IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICAL INDUSTRIES LTD., 5 Basel Street, Petach Tikva 49131 Israel, and TEVA PHARMACEUTICALS USA, INC., 1090 Horsham Road, North Wales, PA 19454, Plaintiffs, v. PFIZER INC., 235 East 42nd Street, New York, NY 10017, GREENSTONE LTD., 701 East Milham Road, Kalamazoo, MI 49002, and WARNER-LAMBERT COMPANY LLC, 201 Tabor Road, Morris Plains, NJ 07950, and FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane, Rockville, MD 20857, LESTER M. CRAWFORD, Acting Commissioner of Food and Drugs, 5600 Fishers Lane, Rockville, MD 20857, and TOMMY G. THOMPSON, Secretary of Health and Human Services, 200 Independence Ave., SW, Washington DC 20204, Defendants.	)	Civil Action No. _____

VERIFIED COMPLAINT

Plaintiffs Teva Pharmaceutical Industries Ltd. ("Teva Pharmaceutical") and Teva Pharmaceuticals USA, Inc. ("Teva USA" and with Teva Pharmaceutical, "Teva" or "Plaintiffs"), for their Verified Complaint against Defendants Pfizer Inc., Greenstone Ltd. ("Greenstone"), and Warner-Lambert Company LLC ("Warner-Lambert" and collectively with Pfizer Inc. and Greenstone, "Pfizer"), and the Food and Drug Administration, Lester M. Crawford, Acting

Commissioner of Food and Drugs, and Tommy G. Thompson, Secretary of Health and Human Services (collectively, the "FDA"), hereby allege as follows upon personal knowledge as to Teva and upon information and belief as to persons other than Teva and matters unrelated to Teva:

PRELIMINARY STATEMENT

REQUEST FOR URGENT RELIEF

1. By this action, Teva seeks to vindicate its commercial rights against Pfizer and its regulatory rights against the FDA in connection with a 180-day period of marketing exclusivity (the "Generic Exclusivity Period") that Congress has conferred upon Teva with respect to the sale of generic drugs containing the active ingredient, quinapril hydrochloride ("quinapril" or "quinapril hydrochloride").

2. Pfizer is about to violate and misappropriate Teva's exclusivity right by selling generic quinapril products when Teva is entitled to be the sole seller of generic quinapril products before the expiration of Teva's Generic Exclusivity Period. Pfizer will do so with the intent of undermining the incentive for Teva and other generic-drug manufacturers to challenge brand-drug patents. Pfizer thus intends to defeat, and will defeat unless restrained by this Court, the congressional purpose of the Generic Exclusivity Period.

3. Teva will request by urgent motion a temporary restraining order, and later a preliminary and permanent injunction, against Pfizer that prohibits Pfizer from selling generic quinapril products before the expiration of Teva's Generic Exclusivity Period.

4. The FDA is required pursuant to its existing regulations and statutory authorities to prevent Pfizer from selling generic quinapril products before the expiration of Teva's exclusivity period. Teva and others have petitioned the FDA to fulfill its legal obligations to protect the Generic Exclusivity Period from the sale of competing generic drugs by brand-drug manufacturers, including the imminent sale of generic quinapril products by

Pfizer. To date, the FDA has failed to act, which inaction is arbitrary, capricious, and contrary to law.

5. Teva will request a preliminary and permanent injunction against the FDA requiring the FDA to grant Teva's request to protect its lawful right to the quinapril Generic Exclusivity Period from intrusion by Pfizer, and, more generally, to protect Generic Exclusivity Periods earned by generic-drug manufacturers from the sale of generic drugs by brand-drug manufacturers.

BASIS FOR RELIEF AGAINST PFIZER

6. Through the investment of millions of dollars and years of research, Teva developed generic quinapril products that are bioequivalent to Pfizer's branded quinapril hydrochloride products, which are sold under the brand name, Accupril®, and pursuant to New Drug Application No. 019885 ("Accupril® products"). By its industry, swiftness, skill, expenditures, and labor, Teva was the first company to file with the FDA an Abbreviated New Drug Application ("ANDA") for generic quinapril products and to challenge the patent purportedly covering Pfizer's Accupril® products.

7. By filing the first challenge to the Accupril® patent, Teva qualified under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (2004) (the "FDCA" or the "Act") for the 180-day period of marketing exclusivity – the Generic Exclusivity Period – for generic quinapril products. Before the expiration of the Generic Exclusivity Period, Teva is entitled to be the sole seller of generic quinapril products.

8. Congress provided the Generic Exclusivity Period to encourage the expeditious introduction of lower cost generic drugs to the marketplace prior to the expiration of

patents that purportedly protect brand drugs from generic competition. Teva responded to that congressional incentive by challenging the Accupril® patent.

9. As a reward for having been the first ANDA applicant to challenge the Accupril® patent, Teva has been granted the Generic Exclusivity Period for generic quinapril products. Teva requests this Court to stop Pfizer from stealing Teva's reward and defeating Congress's intent through false statements and tortious conduct.

10. In the absence of immediate injunctive relief from this Court, Pfizer will begin promptly to sell its branded quinapril products (*i.e.*, Accupril® products) as generic quinapril products (while continuing to sell Accupril® products as brand quinapril products) before the expiration of Teva's Generic Exclusivity Period. Pfizer will thereby violate the Trademark Act of 1946 (the "Lanham Act"), 15 U.S.C. §1125(a), and common law principles prohibiting unfair competition – including the misappropriation of a protectable commercial and monetary interest – and the tortious interference with business relations.

11. Pfizer's threatened conduct is also further to, and part of, an ongoing and persistent campaign to forestall the penetration of Teva's generic quinapril products in the marketplace. Teva has previously described, in proposed counterclaims asserted in the patent action in the District of New Jersey, how Pfizer has misused and manipulated, through a pattern of sham acts and claims, the Hatch-Waxman Amendments. That sham conduct has violated the Sherman Act, unlawfully preserved the monopoly position of Accupril®, and tortiously interfered with Teva's contractual and advantageous business relationships.

12. The conduct complained of is also designed to thwart Teva's competitive effectiveness in the sale of generic quinapril products and in challenging other brand-drug

patents, all in violation of Section 2 of the Sherman Act. Pfizer's conduct also constitutes a violation of Section 17200 of the California Business and Professions Code.

13. Pfizer's imminent sale of Accupril® products as generic quinapril products will irreparably injure the public interest by nullifying the primary incentive that Congress provided to encourage generic-drug manufacturers to introduce low cost drugs and to prevent brand-drug manufacturers from reaping unjustified monopoly profits based upon inapplicable, invalid, or unenforceable patents.

14. Pfizer's imminent sale of Accupril® products as generic quinapril products will irreparably harm Teva by depriving Teva of the commercial and competitive benefits, many of which are intangible or unquantifiable, that flow from its quinapril Generic Exclusivity Period. Remedies at law cannot adequately compensate Teva for those lost commercial and competitive benefits.

BASIS FOR RELIEF AGAINST THE FDA

15. The FDA has established precedent treating ANDA generics, such as Teva's generic quinapril products, and brand generics, such as Pfizer's generic Accupril® products, as legally and functionally equivalent for purposes of enforcing the Generic Exclusivity provisions of the Hatch-Waxman Amendments. The FDA's refusal to take action under its established regulations and statutory authorities to prohibit the sale of Pfizer's Accupril® products as generic quinapril products prior to the expiration of Teva's Generic Exclusivity Period violates the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, as the FDA's inaction is arbitrary, capricious, and contrary to law.

16. Teva and others have filed Citizen Petitions and related Comments with the FDA requesting the FDA to protect the Generic Exclusivity Period. Those petitioners rely on, among other things, established FDA policy, judicial precedent, and a recent congressional

amendment to the FDCA, all of which explicitly recognize that generic drugs made by brand-drug manufacturers and generic-drug manufacturers are legally and functionally equivalent with respect to the Generic Exclusivity Period.

17. Despite that established authority, the FDA has to date refused to protect the Generic Exclusivity Period from intrusion by generic drugs made by brand-drug manufacturers. The FDA's refusal to protect the Generic Exclusivity Period is arbitrary and capricious, contrary to law, and a violation of the APA.

PARTIES

18. Teva Pharmaceutical Industries Ltd. is organized and exists under the laws of Israel and has its principal place of business in Israel. Teva Pharmaceutical is the ultimate parent of Teva USA. Teva Pharmaceutical is the beneficial owner of the ANDA for Teva's generic quinapril products and all the FDA approvals thereof.

19. Teva Pharmaceuticals USA, Inc. is incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva USA develops, manufactures, and sells generic pharmaceutical products in the United States. Teva USA is a wholly owned indirect subsidiary of Teva Pharmaceutical.

20. Pfizer Inc. is a corporation organized under the laws of Delaware and has its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. develops brand-name pharmaceutical products, including Accupril® products, in the United States and other countries. Pfizer Inc. also controls Greenstone, through which Pfizer sells generic drugs in the United States.

21. Parke-Davis is the distributor of Accupril® products. The package insert for Accupril® characterizes Parke-Davis as a "Division of Pfizer Inc, NY, NY 10017."

22. Greenstone Ltd. is a subsidiary of Pfizer Inc., is organized under the laws of Delaware, and has its principal place of business at 701 East Milham Road, Kalamazoo, Michigan 49002. Defendant Greenstone Ltd. currently sells generic drug products that Pfizer Inc. sells as brand drugs. Pfizer intends to market and sell Pfizer's generic quinapril products through Greenstone or another entity owned and controlled by Pfizer Inc. but unknown to Teva.

23. Prior to June 19, 2000, Warner-Lambert Company LLC was organized and existed under the laws of Delaware and had its principal place of business at 201 Tabor Road, Morris Plains, New Jersey 07950. Warner-Lambert had developed brand-name pharmaceutical products for sale in the United States and in other countries.

24. On June 19, 2000, Pfizer Inc. acquired Warner-Lambert and continues to own and control Warner-Lambert.

25. The Food and Drug Administration is an administrative agency within the United States Department of Health and Human Services, with offices at 5600 Fishers Lane, Rockville, Maryland 20857 and 200 C Street, SW, Washington, DC 20204. The FDA has been delegated the authority to administer the FDCA.

26. Lester M. Crawford, D.V.M., Ph.D., is Acting Commissioner of Food and Drugs, and is the senior official of the FDA. He is sued in his official capacity. Dr. Crawford maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857 and 200 C Street, SW, Washington, DC 20204.

