

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
NORFOLK DIVISION

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NORFOLK, VA.

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THE CITY OF NEW YORK,	)	
	)	Docket No.
Plaintiff,	)	
	)	
vs.	)	
	)	
GLAXOSMITHKLINE PLC, and	)	
SMITHKLINE BEECHAM CORPORATION,	)	Jury Trial Demanded
	)	
Defendants.	)	
_____	x	

Plaintiff, the City of New York ("the City"), by its attorneys, GOODKIND LABATON RUDOFF & SUCHAROW LLP, MICHAEL A. CARDOZO, Corporation Counsel of the City of New York, and GLASSER AND GLASSER P.L.C., for its complaint against GlaxoSmithKline PLC and SmithKline Beecham Corporation (collectively "GSK"), upon information and belief, alleges as follows:

**INTRODUCTION**

1. The City brings this complaint for monetary, equitable and injunctive relief from harm caused by Defendants' marketing and sales of the drug Augmentin® in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, New York State's Medicaid fraud statute, Soc. Serv. L. § 145-b, New York State antitrust and unfair business competition laws, Gen. Bus. L. §§ 340 and 349, and the law of unjust enrichment.

2. The City pays approximately 25% of the costs of all Medicaid expenditures incurred on behalf of City residents, including those for prescription drugs. In 2002 alone, Medicaid paid \$14,713,827 to reimburse purchases of Augmentin® by New York City

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residents. Pursuant to state and federal Medicaid law, the City is entitled to seek recovery (including treble damages) for all Medicaid payments for Augmentin® made on behalf of City residents.

3. Augmentin®, a brand-name prescription drug, is a broad-spectrum oral antibacterial combination of the antibiotic amoxicillin and potassium clavulanate. Augmentin® is used to treat a wide range of common bacterial infections, particularly respiratory infections.

4. Through fraud and other unlawful, anticompetitive activities, Defendants have maintained an unlawful monopoly on the manufacture, marketing and sales of Augmentin® in the United States since 1984. Defendants' unlawful conduct has prevented and continues to prevent generic versions of Augmentin® from coming to the United States market, thereby causing injury to the City as a Medicaid payor.

5. Plaintiff alleges that Defendants have unlawfully extended their monopoly in the United States market for amoxicillin-potassium clavulanate by (i) improperly filing and prosecuting a series of redundant patent applications that merely replicated prior art established by earlier, original patents ("double patenting"); (ii) using redundant patents that issued from those applications to prevent generic drug makers from entering the market for generic Augmentin®; and (iii) including at least some of the redundant patents in submissions to the Food and Drug Administration ("FDA") in a manner intended to have the unlawful effect of preventing or inhibiting generic competition in the Augmentin® market.

6. Two series of redundant patents held by Defendants – a series of three patents that issued in 1985, and a series of four patents that issued in the years 2000 and 2001 – have now been held by this Court to be invalid, a decision that has been affirmed by the Court of Appeals for the Federal Circuit.

7. Defendants long enjoyed an unlawful monopoly made possible by these invalid patents, and still benefited during the pendency of the patent litigations by, among other things, threatening generic competitors with monetary damages for infringement of these invalid patents.

8. Generic drug makers have filed applications with the FDA requesting approval to market generic versions of Augmentin®. At least four generic manufacturers<sup>1</sup> have received FDA approval to market generic dosages of Augmentin®. Nevertheless, due to Defendants' multiple patent filings, and threats of economic reprisal, these approved generic formulations of Augmentin® were not immediately made available to the United States market, and generic companies have been slower to satisfy the market demand than they would have been but for Defendants' anticompetitive efforts.

9. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff has been denied the lower costs resulting from free and unrestrained competition in the market for amoxicillin-potassium clavulanate. Defendants' patent filings, litigation and other unlawful conduct constitute, *inter alia*, a deliberate scheme to monopolize the market for Augmentin® and its generic equivalents, and a violation of Medicaid law.

## **PARTIES**

### **Plaintiff**

10. Plaintiff City of New York is a municipal corporation organized pursuant to the laws of the State of New York. By statute, the City pays 25% of most Medicaid costs, including prescription drug costs, for City residents. N.Y. Social Services Law § 368-a.

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<sup>1</sup> Two of these manufacturers, Lek Pharmaceuticals and Geneva Pharmaceuticals, are owned by the same parent, Novartis AG.

Because of Defendants' anticompetitive, fraudulent, and inequitable conduct, which has prevented generic competition for Augmentin® and has led to unlawful monopolistic prices, the City, along with the State and Federal governments, has overpaid for Augmentin® and its generic equivalents on behalf of Medicaid recipients.

**Defendants**

11. Defendant GlaxoSmithKline PLC is a United Kingdom corporation, with its principal place of business at Glaxo Wellcome House, Berkeley Avenue, Grenford, Middlesex, UB6 ONN, United Kingdom. GlaxoSmithKline was formed following the December 2000 merger of SmithKline Beecham PLC and Glaxo Wellcome PLC.

12. Defendant SmithKline Beecham Corporation is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania. Its principal offices are located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham conducts business in the name of GlaxoSmithKline, Inc.

13. The acts alleged in this Complaint to have been done by Defendants were authorized, ordered and performed by their officers, directors, agents, employees, representatives or subsidiaries while engaged in the management, direction, control or transaction of their business affairs.

**JURISDICTION AND VENUE**

14. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief, as well as for reasonable attorneys' fees and costs, with respect to injuries sustained by Plaintiff arising from violations by Defendants of the federal antitrust laws, including Section 2 of the Sherman Act, 15 U.S.C. § 2.

15. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

16. This Court also has jurisdiction by virtue of diversity of citizenship, pursuant to 28 U.S.C. § 1332. The amount in controversy is in excess of \$75,000.

17. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1407, because Defendants do business in this judicial district.

### **INTERSTATE TRADE AND COMMERCE**

18. At all times relevant herein, Defendants manufactured, marketed and sold substantial amounts of Augmentin® in a continuous and uninterrupted flow of interstate commerce. Defendants utilized the United States mails and interstate and international telephone lines as well as means of interstate and international travel in order to effectuate their scheme to monopolize the Augmentin® market. The illegal monopolization and attempt to monopolize the market for Augmentin® has, therefore, substantially affected interstate and foreign commerce.

### **RELEVANT MARKET**

19. To the extent applicable to the claims alleged herein, the relevant product market is the market for the manufacture and sale of Augmentin® and its generic bioequivalents.

20. The relevant geographic market is the United States as a whole.

21. Until July 15, 2002, Defendants' market share in the relevant product and geographic markets was 100 percent.

### **RELEVANT TIME PERIOD**

22. The Relevant Time Period is from December 25, 2001 to the present.

## **FACTS**

### **A. New Drug Applications**

23. The laws governing pharmaceutical products were intended to balance the competing policy goals of allowing new drug innovators to obtain an economic return on their investments, while also allowing consumers, governments and insurers access to more affordable generic versions of brand-name drugs. Defendants have caused Plaintiff to sustain injury to its business or property by thwarting the intention of the law governing pharmaceutical products and forcing Plaintiff to pay supracompetitive prices for Augmentin®.

24. The Federal Food, Drug and Cosmetic Act (the "FDCA") regulates the manufacture and distribution of drugs and medical devices in the United States, 21 U.S.C. § 301 *et seq.* Under the FDCA, the FDA must grant pre-market approval before a company may sell a new drug – often referred to as a "pioneer" or "branded" drug – in interstate commerce in the United States. 21 U.S.C. § 355(a). Pre-market approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FDCA, demonstrating that the drug is safe and effective for its intended use.

25. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to exclude others from making, using or selling that new drug in the United States for the duration of the patents, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("the Hatch-Waxman Act").

26. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a

method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

27. Once the NDA is approved, any claimed patents are listed with the FDA in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), where it can be easily found and consulted by future FDA applicants.

28. If pursuant to 21 U.S.C. § 355(c)(2), the pioneer drug manufacturer is issued a new patent after NDA approval that claims the drug or methods of its use, the company must supplement its NDA by listing such new patents within 30 days of issuance. Thereafter, the FDA publishes the new patent in a supplement to the Orange Book. The FDA is required to accept as true patent information it obtains from patent holders, such as whether a patent covers a particular drug product. If an unscrupulous patent holder is willing to provide false information to the FDA or files frivolous patent infringement actions to delay the onset of generic competition, the FDA is powerless to stop it.

29. Once the FDA approves the safety and effectiveness of a new drug, it may be used in the United States only under the direction and care of a doctor who writes a prescription specifying the drug, which must be purchased from a licensed pharmacist. Generally, the pharmacist must, in turn, fill the prescription with the drug specified by the physician unless a generic version is available that has been approved by the FDA for substitution as bioequivalent.

**B. Abbreviated New Drug Applications For Generic Drugs**

30. *Generic drugs are drugs that the FDA has found to be "bioequivalent" to a corresponding brand-name drug. A generic drug is bioequivalent if it provides the identical therapeutic benefits and has the same active chemical composition as its brand-name counterpart.*

31. The Hatch-Waxman Act provides that companies may seek approval to produce and market a generic form of a previously approved, or "pioneer" drug by filing only an "Abbreviated New Drug Application ("ANDA") that relies on the safety and effectiveness findings reported in the NDA for the previously approved drug. One of Congress' central goals in enacting the Hatch-Waxman Act and the ANDA provision was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

32. The ANDA must include information concerning the generic drug company's position with respect to the patent for the previously approved drug, and must include one of four certifications. Only the so-called "Paragraph IV Certification" is relevant here. It requires the ANDA filer to certify that the patent for the pioneer drug is invalid or will not be infringed upon by the generic drug company's proposed product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

33. If the ANDA does not address all of the patents listed for a drug in the Orange Book by means of the required certifications, the FDA will not approve the generic drug for sale.

34. After filing, a generic company must promptly disclose its Paragraph IV Certification to both the NDA owner and the owner of the patent(s) at issue. Under the terms of the Hatch-Waxman Act, the filing of a Paragraph IV Certification triggers the time by which a patent owner may initiate an action for patent infringement and thereby delays the FDA approval of a generic version of the NDA owner's drug. If the patent owner fails to initiate a patent infringement action within 45 days after receiving the generic manufacturer's Paragraph IV Certification, then the FDA may approve the generic manufacturer's ANDA. If, however, the

patent owner initiates an infringement action against the ANDA within 45 days, the FDA is statutorily prohibited from approving the ANDA until the earlier of either 30 months or a final decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(iii).

35. The Hatch-Waxman Act permits ANDA applicants to perform all necessary testing, submit an application for approval, and receive tentative approval before the relevant patent(s) expire. Prior to the Hatch-Waxman Act, a generic applicant had to wait until all patents had expired prior to beginning the approval process, resulting in unnecessary delays.

**C. The Fraudulent Filing of Multiple Overlapping Patents to Unlawfully Extend Patent Life**

36. Pursuant to 35 U.S.C. § 154(a)(2)(1994), holders of valid patents have the "right to exclude others from making, using, offering for sale or selling the invention throughout the United States."

