IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA, and ARES TRADING SA, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 1:23-cv-00655-GBW

APOTEX'S ANSWER AND COUNTERCLAIMS TO PLAINTIFFS MERCK KGAA, MERCK SERONO SA, AND ARES TRADING SA'S COMPLAINT FOR PATENT INFRINGEMENT

Defendants, Apotex Inc. and Apotex Corp., (collectively, "Apotex" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, "Merck") (all collectively, "Plaintiffs"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Defendants Apotex Inc. and Apotex Corp. of Abbreviated New Drug Application ("ANDA") No. 218425 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Merck's MAVENCLAD® product prior to the expiration of U.S. Patent Nos. 7,713,947, 8,377,903, and 10,849,919 (the "Patents-in-Suit").

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed Abbreviated New Drug Application ("ANDA") No. 218425 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of generic version of cladribine,

("the Apotex ANDA Product"), which is a generic version of MAVENCLAD® oral tablet, respectively, prior to expiration of U.S. Patent Nos. 7,713,947 ("the '947 patent") and 8,377,903 ("the '903 patent"). Apotex denies any and all remaining allegations contained in this Paragraph.

PARTIES

2. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore denies the same.

3. Plaintiff Merck Serono SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Merck Serono SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore denies the same.

4. Plaintiff Ares Trading SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Ares Trading SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore denies the same.

5. On information and belief, Defendant Apotex Inc. is a corporation domiciled and organized under the laws of Canada with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Apotex denies any and all remaining allegations contained in this Paragraph.

6. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Apotex Corp. is a Delaware corporation, having a place of business at 2400 N. Commerce Parkway Suite 400, Weston, FL 33326. Apotex denies any and all remaining allegations contained in this Paragraph.

7. On information and belief, Apotex Inc., itself and through its subsidiaries and agents, including Apotex Corp., manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed ANDA No. 218425 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to expiration of the '947 and '903 patents. Apotex denies the remaining allegations of this Paragraph.

8. On information and belief, Apotex Corp. manufactures, and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of Apotex Inc.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed ANDA No. 218425 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to expiration of the '947 and '903 patents. Apotex denies the remaining allegations of this Paragraph.

9. On information and belief, Defendants acted collaboratively in the preparation of ANDA No. 218425 for Apotex Inc.'s cladribine 10 mg tablets (the "Apotex ANDA Product") and Apotex Inc. submitted ANDA No. 218425 on behalf of both Apotex Inc. and Apotex Corp.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed ANDA No. 218425 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to expiration of the '947 and '903 patents. Apotex denies the remaining allegations of this Paragraph.

10. On information and belief, following any FDA approval of ANDA No. 218425, Apotex Inc., itself and through its subsidiaries and agents, including Apotex Corp., will make, use offer to sell, and/or sell the Apotex ANDA Product throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed ANDA No. 218425 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to expiration of the '947 and '903 patents. Apotex denies the remaining allegations of this Paragraph.

11. Hereinafter, Apotex Inc. and Apotex Corp. are collectively referred to as "Apotex" or "Defendants."

ANSWER: Paragraph 11 contains no allegations to which an answer is required.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, 35 U.S.C. § 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiffs purport to bring this action under the patent laws of the United States. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

13. This Court has personal jurisdiction over Apotex Corp. because it is incorporated in Delaware. Moreover, this Court has personal jurisdiction over Defendants because, on information and belief, Apotex Inc. and Apotex Corp., acting in concert with one another, have engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed themselves of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in Delaware, and deriving substantial revenue from such activities.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiffs purport to bring this action under the patent laws of the United States. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

14. Additionally, venue is proper in this Court under 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) because Apotex Corp. is incorporated in Delaware. Apotex Inc. is a foreign corporation not residing in any United States district and, thus, may be sued in any judicial district. *See* 28 U.S.C. § 1391(c).