27. Tommy G. Thompson is Secretary of Health and Human Services and is the official charged by law with administering the FDCA. He is sued in his official capacity. Secretary Thompson maintains an office at 200 Independence Avenue, SW, Washington, DC 20204.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

28. This Court has jurisdiction pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, the FDCA, 21 U.S.C. § 301 *et seq.*, the APA, 5 U.S.C. § 701 *et seq.*, and 28 U.S.C. §§ 1331, 1337(a), 1338, 1346, 1361 and 1367.

29. Teva Pharmaceutical and Teva USA have begun to collaborate with respect to 5 mg, 10 mg, 20 mg, and 40 mg generic quinapril tablets ("Teva's generic quinapril products"). Teva's generic quinapril products are manufactured by Teva Pharmaceutical for marketing and sale by Teva USA in this judicial district, in the States of New York, Pennsylvania, and California, as well as other states of the United States, and in interstate commerce throughout the United States.

30. Pfizer distributes and sells, and will continue to distribute and sell, through Parke-Davis, 5 mg, 10 mg, 20 mg, and 40 mg tablets of brand quinapril products under the trademark, Accupril®, in this judicial district, in the States of New York, Pennsylvania, and California, as well as all other states of the United States, and in interstate commerce throughout the United States. Greenstone (or another entity owned and controlled by Pfizer Inc. but unknown to Teva) is threatening to sell all strengths of the selfsame drug that has been and is known as Accupril® as generic quinapril products in this judicial district, in the States of New York, as well as Pennsylvania, California, and all other States of the United States, and in interstate commerce throughout the United States.

31. Defendants are subject to personal jurisdiction in this judicial district.

32. Pfizer may be found or transacts business in this judicial district.

33. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), and (e).

THE APPLICABLE REGULATORY SCHEME

HATCH-WAXMAN AMENDMENTS

34. Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 after concluding, among other things, that the Act's then-current drug-approval process unduly delayed the entry of relatively inexpensive generic drugs into the marketplace.

35. The drug product that the FDA approves for manufacture, marketing, and sale pursuant to a New Drug Application ("NDA") is typically referred to as the "brand drug," or the "listed drug." *See* 21 U.S.C. § 355(b)(1).

36. The Hatch-Waxman Amendments permit a generic-drug manufacturer to file an Abbreviated New Drug Application (previously defined as an "ANDA") that need not establish the safety and efficacy of the drug through animal and human testing. An ANDA relies on the safety and efficacy data submitted pursuant to the NDA process in connection with the brand drug to which the generic drug is bioequivalent.

37. Drugs that are approved for sale pursuant to an ANDA are typically referred to as "generic" drugs. In some cases, brand-drug manufacturers offer for sale drugs that were approved pursuant to an NDA in the same commercial manner as generic-drug manufacturers offer for sale their generic drugs. The sale of brand drugs in the manner of generic drugs is sometimes referred to herein as "brand generics." Generic drugs approved by the FDA through the ANDA process are sometimes referred to herein as "ANDA generics."

"PARAGRAPH IV" CERTIFICATIONS

38. An ANDA applicant is required to submit to the FDA one of four certifications with respect to any patent that the brand drug manufacturer has listed as purportedly covering the brand drug in the FDA publication entitled APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (the "Orange Book").

39. If an ANDA applicant seeks approval to market a generic drug before the expiration of a patent listed in the Orange Book, the ANDA applicant must certify, according to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Such a certification is known as a "Paragraph IV" certification.

40. The filing of a Paragraph IV certification permits the holder of the challenged patent to assert a cause of action for patent infringement against the ANDA applicant. If such an action is brought within 45 days from receipt of notification of the Paragraph IV certification, the FDA cannot finally approve the ANDA before the earlier of 30 months from the patent holder's receipt of notification of the Paragraph IV certification(s), the date on which a court holds that the patent(s) is (are) invalid, not infringed, or unenforceable, or the date on which the case is withdrawn, discontinued, dismissed, or otherwise terminated by the patent holder (the "30-month stay period").

41. Before making a Paragraph IV certification, a generic-drug manufacturer invests substantial resources and incurs significant risk. The resources and risk include research and development to determine whether the patents listed in the Orange Book are valid and enforceable; if so, whether the subject drug can be manufactured in a non-infringing and bioequivalent manner; whether the generic-drug manufacturer can sustain its position in the patent litigation that will likely follow the Paragraph IV certification; and whether the generic-drug manufacturer can be the first ANDA applicant to file a Paragraph IV certification.

42. Following a Paragraph IV certification, the Paragraph IV ANDA applicant must successfully defend, at substantial expense, the ensuing patent litigation or face an

injunction against the sale of the generic drug until the expiration of the subject patent, by which time the brand drug is frequently superseded by a new-generation brand drug.

43. In filing a Paragraph IV certification, the generic-drug manufacturer advances at its own expense a congressional policy and the public interest by seeking to introduce, through a lawful though costly and time-consuming procedure, lower cost drugs before the time that the brand drug manufacturer claims the generic drugs can be legally sold.

THE GENERIC EXCLUSIVITY PERIOD

44. To encourage generic companies to invest the resources necessary to make a Paragraph IV certification, challenge brand-drug patents, and incur the consequent risk, Congress granted a limited but valuable right to the first generic company to challenge an Orange Book-listed patent. That right is the right for such first Paragraph IV filers to enjoy a 180-day period in which the first-filer company – and no other company – is entitled to be the only provider of generic versions of the drug at issue (previously defined as the "Generic Exclusivity Period"). The relevant statutory provision, as amended, states that: "if the [ANDA] contains a [Paragraph IV] certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an [ANDA] containing such a certification, the [ANDA] shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed [*i.e.*, brand] drug) by any first applicant." 21 U.S.C. § 355(j)(5)(B)(iv).

45. The purpose of the Generic Exclusivity Period is to provide the applicant that files the first Paragraph IV ANDA with a 180-day period before the expiration of which the applicant has the right to be the *sole* seller of the subject generic drug as a reward for having successfully introduced the generic drug before the expiration of patents that purportedly insulate the brand drug from generic competition.

46. The Generic Exclusivity Period constitutes an important and procompetitive public policy that expedites the introduction of lower cost drugs to the consuming public despite brand-drug company assertions of patents precluding generic competition.

47. The Generic Exclusivity Period constitutes a valuable and protectable private right and commercial interest of the applicant that files the first Paragraph IV ANDA.

THE FDCA PROHIBITS THE SALE OF BRAND GENERICS AS WELL AS SUBSEQUENTLY FILED ANDA GENERICS BEFORE THE EXPIRATION OF THE GENERIC EXCLUSIVITY PERIOD

48. The FDA, the judiciary, and Congress have all construed brand generics and ANDA generics as legally and functionally equivalent under the Hatch-Waxman Amendments with respect to the operation of the Generic Exclusivity Period, regardless of whether the generic product at issue was approved via an ANDA or an NDA.

49. In 2001, the FDA issued a final administrative ruling in which it granted a Citizen Petition filed by Teva that sought a determination that a brand generic must be treated as functionally and legally equivalent to an ANDA generic for purposes of FDA's implementation of the Generic Exclusivity Period. Specifically, Teva requested that the FDA establish that the marketing of a brand generic for nifedipine by a first-filer ANDA applicant was legally equivalent to the marketing of an ANDA generic product for purposes of triggering the Generic Exclusivity Period under the Hatch-Waxman Amendments. Teva Pharmaceuticals USA, Inc. Citizen Petition, Docket No. 00P-1446/CP1, at 2 (Aug. 9, 2000) (the "Nifedipine Petition").

50. In granting Teva's petition, the FDA held that: "*Whether Mylan markets the product approved in its ANDA or the product approved in Pfizer's NDA is of little import to the statutory scheme*; Mylan has begun commercial marketing of *generic* nifedipine. Permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be

inconsistent with the intent of the statutory scheme." Food and Drug Administration Nifedipine Petition Response Letter, Docket No. 00P-1446/CP1, at 7-8 (Feb. 6, 2001) ("Nifedipine Petition Response") (emphasis added).

51. The U.S. District Court for the Northern District of West Virginia upheld the FDA's determination that brand generics are legally equivalent to ANDA generics for purposes of triggering the Generic Exclusivity Period. *Mylan v. Thompson*, 207 F. Supp. 2d 476, 482-83 (N.D. W. Va. 2001). Specifically, the district court endorsed the core principle established by the FDA in its Nifedipine Petition Response by quoting with approval the FDA's decision:

> whether Mylan markets the [product] approved in its ANDA or the product approved [in] Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of generic nifedipine[. P]ermitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

Mylan v. Thompson, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001) (quoting Nifedipine Petition Response, at 7-8) (emphasis added).

52. Mylan appealed the district court's decision. On appeal, the FDA further explained that, for the purpose of applying the Generic Exclusivity Period, it made "no difference" whether Mylan marketed the generic product approved in its ANDA or the brand generic produced by Pfizer. (Brief for Federal Defendants [FDA] at 34-35, *Mylan v. Thompso*n, No. 01-1554 (4th Cir. 2001) ("FDA Nifedipine Appeal Brief"). The FDA explained that the Generic Exclusivity Period "was intended to allow a generic manufacturer 180-days of marketing a drug *without competition from other generic drugs*." FDA Nifedipine Appeal Brief at 38 (emphasis added).

53. Although the Mylan appeal was dismissed voluntarily, Congress recently affirmed the District Court and FDA holdings that brand generics are legally and functionally equivalent with respect to the Generic Exclusivity Period. In 2003, Congress amended the FDCA provision establishing the Generic Exclusivity Period to clarify that the Generic Exclusivity Period is triggered by the first Paragraph IV ANDA filer's sale of a brand generic just as the Generic Exclusivity Period is triggered by the first-filer's sale of its ANDA generic. 21 U.S.C. § 355(j)(5)(B)(iv)(I). Congress thereby confirmed that the sale of a brand generic is legally and functionally equivalent to the sale of an ANDA generic drug with respect to the Generic Exclusivity Period.

54. The FDA and the courts have previously held that the application of the Generic Exclusivity Period cannot be controlled by the brand-drug manufacturer and that only an ANDA containing a Paragraph IV certification may be eligible for the Generic Exclusivity Period. Both principles are violated by the sale of a brand generic during the Generic Exclusivity Period.

55. The sale of a brand generic during the Generic Exclusivity Period deprives the first Paragraph IV ANDA filer of the exclusivity that it rightly deserves. The brand-drug manufacturer, which must approve the sale of a brand generic whether by its own subsidiary or by a licensee, thereby improperly controls whether, to what extent, and for what period of time the first-filer receives the benefit of the Generic Exclusivity Period.