37. At the time the original patents covering Augmentin® were issued, the statutory patent exclusivity period was 17 years. Under current law applicable to new patents, this right of exclusivity extends for a period beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.

38. Because patent holders have tried wrongfully to extend the period of exclusivity by filing claims in a later patent that are not distinct from earlier claims, courts invalidate as obviousness-type double patenting claims that are not "novel and distinct from all previously claimed patented inventions the holder owns." See *Geneva Pharmaceuticals, Inc. v GlaxoSmithKline PLC*, 189 F. Supp. 2d 377, 384 (E.D. Va. Feb. 25, 2002). A later patent is not "patentably distinct" from an earlier claim if the later claim is obvious or inevitable in light of an

earlier claim. If a later claim is anticipated by an earlier claim, there can be no patentable distinction. *See id.*

39. When two patents are not distinct, the doctrine of “obviousness-type double patenting” applies, and “requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue.” *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 957 (Fed. Cir. 2001).

40. Defendants’ filing and defense of obviously invalid patents are part of a policy of Defendants, sometimes euphemistically referred to in the industry as “life-cycle management” or “evergreening,” to file patents without regard to their merits and for the purpose of injuring competitors. Indeed, in a December 2003 meeting for investors, GSK CEO Jean-Pierre Garnier admitted that Defendants seek to be “clever” with their patents in order to defend their “life cycle” through on-going programs at Defendants’ businesses.

#### **D. The Effect on Price of Generic Drug Entry**

41. Generic drugs are invariably priced substantially below the branded drugs to which they are bioequivalent. Typically, the first generic drug is sold at a substantial discount to the brand-name drug, followed by steeper discounts as more companies begin selling the generic. The beneficiaries of this competition are the patients, third-party payors and government entities who bear the cost of these drugs.

42. As additional generic competitors come to market, the price of the generic equivalents 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. Unless the branded manufacturer lowers prices to meet competition, a

branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition.

**E. New York State Medicaid Pricing and New York City's Medicaid Obligations**

43. The Medicaid Program is jointly administered by federal, state and local governments. Fifty percent of New York City's Medicaid program costs are paid for by the federal government. *See* 42 U.S.C. §§ 1396b(a)(1) & 1396d(b). The remaining 50 percent of costs are generally shared equally by the City and the State. In other words, the City pays 25 percent of most of its Medicaid costs, including the cost of prescription drugs. N.Y. Social Services Law § 368-a. As required by federal statute, the federal government has expressly approved of New York State's Medicaid program, including the City's payment of a 25% local share. 42 U.S.C. § 1396a(a) and (b), 42 C.F.R. § 433.32 (at 79-29), 42 C.F.R. § 433.33, at 80-84.

44. In 2002, Medicaid paid \$14.7 million for Augmentin® for New York City residents, of which amount the City paid almost \$3.8 million.

45. Pursuant to New York's Medicaid statute, when only the original brand-name drug is available, the reimbursement rate is based on the Average Wholesale Price ("AWP") for such drug, minus 12 percent. N.Y. Soc. Serv. L. § 367-a(9)(b)(ii).

46. The AWP for Augmentin®, as for other patented drugs, is not independently determined by the federal government, the states or the City. Rather, AWP's for Augmentin®, or wholesale acquisition costs ("WACs") on which Augmentin® AWP's are based, have at all relevant times been self-reported by Defendants to various data collection/publishing companies such as First Data Bank's "Blue Book."

47. Once generic equivalents of a drug become available, the reimbursement rate is based on a federal upper limit ("FUL"), which is set by the U.S. Centers for Medicare and Medicaid Services. N.Y. Soc. Serv. L. §367-a(9)(b)(i). The FUL is generally calculated as "150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists[.]" 42 C.F.R. § 447.332(b). Thus, as lower-priced generic products become available, the cost to Medicaid payors decreases markedly.

48. Medicaid payors, including the City, also benefit from a rebate agreement between the federal government and the manufacturers pursuant to 42 U.S.C. 1396r-8(c) and Soc. Serv. L. 367-a(7)(d). The rebate amount is determined by the difference between the average price for the drug and the best price, defined as the lowest price available from the manufacturer for that drug. Defendants' monopoly prices have caused a reduction in the amount of the rebate received by the City as a result of these provisions.

49. But for Defendants' fraudulent and unlawful patent activity, which prevented generic entry into the market and permitted Defendants to monopolize the amoxicillin-potassium clavulanate market, the price paid by Medicaid for Augmentin® and amoxicillin-potassium clavulanate would have been lower and the City of New York would have paid less under Medicaid for the drug.

**F. The Development of Augmentin<sup>2</sup>**

**1. The Early Discovery of Clavulanic Acid As a  $\beta$ -Lactamase Inhibitor**

50. As early as the 1940s, bacteria were beginning to develop a resistance to penicillins. By the late 1950s-early 1960s, scientists identified  $\beta$ -lactamase enzymes as the primary bacterial response, which neutralized the effectiveness of penicillins' antibiotic activity.

51. After identifying the major cause of the problem, scientists began working on penicillins that were themselves resistant to the  $\beta$ -lactamase enzymes, but this work was not particularly effective.<sup>3</sup>

52. Another approach, where penicillins were *combined* with a compound that was designed to protect the antibiotic from  $\beta$ -lactamase enzymes, held out more promise in the eyes of the scientific community – although meeting only limited success initially.

