IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APOTEX INC. and APOTEX CORP., Plaintiffs, v. SYMPLMED PHARMACEUTICALS, LLC and LES LABORATOIRES SERVIER, Defendants.	C.A. No. _____

APOTEX INC. AND APOTEX CORP.'S COMPLAINT FOR DECLARATORY JUDGMENT

Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by their undersigned counsel, hereby brings their Complaint for Declaratory Judgment against Symplmed Pharmaceuticals LLC ("Symplmed") and Les Laboratoire Servier ("Servier") (collectively, "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. Apotex brings this action seeking declaratory relief with respect to U.S. Patent Nos. 6,696,481 ("the '481 patent") and 7,846,961 ("the '961 patent").

THE PARTIES

2. Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

4. On information and belief, Symplmed Pharmaceuticals, LLC is a limited liability company existing under the laws of the state of Delaware, with a place of business at 5375 Medpace Way, Cincinnati, Ohio 45227. On information and belief, Symplmed may be served with process by and through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801.

5. On information and belief, Les Laboratoire Servier is a corporation organized and existing under the laws of France, with a place of business at 50 Rue Carnot, Suresnes, Hauts De Seine 92150, France.

JURISDICTION AND VENUE

6. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. (including but not limited to at least 35 U.S.C. §§ 101, 102, 103, 112, and 271), which are within the subject matter jurisdiction of this Court under 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 271(e)(5).

7. On information and belief, on February 24, 2004, the United States Patent and Trademark Office ("PTO") issued the '481 patent, entitled "Salt of Perindopril and Pharmaceutical Compositions Containing It." The '481 patent lists on its face, Gérard Damien, François Lefoulon, and Bernard Marchand as purported inventors.

8. A true and correct copy of the '481 patent is attached as Exhibit A.

9. According to face of the '481 patent and the PTO's electronic records, Servier is the purported assignee of the '481 patent.

10. On information and belief, on December 7, 2010, the PTO issued the '961 patent, entitled "α Crystalline Form of the Arginine Salt of Perindopril, a Process for its Preparation and

Pharmaceutical Compositions Containing It." The '961 patent lists on its face, Gérard Coquerel, Loïc Lefebvre, Jean-Claude Souvie, and Pascale Authouart as purported inventors.

11. A true and correct copy of the '961 patent is attached as Exhibit B.

12. According to the face of the '961 patent and the PTO's electronic records, Servier is the assignee of the '961 patent.

13. On information and belief, Symplmed is the approval holder of New Drug Application No. 205003 for a fixed dose combination of perindopril arginine and amlodipine besylate oral tablets marketed under the name PRESTALIA®. On information and belief, pursuant to approval from the U.S. Food & Drug Administration ("FDA"), Symplmed offers for sale, markets, sells, and distributes PRESTALIA® throughout the United States, including in this judicial district.

14. On information and belief, Servier has granted an exclusive license to Symplmed to practice in the United States, including in this judicial district, the subject matter claimed in the '481 patent and the '961 patent.

15. On information and belief, Symplmed represents that the '481 and '961 patents cover PRESTALIA®.[1]

16. On information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Symplmed caused FDA to list the '481 and '961 patents in the FDA's publication "*Approved Drug Products with Therapeutic Equivalence Evaluations*" ("the Orange Book") in connection with NDA No. 205003 for PRESTALIA®. By doing so, Symplmed represented that a claim of patent infringement could reasonably be asserted against any unlicensed manufacture, use or sale of a generic version of PRESTALIA® oral tablets. By listing the '481 and '961 patents in the Orange

[1] *See* http://www.symplmed.com/symplmed_news_february_24_2016/.

Book, Symplmed and/or Servier created a reasonable apprehension that a patent infringement action would be filed against any applicant seeking FDA regulatory approval of a generic pharmaceutical product that references NDA No. 205003 that is made without a license to the ’481 and ’961 patents from Symplmed and/or Servier.

17. On information and belief, this Court has personal jurisdiction over Symplmed.

18. On information and belief, Symplmed has engaged in and maintained systematic and continuous business contacts within the State of Delaware, rendering it at home in Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware.