56. The sale of a brand generic before the expiration of the Generic Exclusivity Period provides the brand-drug manufacturer, or other seller of the brand generic, exclusivity as to the generic drugs covered by subsequently filed ANDAs and thus improperly

awards the seller of the brand generic a portion of the Generic Exclusivity Period to which it has no right.

57. The brand-drug manufacturer's seizure of the first-filer's benefits from the Generic Exclusivity Period is particularly unlawful and inequitable given that those benefits are the first-filer's reward for stopping the brand-drug manufacturer from reaping unwarranted monopoly profits through the assertion of an inapplicable, invalid, or unenforceable patent. By poaching some or all of the first-filer's reward, the brand-drug manufacturer will both take what is rightfully the first-filer's and discourage other generic-drug manufacturers from vindicating the public interest through additional Paragraph IV certifications.

TEVA'S ENTITLEMENT TO THE GENERIC EXCLUSIVITY PERIOD FOR QUINAPRIL PRODUCTS

TEVA'S FIRST-FILED QUINAPRIL PARAGRAPH IV ANDA

58. Teva USA led the research for and the development of Teva's ANDA for Teva's generic quinapril products.

59. Teva spent millions of dollars and years of time and human resources in developing its quinapril ANDA on an expedited basis and researching the applicability and validity of Pfizer's patents listed in the Orange Book that purportedly cover Accupril® products. As a result of those expenditures and investments, Teva filed its quinapril ANDA on November 20, 1998 for the 5 mg, 10 mg, 20 mg, and 40 mg generic quinapril products, and was the first ANDA applicant to file a Paragraph IV certification for generic quinapril products. Teva thereafter spent over 5 years and millions of dollars defending Warner-Lambert's infringement action.

60. Teva received final approval of its ANDA with respect to all strengths of its generic quinapril products on May 30, 2003. Teva USA intends to sell Teva's generic quinapril products in the United States during and after Teva's Generic Exclusivity Period.

61. Upon receipt of final FDA approval of its quinapril ANDA, Teva was awarded the Generic Exclusivity Period with respect to the sale of generic quinapril products in the United States. The FDA expressly stated in its final-approval letter to Teva dated May 30, 2003 (attached hereto as Exhibit A): "***TEVA Pharmaceuticals USA is eligible for 180-days of market exclusivity with respect to the '450 patent for Quinapril Hydrochloride Tablets, 5 mg, 10 mg, 20 mg, and 40 mg.***" (Emphasis added.)

62. Teva has a legally protectable interest in, and right to, the Generic Exclusivity Period applicable to Teva's generic quinapril products. That interest and right have substantial monetary and commercial value and permit Teva, prior to the expiration of the Generic Exclusivity Period, to exclude from the marketplace other products that purport to be, or are sold as, generic quinapril products.

PFIZER HAS ADMITTED THAT TEVA IS ENTITLED TO THE GENERIC EXCLUSIVITY PERIOD FOR QUINAPRIL PRODUCTS

63. Pfizer has acknowledged and admitted, in another case involving quinapril, that Teva is entitled to the Generic Exclusivity Period for generic quinapril products. Pfizer never qualified that admission by excluding or excepting Pfizer's own supposed right, or that of any other brand-drug manufacturer, to sell generic quinapril products.

64. In *Mutual Pharmaceutical Co. v. Pfizer Inc.*, Case No. 1:03CV01116 (RMU) (July 8, 2003 D.D.C.) (the "*Mutual*" case), Mutual Pharmaceutical, another generic drug manufacturer, sought a declaratory judgment of patent non-infringement against Pfizer with respect to the patents that are listed by Pfizer in the Orange Book as covering Accupril®.

According to Pfizer in the *Mutual* case, under the Hatch-Waxman Amendments, a judgment in favor of Mutual Pharmaceutical would have triggered the Generic Exclusivity Period for the first-to-file Paragraph IV ANDA, Teva. Pfizer successfully moved to dismiss the *Mutual* case on the ground that it represented an unripe attack on Teva's protectable interests in the Generic Exclusivity Period for the sale of generic quinapril products.

65. Pfizer argued in the *Mutual* case, and has conceded for the purpose of this case, that, "because Teva was the first generic manufacturer to file an ANDA for quinapril hydrochloride, it is entitled, by statute, to temporary generic market exclusivity." *Mutual Pharm. Co.*, Memorandum of Points and Authorities in Support of Defendant Pfizer Inc.'s Motion to Dismiss for Lack of Subject Matter Jurisdiction ("Pfizer *Mutual* Mem.") at 2.

66. Pfizer sought to prevent Mutual from obtaining "a result in the present suit that would start Teva's exclusivity period before any decision in the Teva litigation. That way, Teva would be deprived of the opportunity to base the marketing of its products on events in its litigation with Pfizer. Mutual's interest in spoiling Teva's statutory benefit for competitive purposes satisfies neither of the requirements of declaratory judgment jurisdiction in an action against Pfizer, and undermines the Congressional intent set forth in the Hatch-Waxman Act." Pfizer *Mutual* Mem. at 2-3 (emphasis in original). Pfizer further admitted that the 180-day exclusivity period is a "statutory benefit for competitive purposes" that is possessed by Teva with respect to generic quinapril products. Pfizer *Mutual* Mem. at 2-3.

67. Pfizer also acknowledged in the *Mutual* case: "The first generic applicant to file an ANDA containing a paragraph IV certification, also known as a 'first-filer,' is eligible for a 180-day exclusivity period during which it is entitled to have the only generic version of the drug at issue on the market. 21 U.S.C. § 355(j)(5)(B)(iv)." Pfizer *Mutual* Mem. at 5.

68. Pfizer has conceded: "As the 'first-filer' of a quinapril hydrochloride ANDA, Teva is entitled to a 180-day period of generic exclusivity from the earlier of either (i) the date it first commercially markets generic quinapril hydrochloride, or (ii) the date of a court decision declaring the '450 patent invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II)." Pfizer *Mutual* Mem. at 6.

69. Pfizer has admitted: "Teva filed the first ANDA with a paragraph IV certification with respect to Pfizer's Accupril® medication. Teva is now entitled to 180 days of exclusivity in the generic market – a period intended by Congress as a reward for being the 'first filer' – which will commence on either (i) the date Teva first commercially markets its generic product, or (ii) the date of a court decision declaring Pfizer's '450 patent invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II)." Pfizer *Mutual* Mem. at 14-15.

70. Pfizer has further admitted: "Although promoting generic competition generally may be an aim of the Hatch-Waxman Act, Congress sought to achieve that purpose through the mechanisms explicitly described in the statute. Specifically, Congress intended to confer the 180-day exclusivity benefit on generic manufacturers like Teva which take the significant risk of being the first to challenge an innovator company's patent, in this case the '450 patent. If Mutual is permitted to proceed in this case then Mutual will have undermined both the Declaratory Judgment Act and the Hatch-Waxman Act." Pfizer *Mutual* Mem. at 15.

71. As alleged in more detail below, Pfizer itself, through false statements made in commercial advertising and promotion and other intentionally tortious conduct, will misappropriate Teva's right to the Generic Exclusivity Period by selling Accupril® products as generic quinapril products before the expiration of the Generic Exclusivity Period.

PFIZER IS THREATENING TO SELL ACCUPRIL® PRODUCTS AS GENERIC QUINAPRIL PRODUCTS IMMINENTLY AND BEFORE THE EXPIRATION OF TEVA'S GENERIC EXCLUSIVITY PERIOD

PFIZER WILL RELABEL ACCUPRIL® PRODUCTS AS GENERIC QUINAPRIL PRODUCTS AND MARKET THE RELABELED PRODUCTS FOR GENERIC SUBSTITUTION

72. Pfizer has threatened to sell generic quinapril products immediately following Teva's launch of its generic quinapril products and long before the expiration of Teva's Generic Exclusivity Period. Pfizer will do so despite Pfizer's admission that "Teva is now entitled to 180 days of exclusivity in the generic market – a period intended by Congress as a reward for being the 'first-filer' . . . ." Pfizer *Mutual* Mem. at 14-15.

73. On or about June 23, 2004, Pfizer Inc. filed a Comment with the FDA in opposition to a Citizen Petition filed by Teva USA, Docket No. 2004P-0261. Pfizer Inc. represented to the FDA in that Comment that it "expects to launch unbranded quinapril hydrochloride tablets through its Greenstone subsidiary, commencing with Teva's launch of its generic quinapril product." Comments of Pfizer Inc. on Docket No. 2004P-0261, at n.1 (June 23, 2004).

74. Representatives of Greenstone have stated to potential customers that Greenstone is ready to, and will, launch generic quinapril products as soon as Teva USA launches Teva's generic quinapril products.

75. Representatives of Greenstone made sales presentations to potential customers during the 2004 Annual Meeting of the National Association of Chain Drug Stores, which took place on April 17-21, 2004 at The Phoenician in Scottsdale, Arizona, wherein Greenstone representatives: (a) showed promotional pictures of Accupril® products that had been relabeled to be sold by Greenstone as generic quinapril products during the Generic

Exclusivity Period; and (b) indicated that Greenstone plans to market its generic quinapril products as soon as Teva USA launches Teva's generic quinapril products.

76. Teva USA has learned from its customers that Pfizer has already offered incentives to customers to purchase Pfizer's brand generic quinapril product immediately after Teva begins to sell its generic quinapril products.

77. Pfizer will sell Accupril® products as generic quinapril products by replacing the brand name, Accupril®, on the exterior of Pfizer's brand quinapril products with only the name of its generic-drug subsidiary, Greenstone, so as to mimic the labeling used by generic-drug manufacturers. Pfizer will also cause its generic quinapril products to be listed in industry pricing compendia so that the generic quinapril products will qualify for "generic substitution" (as defined below) under federal and state laws and under the industry practices of drug purchasers, dispensers and reimbursers.

78. Pfizer will sell Accupril® products as generic quinapril products with the intent of undermining the incentive for Teva and other generic-drug manufacturers to challenge patents that purportedly cover brand drugs. Pfizer thus intends to defeat, and will defeat unless restrained by this Court, the congressional purpose and intent of the Generic Exclusivity Period.