53. A lead researcher in the field to develop a  $\beta$ -lactamase inhibitor that could serve as a first line of defense for penicillin was a British scientist, Martin Cole ("Cole"), who worked for Beecham Group p.l.c. ("Beecham Group"), a predecessor corporation of Defendant GlaxoSmithKline. Cole's work in the late-1960s included testing numerous substances for their ability to produce a  $\beta$ -lactamase inhibitory effect. In 1968, Cole's team discovered a promising compound that was potent in defending penicillin against  $\beta$ -lactamase enzymes; unfortunately, its properties were not suitable for wide-scale use in human and animal subjects.

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<sup>2</sup> Many of the background facts for this section are drawn directly from the Order and Opinion dated July 19, 2002 of this Court in *Geneva Pharmaceuticals, Inc., et al. v GlaxoSmithKline plc, et al.*, 213 F. Supp. 2d 597 (E.D. Va. July 19, 2002). This Order and Opinion are referred to later in this complaint.

<sup>3</sup> While scientists were able to develop penicillin compounds that were resistant to specific  $\beta$ -lactamase enzymes, they were not able to develop penicillin that would itself combat the broad range and variety of the  $\beta$ -lactamase enzymes produced by bacteria. Without a penicillin with the ability to fight off the wide range of  $\beta$ -lactamase enzymes that any given bacteria was producing, these medications were of little use to treating physicians who lacked the tools to determine with complete specificity what  $\beta$ -lactamase enzymes were present.

54. As research continued into 1972, Cole had become aware of work conducted by researchers at Eli Lilly & Company, another pharmaceutical producer. When comparing the structure of his earlier discovered promising compound with that of a substance first identified in a paper published by Eli Lilly & Company, he noticed that its structure looked to portend a similarly potent ability to inhibit  $\beta$ -lactamase enzymes, but with a greater usefulness in human and animal subjects. After extensive testing, Cole and his group of researchers determined that this compound could be effectively used in combination with penicillin to block  $\beta$ -lactamase enzymes from neutralizing the antibiotic, so that the penicillin could in turn work to defuse the bacteria. Cole had discovered that this substance was a revolutionary  $\beta$ -lactamase inhibitor, and it became known as clavulanic acid.

## 2. The Early Cole and Crowley Applications

55. The discovery was announced publicly to the scientific community in 1974.<sup>4</sup> On April 17, 1975, Cole and others filed the first patent application with the United States Patent and Trade Office (the "PTO") for clavulanic acid as a  $\beta$ -lactamase inhibitor (the "1975 Cole Application").

56. Meanwhile, Patrick Crowley, another researcher for Beecham Group along with Cole, discovered that a potassium salt of clavulanic acid made the drug even more useful in human and animal subjects by increasing the compounds' stability. As a result, on October 6, 1978, Crowley filed a patent application with the U.S. PTO for the combination of amoxicillin trihydrate and potassium clavulanate (the "1978 Crowley Application").

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<sup>4</sup> Since 1974, GlaxoSmithKline and its predecessors have, through acquisitions and multiple patent applications, sought to present obvious variants of clavulanic acid in a variety of semantically different forms. While some of GlaxoSmithKline's multiple patent applications based on discovery of clavulanic acid as a  $\beta$ -lactamase inhibitor have been granted, others have been denied.

**3. The 1976 Fleming Application and The Fleming '175 Patent**

57. Another research group, led by Dr. Ian Fleming ("Fleming") of Glaxo Laboratories, Inc. (which itself is a predecessor of Defendant GlaxoSmithKline through the eventual year 2000 merger of Glaxo Wellcome and SmithKline Beecham), also had been working in this field during the same time as Cole, in a wholly independent effort to discover a  $\beta$ -lactamase inhibitory compound. Shortly after Cole made his discovery, Fleming isolated clavulanic acid in a highly purified form. Glaxo Laboratories, Inc. never itself created a commercial product containing clavulanic acid. In February 1976, ten months after a patent application was filed to protect Cole's research, an application was filed for Fleming's highly purified clavulanic acid (the "1976 Fleming Application").

58. The 1976 Fleming Application was the first to result in an approved patent. On March 13, 1979, the PTO issued U.S. Patent No. 4,144,242 titled Process for the Purification of Clavulanic Acid (the "Fleming '242 patent"). Second, on January 4, 1983, the U.S. PTO issued Patent No. 4,367,175 titled Pure Potassium Salt of Clavulanic Acid (the "Fleming '175 patent").

59. The 1975 Cole Application and the 1976 Fleming Application were competing patent applications relating to clavulanic acid as a  $\beta$ -lactamase inhibitor. When two applications claim nearly identical inventions, the PTO issues an interference. 35 U.S.C. 135. During that process, an intensive investigation is mounted to determine which party is actually entitled to patent protection as the first inventor. The patents in the names of Cole and Fleming became the subject of U.S. PTO Interference No. 100,451, which was initiated due to the similar nature of the Fleming and Cole patents. Rather than contest the issue through the processes of the PTO, Beecham Group plc purchased the rights to the Fleming '175 patent from Glaxo Laboratories.

**4. The Crowley '609 Patent**

60. Meanwhile, Crowley's research resulted in U.S. Patent No. 4,441,609, and issued on April 10, 1984 titled Pharmaceutical Compositions (the "Crowley '609 patent"). As a result, by 1984 the Beecham Group owned both the Crowley '609 patent") and the Fleming '175 patent.

