IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
Civil Action No.:

APOTEX, INC., a Canadian corporation and APOTEX CORP., a Delaware corporation, Plaintiffs, vs. TEVA PHARMACEUTICAL INDUSTRIES, LTD., an Israeli Company and TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, Defendants.	**COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs, Apotex Inc. and Apotex Corp. (collectively "Apotex"), sue Defendants, Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Defendants"), and state:

NATURE OF THE ACTION

1. This is an action for patent infringement of certain process claims arising under the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285. Jurisdiction is based upon 28 U.S.C. §§ 1331 and 1338(a).

PARTIES

2. Plaintiff Apotex Inc. is a Canadian corporation having its principal place of business in Toronto, Ontario, Canada.

3. Apotex Inc. is a pharmaceutical company that specializes in offering life-saving, generic medications to consumers at a lower cost than branded medications.

4. Plaintiff Apotex Corp. is a Delaware corporation having its principal place of business in Broward County, Florida.

5. Apotex Corp. is the exclusively licensed distributor of Apotex Inc.'s generic quinapril medication in the United States.

6. Defendant Teva Pharmaceutical Industries, Ltd. ("TPI") is an Israeli company with its principal place of business at 5 Basel Street, Petach Tikva, 49131, Israel.

7. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva USA has designated a registered agent for the service of process in Florida, namely Corporate Creations Network, Inc. located in Palm Beach Gardens. Teva USA develops, manufactures, and sells generic pharmaceutical products in the United States.

8. Teva USA is a wholly-owned subsidiary of TPI. TPI is the parent company of Teva USA.

9. On information and belief, Defendants develop, manufacture, test, package, market, promote, offer to sell, sell and distribute pharmaceutical products containing quinapril in the United States, including this judicial district.

JURISDICTION AND VENUE

10. Venue is proper in this district under 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b) and (c) 100 *et seq*. because Defendants committed acts of patent infringement in this judicial district, a substantial part of the events giving rise to this claim occurred in this judicial district, and Defendants are subject to personal jurisdiction in this judicial district.

11. This Court has personal jurisdiction over Defendants by virtue of their offers for sale, sales and distribution of products, including the products manufactured by the process that are the subject of this Complaint, throughout the State of Florida and in this District. Defendants have also placed, and are continuing to place, products into the stream of commerce in this

District, and it is reasonable to expect that such products will continue to enter and be used by consumers in Florida, including in this judicial district.

GENERAL ALLEGATIONS

Apotex's '486 Patent

12. U.S. Patent No. 6,531,486 ("the '486 Patent"), entitled "Pharmaceutical Compositions Comprising Quinapril Magnesium," was duly and lawfully issued by the U.S. Patent and Trademark Office on March 11, 2003. A true and correct copy of the '486 Patent is attached hereto as Exhibit A.

13. Apotex Inc. is the lawful owner by assignment of all right, title and interest in the '486 Patent.

14. Apotex Corp. is the exclusive licensee of the '486 patent.

15. The sole inventor listed on the '486 patent is Bernard C. Sherman.

16. The '486 patent relates to, *inter alia*, processes for making solid pharmaceutical compositions (e.g., tablets) comprising quinapril magnesium made by reacting quinapril or an acid addition salt thereof (e.g., quinapril hydrochloride) with an alkaline magnesium compound (e.g., magnesium carbonate or magnesium hydroxide) in the presence of a solvent (e.g., water) so as to convert the quinapril or quinapril salt to quinapril magnesium. Represented another way, the '486 patent claims certain methods of making tablets comprising quinapril magnesium, which include, but are not limited to, methods that result in the following chemical reaction:

$$2\ QH{\cdot}HCl + 2\ MgCO_3 \rightarrow MgQ_2 + MgCl_2 + 2\ CO_2 + 2\ H_2O$$

wherein QH·HCl is quinapril hydrochloride, $MgCO_3$ is magnesium carbonate, MgQ_2 is quinapril magnesium, $MgCl_2$ is magnesium chloride, CO_2 is carbon dioxide (a gas), and H_2O is water. See Ex. A, at Col. 3:15-22.