GENERIC DRUGS ARE SUBSTITUTED QUICKLY AND WIDELY FOR EQUIVALENT BRAND DRUGS BASED ON REPRESENTATIONS MADE IN COMMERCIAL ADVERTISING AND PROMOTION

79. For commercial purposes, "generic quinapril products" are products containing the active ingredient, quinapril hydrochloride, and sold in a manner that qualifies for substitution by dispensing pharmacists (or other qualified dispensers) for Accupril® products, pursuant to state law, federal law, and/or industry practice, unless the prescribing physician expressly prohibits such substitution. A generic quinapril product: (a) has the same active chemical ingredient (quinapril hydrochloride) of the same strength, quantity, and dosage form

as does the corresponding Accupril® product; (b) has a name, or other means of identification, that includes or refers to quinapril hydrochloride; (c) is bioequivalent to or the same as the corresponding Accupril® product; and (d) has a lower list price (frequently referred to as the suggested wholesale price ("SWP") or average wholesale price ("AWP")) than the AWP of the corresponding Accupril® product as reported by pricing compendia such as First Data Bank's Price Alert.

80. The laws of some states will, upon the entry of generic quinapril products, mandate the substitution of generic quinapril products for prescriptions of Accupril® products in the absence of a direction from the prescribing physician not to do so, and authorize a pharmacist or other dispenser to fill a physician's prescription for the Accupril® product with a generic quinapril product ("Mandatory Generic Substitution"). For example, Massachusetts requires such Mandatory Generic Substitution. MASS. GEN. LAWS ch. 112, § 12D (2004).

81. The laws of other states will, upon the listing of generic quinapril products on the state's list of interchangeable drug products, permit the substitution of generic quinapril products for prescriptions of Accupril® products that appear on the state's list in the absence of a direction from the prescribing physician not to do so, and authorize a pharmacist or other dispenser to fill a physician's prescription for the Accupril® product with a generic quinapril product ("State Listing-Based Generic Substitution"). Illinois is an example of a state providing for such permissive substitution to be made from the state's list of interchangeable drugs. 410 Ill. Comp. Stat. 620/3.14 (2004) and 225 Ill. Comp. Stat. 85/25 (2004).

82. The laws of still other states will, upon the entry of generic quinapril products, permit but not mandate the substitution of generic quinapril products for prescriptions of Accupril® products in the absence of a direction from the prescribing physician not to do so,

and authorize a pharmacist or other dispenser to fill a physician's prescription for the Accupril® product with a generic quinapril product ("Permissive Generic Substitution"). California is one such state. CAL. BUSINESS AND PROFESSIONS CODE § 4073 (West 2004).

83. The laws of many states will, upon the entry of generic quinapril products, absent an express exemption by the Department of Health or a similar entity or the prescribing physician, mandate the substitution of generic quinapril products for prescriptions of Accupril® products where the consumer cost of the drug is being paid for or subsidized by a government-funded program (*e.g.*, Medicaid), and authorize a pharmacist or other dispenser to fill a physician's prescription with a generic quinapril product for the Accupril® product ("Medicaid Generic Substitution".) New York is an example of a state with Medicaid Generic Substitution. N.Y. SOC. SERV. § 365-a (Consol. 2004).

84. Private insurers, third-party payers, healthcare plans, and managed care entities will require, or encourage through economic incentives, the substitution of generic quinapril products for Accupril® products in the absence of a direction from the physician not to do so ("Industry Generic Substitution").

85. Many insurance plans will issue a formulary that lists drugs that physicians may prescribe and/or that pharmacists may dispense for some or all of the drug price to be reimbursed. If a drug is not included in the formulary, or depending on its status in the formulary, purchase of the drug may require a higher co-payment from the patient or may not be covered by the insurance plan unless the physician obtains prior authorization from the insurance company. After a generic drug product becomes available, reimbursement for the purchase of the corresponding brand drug may be reduced because of inclusion of the generic drug product in the formulary.

86. Mandatory Generic Substitution, State Listing-Based Generic Substitution, Permissive Generic Substitution, Medicaid Generic Substitution, and Industry Generic Substitution are collectively referred to herein as "Generic Substitution." Generic Substitution occurs quickly and broadly upon the introduction of a new generic drug. For example, IMS Health reports that, on average, generic drugs account for nearly 80% of new prescriptions of the corresponding drug molecule thirteen weeks after the introduction of a new generic drug.

87. A brand generic and an ANDA generic equally can qualify for Generic Substitution and are otherwise functionally equivalent for all commercial purposes.

88. Purchasers, dispensers, and reimbursers of pharmaceuticals use compendia ("data banks") of drug-pricing information to identify generic drugs that are interchangeable with, and lower priced than, brand drugs for the purpose of Generic Substitution.

89. Manufacturers and distributors of generic drugs submit information to data banks that specify that a subject drug: (a) has the same active chemical ingredients of the same strength, quantity, and dosage form as the brand drug; (b) is bioequivalent to or the same as a brand drug (either as approved by the FDA through the ANDA process or by marketing the brand drug, approved through the NDA process, as a generic drug); and (c) has an SWP or AWP that is materially (*i.e.*, approximately 10% or more) lower than the AWP for the brand drug.

90. Upon receipt of the information specified in the immediately preceding paragraph, data banks list the subject drug, regardless of whether it is made by a brand-drug manufacturer or a generic-drug manufacturer, as a drug that is bioequivalent to or the same as, and a lower cost alternative to, the brand drug. When the subject drug is so listed, it is treated by dispensers and purchasers as a generic drug that qualifies for Generic Substitution.

PFIZER WILL SELL ACCUPRIL® PRODUCTS AS GENERIC QUINAPRIL PRODUCTS, OR OTHERWISE AS QUALIFYING FOR GENERIC SUBSTITUTION, IN VIOLATION OF TEVA'S RIGHT TO THE GENERIC EXCLUSIVITY PERIOD

91. Pfizer will advise data banks that its generic quinapril products are equivalent to and interchangeable with Accupril® products and will be sold at an SWP or an AWP that is lower than the AWP that Pfizer lists for Accupril® products. Based upon such representations, which will be made in commercial advertising and promotion, the data banks will list Pfizer's generic quinapril products as equivalent to, interchangeable with, and a lower cost alternative to, Accupril® products. Pfizer's generic quinapril products will thereby be substituted for Accupril® products pursuant to Generic Substitution.

92. Pfizer's generic quinapril products will compete with, and take substantial sales from, Teva's generic quinapril products before the expiration of Teva's Generic Exclusivity Period. Pfizer will thereby intrude upon, and misappropriate, Teva's rightful and exclusive interest in the Generic Exclusivity Period.

93. Pfizer also will usurp a portion of Teva's exclusivity for itself by selling, unlawfully and inequitably, its generic quinapril product protected from all generic competition (other than that from the first-filer, Teva) before the expiration of the Generic Exclusivity Period without any warrant or justification.

94. Pfizer will also poach a portion of Teva's reward for having been the first Paragraph IV ANDA applicant to challenge the Accupril® patent. Pfizer thereby will subvert intentionally the incentive that Congress established in the Hatch-Waxman Amendments for generic-drug manufacturers to promote competition by challenging invalid, unenforceable, and inapplicable patents.

PFIZER'S CONDUCT WILL VIOLATE THE LANHAM ACT, COMMON LAW PRINCIPLES PROHIBITING MISAPPROPRIATION AND TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS, SECTION TWO OF THE SHERMAN ACT, AND SECTION 17200 OF THE CALIFORNIA BUSINESS AND PROFESSIONS CODE

95. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will make intentional and materially false statements in commercial advertising and promotion that Accupril® products are generic quinapril products that qualify for Generic Substitution before the expiration of Teva's Generic Exclusivity Period. In fact, Accupril® products cannot be sold as generic quinapril products or qualify for Generic Substitution before the expiration of Teva's Generic Exclusivity Period. Pfizer's false statements will violate the Lanham Act.

96. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will violate the common law prohibiting Pfizer from misappropriating a commercial benefit or legal right of monetary value from Teva.

97. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will violate the common law prohibiting Pfizer from tortiously interfering with Teva's contractual or advantageous business relations.

98. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will thwart Teva's market entry, protect the monopoly position that Pfizer currently holds in the sale of quinapril products, and diminish generic competition with

respect to quinapril products and other pharmaceutical products that do not yet face generic competition. Pfizer will thereby violate Section 2 of the Sherman Act.

99. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will engage in unfair competition and will violate Teva's right to the Generic Exclusivity Period under the FDCA and other legal rights alleged herein. As a result, Pfizer will violate Section 17200 of the California Business and Professions Code.

THE RELEVANT MARKETS UNDER THE SHERMAN ACT CONSIST OF ACCUPRIL® AND GENERIC QUINAPRIL PRODUCTS AND OTHER PARAGRAPH IV DRUG MARKETS

100. The markets relevant to Teva's Sherman Act claim consist of (a) Accupril® and the generic quinapril products that are equivalent to and interchangeable with, or bioequivalent to, Accupril®, and (b) brand drugs that are subject to competition from current or prospective Paragraph IV ANDA applicants and bioequivalent generic products.

101. Teva's generic quinapril products and other FDA-approved quinapril products that are bioequivalent to Accupril® (collectively, "ANDA quinapril products") are reasonably interchangeable with, and are reasonably substitutable for, Accupril®, and are in the same relevant product market as is Accupril®.

102. ANDA quinapril products are bioequivalent to, and interchangeable with, comparable strengths of tablets of Accupril®.

103. Pfizer's generic quinapril products will be the same as Accupril® products and, accordingly, will be reasonably (and entirely) interchangeable with, and reasonably (and entirely) substitutable for, Accupril®.

104. As both patients and their physicians recognize that generic quinapril products are bioequivalent to Accupril® and because of Generic Substitution, most patients

taking Accupril® rapidly will switch to generic quinapril products at the first prescribing opportunity after generic quinapril products become available.

105. The Generic Exclusivity Period is predicated upon, and recognizes, the fact that competition between and among Accupril® and generic quinapril products is commercially discrete and relevant from the perspective of both sellers and purchasers of quinapril products.

106. Accupril® is an ACE inhibitor. Other ACE inhibitors that are not bioequivalent to Accupril® or generic quinapril products are not reasonably interchangeable with, or reasonably substitutable for, Accupril® or generic quinapril products.

107. ACE inhibitors other than generic quinapril products have not been shown to be bioequivalent to Accupril®.

108. Generic Substitution with respect to Accupril® does not apply to any ACE inhibitor other than generic quinapril products.

109. Most patients who are currently treated with Accupril® will continue to be treated with Accupril® or generic quinapril products on a long-term basis, often for the rest of the patient's life. Once a patient begins treatment with Accupril® and responds favorably to it, the patient generally would not switch to another, non-bioequivalent ACE inhibitor. The patient would not switch to another, non-bioequivalent ACE inhibitor even if, due to a significant and nontransitory change in the price of Accupril® or another ACE inhibitor, Accupril® became relatively more expensive after the patient had successfully begun taking Accupril®.