**5. Beecham's 1984 U.S. Launch of Augmentin®**

61. Using these patents, Defendants' predecessor Beecham Group sought and obtained FDA approval for the manufacture and sale of the combination of amoxicillin and clavulanic potassium under the brand-name "Augmentin®." On August 6, 1984, the FDA approved 250 mg. and 500 mg. dosages of Augmentin® tablets and oral suspensions. The FDA approvals were for the pharmaceutical combination of the penicillin derivative amoxicillin and potassium salt of clavulanic acid, potassium clavulanate. By combining the two substances, the clavulanic acid countered the attack of the  $\beta$ -lactamase enzymes before they had the opportunity to destroy the antibacterial effect of the amoxicillin – the amoxicillin was then able to destroy the harmful bacteria. Defendants chose to market the commercial pharmaceutical product under the trademark Augmentin®, to reflect the fact that the clavulanic acid was Augmentin® the natural antibacterial properties of amoxicillin by presenting the  $\beta$ -lactamase enzymes from neutralizing it.

62. Shortly after FDA approval for the sale of Augmentin®, the Fleming 1976 Application bore additional fruit. On December 25, 1984, the PTO issued two patents: U.S. Patent No. 4,490,294, titled Pure Salts of Clavulanic Acid (the "1984 '294 patent") and U.S.

Patent No. 4,490,295, titled Pure Sodium Salt of Clavulanic Acid (the "1984 '295 patent")

63. As a result, since 1984, Defendants' predecessors have enjoyed protection under United States patent laws with respect to the manufacture and sale of Augmentin®. At least two patents (the Fleming '175 patent and the Crowley '609 patent) and ostensibly the additional two later 1984 patents ('294 and '295) provided protection under patent laws which would expire at the latest on December 26, 2001.

**G. The Redundant Patents Issued in 1985**

64. In 1985, ten years after the original patent filing of the 1975 Cole Application, that Application resulted in three more patents issued to Beecham Group:

(a) On June 25, 1985, the PTO issued U.S. Patent No. 4,525,352, titled Antibiotics (the "1985 '352 patent");

(b) On June 15, 1985, the PTO issued U.S. Patent No. 4,529,720, titled Antibiotic From Streptomyces Clavulicerus (the "1985 '720 patent"); and

(c) On December 24, 1985, the PTO issued U.S. Patent No. 4,560,552, titled Antibiotics (the "1985 '552 patent"). (These three patents are sometimes referred to as the "1985 Patents").

65. The three 1985 patents were obvious in light of the Fleming '175 patent and the Crowley '609 patent. Commonly held by Beecham Group, the three 1985 patents were nearly identical to, or at least anticipated by, Beecham Group's commonly held Fleming '175 patent and Crowley '609 patent.

66. Of course, at this time Defendants already had FDA approval for Augmentin® and were marketing and selling the drug in the United States. The three 1985 patents played no role in a necessary protection of Defendants for the marketing and sale of

Augmentin®. As a result, attempted enforcement of the three 1985 patents would have the effect

of providing Beecham Group, or its successors, with an unlawful extension of the term of its existing patent rights for the sale of Augmentin®.

67. Although in 1985 Defendants' predecessor, Beecham Group, held a series of redundant United States patents relating to the combination of amoxicillin with clavulanic acid, Beecham (and its successors) continued as pending before the PTO, the original 1975 Cole Application or divisions and continuations of that application. At various times over the years, Defendants' predecessors sought to prosecute divisions or continuations of that application and to obtain additional patent issuances.

#### **H. Generics Attempt to Enter the Augmentin® Market**

68. Throughout the 1980s and 1990s, Defendants and their predecessors enjoyed a monopoly in the manufacture and sale of amoxicillin combined with clavulanate potassium through the manufacture and sale of Augmentin®.

69. By early year 2000 and with the prospect of the expiration of the Fleming and Crowley patents, generic drug makers sought approval for generic equivalents to Augmentin®.

70. On February 11, 2000, Geneva Pharmaceuticals, Inc. ("Geneva"), a subsidiary of Novartis AG, filed an ANDA seeking FDA approval to manufacture, market and sell a generic version of Augmentin® in the United States. Other generic makers followed suit, including Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), and Teva Pharmaceuticals USA, Inc. ("Teva").

#### **I. The 2000/2001 Patents**

71. Remarkably at this time, i.e. early 2000 and 2001, with generic

competition right around the corner, Defendants' long-pending patent applications – all stemming back to the 1975 Cole Application of 25 years earlier – conveniently bore fruit:

(a) On February 29, 2000, the PTO issued U.S. Patent No. 6,031,093, titled Solid Salts of Clavulanic Acid (the "093 patent"), which ostensibly would have expired on February 28, 2017;

(b) On April 11, 2000, the PTO issued U.S. Patent No. 6,048,977, titled Clavulanic Acid and Salts Thereof (the "977 patent"), which ostensibly would have expired on April 11, 2017;

(c) On April 18, 2000, the PTO issued U.S. Patent No. 6,051,703, titled Purified Clavulanic Acid and Salts Thereof (the "703 patent"), which ostensibly would have expired on April 18, 2017; and

(d) On April 17, 2001, the PTO issues U.S. Patent No. 6,218,380, titled Pharmaceutical Composition (the "380 patent"), which ostensibly would have expired on April 17, 2018.

72. The 2000/2001 patents all trace back to the original 1975 Cole patent of twenty-five years earlier. The practical effect of the 2000/2001 patents was that they could extend Defendants' patent protection for Augmentin® another 17 years, until April 17, 2018.

