “095 patent”) and No. 5,504,207 (the “207 patent”). Prior to April 1995, the 894, 097, and 532 patents were the only patents claimed to be applicable to Hytrin that Abbott had submitted for listing in the Orange Book. In particular, Abbott had not submitted the 615 patent for inclusion in the Orange Book prior to 1995.

#### **Generic Terazosin Hydrochloride (Zenith)**

25. On or about June 2, 1994, Zenith Goldline Pharmaceuticals, Inc. (“Zenith”) filed an Abbreviated New Drug Application with the FDA seeking permission to market a generic version of anhydrous terazosin hydrochloride. Zenith develops, manufactures and markets generic drugs. Anhydrous terazosin hydrochloride, unlike terazosin hydrochloride dihydrate (Hytrin), contains no water molecules.

26. In submitting its ANDA, Zenith made several certifications to the FDA pursuant to the Hatch-Waxman Act, including a Paragraph IV certification with respect to Abbott’s 532 patent (the patent covering terazosin hydrochloride dihydrate). Zenith’s Paragraph IV certification stated that its proposed generic product would not infringe the 532 patent because Zenith’s proposed generic product was a form of anhydrous terazosin hydrochloride rather than a form of terazosin hydrochloride dihydrate. Zenith’s ANDA did not address potential infringement of the 615 patent, which Abbott had not submitted for listing in the Orange Book.

27. On or about November 14, 1994, Abbott filed an action against Zenith in the United States District Court for the Southern District of Illinois, alleging that Zenith's application infringed the 615 patent, a patent which Abbott had failed to submit for listing in the Orange Book prior to Zenith's application. Pursuant to Zenith's motion, that complaint was dismissed on March 15, 1995 for failure to state a claim, based on Abbott's failure to submit the 615 patent for listing in the Orange Book. Abbott appealed. Abbott's 1994 action against Zenith, and its subsequent appeal in that action, required the FDA to delay approval of Zenith's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

28. In April 1995, Abbott belatedly submitted the 615 patent for inclusion in the Orange Book. On or about June 5, 1995, Abbott filed a second action against Zenith in the United States District Court for the Northern District of Illinois, again alleging that Zenith's proposed generic product infringed the 615 patent. Zenith again moved to dismiss for failure to state a claim. On September 28, 1995, the District Court in Illinois issued an order dismissing Abbott's complaint for failure to state a claim, based on the Court's holding that the listing of the 615 patent in the Orange Book was untimely. Abbott appealed. Abbott's submission of the 615 patent to the FDA, its 1995 action against Zenith and its subsequent appeal in that action again required the FDA to delay approval of Zenith's ANDA.

29. During 1995 and 1996, Abbott submitted the 176, 095 and 207 patents to the FDA for inclusion in the Orange Book. Because of Abbott's submissions, the FDA required Zenith to make certifications with respect to these three patents before it would consider Zenith's ANDA.

30. In April 1996, Zenith filed a complaint against Abbott in the United States District Court for the District of New Jersey seeking, among other relief, 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 an injunction ordering Abbott to delist those five patents.

31. On August 7, 1996, the District Court in New Jersey denied Abbott's motion to dismiss. On or about August 20, 1996, Abbott filed an answer and counterclaims against Zenith for infringement of the 615 patent, the 207 patent and the 097 patent. On October 2, 1997, the Court denied a motion filed by Zenith seeking to preliminarily enjoin Abbott from continuing to list the 207 patent and the 097 patent in the Orange Book, a ruling which Zenith appealed. The New Jersey litigation remained pending until Zenith and Abbott entered into an agreement settling the litigation.

32. Thus, Zenith consistently took the position throughout 1995, 1996 and 1997 that its proposed generic product did not infringe any valid patent owned by Abbott, including specifically the 532 patent covering terazosin hydrochloride dihydrate. Zenith certified to the FDA at the time it filed its ANDA that its proposed generic product would not infringe the 532 patent, and Abbott has never challenged that certification in any of its patent litigation with Zenith. Nevertheless, Abbott and Zenith ultimately entered into an agreement under which Abbott agreed to pay Zenith \$24 million per year not to market its generic version of Hytrin until the expiration of the 532 patent in February 2000.

#### **Generic Terazosin Hydrochloride (Geneva)**

\_\_\_\_\_33. Geneva filed an ANDA for a generic tablet version of terazosin hydrochloride in January 1993 and in December 1995, Geneva filed an ANDA for a generic capsule version of terazosin hydrochloride. Geneva made the necessary certifications to the FDA, including a

certification that Abbott's 097 patent would expire in October 1995, prior to Geneva's marketing of its proposed generic product. On November 16, 1995, Abbott filed a patent infringement action against Geneva in the United States District Court for the Northern District of Illinois based on its contention that the 097 patent would not expire until 1997. That action was consolidated with a similar action filed by Abbott against Novopharm Ltd. ("Novopharm").