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiffs purport to bring this action under the patent laws of the United States. Solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

15. On information and belief, Apotex Inc. and Apotex Corp., acting in concert with one another, have purposefully conducted business and/or will conduct business in the State of Delaware, and Delaware is a likely destination of Apotex's products, including its proposed generic version of MAVENCLAD® that is at issue in this action.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiffs purport to bring this action under the patent laws of the United States. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

16. On information and belief, upon approval of ANDA No. 218425, Apotex will market and sell the Apotex ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiffs purport to bring this action under the patent laws of the United States. Solely to conserve the resources of

the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

17. On information and belief, upon approval of Apotex's ANDA No. 218425, Apotex will place the Apotex ANDA Product into the stream of commerce with the expectation or knowledge and the intent that such product will be purchased and used by consumers in Delaware and throughout the United States.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiffs purport to bring this action under the patent laws of the United States. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

PATENTS-IN-SUIT

18. United States Patent No. 7,713,947 ("the '947 patent"), entitled "Cladribine Regimen for Treating Multiple Sclerosis" (attached as Exhibit A), was duly and legally issued on May 11, 2010.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that what purports to be a copy of the '947 patent was attached to the Complaint as Exhibit A, that the patent is entitled "Cladribine Regimen for Treating Multiple Sclerosis," that it bears an issue date of May 11, 2010. Apotex denies that the '947 patent was duly and legally issued and further denies any suggestion that the '947 patent is valid or enforceable. Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

19. United States Patent No. 8,377,903 ("the '903 patent"), entitled "Cladribine Regimen for Treating Multiple Sclerosis" (attached as Exhibit B), was duly and legally issued on February 19, 2013.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that what purports to be a copy of the '903 patent was attached to the Complaint as Exhibit B, that the patent is entitled "Cladribine Regimen for Treating Multiple Sclerosis," that it bears an issue date of February 19, 2013. Apotex denies that the '903 patent was duly and legally issued and further denies any suggestion that the '903 patent is valid or enforceable. Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

20. United States Patent No. 10,849,919 ("the '919 patent"), entitled "Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis" (attached as Exhibit C), was duly and legally issued on December 1, 2020.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

21. The '947 and '903 patents are owned by Merck Serono SA. The '919 patent is owned by Ares Trading SA. The claims of the '947, '903, and '919 patents are valid, enforceable, and not expired.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that the faces of the '947 and '903 patents state that the assignee is Merck Serono SA. Apotex denies that the claims of the '947 and '903 patents are valid, enforceable, and not expired. The allegations of this Paragraph relating to the '919 patent pertain to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to allegations of

this Paragraph relating to the '919 patent, if appropriate, after the resolution of the Motion to Dismiss. Apotex is without sufficient knowledge or information to form a belief as to any remaining allegations of this Paragraph, and therefore denies the same.

MERCK'S MAVENCLAD® PRODUCT

22. EMD Serono, Inc. holds New Drug Application ("NDA") No. 022561, which the FDA approved on March 29, 2019 for the marketing and sale of 10 mg strength cladribine tablets. EMD Serono, Inc. markets 10 mg strength cladribine tablets in the United States under the trade name "MAVENCLAD®." EMD Serono, Inc. is a wholly owned subsidiary of Merck KGaA.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that, according to the FDA's Orange Book, the applicant holder full name for NDA No. 022561 for MAVENCLAD (cladribine) tablets is EMD Serono, Inc., the dosage strength is listed as 10 mg, and the approval date is listed as March 29, 2019. Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

23. MAVENCLAD® is a purine antimetabolite. It is approved by the FDA for the treatment of relapsing forms of multiple sclerosis, including relapsing-remitting disease and active secondary progressive disease, in adults. A copy of the complete prescribing information for MAVENCLAD® is attached as Exhibit D.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that what purports to be a copy of the prescribing information for MAVENCLAD® was attached to the Complaint as Exhibit D, and that document states that Mavenclad® is a purine antimetabolite, indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Apotex denies any and all remaining allegations contained in this Paragraph.

24. The FDA's official publication of approved drugs (the "Orange Book") includes MAVENCLAD®. The Orange Book lists the '947, '903, and '919 patents as patents covering MAVENCLAD® and its use.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the Orange Book lists the '947 and '903 patents in connection with NDA No. 022561 for MAVENCLAD (cladribine) tablets. The allegations of this Paragraph relating to the '919 patent pertain to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to allegations of this Paragraph relating to the '919 patent, if appropriate, after the resolution of the Motion to Dismiss. Apotex denies any and all remaining allegations contained in this Paragraph.