110. The manufacture of Accupril® and generic quinapril products for sale in the United States and the marketing and sale of Accupril® and generic quinapril products in the United States constitute a relevant market or, in the alternative, a relevant submarket (the

"Accupril® and Bioequivalents Market" or the "Accupril® Market"). The relevant product market (or product submarket) consists of the manufacture, marketing, and sale of Accupril® and generic quinapril products. The corresponding relevant geographic market consists of the United States and its possessions and territories.

111. Since on or about December 1, 1991, Pfizer has sold Accupril® in interstate commerce throughout the United States.

112. Pfizer's sales of Accupril® have accounted for 100% of all sales in the Accupril® Market since on or about December 1, 1991.

113. Pfizer will continue to sell Accupril® in the Accupril® Market and, in the absence of relief from this Court, will begin imminently to sell generic quinapril products in the Accupril® Market.

114. The manufacture of brand drugs that are subject to competition from current or prospective Paragraph IV ANDA applicants with bioequivalent generic products for sale in the United States, and the marketing and sale of such brand and generic products in the United States, constitute relevant markets or, in the alternative, relevant submarkets (the "Paragraph IV Drug Markets"). The relevant product markets (or product submarkets) consist of the manufacture, marketing, and sale of brand drugs that are subject to competition from current or prospective Paragraph IV ANDA applicants with bioequivalent generic products. The corresponding relevant geographic markets each consist of the United States and its possessions and territories.

PFIZER'S INTRODUCTION OF GENERIC QUINAPRIL PRODUCTS BEFORE THE EXPIRATION OF TEVA'S GENERIC EXCLUSIVITY PERIOD IS PART OF A LONG COURSE OF CONDUCT BY PFIZER TO PROTECT ITS MONOPOLY IN THE RELEVANT MARKETS AND TO IMPEDE GENERIC COMPETITION

115. Teva has alleged elsewhere that, through a long and continuous course of anticompetitive conduct, first directed to the United States Patent and Trademark Office ("USPTO"), then other regulatory processes, and finally maintained so as to block Teva's market entry, Pfizer has unlawfully preserved a monopoly and has tortiously interfered with Teva's business relationships to the detriment of Teva and consumers alike.

116. Pfizer's course of anticompetitive and tortious conduct began in the 1980s when it engaged in inequitable conduct in connection with the prosecution of a patent purportedly covering Accupril®; proceeded to wrongfully list that patent in the Orange Book, a government publication, with significant regulatory consequences; and, since May 30, 2003, the date Teva received final approval of its ANDA with respect to all strengths of its generic quinapril products, has blocked Teva's rightful entry into the Accupril® Market.

117. By way of the conduct complained of herein, Pfizer threatens to continue to act unlawfully to thwart, impede, and undermine the effectiveness of generic competition. Pfizer's conduct will violate the statutory and common law rights asserted herein and will seriously injure the public interest.

PFIZER'S CONDUCT WILL IRREPARABLY HARM THE INTERESTS OF BOTH THE PUBLIC AND TEVA

PFIZER WILL IRREPARABLY HARM THE PUBLIC INTEREST

118. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will eviscerate, and intends to eviscerate, the primary incentive enacted by Congress to encourage generic-drug manufacturers to challenge inapplicable,

invalid, or unenforceable patents that brand-drug manufacturers use to block generic competition. The Congressional Budget Office has estimated that, in 1994, the availability of generic drugs saved purchasers between $8 billion and $10 billion.

119. Pfizer's sale of generic quinapril products will enable Pfizer to extend its high market share in the Accupril® market and profitably increase prices for Accupril®.

120. By seizing a substantial portion of Teva's Generic Exclusivity Period for quinapril, Pfizer will reduce the value of that period to Teva. By reducing the value of Teva's Generic Exclusivity Period for quinapril, Pfizer will also reduce the expected value to Teva and others of Generic Exclusivity Periods for other Pfizer Paragraph IV Drug Markets. Should Pfizer succeed in its strategy, other brand manufacturers are likely to adopt Pfizer's strategy. The result of such further diminishing of the incentives for Teva and others to challenge or avoid patents likely will be further losses of competition in Paragraph IV Drug Markets.

121. By reducing the incentive for Teva and others to challenge or avoid patents in Pfizer Paragraph IV Drug Markets, Pfizer thereby will deter and diminish generic entry, reduce generic competition, and prolong the possession, use, and abuse of monopoly power by brand-drug companies, within the relevant markets. By the unlawful conduct complained of herein, Pfizer will harm the competitive significance of Teva, and with it, the interests of consumers and Teva alike.

122. The injury to the public interest, including to competition, will flow directly from Teva's injuries (and vice-versa), and both Teva's injuries and the injury to the public interest, including to competition, will result directly from Pfizer's unlawful conduct complained of herein.

PFIZER WILL IRREPARABLY HARM THE INTERESTS OF TEVA

123. Pfizer will sell Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period with the specific intent to achieve the following objectives:

- to intrude upon, and misappropriate, Teva's right to the Generic Exclusivity Period for the sale of generic quinapril products;
- to deprive Teva of the competitive benefits of the Generic Exclusivity Period, including the first-mover advantage and important customer relationships that are established during, and continue long after the expiration of, the Generic Exclusivity Period;
- to seize for Pfizer competitive benefits and advantages to which it has no lawful right;
- to seize for Pfizer a portion of the reward that Congress has conferred on Teva for having been the first generic company to challenge Pfizer's own patent covering Accupril® products;
- to thwart and marginalize the immediate and long-term competitive significance of Teva's entry;
- to maintain unlawfully a monopoly in the Accupril® Market before the expiration of the Generic Exclusivity Period;
- to frustrate and undermine, by repeatedly intruding in the future upon Generic Exclusivity Periods with brand generic products, the Hatch-Waxman statutory scheme that encourages manufacturers, including Teva, to invest in Paragraph IV certifications, to challenge invalid, unenforceable, and inapplicable patents underlying brand drugs, and to sell as soon as possible lower priced generic drugs, all to the detriment of consumers of pharmaceutical drugs in the United States; and
- to maintain unlawfully a monopoly in the Paragraph IV Drug Markets.

124. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will succeed, or will have a dangerous probability of succeeding, in accomplishing the objectives set forth in the immediately preceding paragraph.

125. By selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will injure Teva during that period and thereafter in at least the following ways:

- Teva will lose the first-mover and related competitive advantages among sellers of generic quinapril products that it otherwise would have obtained during the Generic Exclusivity Period;
- Teva will lose valuable market share and position in connection with its sale of generic quinapril products that it otherwise would have obtained during the Generic Exclusivity Period;
- Teva will lose valuable and specific advantageous business and customer relationships, and the goodwill associated therewith, in connection with the sale of generic quinapril products that it otherwise would have established during the Generic Exclusivity Period;
- Teva will lose during the Generic Exclusivity Period millions of dollars in profits from lost sales of its generic quinapril products that Teva will never be able to recover, which sales will be unjustly taken by, and will unjustly enrich, Pfizer;
- Teva will lose the commercial benefit and reward for having been the first to challenge Pfizer's own patent covering Accupril® products, to which Teva is entitled by congressional mandate; and
- Teva will receive fewer benefits from pursuing costly Paragraph IV certifications in Paragraph IV Drug Markets, thereby negatively altering the cost-benefit calculus that Congress intended to promote through the Generic Exclusivity Period.

126. Many of the competitive and commercial benefits that Teva will obtain during the Generic Exclusivity Period will extend beyond the expiration of the Generic Exclusivity Period. For example, an exclusive supplier relationship with respect to generic quinapril products established with a drug wholesaler or retailer during the Generic Exclusivity Period will continue with that drug wholesaler or retailer beyond the Generic Exclusivity Period. Teva will lose such continuing benefits as a result of Pfizer's unlawful conduct.

127. The value of Teva's Generic Exclusivity Period is a depreciable asset the value of which depends, day-to-day, upon unique market conditions that can be maintained for a limited duration (180 days). At least five other generic-drug manufacturers have received tentative approval from the FDA of their Paragraph IV ANDAs for generic quinapril products. Upon the expiration of the Generic Exclusivity Period, some or all of those tentatively approved ANDAs likely will receive final FDA approval and the generic quinapril products covered thereby may be sold in competition with Teva's generic quinapril products. Upon the entry of competing generic quinapril products, the unique benefits or value of the Generic Exclusivity Period can never be recovered or reproduced.

128. As a direct and proximate result of the unlawful conduct complained of herein, Teva is threatened with immediate and irreparable harm and damage for which it has no adequate remedy at law.

129. Money damages and other remedies at law will be insufficient to compensate Teva for the injuries alleged above. The Generic Exclusivity Period is a temporary and unique asset the value of which is not practicably quantifiable in monetary terms. Once the benefits and advantages alleged above are lost, they can never be regained.

130. The irreparable harm to Teva caused by depriving Teva of the commercial and competitive benefits, many of which are unrecoverable, intangible, and/or unquantifiable, that flow from its Generic Exclusivity Period will outweigh any harm to Pfizer from enjoining the sale of its Accupril® products as generic quinapril products prior to the expiration of the Generic Exclusivity Period. Pfizer will remain free to sell its Accupril® products as brand quinapril products to any purchaser and at any price.

131. Teva is entitled to temporary, preliminary, and permanent injunctive relief that bars Pfizer from selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

PFIZER'S UNJUST ENRICHMENT

132. In the absence of the temporary and preliminary injunctive relief requested by Teva, Teva will suffer injury for which restitution and/or disgorgement, among other remedies, will be appropriate, as alleged below.

133. In the absence of the temporary and preliminary injunctive relief requested herein, Pfizer will be unjustly enriched insofar as it will benefit, at Teva's and consumers' expense, from the sale of Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

134. By wrongfully and inequitably selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, Pfizer will knowingly, intentionally, wrongfully, and inequitably have seized from Teva an economic benefit arising from the Generic Exclusivity Period to Teva's economic detriment. Pfizer's economic benefit consists of the wrongful and inequitable profits that it will make and hold at the direct expense of Teva. Pfizer will make and hold those profits through the unlawful, unfair, unconscionable, and inequitable means complained of herein, and it will be unjustly enriched by those profits.

135. Teva's losses as complained of herein will be directly and proximately caused by the inequitable conduct and unjust enrichment that are complained of herein.

136. The monies that will be inequitably made or held by Pfizer will constitute unjust enrichment and will be traceable, and rightly belong, to Teva.