17. Claims 1, 8, 9, 11, 12 and 16-19 claim such processes. In this action, Apotex is not asserting Claims 2-7, 10 and 13-15 of the '486 patent. Independent Claim 1 of the '486 patent claims:

> A process of making a solid pharmaceutical composition comprising quinapril magnesium, said process comprising the step of reacting quinapril or an acid addition salt thereof with an alkaline magnesium compound in the presence of solvent so as to convert the quinapril or quinapril acid addition salt to quinapril magnesium.

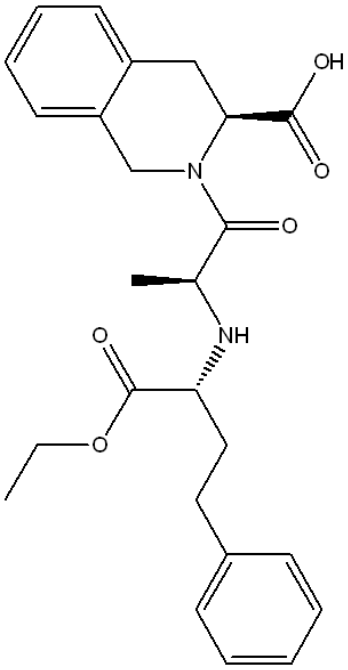
18. Claim 8 of the '486 patent, depends on Claim 1 and claims methods of making such compositions by certain types of wet granulation techniques:

> The process of Claim 1 comprising the steps of:
>
> i) mixing the quinapril or acid addition salt thereof and alkaline magnesium compound with 1 or more other excipients;
> ii) adding a solvent and mixing to obtain a wet mass;
> iii) drying the wet mass to obtain a dry mass; and
> iv) further processing the dried mass into the solid pharmaceutical reacting quinapril or an acid addition salt thereof with an alkaline magnesium compound in the presence of solvent so as to convert the quinapril or quinapril acid addition salt to quinapril magnesium.

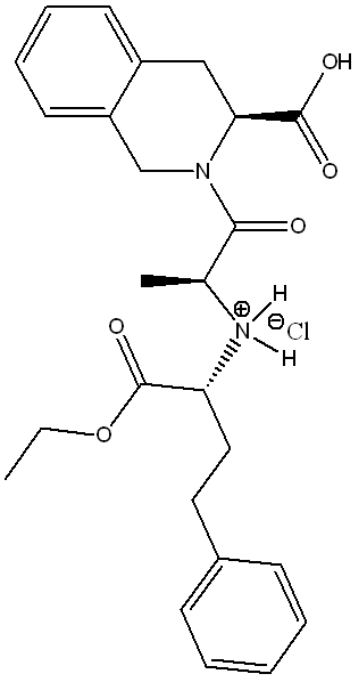
19. Claims 16-19 of the '486 patent, depend on, *inter alia*, Claim 8, and encompass within their scope wet granulation methods wherein specified percentages of the quinapril or quinapril salt starting material is converted to quinapril magnesium. For example, Claim 16 claims:

> The process of Claim 1, 2, 3, 4, 5, 6, 7 or 8 wherein the percentage of the quinapril and/or a salt thereof or acid addition salt converted to quinapril magnesium is at least about 80%.

20. Quinapril has the following chemical structure:



21. Quinapril hydrochloride is an acid addition salt of quinapril that has the following structure:



Apotex's ANDA Products

22. Apotex Inc. has manufactured generic Quinapril tablets for Apotex Corp by a process described and claimed in the '486 Patent as described in Abbreviated New Drug Application ("ANDA") No. 076-240.

23. The U.S. Food and Drug Administration ("FDA") approved ANDA No. 076-240 on January 26, 2006 allowing Apotex to market quinapril tablets for the treatment of hypertension when administered alone or in combination with thiazide diuretics. ANDA No. 076-240 was approved for four such Products that have varying doses of the active ingredient quinapril and contain an amount of quinapril salt equivalent to (a) 5 mg quinapril; (b) 10 mg quinapril; (c) 20 mg quinapril; and (d) 40 mg quinapril. Apotex's ANDA products are manufactured by a process where quinapril hydrochloride and magnesium hydroxide starting materials are mixed and wet granulated in a water-based solvent under conditions that allows for the quinapril hydrochloride to convert to quinapril magnesium.