INFRINGEMENT BY APOTEX

25. By letter dated May 19, 2023 (the "Notice Letter"), Apotex notified Merck that it had submitted to the FDA ANDA No. 218425 seeking approval to market and sell the Apotex ANDA Product in the United States prior to the expiration of the '947 and '903 patents. The '947 and '903 patents expire on October 16, 2026 and May 31, 2026, respectively. The '919 patent expires on November 23, 2038. Therefore, Apotex is necessarily seeking approval of the Apotex ANDA Product before the '919 patent's later expiration.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a notice letter to Merck, dated May 19, 2023, which served as written notification to Merck pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218425 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '947 and '903 patents, which satisfied all statutory, legal, and regulatory requirements. The allegations of this Paragraph relating to the '919 patent pertain to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to allegations of this

Paragraph relating to the ’919 patent, if appropriate, after the resolution of the Motion to Dismiss. Apotex denies any and all remaining allegations contained in this Paragraph.

26. By submitting ANDA No. 218425, Apotex has represented to the FDA that the Apotex ANDA Product has the same active ingredient as MAVENCLAD®, has the same dosage forms and strengths as MAVENCLAD®, and is bioequivalent to MAVENCLAD®.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a notice letter to Merck, dated May 19, 2023, which served as written notification to Merck pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218425 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the ’947 and ’903 patents, which satisfied all statutory, legal, and regulatory requirements. Apotex denies any and all remaining allegations contained in this Paragraph.

27. In the Notice Letter, Apotex stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) with respect to the '947 and '903 patents and alleged that these patents are invalid and/or will not be infringed. The Notice Letter demonstrates that Apotex seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Apotex ANDA Product before the '947 and '903 patents expire.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a notice letter to Merck, dated May 19, 2023, which served as written notification to Merck pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218425 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the ’947 and ’903 patents, which satisfied all statutory, legal, and regulatory requirements. Apotex denies any and all remaining allegations contained in this Paragraph.

28. This action is being commenced before the expiration of forty-five days from the date of Merck's receipt of the Notice Letter.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a notice letter to Merck, dated May 19, 2023, which served as written notification to Merck pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218425 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '947 and '903 patents, which satisfied all statutory, legal, and regulatory requirements, and that Plaintiffs filed their Complaint on June 15, 2023. Apotex denies any and all remaining allegations contained in this Paragraph.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 7,713,947

29. Plaintiffs incorporate each of the preceding paragraphs 1-28 as if fully set forth herein.

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 28 as if fully set forth herein.

30. Apotex's submission of ANDA No. 218425 to the FDA for the purpose of obtaining approval to engage in the commercial importation, manufacture, use, offer for sale, and/or sale of the Apotex ANDA Product in the United States before the expiration of the '947 patent was an act of infringement of the '947 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

31. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex ANDA Product in the United States would infringe one or more claims of the '947 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents. The infringed claims of the '947 patent include at least claim 36. Such infringement is imminent because, among other things, Apotex has

notified Merck of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product before the expiration of the '947 patent.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

32. Apotex had knowledge of the '947 patent prior to submitting its ANDA to the FDA, as demonstrated by Apotex's 21 U.S.C. § 355(j)(2)(vii)(IV) allegation with respect to the '947 patent.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex states that ANDA No. 218425 included a paragraph IV certification as to the '947 patent. Apotex denies any and all remaining allegations of this Paragraph.

33. On information and belief, use of the Apotex ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '947 patent.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

34. On information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218425.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218425 seeking approval to engage in the commercial manufacture, use or sale of the Apotex

ANDA Product prior to the expiration of the '947 and '903 patents. Apotex denies any and all remaining allegations of this Paragraph.

35. On information and belief, Apotex will infringe and will actively induce or contribute to the infringement of the '947 patent when ANDA No. 218425 is approved, and plans and intends to, and will do so upon approval.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

36. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '947 patent.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

37. Pursuant to 28 U.S.C. § 2201, Merck is entitled to a declaratory judgment that Apotex's making, using, offering to sell, selling, and/or importing the Apotex ANDA Product, and inducement thereof or contribution thereto, will infringe the '947 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

38. On information and belief, Apotex acted without a reasonable basis for believing that it would not be liable for infringing the '947 patent and/or actively inducing or contributing to the infringement of the '947 patent.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

39. Unless Apotex is enjoined from infringing the '947 patent and/or actively inducing or contributing to the infringement of the '947 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 8,377,903

40. Plaintiffs incorporate each of the preceding paragraphs 1-39 as if fully set forth herein.

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 39 as if fully set forth herein.