137. Unless Pfizer is divested of the illicit profits that it will hold in its possession and to which it has no right, Pfizer will have a compelling incentive in the future to repeat, and to use such profits to fund, such acts, practices, and patterns of unlawful conduct as complained of herein. Teva is further entitled to the divestiture, disgorgement, restitution, and/or return of all proceeds that were unlawfully and inequitably made or held, or are unlawfully and inequitably being held, by Pfizer that are rightfully the property of Teva. In partial or full alternative to other allegations made herein, Teva has no adequate remedy at law for the injury sought to be enjoined herein and seeks such relief to remedy otherwise irreparable harm.

THE FDA HAS FAILED TO PROTECT TEVA'S GENERIC EXCLUSIVITY PERIOD FROM PFIZER'S IMMINENT INTRUSION

TEVA AND OTHERS HAVE PETITIONED THE FDA FOR PROTECTION OF THE GENERIC EXCLUSIVITY PERIOD

138. On or about February 17, 2004, Mylan Pharmaceuticals Inc. ("Mylan"), a generic-drug manufacturer, filed with the FDA a Citizen Petition (the "Mylan Citizen Petition") requesting that the FDA "prohibit the marketing and distribution of 'authorized generic' [*i.e.*, brand generic] versions of brand name products, until the expiration of any 180-day generic drug exclusivity to which an ANDA applicant is entitled." Mylan requested that the FDA render an expedited decision on its petition. Mylan Pharmaceuticals Inc. Citizen Petition, Docket No. 2004P-0075, at 1 (Feb. 17, 2004).

139. On or about March 24, 2004, generic-drug manufacturer Apotex Corp. filed a Comment with the FDA supporting the Mylan Citizen Petition. Apotex urged that the introduction of a generic drug by any company other than the first Paragraph IV ANDA filer

during the 180-day exclusivity period would contradict the basic meaning of "exclusivity." Apotex also observed that introduction of a brand generic during the Generic Exclusivity Period would disrupt the "compromise between protecting patent rights and stimulating generic innovation" that is inherent in the Hatch-Waxman Amendments. Comment of Apotex Corp. in Support of Citizen Petition Docket No. 2004P-0075/CP1, at 5-6 (March 24, 2004).

140. On or about May 21, 2004, the Generic Pharmaceutical Association ("GPhA") filed a Comment with the FDA supporting the Mylan Citizen Petition. In addition to concurring in Apotex's Comment, GPhA asserted that "the brand company practice of licensing authorized generics [*i.e.*, brand generics] to undercut 180-day generic exclusivity is contrary to Hatch-Waxman and its basic goal of increased public access to affordable, generic drugs." Comment of the Generic Pharmaceutical Association in Support of Citizen Petition Docket No. 2004P-0075/CP1, at 1 (May 21, 2004) ("GPhA Comment").

141. After identifying the FDA's authority to grant the relief requested in the Mylan Citizen Petition, GPhA further stated that: "[The] FDA should exercise its broad regulatory authority to address practices that are directly contrary to the language and remedial goals of Hatch-Waxman. The licensing of authorized generics [*i.e.*, brand generics] during the 180-day exclusivity period is such a practice." (Footnote omitted.) GPhA Comment, at 2.

142. On or about May 11, 2004, Johnson & Johnson filed a Comment with the FDA in opposition to the Mylan Citizen Petition.

143. On June 9, 2004, Teva USA filed a Citizen Petition (the "Teva Citizen Petition") with the FDA requesting that the FDA "take immediate action to enforce its existing regulations and established policy in order to prevent Pfizer Inc. from marketing a generic version of its Accupril® (quinapril) drug until after expiration of Teva's 180-day exclusivity

period." Teva Pharmaceuticals USA, Inc. Citizen Petition, Docket No. 2004P-0261, at 1 (June 9, 2004). The Teva Citizen Petition was also submitted as a comment to the Mylan Citizen Petition. Given the urgency and immediacy of the harm to Teva if the Petition is not granted, Teva requested that the FDA render an expedited decision on the Teva Citizen Petition.

144. On or about June 23, 2004, Pfizer Inc. filed a Comment with the FDA in opposition to the Teva Citizen Petition. Pfizer Inc. stated in its Comment that it "expects to launch unbranded quinapril hydrochloride tablets through its Greenstone subsidiary, commencing with Teva's launch of its generic quinapril product." Comments of Pfizer Inc. on Docket No. 2004P-0261, at n.1 (June 23, 2004).

THE FDA HAS FAILED TO RESPOND TO THE PETITIONS AND COMMENTS FILED BY TEVA AND OTHERS

145. Clear precedent and established policy require that the FDA grant the relief requested in the Mylan Citizen Petition, the Comments supporting the Mylan Citizen Petition, and the Teva Citizen Petition. Nonetheless, to date, the FDA has failed to take any action in response to the Mylan Citizen Petition (more than 130 days after its filing), the supporting Comments, or the Teva Citizen Petition.

146. As alleged above, the FDA has an established policy to treat brand generics as the legal and functional equivalents of generic drugs approved through the ANDA process. A federal court and Congress have affirmed that policy.

147. The FDA's failure to respond to the Teva Citizen Petition (and the Mylan Citizen Petition as well as the Comments supporting the Mylan Citizen Petition), in light of the irreparable harm that will imminently befall the public and Teva, constitutes final agency action that is arbitrary, capricious, and contrary to law.

FIRST CLAIM FOR RELIEF
(AGAINST ALL DEFENDANTS)
FOR DECLARATORY JUDGMENT

148. Teva repeats and realleges Paragraphs 1 through 147 as though fully set forth herein.

149. Teva asserts this claim for declaratory judgment pursuant to 28 U.S.C. §§ 2201, *et seq*.

150. A justiciable controversy exists between the parties hereto as to the lawfulness of: (a) Pfizer's threatened sale of Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period; and (b) the FDA's failure to respond to Teva's Citizen Petition and to act to protect Teva's Generic Exclusivity Period from intrusion by Pfizer's generic quinapril products.

151. Teva is an interested party within the meaning of 28 U.S.C. § 2201(a).

152. Teva requests, and is entitled to, a judicial determination and declaration that Pfizer's threatened conduct complained of herein would be unlawful as set forth below in the Second through Eighth Claims for Relief and in the Tenth Claim for Relief and that, as alleged in the Ninth Claim for Relief, the FDA's failure to respond to Teva's Citizen Petition and to act to protect Teva's Generic Exclusivity Period from intrusion by Pfizer's generic quinapril product constitutes final agency action that is arbitrary, capricious, and contrary to law.

153. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

154. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period.

155. Teva requests, and is entitled to, an order compelling the FDA to respond to Teva's Citizen Petition and to act to protect Teva's Generic Exclusivity Period from intrusion by Pfizer's generic quinapril products.

SECOND CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR VIOLATION OF 15 U.S.C. § 1125(A) FALSE AND MISLEADING ADVERTISING AND PROMOTION

156. Teva repeats and realleges Paragraphs 1 through 155 as though fully set forth herein.

157. Pfizer is threatening to present, through false and/or misleading statements and representations made in commercial advertising or promotion, willfully and intentionally, Accupril® products for sale as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period. Upon Pfizer's so presenting, advertising, and promoting Accupril® products: (a) data banks will list Pfizer's generic quinapril products in a manner that qualifies for Generic Substitution; and (b) purchasers, dispensers, and reimbursers will purchase, dispense, and reimburse Pfizer's generic quinapril product in substitution for Accupril® products pursuant to Generic Substitution.

158. The false and/or misleading statements and representations that Pfizer threatens to make in commercial advertising or promotion are or will be material, willful and intentional, and literally false or literally false by means of necessary implication.

159. Pfizer's presenting, advertising, and promoting Accupril® products for sale as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, will cause purchasers, dispensers, and reimbursers to be confused and deceived into believing that Pfizer is lawfully and properly authorized to sell generic quinapril products before the expiration of Teva's Generic Exclusivity Period.

160. Pfizer will violate the Lanham Act, 15 U.S.C. § 1125(a), by falsely and/or misleadingly stating and representing in commercial advertising and promotion, willfully and intentionally, the nature, characteristics, and qualities of Accupril® products as being those of generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period. Pfizer will thereby falsely and/or misleadingly state and represent to purchasers, dispensers, and reimbursers that Pfizer's generic quinapril products are fully substitutable for Accupril® products before the expiration of Teva's Generic Exclusivity Period when Pfizer's generic quinapril products cannot by law be so substituted.

161. Pfizer's sale of Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period will compete with, and take substantial sales from, Teva's generic quinapril products, all within interstate commerce.

162. By engaging in false and misleading commercial advertising and/or promotion as alleged herein, Pfizer will devalue Teva's right to its Generic Exclusivity Period without warrant, justification, the authorization or consent of Teva, or the authorization of any entity empowered to grant such authorization.

163. As a direct and proximate result of the unlawful conduct complained of herein, Teva is threatened with immediate and irreparable harm and damage for which it has no adequate remedy at law.

164. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, pursuant to 15 U.S.C. § 1116.

165. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period, pursuant to 15 U.S.C. § 1116.

166. In the absence of and/or in addition to the injunctive relief requested above, Teva is entitled to recover from Pfizer such actual damages as the jury finds Teva to have incurred from Pfizer's willfully and intentionally wrongful conduct, trebled, plus Teva's cost of suit, including in this exceptional case reasonable attorneys' fees, pursuant to 15 U.S.C. § 1117.

167. In the alternative and to the extent that the Court determines that damages are not available to Teva, Teva is entitled to an order providing for the return, by way of divestiture, restitution, disgorgement, or other equitable remedy, of the illicit profits that are made or held by Pfizer at the expense of Teva, plus Teva's cost of suit, including in this exceptional case reasonable attorneys' fees, all pursuant to 15 U.S.C. § 1117.

THIRD CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR UNFAIR COMPETITION – COMMON LAW

168. Teva repeats and realleges Paragraphs 1 through 167 as though fully set forth herein.

169. Teva made substantial investments of skill, money, and labor in filing the first Paragraph IV ANDA for generic quinapril products. Teva thereby earned the right to the Generic Exclusivity Period with respect to the sale of generic quinapril products.

170. The Generic Exclusivity Period constitutes a commercial benefit and/or legal right of substantial monetary and economic value that Teva possesses and that this Court can protect pursuant to established common law.

171. The monetary and economic value to Teva of its Generic Exclusivity Period consists of Teva's being the first and only firm permitted to sell generic quinapril products, or quinapril products that qualify for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

172. Pfizer has knowledge of Teva's right to the Generic Exclusivity Period with respect to the sale of generic quinapril products.