24. As part of its development of its ANDA product, Dr. Sherman and Apotex conducted experiments to generate a stable quinapril tablet. From these experiments, it was determined that mixtures of quinapril hydrochloride and magnesium salts (e.g., carbonate or hydroxide) were not sufficiently stable to be marketed as a pharmaceutical product.

Teva's Quinapril Products

25. Defendant Teva USA received FDA approval for ANDA No. 075-504 to market generic quinapril hydrochloride products ("Teva's Quinapril Products") in the United States on August 24, 2007. ANDA No 075-504 was approved for four such Products that have varying doses quinapril. Teva's Quinapril Products contain 5 mg, 10 mg, 20 mg or 40 mg of quinapril. Thus, all of Teva's Quinapril Products include at least 5 mg of quinapril.

26. According to the product insert, Teva's Quinapril Products contain quinapril hydrochloride, magnesium carbonate, and magnesium stearate. A true and correct copy of the publicly available product insert for Teva's Quinapril Products is attached hereto as Exhibit B.

27. On information and belief, all four of Teva's Quinapril Products are made using the same or similar processes because they were the subject of the same ANDA. According to data available from IMS Health, Defendants have sold over 100 million units of Teva's Quinapril Products in the United States.

Defendants' Proprietary Manufacturing Process

28. On September 10, 2012, Apotex notified Teva USA that publicly available information suggests that the process used to manufacture Teva's Quinapril Products infringes certain claims of the '486 patent. Apotex further requested production of documents that completely and accurately describe the manufacturing processes used to make Teva's Quinapril Products and a sample of those products.

29. Defendants supplied Master Batch Records for each strength of Teva's Quinapril Products dated July 19, 2001. Defendants requested that the data be kept confidential. The following paragraphs 30-36 contain Defendants' confidential information and therefore have been redacted for this publicly filed complaint and will be filed under seal with permission of the Court.

30. [redacted]

31. [redacted]

32. [redacted]

33. [redacted]:

[redacted]

[redacted]

- [redacted].

34. [redacted].

35. [redacted].

36. [redacted].

COUNT I
INFRINGEMENT OF THE PROCESS CLAIMS OF U.S. PATENT NO. 6,531,486
(Quinapril Combination Products)

37. The allegations of paragraphs 1-36 are realleged and incorporated herein by reference.

38. This is an action for patent infringement of certain process claims arising under the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285. Jurisdiction is based upon 28 U.S.C. §§ 1331 and 1338(a).

39. On March 11, 2003, United States Letters Patent No. 6,531,486 was issued to the Plaintiffs for inventions in methods of making pharmaceutical compositions comprising quinapril magnesium. Apotex Inc., through an assignment from Bernard Sherman made *nunc pro tunc* as of March 11, 2003, has owned the patent throughout the period of Defendants' infringing acts and still owns the patent.

40. Upon information and belief, which is likely to be substantiated through discovery, Defendants have infringed and are still infringing one or more of claims 1, 8, 9, 11, 12 and/or 16-19 of the '486 Patent by using a process covered by those claims to manufacture pharmaceutical products, including Teva's Quinapril Products, and/or by importing, selling and/or offering for sale the product of such process into the United States in violation of 35 U.S.C. §271 (a) and/or (g). On information and belief, Defendants will continue to do so unless enjoined by this Court.

41. Apotex does not have to provide statutory notice by marking its products with the '486 patent because it is only asserting method claims.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants and grant the following relief:

a. A judgment and decree that the '486 Patent is valid and enforceable;

b. A judgment and decree that Defendants have infringed one or more of the method claims of the '486 Patent in violation of 35 U.S.C. § 271;

c. A preliminary and permanent injunction, pursuant to 35 U.S.C. § 283, enjoining Defendants and its officers, agents, employees and all others in concert or participation with them from acts of infringement of the '486 Patent;

d. An Order, pursuant to 35 U.S.C. § 284, awarding Plaintiffs damages adequate to compensate for Defendants' infringement of the '486 Patent, in an amount to be determined at trial, but in no event less than a reasonable royalty; and

e. Such other and further relief that the Court may deem just and proper.

JURY DEMAND

Apotex demands a trial by jury.

Dated: March 14, 2013

Respectfully submitted,

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