41. Apotex's submission of ANDA No. 218425 to the FDA for the purpose of obtaining approval to engage in the commercial importation, manufacture, use, offer for sale, and/or sale of the Apotex ANDA Product in the United States before the expiration of the '903 patent was an act of infringement of the '903 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

42. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex ANDA Product in the United States would infringe one or more claims of the '903 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents. The infringed claims of the '903 patent include at least claim 17. Such infringement is imminent because, among other things, Apotex has notified Merck of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product before the expiration of the '903 patent.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

43. Apotex had knowledge of the '903 patent prior to submitting its ANDA to the FDA, as demonstrated by Apotex's 21 U.S.C. § 355(j)(2)(vii)(IV) allegation with respect to the '903 patent.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex states that ANDA No. 218425 included a paragraph IV certification as to the '903 patent. Apotex denies any and all remaining allegations of this Paragraph.

44. On information and belief, use of the Apotex ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '903 patent.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

45. On information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218425.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218425 seeking approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to the expiration of the '947 and '903 patents. Apotex denies any and all remaining allegations of this Paragraph.

46. On information and belief, Apotex will infringe and will actively induce or contribute to the infringement of the '903 patent when ANDA No. 218425 is approved, and plans and intends to, and will do so upon approval.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

47. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '903 patent.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

48. Pursuant to 28 U.S.C. § 2201, Merck is entitled to a declaratory judgment that Apotex's making, using, offering to sell, selling, and/or importing the Apotex ANDA Product, and inducement thereof or contribution thereto, will infringe the '903 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

49. On information and belief, Apotex acted without a reasonable basis for believing that it would not be liable for infringing the '903 patent and/or actively inducing or contributing to the infringement of the '903 patent.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

50. Unless Apotex is enjoined from infringing the '903 patent and/or actively inducing or contributing to the infringement of the '903 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 10,849,919

51. Plaintiffs incorporate each of the preceding paragraphs 1-50 as if fully set forth herein.

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 50 as if fully set forth herein.

52. Apotex's submission of ANDA No. 218425 to the FDA for the purpose of obtaining approval to engage in the commercial importation, manufacture, use, offer for sale, and/or sale of the Apotex ANDA Product in the United States before the expiration of the '919 patent was an act of infringement of the '919 patent under 35 U.S.C. § 271(e)(2).

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

53. The commercial manufacture, use, offer for sale, sale and/or importation of the Apotex ANDA Product in the United States would infringe one or more claims of the '919 patent under 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents. The infringed claims of the '919 patent include at least claims 1, 14, and 27. Upon information and belief, Apotex has made and will continue to make substantial and meaningful preparations to practice, induce and/or contribute to practicing of one or more of the claims of the '919 patent and/or import, offer to sell, sell, make, and/or use within the United States the Apotex ANDA Product prior to the expiration of the '919 patent. For example, infringement of the '919 patent is imminent because, among other things, Apotex

has notified Merck of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product before the expiration of the '947 and '903 patents, which is before the expiration of the '919 patent.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

54. Apotex knew or should have known of the '919 patent no later than September 12, 2022, when the '919 patent was listed in the Orange Book for MAVENCLAD®.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

55. On information and belief, use of the Apotex ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '919 patent.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

56. On information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218425.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No.

218425 seeking approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to the expiration of the '947 and '903 patents. Apotex denies any and all remaining allegations of this Paragraph.

57. On information and belief, Apotex will infringe and will actively induce or contribute to the infringement of the '919 patent when ANDA No. 218425

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

58. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '919 patent.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

59. Pursuant to 28 U.S.C. § 2201, Merck is entitled to a declaratory judgment that Apotex's making, using, offering to sell, selling, and/or importing the Apotex ANDA Product, and inducement thereof or contribution thereto, will infringe the '919 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex's pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

60. On information and belief, Apotex acted without a reasonable basis for believing that it would not be liable for infringing the ’919 patent and/or actively inducing or contributing to the infringement of the ’919 patent.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex’s pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

61. Unless Apotex is enjoined from infringing the '919 patent and/or actively inducing or contributing to the infringement of the '919 patent, Plaintiffs will suffer irreparable injury.