**J. The 1985 Patents and the 2000/2001 Patents Are Declared Invalid**

73. Facing a delay in their ability to market generic forms of Augmentin®, and the likelihood of a patent infringement action, the generic drug manufacturers (Geneva, Teva, and Ranbaxy) commenced litigation against Defendants in this Court over the validity and enforceability of the three 1985 patents, which ostensibly extended Defendants' exclusivity until December 25, 2002, and the four 2000/2001 patents, which ostensibly extended Defendants'

exclusivity until year 2018. Defendants aggressively defended the patent litigation brought by

the generic manufacturers and sought to maintain their hold on the Augmentin® market.

74. This Court has issued a series of three rulings which, combined, hold that each of the three 1985 patents and each of the four 2000/2001 patents are invalid and unenforceable.

75. First, at a December 14, 2001 hearing, the Court invalidated one of the 2000/2001 patents, the '380, finding it to be an obvious variation of the earlier Cole '720 patent. *See Geneva Pharmaceuticals, Inc. v GlaxoSmithKline PLC, et al.*, 189 F. Supp. 2d 377, 383 (E.D. Va. Feb. 25, 2002).

76. Claim 1 of the '720 patent provides as follows:

1. A method of effecting  $\beta$ -lactamase inhibition in a human or animal in need thereof arising from a  $\beta$ -lactamase producing bacteria which comprises administering to said human or animal a  $\beta$ -lactamase inhibitory amount of clavulanic acid or a pharmaceutically acceptable salt thereof.

Claim 1 of the '380 patent, which follows in relevant part, is virtually the same as Claim I of the '720 patent:

1. A pharmaceutical composition useful for effecting  $\beta$ -lactamase inhibition in humans and animals which comprises  $\beta$ -lactamase inhibitory amount of clavulanic acid, in combination with a pharmaceutically acceptable carrier.

77. This Court found that "the '380 patent appears to be either a rewording of the '720 patent or an obvious by-product of something already included in that earlier patent." *Geneva*, 189 F. Supp. 2d at 384. The Court concluded "by clear and convincing evidence that the difference between these two patents are not patently distinct." *Id.* at 386. Accordingly, the Court held the '380 patent was invalid "on the ground of obviousness-type double patenting." *Id.*

78. Second, at a March 13, 2002 hearing, the Court found that the three remaining 2000/2001 patents - '977, '903 and '093 - were invalid for obviousness-type double

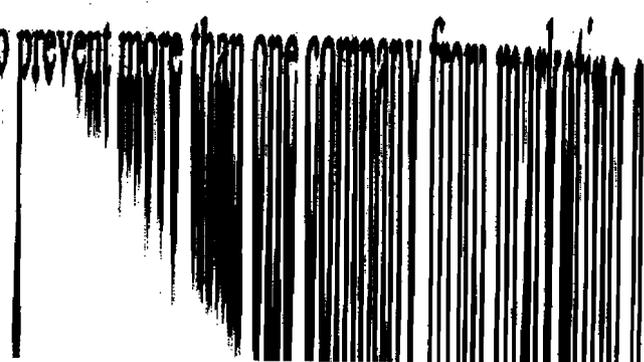
patenting. *Geneva Pharms., Inc. v. GlaxoSmithKline, PLC*, 213 F. Supp. 2d 597 (E.D. Va. 2002).

79. Third, on May 23, 2002, this Court found that the three 1985 patents – ‘552, ‘352 and ‘720 – were invalid, a decision that it further explained in an opinion and order on July 19, 2002. The Court found that the ‘552 patent “is merely an obvious variant of the Crowley ‘609 patent,” Order at 17, and thus “both obvious in light of and anticipated by the Crowley ‘609 patent,” *Id.* at 19. The Court made similar findings with regard to GlaxoSmithKline’s ‘352 patent. *See id.* at 21. The Court also found that the claimed characteristics of Defendants’ ‘720 patent “flow[ed] inherently from the Fleming ‘175 patent” and thus was invalid in light of the ‘175 patent. *Id.* at 24. These judgments invalidating GSK’s patents were all affirmed by the Federal Circuit. *See Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC*, 349 F.3d 1373 (Fed. Cir. 2003).

**K. Defendants’ Further Attempts To Perpetuate  
Their Monopoly on Augmentin®**

80. In addition to their aggressive litigation posture regarding the patent appeal, on August 9, 2002, Defendants sued Novartis AG (“Novartis”), and its subsidiaries Geneva and Biochemie GmbH, in Colorado state court, claiming that the company misappropriated an unpatented trade secret in using a strain of bacteria developed by Defendants as part of their production process. In tandem with their Colorado state court filing, Defendants have also initiated suits against Teva and Ranbaxy in Pennsylvania state court, making the same claims about stolen bacteria, all in order to stop them from marketing generic Augmentin®.

Defendants have a financial incentive to prevent more than one company from



competing generic product, because the more competitors there are in the market, the greater the loss of market share by Defendants for their monopoly-priced Augmentin®.

81. In November 2002, Defendants initiated a similar lawsuit against Lek Pharmaceuticals ("Lek"), about the same time as Lek's generic product was approved.

82. On August 9, 2002, Defendants petitioned the United States International Trade Commission to block Novartis from importing generic Augmentin®, making similar claims about stolen bacteria. "Patents have a finite life, but trade secrets go on forever," explained a spokesperson for GSK. The International Trade Commission disagreed. It dismissed Defendants' complaint and terminated its investigation in a decision dated April 3, 2003. It held that Defendants' claim that the bacteria was secret was completely foreclosed by a settlement agreement it had entered into with Biochemie and Novartis on May 20, 1998.