34. Abbott's position that the 097 patent would remain in effect until 1997 was reflected in the patent information Abbott had provided to the FDA for inclusion in the Orange Book, which the FDA was required to accept as true. Abbott's submission of false expiration information to the FDA, and its commencement of the 1995 patent infringement action against Geneva, required the FDA to delay approval of Geneva's ANDA.

35. On March 15, 1996, the Illinois District Court ruled that Abbott's 097 patent had expired on October 14, 1995, as Geneva and Novopharm contended. On April 9, 1996, the Illinois District Court amended its judgment by ordering Abbott to delist the expired 097 patent from the Orange Book. Abbott appealed both rulings and, on January 14, 1997, the United States Court of Appeals for the Federal Circuit affirmed the District Court's rulings in all respects. *Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305 (Fed. Cir. 1997). Abbott's appeal of the district court's judgment required the FDA to delay approval of Geneva's ANDA.

36. In April 1996, Geneva made a Paragraph IV certification stating that its proposed generic product did not infringe the 207 patent and, on April 29, 1996, Geneva sent the statutorily required notice of its Paragraph IV certification to Abbott. On June 4, 1996, Abbott brought a second patent infringement action against Geneva based on Geneva's tablet certification, alleging that Geneva's proposed product infringed the 207 patent. On September 1,

1998, the District Court in Illinois held that the 207 patent was invalid. On July 1, 1999, the Federal Circuit affirmed the District Court's ruling in all respects. *Abbott Laboratories v. Geneva Pharmaceuticals, Inc. et al.*, Case No. 98-1593 (Fed. Cir. July 1, 1999).

37. Abbott's 1996 action against Geneva, and its subsequent appeal in that action, required the FDA to delay approval of Geneva's tablet ANDA.

38. On or about March 30, 1998, the FDA approved Geneva's capsule ANDA.<sup>1</sup> However, Geneva did not market its generic product until August 12, 1999 because of the unlawful conspiracy described below.

### **Abbott's Exclusionary Conduct**

39. Between November 1994 and April 1998, Abbott filed multiple patent infringement lawsuits against potential generic competitors seeking to market a generic version of Hytrin: against Zenith, against Geneva, against Novopharm, against Invamed, against Mylan, and against Warner. Abbott lost or voluntarily dismissed all lawsuits at the district court level. When it chose to appeal those district court rulings, Abbott lost at the appellate level as well. Although Abbott has been uniformly unsuccessful in obtaining legal relief, its lawsuits succeeded in delaying the entry of a generic competitor to Hytrin. The lawsuits had that effect not because generic competitors were dissuaded by the threat of potential patent liability, but because the mere pendency of such litigation prevented the FDA from permitting a generic competitor to enter the market.

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<sup>1</sup>Abbott neglected to sue Geneva for infringement of the 207 based on Geneva capsule certification.

40. The patent infringement actions brought by Abbott against its generic competitors have been objectively baseless in the sense that no reasonable litigant could have realistically expected success on the merits. Each action has lacked probable cause. Each action has been a sham.

41. Moreover, Abbott's purpose in bringing the patent infringement actions has been to use the litigation process, rather than the outcome of that process, as an anticompetitive weapon. Its purpose in filing each action has not been to obtain the relief requested in its complaint, but rather to trigger legally required delays in the FDA approval process. Abbott was subjectively aware that its patent infringement actions would not succeed.

42. In addition to bringing sham and baseless litigation, Abbott has submitted false information to the FDA which the FDA was required to accept as true, and on the basis of which the FDA was required to delay or withhold approval of proposed generic products. Its purpose in providing false information to the FDA has not been to obtain favorable rulings from the FDA (rulings which the FDA is incapable of giving), but merely to trigger legally required regulatory delays and force its competitors to seek relief in court.

43. The purpose and effect of Abbott's regulatory and litigation efforts have been to extend its patent monopoly beyond the term to which it was lawfully entitled, to delay the commencement of generic competition and to maintain supracompetitive profits on sales of Hytrin. Those efforts were successful in delaying FDA approval of a generic version of Hytrin from 1995 until March 30, 1998 (the date on which FDA permitted Geneva to begin marketing its capsule product). When it became clear that those efforts had run their course, Abbott turned from unilateral anticompetitive conduct to conspiracy.

### **Abbott's Illegal Agreements with Geneva**

44. On or about April 1, 1998, Defendants Abbott and Geneva entered into an agreement under which Abbott agreed to make monthly payments of \$4.5 million in exchange for Geneva's agreement not to market its FDA-approved generic capsule version of Hytrin until the conclusion of Abbott's 1996 patent infringement action against Geneva's tablet product.