173. Pfizer is threatening, intentionally and maliciously, to sell Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period in New York, Pennsylvania, California, and elsewhere. Upon Pfizer's so presenting Accupril® products for sale: (a) data banks will list Pfizer's generic quinapril products in a manner that qualifies for Generic Substitution; and (b) purchasers, dispensers, and reimbursers will purchase, dispense, and reimburse Pfizer's generic quinapril products in substitution for Accupril® products pursuant to Generic Substitution.

174. Upon Pfizer's sale of Accupril® products as generic quinapril products, or in a manner that qualifies for Generic Substitution, Pfizer will compete with, and take substantial sales from, Teva's generic quinapril products.

175. Pfizer's threatened sale of Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's generic quinapril Generic Exclusivity Period will constitute unfair competition, unlawful misappropriation of Teva's protectable interests, unfair trade practices, and/or deceptive trade practices (collectively, "unfair competition") in violation of the common law.

176. By engaging in unfair competition as alleged herein, Pfizer intentionally and maliciously: (a) will misappropriate for itself Teva's right to the Generic Exclusivity Period; (b) will misappropriate substantial sales from Teva's generic quinapril products both before the expiration of the Generic Exclusivity Period and thereafter; (c) will benefit from marketing exclusivity as to all subsequently filed Paragraph IV quinapril ANDAs by virtue of Teva's Generic Exclusivity Period; and (d) will irreparably harm Teva's competitive position, all without warrant, justification, the authorization or consent of Teva, or the authorization of any entity empowered to grant such authorization.

177. As a direct and proximate result of the unlawful conduct complained of herein, Teva is threatened with immediate and irreparable harm and damage for which it has no adequate remedy at law.

178. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

179. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period.

180. In the absence of and/or in addition to the temporary and permanent injunctive relief sought herein, Teva is entitled to recover from Pfizer such actual damages as the jury finds Teva to have incurred, and such punitive damages as applicable law may permit, or, in the alternative, to an order providing for the return, by way of divestiture, restitution, disgorgement or other equitable remedy, of illicit profits that are made or held by Pfizer at the expense of Teva.

FOURTH CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR TORTIOUS INTERFERENCE WITH CONTRACTUAL AND/OR ADVANTAGEOUS BUSINESS RELATIONSHIPS

181. Teva repeats and realleges Paragraphs 1 through 180 as though fully set forth herein.

182. By selling Accupril® products as generic quinapril products, or in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period in New York, Pennsylvania, California, and elsewhere, Pfizer will tortiously interfere with Teva's current and prospective contractual and/or advantageous business relationships. Pfizer will so act intentionally, maliciously, and improperly.

183. Teva will manufacture, market, and sell its generic quinapril products. Teva has obtained and will obtain contractual relationships and/or advantageous business relationships with numerous customers in connection with which Teva intends to sell its generic

quinapril products. Teva will pursue, act upon, and benefit from those contractual relationships and/or advantageous business relationships with the full expectation of economic benefit.

184. Pfizer has knowledge of Teva's current and prospective contractual and/or advantageous business relationships, which are part of the ordinary course of dealing and industry practice in the pharmaceutical industry.

185. The wrongful acts complained of herein will constitute improper means by which Pfizer intentionally, maliciously, and improperly will interfere with Teva's current and prospective contractual relationships and/or advantageous business relationships without privilege or lawful justification. As a direct and proximate result of Pfizer's wrongful conduct, Teva will be unlawfully precluded from pursuing and securing the business opportunities identified above.

186. Pfizer's wrongful acts will be a direct and proximate cause of Teva's loss of contractual relationships and/or advantageous business relationships, including millions of dollars in lost profits from sales of Teva's generic quinapril products lost to Pfizer's generic quinapril products.

187. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

188. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period.

189. In the absence of and/or in addition to the temporary and permanent injunctive relief sought herein, Teva is entitled to recover from Pfizer such actual damages as the jury finds Teva to have incurred, and such punitive damages as applicable law may permit, or, in the alternative, to an order providing for the return, by way of divestiture, restitution, disgorgement, or other equitable remedy, of illicit profits that are made or held by Pfizer at the expense of Teva.

FIFTH CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR VIOLATION OF 15 U.S.C. § 2 –
MONOPOLIZATION/ATTEMPTED MONOPOLIZATION
OF THE ACCUPRIL® AND BIOEQUIVALENTS MARKET

190. Teva repeats and realleges Paragraphs 1 through 189 as though fully set forth herein.

191. Pfizer has maintained monopoly power in the Accupril® and Bioequivalents Market through the launch of Teva's generic quinapril products as Pfizer has maintained a 100% share of such Accupril® Market up to that date.

192. Pfizer threatens to violate Section 2 of the Sherman Act (15 U.S.C. § 2) by willfully and unlawfully maintaining monopoly power in the Accupril® Market by introducing Accupril® products for sale as generic quinapril products, or in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period. Pfizer threatens to so act with the specific intent of unlawfully maintaining a monopoly in the Accupril® Market.

193. In violation of Section 2 of the Sherman Act, by the conduct complained of herein, Pfizer will succeed, or have a dangerous probability of succeeding, in unlawfully maintaining a monopoly in the Accupril® Market.

194. Pfizer, by willfully and unlawfully maintaining, or attempting to maintain, a monopoly in the Accupril® Market, will thwart, forestall, and otherwise delay Teva from entering and competing in the Accupril® Market with its generic quinapril products.

195. Pfizer, by willfully and unlawfully maintaining, or attempting to maintain, a monopoly in the Accupril® Market, will thereby alter to its commercial benefit and to the detriment of competition the incentives and structure of the Accupril® Market that have been ordained by Congress.

196. Pfizer, by willfully and unlawfully maintaining, or attempting to maintain, a monopoly in the Accupril® Market, directly and proximately will cause injury to consumers and competition by thwarting, forestalling, and otherwise undermining the effectiveness and speed of Teva's entry into, and otherwise reducing competition in, the Accupril® Market.

197. Pfizer, by willfully and unlawfully maintaining, or attempting to maintain, a monopoly in the Accupril® Market, will directly and proximately cause antitrust injury to Teva's business and property, including, without limitation, the loss of the first-mover and related competitive advantages, market share and position, advantageous business relationships and related good will, and millions of dollars in profits from current and future lost sales of Teva's generic quinapril products before the expiration of the Generic Exclusivity Period and thereafter.

198. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, and awarding Teva its reasonable attorneys' fees, all pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

199. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period, and awarding Teva its reasonable attorneys' fees, all pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

200. In the absence of and/or in addition to the injunctive relief requested above, Teva is entitled to recover from Pfizer such actual damages as the jury finds Teva to have incurred from Pfizer's wrongful monopolization and/or attempted monopolization, trebled, plus Teva's cost of suit, including reasonable attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

201. In the alternative and to the extent that the Court determines that damages are not available to Teva under Section 4 of the Clayton Act, Teva is entitled to an order providing for the return, by way of divestiture, restitution, disgorgement, or other equitable remedy, of the illicit profits that are made or held by Pfizer at the expense of Teva, plus Teva's cost of suit, including reasonable attorneys' fees, all pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

202. The injuries that Pfizer's conduct will cause to Teva's business are of the type that the Sherman and Clayton Acts were intended to prevent and will flow from that which makes Pfizer's acts unlawful under the Sherman and Clayton Acts.

SIXTH CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR VIOLATION OF 15 U.S.C. § 2 –
MONOPOLIZATION/ATTEMPTED MONOPOLIZATION
OF THE PARAGRAPH IV DRUG MARKETS

203. Teva repeats and realleges Paragraphs 1 through 202 as though fully set forth herein.

204. Pfizer threatens to violate Section 2 of the Sherman Act (15 U.S.C. § 2) by willfully and unlawfully maintaining monopoly power, attempting to monopolize, or attempting to maintain a monopoly in the Paragraph IV Drug Markets in which Pfizer sells a brand drug. Pfizer's unlawful means of maintaining monopoly power, attempting to monopolize, or attempting to maintain a monopoly will consist of: (a) the sale of Accupril® products as generic quinapril products, or in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period; and (b) the sale of brand drugs other than Accupril® products as generic drug products, or in a manner that qualifies for Generic Substitution, in Paragraph IV Drug Markets before the expiration of the applicable Generic Exclusivity Period. Pfizer threatens to so act with the specific intent of unlawfully maintaining a monopoly, attempting to monopolize, or attempting to maintain a monopoly in each of the Paragraph IV Drug Markets.

205. In violation of Section 2 of the Sherman Act, by the conduct complained of herein, Pfizer will succeed, or have a dangerous probability of succeeding, in unlawfully monopolizing, or maintaining a monopoly in, the Paragraph IV Drug Markets.

206. Pfizer, by willfully and unlawfully maintaining a monopoly, attempting to monopolize, or attempting to maintain a monopoly in the Paragraph IV Drug Markets, will thwart, forestall, and otherwise delay entry by generic-drug manufacturers into Paragraph IV Drug Markets and harm the competition that would have resulted therefrom.

207. Pfizer, by willfully and unlawfully maintaining a monopoly, or attempting to maintain, a monopoly in the Paragraph IV Drug Markets, will thereby alter to its commercial benefit and to the detriment of competition the incentives and structure of the Paragraph IV Drug Markets that have been ordained by Congress.

208. Pfizer, by willfully and unlawfully maintaining a monopoly, attempting to monopolize, or attempting to maintain a monopoly in the Paragraph IV Drug Markets, directly and proximately will cause injury to consumers and competition by thwarting, forestalling, and otherwise undermining entry by generic-drug manufacturers into Paragraph IV Drug Markets.

209. Pfizer, by willfully and unlawfully maintaining a monopoly, attempting to monopolize, or attempting to maintain a monopoly in the Paragraph IV Drug Markets, will directly and proximately cause antitrust injury to Teva's business and property, including, without limitation, the loss of the first-mover and related competitive advantages, market share and position, advantageous business relationships and related good will, and millions of dollars in profits from current and future lost sales of Teva's generic quinapril products, and other Paragraph IV generic drug products, before the expiration of the quinapril or other applicable Generic Exclusivity Periods and thereafter.

210. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, and awarding Teva its reasonable attorneys' fees, all pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

211. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril®

products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period, and awarding Teva its reasonable attorneys' fees, all pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

212. In the absence of and/or in addition to the injunctive relief requested above, Teva is entitled to recover from Pfizer such actual damages as the jury finds Teva to have incurred from Pfizer's wrongful monopolization and/or attempted monopolization, trebled, plus Teva's cost of suit, including reasonable attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

213. In the alternative and to the extent that the Court determines that damages are not available to Teva under Section 4 of the Clayton Act, Teva is entitled to an order providing for the return, by way of divestiture, restitution, disgorgement, or other equitable remedy, of the illicit profits that are made or held by Pfizer at the expense of Teva, plus Teva's cost of suit, including reasonable attorneys' fees, all pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

214. The injuries that Pfizer's conduct will cause to Teva's business are of the type that the Sherman and Clayton Acts were intended to prevent and will flow from that which makes Pfizer's acts unlawful under the Sherman and Clayton Acts.