83. In adjudging invalid another GSK patent, for the anti-inflammatory drug Relafen, the district court held that GSK had "engaged in a pattern of misrepresentation in its dealings with the PTO so pervasive as to negate any possibility that Beecham's misrepresentations to the PTO were inadvertent 'loose language' or otherwise 'negligently made.'" *In re '639 Patent Litig.*, 154 F. Supp. 2d 157, 194 (D. Mass. 2001), *aff'd sub nom. SmithKline Beecham Corp. v Copley Pharm.*, 2002 U.S. App. LEXIS 16594 (Fed. Cir. Aug. 15, 2002). The Court further found that GSK was attempting to persuade the PTO that there was no prior art anticipating its patent, while evidence before the Court revealed that Defendants' patent department knew this was false, could not believe its success in getting the patent approved, and were happy that it had "put one over on" the PTO. *Id.*

**L. GSK's Success in Delaying Generic Entry**

84. Defendants' aggressive litigation and other illegal tactics succeeded in delaying the introduction of generic products, and these effects continue to be felt in the market for Augmentin® and its generic bioequivalents. In March of 2002, and again in April and June of 2002, Geneva received approval from the FDA for the manufacture and sale of a variety of dosages of a generic equivalent of Augmentin®. It received approval for the 500 and 875 mg dosages in March 2002, and the 200 mg and 400 mg dosages in April 2002. Similarly, Ranbaxy also received FDA approval for the 875 mg dosage in September 2002 and for the 200, 400, and 500 mg dosages in November 2002, Lek Pharmaceuticals received approval for the 500 mg dosage in November 2002, and Teva Pharmaceuticals received approval for the 500 mg dosage in October 2002 and for the 875 mg dosage in December 2002. The generic companies might well have obtained approval sooner, had it not been for the deterrent effect and diversion of resources resulting from Defendants' invalid patents and aggressive pattern of sham litigation.

85. Upon information and belief, the generic companies were slow to meet consumer demand for generic Augmentin®, even after they brought their generic products to market. For example, Ranbaxy stated that it would not bring its generic version of Augmentin® to market while the patent appeal was pending, due to the overt threats of reprisal by Defendants.

86. Upon information and belief, if Defendants had not engaged in the unlawful conduct alleged in this complaint (including but not limited to seeking enforcement of the redundant 1985 patents and seeking enforcement of the redundant 2000/2001 patents) intended to prolong its monopoly for Augmentin® in the United States market beyond year

~~2001, generic companies would have sought and/or obtained FDA approval and gone to market~~

with a generic equivalent to Augmentin® at a markedly earlier period of time.

87. The fraudulent claims and exclusionary acts and practices of Defendants had and have the purpose and effect of preventing the entry of generic Augmentin® products into the relevant market, and of overcharging Plaintiff.

88. But for Defendants' illegal conduct, a generic competitor would have begun marketing a generic version of Augmentin® as early as December 25, 2001.

89. If a generic competitor had been able to enter the relevant market and compete with Defendants, Plaintiff would have been able to purchase and reimburse a lower-priced generic, and thus would have paid less for Augmentin® and its generic bioequivalents.

### COUNT I

#### Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Violations of Section 2 of the Sherman Act

90. Plaintiff incorporates by reference the preceding allegations.

91. To the extent applicable to this and other claims alleged in this complaint, the relevant product market is the market for the manufacture and sale of Augmentin® and its generic bioequivalents. The relevant geographic market is the United States as a whole. Defendants' market share in the relevant product and geographic markets was one hundred percent (100%) until July 15, 2002, and they still maintained a monopoly market share after that date.

92. Exploiting U.S. patent laws, Defendants obtained a monopoly over sales of prescription Augmentin® drug products, but that monopoly was unlawful because the drug was not covered by valid, unexpired patents during the Relevant Time Period.

93.

Defendants knowingly and willfully engaged in a course of conduct

replicated prior art established by the original patents in order to prevent Geneva, Teva and Ranbaxy and other potential generic manufacturers from obtaining final FDA approval to sell a generic version of Augmentin®; and (2) prosecuting frivolous trade secret litigation regarding the allegedly proprietary bacteria strain used in the manufacture of Augmentin®. Defendants' filing and defense of obviously invalid patents violates Section 2 of the Sherman Act. Defendants filed and defended the subsequent patents with knowledge that they were invalid due to obviousness-type double patenting, and were otherwise not new art.

94. The intended effect of these objectively baseless actions was to delay the introduction of generic formulations of Augmentin® into the market.

95. Defendants possessed monopoly power in the relevant market during the Relevant Time Period. Defendants intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. While obtaining and possessing their unlawful monopoly power over the market for Augmentin®, Defendants set, maintained and raised the price of Augmentin® to artificially high and/or supracompetitive levels.

96. Plaintiff has been injured in its business or property by reason of Defendants' antitrust violation alleged in this Count. Its injury consists of paying higher prices for Augmentin® and its generic bioequivalents than it would have paid in the absence of that violation. Such injury is of the type antitrust laws were designed to prevent and flows from Defendants' unlawful conduct.

## COUNT II

### **Damages Under New York's Donnelly Act, General Business Law § 340 et seq.**

97. Plaintiff incorporates by reference the preceding allegations.

98. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to extend their monopoly power. This course of conduct included, *inter alia*: (1) improperly filing and prosecuting a series of patents that merely replicated prior art established by the original patents, in order to prevent Geneva, Teva, Ranbaxy, and any other potential generic manufacturer from obtaining final FDA approval to sell a generic version of Augmentin®; and (2) prosecuting trade secret litigation regarding the allegedly proprietary bacteria strain used in the manufacture of Augmentin®.