45. Because of the 180-day period of exclusivity described above, Defendants' illegal conduct prevented any other generic competitor (such as Novopharm, Invamed, Mylan or Warner) from marketing a generic version of Hytrin. The net result of Defendants' conduct is that competition did not begin until August 13, 1999 when Geneva began marketing its capsule product.

46. The agreement between Abbott and Geneva is a horizontal market allocation agreement and has been held illegal *per se* under federal case law. *In re Terazosin Hydrochloride Antitrust Litigation*, Case No. 99-MDL-1317-Seitz/Garber (S.D. Fla. Dec. 15, 2000).

47. Defendants' unlawful market allocation agreement is a private agreement between private parties, and the anticompetitive effects that flow from it are the result of purely private action. No agency or official of any government, whether federal, state or local, has chosen to create those anticompetitive effects.

### **Relevant Markets**

48. At all material times, the relevant product market is the manufacture and sale of terazosin-based prescription drugs.

49. At all material times, the relevant geographic market is West Virginia.

50. At all material times, before Geneva's entry on August 13, 1999, Abbott's share of the relevant market has been 100%.

**Market Effects**

51. Abbott's exclusionary conduct, and its market allocation agreement with Defendant Geneva, unlawfully protected Hytrin from generic competition since 1995. But for Defendants' illegal conduct, a generic competitor would have begun marketing a generic version of Hytrin some time in 1995. If a generic competitor had been able to enter the market and compete with Abbott, purchasers would have been free to substitute lower-priced generics for the higher-priced brand name drug, or Abbott would have been forced to reduce prices on Hytrin to a level closer to those of its generic competitors, or both. By preventing generic competitors from entering the market, Defendants have deprived Plaintiff of the benefits of competition.

52. Zenith, Geneva and other generic drug manufacturers have been ready and able to begin marketing a generic version of Hytrin since 1995. By unlawfully extending Abbott's patent monopoly, Defendants' conduct has caused the State of West Virginia, and its citizens to make excessive payments for Hytrin.

**COUNT I**

**(Action For Damages Under W. Va. Code §§ 47-18-1, et seq.**

**Against Defendants On Behalf of the State and Its Citizens)**

53. Plaintiff repeats and realleges each and every allegation of this Complaint with the same force and effect as if fully set forth herein.

54. W. Va. Code § 47-18-3 provides:



(a) Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in this State shall be unlawful.

(b) Without limiting the effect of subsection (a) of this section, the following shall be deemed to restrain trade or commerce unreasonably and are unlawful:

(1) A contract, combination or conspiracy between two or more persons: (A) For the purpose or with the effect of fixing, controlling, or maintaining the market price, rate or fee of any commodity or service; or (B) Fixing, controlling, maintaining, limiting or discontinuing the production, manufacture, mining, sale or supply of any commodity, or the sale or supply of any service, for the purpose or with the effect of fixing, controlling or maintaining the market price, rate or fee of the commodity or service; or (C) Allocating or dividing customers or markets, functional or geographic, for any commodity or service.

55. The Abbott-Geneva Agreement is an agreement between horizontal competitors in the same chain of distribution, which has the effect of allocating market share and restraining trade. Such an allocation is a classic example of a “contract, combination or conspiracy between two or more persons...[f]or the purpose or with the effect of fixing, controlling, or maintaining the market price...of [a] commodity ...; [f]ixing, controlling, maintaining, limiting or discontinuing the production, manufacture, ... sale or supply of [a] commodity, ...for the purpose or with the effect of fixing, controlling or maintaining the market price ... of the commodity ...; and/or [a]llocating or dividing customers or markets, functional or geographic, for [a] commodity ...,” which is per se prohibited under W. Va. Code § 47-18-3.

56. Abbott and Geneva combined to form a trust and conspired to unreasonably

restrain trade in the market for Hytrin and its generic bioequivalents as evidenced by the Abbott-Geneva Agreement, and succeeded in restraining trade in West Virginia for Hytrin and its generic bioequivalents.

57. The foregoing conduct violates W. Va. Code § 47-18-1, *et seq.*

58. The State, its citizens and residents who have purchased Hytrin or its generic bioequivalents have been damaged by Defendants' unlawful acts.

## COUNT II

**(Action for Damages Under W. Va. Code §§ 47-18-1, *et seq.***

**Against Abbott On Behalf of the State and Its Citizens)**

59. Plaintiff repeats and realleges each and every allegation of this Complaint with the same force and effect as if fully set forth herein.