SEVENTH CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR VIOLATION OF SECTION 17200 OF THE
CALIFORNIA BUSINESS AND PROFESSIONS CODE

215. Teva repeats and realleges Paragraphs 1 through 214 as though fully set forth herein.

216. Pfizer Inc., Greenstone, Parke-Davis, and Warner-Lambert separately and/or together, qualify as a "business" within the meaning of California Business and Professions Code §17200 ("Section 17200"). CAL. BUS. & PROF. CODE § 17200 (West 2004).

217. Teva USA maintains generic-drug manufacturing facilities in Irvine, California. Teva expects that its California manufacturing facilities will produce generic drugs for which Teva will, or would in the absence of Pfizer's conduct complained of herein, make Paragraph IV certifications with the relevant ANDAs.

218. The acts and practices of Pfizer complained of herein are unlawful and unfair business acts and practices, and are unfair, deceptive, untrue, and/or misleading advertising. As such, they constitute unfair competition within the meaning of, and violate, Section 17200.

219. By way of the conduct complained of herein, and as alleged above, Pfizer willfully, knowingly, and with specific intent, will violate Teva's right to the Generic Exclusivity Period under the FDCA, the Lanham Act, common law principles prohibiting unfair competition and the tortious interference with business relations, and Section 2 of the Sherman Act.

220. Because the acts and practices of Defendants complained of herein constitute violations of Teva's right to the Generic Exclusivity Period under the FDCA, the Lanham Act, common law principles prohibiting unfair competition and the tortious interference with business relations, and Section 2 of the Sherman Act, they constitute unfair competition within the meaning of, and violate, Section 17200.

221. Because the acts and practices of Pfizer complained of herein violate the policy and spirit of Teva's right to the Generic Exclusivity Period under the FDCA, the Lanham

Act, common law principles prohibiting unfair competition and the tortious interference with business relations, and Section 2 of the Sherman Act and otherwise significantly threaten or harm competition, they constitute unfair competition within the meaning of, and violate, Section 17200.

222. Teva received final approval of its ANDA with respect to all strengths of its generic quinapril products on May 30, 2003 and intends to sell its generic quinapril products in the United States, including in the State of California.

223. Pfizer, by way of the unlawful and unfair conduct complained of herein, will directly and proximately harm Teva's sales of its generic quinapril products, which conduct will directly and proximately affect the commerce of the State of California.

224. Pfizer will cause such injuries to Teva, consumers, and competition as complained of above within the State of California.

225. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, as provided for by Section 17203 of the California Business and Professions Code. CAL. BUS. & PROF. CODE § 17203 (West 2004).

226. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period, as provided for by Section 17203 of the California Business and Professions Code. CAL. BUS. & PROF. CODE § 17203 (West 2004).

227. In partial or full alternative to the other allegations and/or preceding claims for relief, Teva has no adequate remedy at law for the injunctive relief sought herein and seeks such relief to remedy otherwise irreparable harm.

EIGHTH CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR DISGORGEMENT AND/OR RESTITUTION FOR UNJUST ENRICHMENT

228. Teva repeats and realleges Paragraphs 1 through 227 as though fully set forth herein.

229. In the absence of the injunctive relief sought herein, Pfizer will be unjustly enriched insofar as it will benefit, at Teva's expense and consumers' expense, from the unlawful and inequitable acts complained of herein. Those acts will result in injuries to Teva as alleged herein.

230. By the unlawful and inequitable conduct alleged herein, Pfizer will knowingly, intentionally, wrongfully, and inequitably seize an economic benefit from Teva to Teva's economic detriment. Pfizer's economic benefit will consist, among things, of the profits that are made or held at the direct, wrongful, and inequitable expense of Teva. Pfizer will make and hold those profits through the unlawful, unfair, unconscionable, and inequitable means complained of herein and will be unjustly enriched by those profits.

231. Teva's losses as alleged herein will be directly and proximately caused by Pfizer's inequitable conduct.

232. The monies that will be inequitably made or held by Pfizer will constitute unjust enrichment and will be traceable, and rightly belong, to Teva.

233. In the absence of the temporary and preliminary injunctive relief sought herein, Teva hereby requests an order providing for the return, by way of disgorgement,

restitution, divestiture, and/or other equitable remedy, of all proceeds that will be unlawfully and inequitably made or held by Pfizer that are rightfully the property of Teva.

234. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period.

235. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period.

236. In partial or full alternative to the other allegations and/or preceding claims for relief, Teva has no adequate remedy at law for the injunctive relief sought herein and seeks such relief to remedy otherwise irreparable harm.

NINTH CLAIM FOR RELIEF
(AGAINST THE FDA)
FOR VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

237. Teva repeats and realleges Paragraphs 1 through 236 as though fully set forth herein.

238. The FDA has an established policy to treat brand generics as the legal and functional equivalents of ANDA generics with respect to Generic Exclusivity Periods.

239. The judiciary and Congress have confirmed that brand generics are the legal and functional equivalents of ANDA generics with respect to Generic Exclusivity Periods.

240. Teva has a protectable right to the benefits of the Generic Exclusivity Period without competition from Pfizer's generic quinapril products.

241. Teva has duly petitioned the FDA, specifically with respect to Pfizer's imminent sale of Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, to "take immediate action to enforce its existing regulations and established policy in order to prevent the marketing of brand generic drug products until after expiration of any other company's 180-day exclusivity period." Teva requested that the FDA render an expedited decision on its petition. Teva Citizen Petition, at 1.

242. Others, including Mylan, Apotex, and the GPhA, have requested the FDA to prevent the marketing of brand generic drug products before expiration of applicable Generic Exclusivity Periods.

243. To date, the FDA has failed to respond to the Teva Citizen Petition, the Mylan Citizen Petition, the Apotex Comment, or the GPhA Comment.

244. Teva will be irreparably harmed if the FDA's unlawful actions and failure to act are not enjoined, and Teva has no adequate remedy at law for the violations alleged herein. Neither defendants nor any other entity will suffer cognizable harm if the relief requested herein is granted, and the public interest will be served by such relief.

245. The FDA's failure to respond to the Teva Citizen Petition (and the Mylan Citizen Petition, the Apotex Comment, or the GPhA Comment), in light of the irreparable harm that will imminently befall the public and Teva, constitutes final agency action that is arbitrary, capricious, and contrary to law.

246. Teva requests, and is entitled to, an order compelling the FDA to respond to Teva's Citizen Petition and to act to protect Teva's Generic Exclusivity Period from intrusion by Pfizer's generic quinapril products.

TENTH CLAIM FOR RELIEF
(AGAINST PFIZER)
FOR AN INJUNCTION IN AID OF AGENCY
ACTION AND THIS COURT'S JURISDICTION

247. Teva repeats and realleges Paragraphs 1 through 246 as though fully set forth herein.

248. Teva has duly petitioned the FDA, specifically with respect to Pfizer's imminent sale of Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period, to "take immediate action to enforce its existing regulations and established policy in order to prevent the marketing of brand generic drug products until after expiration of any other company's 180-day exclusivity period." Teva requested that the FDA render an expedited decision on its petition. Teva Citizen Petition, at 1.

249. Others, including Mylan, Apotex, and the GPhA, have requested the FDA to prevent the marketing of brand generic drug products before expiration of applicable Generic Exclusivity Periods.

250. To date, the FDA has failed to respond to the Teva Citizen Petition or to the Mylan Citizen Petition, the Apotex Comment, and the GPhA Comment.

251. Teva has requested, and is entitled to, an order compelling the FDA to respond to Teva's Citizen Petition and to act to protect Teva's Generic Exclusivity Period from intrusion by Pfizer's generic quinapril products.

252. Pfizer currently threatens to sell Accupril® products as generic quinapril products, or in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period and thereby to harm irreparably the interest of the public and Teva.

253. In the absence of the temporary and preliminary injunctions requested herein, Pfizer's conduct will render moot the Teva Citizen Petition currently pending before the FDA and irreparably harm the interest of the public and of Teva. As a result, before the FDA acts to protect Teva's Generic Exclusivity Period, this Court will be deprived of its rightful jurisdiction to review meaningfully under the provisions of the Administrative Procedure Act the FDA's decision regarding the Teva Citizen Petition.

254. Teva requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling Accupril® products as generic quinapril products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of Teva's Generic Exclusivity Period pending the FDA's response to the Teva Citizen Petition and this Court's review thereof, pursuant to the inherent equitable powers of this Court and/or the All Writs Act, 28 U.S.C. § 1651(a).

255. Teva further requests, and is entitled to, an order prohibiting Pfizer from presenting, advertising, marketing, promoting, or selling brand products other than Accupril® products as generic drug products, or otherwise in a manner that qualifies for Generic Substitution, before the expiration of any applicable Generic Exclusivity Period pending the FDA's response to the Teva Citizen Petition and this Court's review thereof, pursuant to the inherent equitable powers of this Court and/or the All Writs Act, 28 U.S.C. § 1651(a).

JURY TRIAL DEMANDED AS PERMITTED BY LAW

WHEREFORE, by reason of the foregoing Claims for Relief, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. respectfully demand that the Court enter judgment against Defendants and in favor of Plaintiffs, that the Court grant the relief requested in each and every Claim for Relief alleged above, and that the Court order such other, further, and different relief as the Court may deem just, proper, and equitable.

Dated: June 29, 2004

Respectfully submitted,

TEVA PHARMACEUTICAL INDUSTRIES LTD.
and TEVA PHARMACEUTICALS USA, INC.

By: _____
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Their attorneys

2536921

VERIFICATION

WILLIAM S. MARTH, pursuant to 28 U.S.C. § 1746, verifies that:

I am the Executive Vice President of Sales and Marketing of Teva Pharmaceuticals USA, Inc. ("Teva USA"), a plaintiff in this action with Teva Pharmaceutical Industries Ltd. (collectively with Teva USA, "Teva"). I have read the foregoing complaint and am authorized by Teva and qualified to make this verification, and all statements of fact contained in the complaint as to Teva are true based upon my personal knowledge and all statements of fact as to persons other than Teva and matters unrelated to Teva contained in the complaint are true to the best of my knowledge, information, and belief.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on June 28th, 2004

William S. Marth