19. On information and belief, Symplmed is a limited liability corporation that is incorporated under the laws of the State of Delaware, regularly conducts business in the State of Delaware, and has a state-issued license to sell and/or distribute pharmaceutical products in the State of Delaware.

20. On information and belief, Symplmed has entered into agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including PRESTALIA® oral tablets.

21. On information and belief, this Court has personal jurisdiction over Servier.

22. On information and belief, as the assignee and licensor of the’481 and ’961 patents to Symplmed, Servier derives substantial revenue from the sale of PRESTALIA® throughout the United States, including from sales of PRESTALIA® in this judicial district.

23. On information and belief, the perindopril arginine active pharmaceutical ingredient that is included in Symplmed’s PRESTALIA® product is manufactured by Servier through its subsidiary Oril Industrie SAS, pursuant to Drug Master File No. 27822 that was filed at FDA. On information and belief, Servier derives substantial revenue from the sale of

perindopril arginine that enters the stream of commerce in this judicial district through the sale of PRESTALIA®.

24. On information and belief, this Court has personal jurisdiction over Servier for the reasons stated herein, including, *inter alia*, Servier's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Servier at home in this judicial district.

25. This Court also has personal jurisdiction over Servier under Federal Rule of Civil Procedure 4(k)(2).

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

THE PRESENCE OF A CASE OR CONTROVERSY

27. Apotex filed Abbreviated New Drug Application ("ANDA") No. 209749 with FDA seeking approval to market amlodipine besylate; perindopril arginine oral tablets (2.5 mg / 3.5 mg, 5 mg / 7 mg, and 10 mg / 14 mg) described therein ("Apotex's Proposed ANDA Products"). Apotex's ANDA No. 209749 references Symplmed's NDA No. 205003, and Apotex's Proposed ANDA Products are bioequivalent to PRESTALIA®.

28. Apotex's ANDA No. 209749 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '481 patent and the '961 patent are invalid or will not be infringed by the manufacture, use, or sale of Apotex's Proposed ANDA Products.

29. In accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Apotex provided notice to Symplmed and Servier ("Apotex's Notice Letter") that Apotex is seeking FDA-approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Apotex's Proposed ANDA Products before the expiration of the '481 patent and the '961 patent.

30. On information and belief, Symplmed received Apotex's Notice Letter on or about December 30, 2016.

31. On information and belief, Servier received Apotex's Notice Letter on or about January 2, 2017.

32. Apotex's Notice Letter included an Offer of Confidential Access to Apotex's ANDA No. 209749.

33. Receipt of Apotex's Notice Letter by Defendants triggered a 45-day statutory period during which Defendants had the opportunity to initiate patent infringement litigation. On information and belief, more than 45 days have passed since Symplmed and Servier received Apotex's Notice Letter. On information and belief, Symplmed and Servier have not filed a patent infringement action against Apotex Inc. or Apotex Corp. to assert either the '481 patent or the '961 patent.

34. Because Defendants filed no action for patent infringement within the statutory 45-day period following receipt of Apotex's Notice Letter, 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 27l(e)(5) provide for a civil action to obtain patent certainty and allow Apotex to obtain a declaratory judgment with respect to the '481 and '961 patents that are listed in the Orange Book in connection with PRESTALIA®. On information and belief, all of the conditions specified in 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc) have been satisfied.

35. By maintaining the Orange Book listing of the '481 patent and the '961 patent in connection with NDA No. 205003 for PRESTALIA®, Defendants continue to represent that the '481 patent and the '961 patent could reasonably be asserted against anyone making, using or selling amlodipine besylate; perindopril arginine tablets (2.5 mg / 3.5 mg, 5 mg / 7 mg, and 10 mg / 14 mg) without a license from Symplmed and/or Servier. *See* 21 U.S.C. § 355(b)(1)(G).

36. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Apotex's ANDA No. 209749 is eligible for immediate approval, and Apotex expects to receive tentative and/or final approval from the FDA to engage in the commercial manufacture, use, and/or sale of its Proposed ANDA Products within thirty months from the filing date of Apotex's ANDA No. 209749.

37. If Apotex succeeds in proving that the claims of the '481 patent and the '961 patent, are invalid or not infringed by Apotex's Proposed ANDA Products, such a judgment will remove any existing uncertainty that precludes commercial manufacture, use, importation, offer for sale, or sale of Apotex's Proposed ANDA Products before the expiration of the '481 patent and the '961 patent.

38. Apotex desires to bring Apotex's Proposed ANDA Products to market to allow the public to enjoy the benefits of generic competition for these products at the earliest possible date under the applicable statutory and FDA regulatory provisions.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 7,846,961)

39. Apotex repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

40. There is a substantial and continuing controversy between Apotex and Defendants and a declaration of rights is both necessary and appropriate to establish that Apotex does not infringe any valid or enforceable claim of the '961 patent and allow Apotex to bring Apotex's Proposed ANDA Products to market.

41. Apotex asserts that no valid claim of the '961 patent is infringed by Apotex's ANDA No. 209479, and that no valid claim of the '961 patent will be infringed by the commercial manufacture, use, offer for sale, or sale of Apotex's Proposed ANDA Products.

COUNT II
(Declaratory Judgment of Noninfringement of U.S. Patent No. 6,696,481)

42. Apotex repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

43. There is a substantial and continuing controversy between Apotex and Defendants and a declaration of rights is both necessary and appropriate to establish that Apotex does not infringe any valid or enforceable claim of the ’481 patent and allow Apotex to bring Apotex’s Proposed ANDA Products to market.

44. Apotex asserts that no valid claim of the ’481 patent is infringed by Apotex’s ANDA No. 209479, and that no valid claim of the ’481 patent will be infringed by the commercial manufacture, use, offer for sale, or sale of Apotex’s Proposed ANDA Products.

COUNT III
(Declaratory Judgment of Invalidity of U.S. Patent No. 6,696,481)

45. Apotex repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

46. There is a substantial and continuing controversy between Apotex and Defendants and a declaration of rights is both necessary and appropriate to establish that Apotex does not infringe any valid or enforceable claim of the ’481 patent and allow Apotex to bring Apotex’s Proposed ANDA Products to market.

47. Apotex asserts that the claims of the ’481 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or other judicially created bases for invalidation.

COUNT IV
(No injunctive remedy for Defendants)

48. Apotex repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

49. Neither Servier nor Symplmed will in fact experience any harm from Apotex's sales of Apotex's Proposed ANDA Products that has nexus to the claims of the '961 patent or the claims of the '481 patent.

50. Defendants have unacceptably delayed in asserting the '961 patent and the '481 patent.

51. Defendants cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

52. Defendants are not entitled to any injunctive remedy of any kind.

PRAYER FOR RELIEF

Wherefore, Apotex respectfully requests that this Court enter judgment in its favor and against Defendants and prays:

A. That this Court find and declare that the making, using, selling, offering for sale, marketing, or importation of Apotex's Proposed ANDA Products, and any actions by Apotex relating thereto, does not and will not directly or indirectly infringe, or induce or contribute to the infringement of, any valid claim of the '961 patent;

B. That this Court find and declare that the making, using, selling, offering for sale, marketing, or importation of Apotex's Proposed ANDA Products, and any actions by Apotex relating thereto, does not and will not directly or indirectly infringe, or induce or contribute to the infringement of, any valid claim of the '481 patent;

C. That this Court find and declare that the'481 patent and all of its claims are invalid;

D. That this Court enjoin Symplmed and Servier, and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Apotex or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Apotex's Proposed ANDA Products, or charging them either orally or in writing with infringement of the '961 patent and/or the '481 patent;

E. That this Court award Apotex all of its costs for this action; and

F. That this Court grant Apotex such other and further relief as the Court deems just and proper under the circumstances.

Dated: March 15, 2017

Respectfully submitted,

/s/ Joseph J. Bellew

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