99. During the Relevant Time Period, Defendants possessed monopoly power in the relevant market.

100. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of New York Gen. Bus. Law § 340 *et seq.* with respect to purchases and payments for Augmentin® by the City of New York.

101. Plaintiff has been injured in its business or property by reason of Defendants' antitrust violation alleged in this Count. Plaintiff's injury consists of paying higher prices for Augmentin®-based prescription drug products than it would have paid in the absence of those violations. This injury is of the type the Donnelly Act was designed to prevent and flows from Defendants' unlawful conduct.

### **COUNT III**

#### **Damages Under the New York Medicaid Fraud Statute, Social Services Law § 145-b**

102. Plaintiff incorporates by reference the preceding allegations.

103. Defendants have knowingly made false statements and representations to

the PTO and to the FDA.

104. By reason of Defendants' false statements and representations, as alleged herein, Medicaid payors, including the City's Medicaid program, were required to pay more for Augmentin® and its generic bioequivalents than they would have in the absence of Defendants' anticompetitive and unlawful activities, alleged herein.

105. Defendants' intentional false and fraudulent statements to the PTO and to the FDA were made for the specific purpose of preventing generic amoxicillin-potassium clavulanate from entering the market. Defendants thereby extended their monopoly over the market for amoxicillin-potassium clavulanate and, as a result, were able to report and/or charge inflated prices for these products.

106. Defendants made false and fraudulent statements to the PTO and the FDA on their own behalf and on behalf of others, knowing and expecting that these representations would result in the overpayment of public funds for Augmentin® and amoxicillin-potassium clavulanate by the New York State Medicaid program.

107. The Average Wholesale Price and Best Price for amoxicillin-potassium clavulanate used as the basis for charges and rebates to Medicaid as a result of false statements by Defendants have constituted and may continue to constitute fraudulent reports of data which serve as the basis for claims or rates of payment, as defined in Social Services Law § 145-b (1) (b).

108. Defendants attempted to and did obtain public funds when such funds were used to reimburse or make prospective payment to entities from which Defendants sought payment, as defined in Social Services Law § 145-b(1)(c).

109. As a result of Defendants' false statements, deliberate concealment of material facts, and/or fraudulent schemes or devices, they obtained higher payments from public

funds for Augmentin®, and Plaintiff was forced to pay more than it otherwise would have for Augmentin® and amoxicillin-potassium clavulanate, in violation of state and federal Medicaid law.

#### COUNT IV

##### Damages For False Statements Or Misrepresentations Under New York General Business Law § 349

110. Plaintiff incorporates by reference the preceding allegations.

111. Defendants have engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of General Business Law § 349, when they re-filed prior art and obtained invalid patents in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Augmentin®. In addition, Defendants prosecuted baseless trade secret litigation, as described herein. As a direct result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff was deprived of the lower prices it would have paid had generic Augmentin® been available sooner.

112. Defendants have engaged in unfair competition or deceptive acts or practices in violation of New York General Business Law § 349 *et seq.*

113. Plaintiff has been injured in its business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Plaintiff's injury consists of paying higher prices for Augmentin® and its generic bioequivalents than it would have paid in the absence of these violations. This injury is of the type GBL § 349 was designed to prevent and directly results from Defendants' unlawful conduct.

**COUNT V**

**Unjust Enrichment Under New York State Law**

114. Plaintiff incorporates by reference the preceding allegations.

115. Defendants have benefited from their unlawful acts through the receipt of the overpayments for Augmentin® products by Plaintiff. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Augmentin® by Plaintiff.

116. Plaintiff has conferred upon Defendants an economic benefit, in the nature of the profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff.

117. Defendants have been unjustly enriched by their unlawful and inequitable conduct, in violation of the common law of New York.

118. It would be inequitable for Defendants to be permitted to retain the benefit of these overpayments, which were conferred by Plaintiff and retained by Defendants.

119. The financial benefits derived by Defendants by reason of their unlawful conduct rightfully belong to Plaintiff, because Plaintiff paid anti-competitive and monopolistic prices during the Relevant Time Period, inuring to the benefit of Defendants.

120. It would be inequitable and unjust for Defendants to be permitted to retain any of the unlawful proceeds from their illegal and anticompetitive behavior.

121. Defendants should be compelled to disgorge into a common fund for the benefit of Plaintiff all unlawful or inequitable proceeds received by them.

122. *Plaintiff has no adequate remedy at law.*

**DEMAND FOR RELIEF**

**WHEREFORE**, Plaintiff prays that the Court declare, adjudge and decree the following:

(a) That the conduct alleged herein constitutes unlawful monopolization and an attempt to monopolize in violation of Section 2 of the Sherman Act, the New York Medicaid Statute, the antitrust and consumer protection statutes of the State of New York, and the common law of unjust enrichment, set forth above;

(b) That Plaintiff is entitled to damages, penalties and other monetary relief provided by applicable law, including treble damages under Gen. Bus. L. § 340 (the Donnelly Act) and under Soc. Serv. L. § 145-b (Medicaid fraud);

(c) That Plaintiff is entitled to the amounts by which Defendants have been unjustly enriched;

(d) That Defendants are enjoined from continuing the illegal activities alleged herein;

(e) That Plaintiff is awarded its costs of suit, including reasonable attorneys' fees and expenses as provided by Gen. Bus. L. § 340 and other applicable law; and

(f) That Plaintiff is granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

**JURY DEMAND**

Plaintiff demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: May 17, 2004

GLASSER AND GLASSER, P.L.C.

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