ANSWER: This Paragraph of the Complaint relates to the subject matter of Apotex’s pending Motion to Dismiss, filed concurrently herewith, and therefore no response is required at this time. Apotex will respond to this paragraph, if appropriate, after the resolution of the Motion to Dismiss.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

(A) A judgment that Apotex’s submission of ANDA No. 218425 to the FDA was an act of infringement of the claims of the ’947, ’903, and ’919 patents, and that Apotex’s manufacture, use, offer to sell, sale, or importation of the Apotex ANDA Product in or into the United States prior to the expiration of the ’947, ’903, and ’919 patents, will infringe and/or actively induce or contribute to the infringement of the claims of the ’947, ’903, and ’919 patents;

(B) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Apotex’s ANDA No. 218425, shall not be earlier than the latest expiration date of the ’947, ’903, and ’919 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(C) A declaratory judgment that Apotex's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Apotex ANDA Product prior to the expiration of the '947, '903, and '919 patents, would infringe the claims of the '947, '903, and '919 patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

(D) A judgment declaring that the claims of the '947, '903, and '919 patents are not invalid or unenforceable;

(E) An Order permanently enjoining Apotex, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, or importing in or into the United States the Apotex ANDA Product, or any product or compound that infringes the '947, '903, and '919 patents, or inducing and/or contributing to the infringement of the '947, '903, and '919 patents until after the latest expiration date of the '947, '903, and '919 patents, including any extension and/or additional periods of exclusivity to which Merck is or becomes entitled.

(F) A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. §§ 285 and 271(e)(4), together with reasonable costs; and

(G) Such further and other relief as this Court deems proper and just.

ANSWER: Apotex denies all allegations not expressly admitted herein. Apotex further denies that Plaintiffs are entitled to any of the relief requested in paragraphs (A) through (G), and

requests that Plaintiffs' Complaint be dismissed with prejudice and that Apotex be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

AFFIRMATIVE AND OTHER DEFENSES

Apotex asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY OF THE '947 PATENT)

The claims of the '947 patent are invalid under 35 U.S.C. §§ 101, et seq. including, *inter alia*, §§ 102, 103 and 112.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY OF THE '903 PATENT)

The claims of the '903 patent are invalid under 35 U.S.C. §§ 101, et seq. including, *inter alia*, §§ 102, 103 and 112.

THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '947 PATENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 218425 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '947 patent.

FOURTH AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '903 PATENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 218425 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '903 patent.

FIFTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '947 PATENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 218425 do not and will not induce the infringement of, and has not contributed to and does not and will not contribute to the infringement of any valid and enforceable claim of the '947 patent.

SIXTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '903 PATENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products specified in ANDA No. 218425 do not and will not induce the infringement of, and has not contributed to and does not and will not contribute to the infringement of any valid and enforceable claim of the '903 patent.

SEVENTH AFFIRMATIVE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

There is no subject matter jurisdiction over any and all claims asserted against Apotex at least for the reasons provided in Apotex's pending Motion to Dismiss, filed concurrently herewith.

EIGHTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted at least for the reasons provided in Apotex's pending Motion to Dismiss, filed concurrently herewith.

RESERVATION OF ADDITIONAL DEFENSES

Apotex reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), by way of its attorneys, hereby states for its Counterclaims against Merck KGaA and Merck Serono SA(each individually "Plaintiff/Counterclaim-Defendants," or "Merck"), and, the following, without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiffs/Counterclaim-Defendants:

Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Affirmative Defenses to the Complaint.

THE PARTIES

1. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint.

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. Upon information and belief, Plaintiff/Counterclaim-Defendant Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant Merck Serono SA is a Swiss corporation having a principal place of business at Rue de l'Ouriette, 151, Zone

industrielle de l'Ouriettaz, Aubonne 1170, Switzerland. Merck Serono SA is a wholly owned subsidiary of Plaintiff Merck KGaA.

JURISDICTION

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Apotex and Plaintiffs/Counterclaim-Defendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

9. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants based, *inter alia*, on their filing of this lawsuit in this jurisdiction and because Plaintiffs/Counterclaim-Defendants does business in this jurisdiction.

10. Venue is proper in this judicial district under 28 U.S. C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

11. This is an action for a declaratory judgment of invalidity and noninfringement of U.S. Patent No. 7,713,947 ("the '947 patent") and U.S. Patent No. 8,377,903 ("the '903 patent")

(collectively "Dosing Regimen Patents"). Upon information and belief, true and correct copies of the Dosing Regimen Patents were attached to the Complaint as Exhibits A and B.