60. W. Va. Code § 47-18-4 provides:

The establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade of commerce, any part of which is within the State, by any persons for the purpose of excluding competition or controlling, fixing or maintaining prices is unlawful.

61. Abbott engaged in the submission of false patent information to the FDA, and the initiation and continued prosecution of baseless, sham patent infringement actions against prospective horizontal competitors, including Zenith and Geneva, solely for the purpose of delaying the entry of other manufacturers' generic versions of Hytrin to the market for Hytrin and its generic bioequivalents. By preventing the entry of bioequivalent generics for Hytrin, Abbott

illegally maintained its 100% market share and ensured that prices paid by Plaintiff for terazosin hydrochloride remained supra-competitive, in violation of W. Va. Code § 47-18-1, *et seq.*

62. Abbott's illegal conduct referenced in this count began prior to October 15, 1995, when, but for its illegal conduct, a generic version of Hytrin would have first been marketed, and such illegal conduct continued without interruption into 1999. This course of conduct amounted to a continuing violation within the meaning of W. Va. Code § 47-18-11, and therefore is deemed to have arisen within the applicable limitations period established by that provision.

63. At all relevant times, Abbott acted with specific intent to monopolize the relevant market, and to destroy competition in the market for Hytrin and its generic bioequivalents in violation of W. Va. Code § 47-18-4.

64. The State and its citizens who have purchased Hytrin or its generic bioequivalents have been damaged by Defendant Abbott's unlawful acts in violation of W. Va. Code § 47-18-4 and which amount to a continuing violation within the meaning of W. Va. Code § 47-18-11.

### **COUNT III**

**(Action for Equitable Relief Under W.Va. Code § 46A-1-101 *et seq.***

**Against Abbott)**

65. Plaintiff repeats and realleges each and every allegation of this Complaint with the same force and effect as if fully set forth herein.

66. The State has, through its legislature, enacted Title 6 of the West Virginia

Consumer Credit Protection Act, entitled “General Consumer Protection,” which is designed to protect consumers from fraudulent and deceptive practices. W. Va. Code §§ 46A-6-101 to -110, 46A-7-102 and 46A-7-108.

67. The Attorney General of the State of West Virginia is specifically charged with the administration of W. Va. Code §§ 46A-6-101, *et seq.*, and may act on his own motion as the agent and legal representative of the State in civil proceedings to enforce said statute. W. Va. Code §§ 46A-6-103, W. Va. Code §§ 46A-7-102, 108, 110, 111.

68. The Defendants illegal actions which violate the antitrust laws of the State of West Virginia pursuant to W. Va. Code § 47-18-1, *et seq.*, in unreasonably restraining trade, in creating a monopoly and in misrepresenting the true nature of Hytrin, constitute unfair methods of competition and/or unfair and/or deceptive acts or practices injurious to the public interest and in violation of W. Va. Code § 46A-6-104.

69. As described in this Complaint, the actions of Defendants required the State of West Virginia and its citizens and residents to purchase Hytrin when they could have purchased a less expensive generic equivalent and thus violated the West Virginia Consumer Credit Protection Act and W. Va. Code § 46A-6-104, in that Defendants’ actions are unfair methods of competition and/or unfair deceptive acts or practices in violation of W. Va. Code § 46A-1-101, *et seq.*

70. The Defendant has repeatedly and willfully violated W. Va. Code § 46A-1-101, *et seq.*

71. The Defendants’ unfair competition and unfair or deceptive acts or practices have

injured the State of West Virginia and its citizens and residents and they are entitled to all equitable relief including restitution and/or disgorgement of unlawful profits from the Defendants.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, the State of West Virginia, prays for a judgment against Defendants as follows:

- a. Adjudge and decree that Defendants have engaged in conduct in violation of the West Virginia Antitrust Act, W. Va. Code § 47-18-1 *et seq.*;
- b. Adjudge and decree that Defendants have engaged in conduct in violation of the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101 *et seq.*;
- c. Enjoin and restrain the Defendants, 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 set forth above;
- d. Awarding Plaintiff treble damages for Defendants' violations of W. Va. Code § 47-18-1, *et seq.*, in an amount to be determined at trial;
- e. Granting Plaintiff equitable relief in the nature of disgorgement and/or restitution due to defendants' wrongful conduct, with said amount to be determined at trial pursuant to the West Virginia Consumer Credit and Protection Act;
- f. Awarding maximum civil penalties as provided for by law;
- g. Granting Plaintiff the costs of prosecuting this action, together with interest and reasonable attorneys' fees in connection with the prosecution of this case; and
- h. Granting such further relief as this Court may deem just and proper under the circumstances.

**JURY DEMAND**

Plaintiff demands a trial by jury on all claims for which there is a right to a jury trial.

Dated: September \_\_\_\_\_, 2001

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