12. On or about May 11, 2010, the U.S. Patent & Trademark Office ("USPTO") issued the '947 patent.

13. On or about February 19, 2013, the USPTO issued the '947 patent.

14. Upon information and belief, Plaintiff/Counterclaim-Defendant Merck Serono SA is the assignee of the Dosing Regimen Patents.

15. Plaintiff/Counterclaim-Defendant Merck Serono SA purports to be the holder of New Drug Application ("NDA") No. 022561 for cladribine tablets, 10 mg. Merck sells its drug product in the United States under the trademark MAVENCLAD®.

16. Plaintiffs/Counterclaim-Defendants purport and claim to have the rights to enforce the Dosing Regimen Patents, and have listed the Dosing Regimen Patents in the FDA's Approved Drug Products and Therapeutic Equivalence Evaluations (the "Orange Book") in connection with MAVENCLAD®.

17. Apotex has filed Abbreviated New Drug Application ("ANDA") No. 218425 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Apotex's proposed cladribine tablets, 10 mg base product described therein ("Apotex's MAVENCLAD ANDA Product"), identifying NDA No. 022561 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3 ("Apotex's MAVENCLAD ANDA").

18. Apotex's MAVENCLAD ANDA No. 218425 seeks FDA approval to market Apotex's MAVENCLAD ANDA Product described within ANDA No. 218425 before the

expiration of the Dosing Regimen Patents, and includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to those patents.

19. Plaintiffs/Counterclaim-Defendants sued Apotex in this District for alleged infringement of the Dosing Regimen Patents.

COUNT I

(DECLARATORY JUDGMENT OF INVALIDITY OF THE '947 PATENT)

20. Apotex realleges and incorporates by reference the allegations of paragraphs 1-19 as though full set forth herein.

21. There is an actual, substantial, and continuing case or controversy between Apotex and the Plaintiffs/Counterclaim-Defendants regarding the invalidity and noninfringement of the '947 patent, and a judicial declaration of invalidity and noninfringement is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '947 patent.

22. The claims of the '947 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

23. The claims of the '947 patent are invalid at least under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Apotex's Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every element of each and every claim of the '947 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '947 patent, including, but not limited to, those references and/or products disclosed in Apotex's Notifications of Certification of Noninfringement, Invalidity and/or Unenforceability of U.S. Patent Nos.

7,713,947 and 8,377,903, mailed on May 19, 2023, in connection with Apotex's MAVENCLAD ANDA, namely:

1. Bodor, N.S. *et al.*, PCT Publication No. WO 2004/087101, "Oral Formulations of Cladribine," published October 14, 2004 ("Bodor");
2. JC Sipe, *et al.*, "Development of cladribine treatment in multiple sclerosis," 1 Multiple Sclerosis 343-347 (1996) ("Sipe");
3. Beutler, E., U.S. Patent No. 5,506,214, "Use of Substituted Adenine Derivatives for Treating Multiple Sclerosis," issued April 9, 1996 ("Beutler");
4. Stelmasiak, Z. *et al.*, "A Pilot Trial of Cladribine (2-chlorodeoxyadenosine) in Remitting-Relapsing Multiple Sclerosis," Medical Science Monitor, 4(1):4-8 (1998) ("Stelmasiak");
5. Cairo, M.S., "Dose Reduction and Delays: Limitations of Myelosuppressive Chemotherapy," 21 (Abstract) Oncology 14 (Suppl. 8) (2000) ("Cairo");
6. Page, *et al.*, "Cancer Management: A Multidisciplinary Approach," Ch. 3: Principles of Chemotherapy at 24 (2004)("Page");
7. Crawford, *et al.*, "Chemotherapy-Induced Neutropenia: Risks, Consequences, and New Directions for its Management," 100:2 Cancer 228 (2004) ("Crawford").

24. Any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '947 patent, and would have had a reasonable expectation of success in doing so.

25. There is no objective evidence of non-obviousness of the claims of the '947 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '947 patent .

26. Apotex is entitled to a judicial declaration that the claims of the '947 patent are invalid.

27. Apotex reserves the right to provide additional bases for invalidity of each claim of the '947 patent in its contentions, responses to discovery requests, expert reports, or pleadings filed or served as this action progresses.

COUNT II

(DECLARATORY JUDGMENT OF INVALIDITY OF THE '903 PATENT)

28. Apotex realleges and incorporates by reference the allegations of paragraphs 1-27 as though full set forth herein.

29. There is an actual, substantial, and continuing case or controversy between Apotex and the Plaintiffs/Counterclaim-Defendants regarding the invalidity and noninfringement of the '903 patent, and a judicial declaration of invalidity and noninfringement is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '903 patent.

30. The claims of the '903 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

31. The claims of the '903 patent are invalid at least under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Apotex's Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every element of each and every claim of the '903 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '903 patent, including, but not limited to, those references and/or products disclosed in Apotex's Notifications of Certification of Noninfringement, Invalidity and/or Unenforceability of U.S. Patent Nos. 7,713,947 and 8,377,903, mailed on May 19, 2023, in connection with Apotex's MAVENCLAD ANDA, namely:

1. Bodor, N.S. *et al.*, PCT Publication No. WO 2004/087101, "Oral Formulations of Cladribine," published October 14, 2004 ("Bodor");

2. JC Sipe, *et al.*, "Development of cladribine treatment in multiple sclerosis," 1 Multiple Sclerosis 343-347 (1996) ("Sipe");
3. Beutler, E., U.S. Patent No. 5,506,214, "Use of Substituted Adenine Derivatives for Treating Multiple Sclerosis," issued April 9, 1996 ("Beutler");
4. Stelmasiak, Z., *et al.*, "A Pilot Trial of Cladribine (2-chlorodeoxyadenosine) in Remitting-Relapsing Multiple Sclerosis," Medical Science Monitor, 4(1):4-8 (1998) ("Stelmasiak");
5. Cairo, M.S., "Dose Reduction and Delays: Limitations of Myelosuppressive Chemotherapy," 21 (Abstract) Oncology 14 (Suppl. 8) (2000) ("Cairo");
6. Page, *et al.*, "Cancer Management: A Multidisciplinary Approach," Ch. 3: Principles of Chemotherapy at 24 (2004)("Page");
7. Crawford, *et al.*, "Chemotherapy-Induced Neutropenia: Risks, Consequences, and New Directions for its Management," 100:2 Cancer 228 (2004) ("Crawford").

32. Any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '903 patent, and would have had a reasonable expectation of success in doing so.

33. There is no objective evidence of non-obviousness of the claims of the '903 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '903 patent .

34. Apotex is entitled to a judicial declaration that the claims of the '903 patent are invalid.

35. Apotex reserves the right to provide additional bases for invalidity of each claim of the '903 patent in its contentions, responses to discovery requests, expert reports, or pleadings filed or served as this action progresses.

COUNT III

(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '947 PATENT)

36. Apotex realleges and incorporates by reference the allegations of paragraphs 1-35 as though fully set forth herein.

37. There is an actual, substantial, and continuing case or controversy between Apotex and the Plaintiff/Counterclaim-Defendants regarding, inter alia, non-infringement of the claims of the '947 Patent.

38. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in Apotex's ANDA No. 218425 has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '947 Patent, either literally or under the doctrine of equivalents.

39. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in Apotex's ANDA No. 218425 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '947 Patent, either literally or under the doctrine of equivalents.

COUNT IV

(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '903 PATENT)

40. Apotex realleges and incorporates by reference the allegations of paragraphs 1-39 as though fully set forth herein.

41. There is an actual, substantial, and continuing case or controversy between Apotex and the Plaintiff/Counterclaim-Defendants regarding, inter alia, non-infringement of the claims of the '903 Patent.

42. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in Apotex's ANDA No. 218425 has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '903 Patent, either literally or under the doctrine of equivalents.

43. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in Apotex's ANDA No. 218425 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '903 Patent, either literally or under the doctrine of equivalents.

REQUEST FOR RELIEF

WHEREFORE, Apotex respectfully requests that the Court enter judgment in its favor and against Plaintiffs/Counterclaim Defendants as follows:

(A) Dismissing Plaintiffs' Complaint, and each and every claim by Plaintiffs against Apotex for relief contained therein, with prejudice;

(B) Declaring that the filing of Apotex's MAVENCLAD ANDA Product has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the Dosing Regimen Patents;

(C) Declaring that the claims of the Dosing Regimen Patents are invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, *et seq*. including, *inter alia*, §§ 102, 103, and 112;

(D) Declaring this case exceptional and awarding Apotex reasonable attorneys' fees and costs under 35 U.S.C. § 285;

(E) Awarding Apotex its costs and expenses; and

(F) Awarding Apotex such other and further relief as the Court deems just and proper.

Dated: October 3, 2023

/s/ Cortlan S. Hitch
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