IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA, and ARES TRADING SA,	)	
Plaintiffs,	)	
v.	)	C.A. No. 22-1365-GBW
HOPEWELL PHARMA VENTURES, INC.,	)	
Defendant.	)	

ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendant Hopewell Pharma Ventures, Inc. ("Hopewell") hereby answers the Complaint for patent infringement brought by Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, "Plaintiffs"). Additionally, Hopewell hereby asserts counterclaims for declaratory judgment of invalidity of U.S. Patent Nos. 7,713,947 (the "'947 patent"), 8,377,903 (the "'903 patent"), and 10,849,919 (the "'919 patent") (collectively, the "Patents-in-Suit"), and for declaratory judgment of unenforceability of the '919 patent.

With respect to the allegations made in the Complaint, Hopewell responds as follows:

NATURE OF THE ACTION[1]

1. Hopewell admits that the above-captioned action purports to be an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. Hopewell further admits that it submitted Abbreviated New Drug Application ("ANDA") No. 215547 to the United States Food and Drug Administration ("FDA") seeking

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

approval for the manufacture and sale of cladribine 10 mg tablets prior to the expiration of the Patents-in-Suit. Hopewell denies the remaining allegations in Paragraph 1 of the Complaint.

PARTIES

2. Hopewell lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies them.

3. Hopewell lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore denies them.

4. Hopewell lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint and therefore denies them.

5. Admitted.

6. Hopewell admits that it submitted ANDA No. 215547 to the FDA to obtain approval for the commercial manufacture, use, offer for sale, sale, or importation of cladribine tablets, 10 mg. Hopewell denies the remaining allegations of Paragraph 6 of the Complaint.

7. Admitted.

8. The allegations in Paragraph 8 relate to future conduct to which no final decision has been made and Hopewell therefore denies those allegations.

JURISDICTION AND VENUE

9. The allegations in Paragraph 9 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Hopewell does not contest that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Hopewell responds that the allegations in Paragraph 10 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required,

Hopewell does not contest that this Court has personal jurisdiction over Hopewell for purposes of this action only. Hopewell denies the remaining allegations in Paragraph 10 of the Complaint.

11. Hopewell admits it conducts business in the State of Delaware. The allegations in Paragraph 11 pertaining to the likely destination of a proposed generic version of MAVENCLAD relate to future conduct to which no final decision has been made and Hopewell therefore denies those allegations.

12. The allegations in Paragraph 12 relate to future conduct to which no final decision has been made or to events that have not happened and Hopewell therefore denies those allegations.

13. The allegations in Paragraph 13 of the Complaint relate to future conduct to which no final decision has been made and Hopewell therefore denies those allegations.

PATENTS-IN-SUIT

14. Hopewell admits that the face of the '947 patent bears the title "Cladribine Regimen for Treating Multiple Sclerosis." Hopewell further admits that the face of the '947 patent states that it was issued on May 11, 2010. Hopewell denies the remaining allegations of Paragraph 14 of the Complaint.

15. Hopewell admits that the face of the '903 patent bears the title "Cladribine Regimen for Treating Multiple Sclerosis." Hopewell further admits that the face of the '903 patent states that it was issued on February 19, 2013. Hopewell denies the remaining allegations of Paragraph 15 of the Complaint.

16. Hopewell admits that the face of the '919 patent bears the title "Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis." Hopewell further admits that the

face of the '919 patent states that it was issued on December 1, 2020. Hopewell denies the remaining allegations of Paragraph 16 of the Complaint.

17. Hopewell admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists the expiration date of the '947 patent as October 16, 2026, the expiration date of the '903 patent as May 31, 2026, and the expiration date of the '919 patent as November 23, 2038. Hopewell lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17 of the Complaint pertaining to the ownership status of the '947, '903, and '919 patents and therefore denies those allegations. Hopewell denies the remaining allegations of Paragraph 17 of the Complaint.

MERCK'S MAVENCLAD PRODUCT

18. Hopewell admits that the New Drug Application ("NDA") No. 022561 associated with 10 mg cladribine tablets was approved by the FDA on March 29, 2019. Hopewell admits that the FDA lists EMD Serono, Inc. as the current holder of NDA No. 022561. Hopewell admits that the prescribing information for MAVENCLAD states that it is a 10 mg strength cladribine tablet and that it is distributed by EMD Serono. Hopewell lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18 of the Complaint and therefore denies them.

19. Hopewell admits that the Prescribing Information for MAVENCLAD states that it is a purine antimetabolite indicated for the treatment of relapsing forms of multiple sclerosis (MS), including relapsing-remitting disease and active secondary progressive disease, in adults. Hopewell admits that Exhibit D purports to be the prescribing information for MAVENCLAD. Hopewell denies the remaining allegations in Paragraph 19 of the Complaint.

20. Hopewell admits that the Orange Book includes MAVENCLAD. Hopewell further admits that the Orange Book lists the '947, '903, and '919 patents in connection with MAVENCLAD and that the '919 patent was listed in the Orange Book on September 12, 2022. Hopewell denies the remaining allegations in Paragraph 20 of the Complaint.

ALLEGED INFRINGEMENT

21. Admitted.

22. Admitted.

23. Hopewell admits that the Notice Letter states that Hopewell's ANDA product as described in ANDA No. 215547 will be marketed for the same indications as MAVENCLAD. Hopewell denies the remaining allegations of Paragraph 23 of the Complaint.

24. Admitted

25. On information and belief, admitted.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 7,713,947

26. Hopewell incorporates by reference each and every response to Paragraphs 1-25 as though fully set forth herein.

27. Denied.

28. Denied.

29. Admitted.

30. Denied.

31. The allegations in Paragraph 31 of the Complaint relate to future conduct to which no final decision has been made and Hopewell therefore denies those allegations.

32. Denied

33. Admitted.

34. Denied.

35. Denied.

36. Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,377,903

37. Hopewell incorporates by reference each and every response to Paragraphs 1-36 as though fully set forth herein.

38. Denied.

39. Denied.

40. Admitted.

41. Denied.

42. The allegations in Paragraph 42 of the Complaint relate to future conduct to which no final decision has been made and Hopewell therefore denies those allegations.

43. Denied.

44. Admitted.

45. Denied.

46. Denied.

47. Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,849,919

48. Hopewell incorporates by reference each and every response to Paragraphs 1-47 as though fully set forth herein.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. The allegations in Paragraph 42 of the Complaint relate to future conduct to which no final decision has been made and Hopewell therefore denies those allegations.

54. Denied.

55. Admitted.

56. Denied.

57. Denied.

58. Denied.

PRAYER FOR RELIEF

This section of the Complaint constitutes Prayers for Relief that do not require a response. Hopewell denies that Plaintiffs are entitled to any of the requested relief or any other relief. Each averment and/or allegation contained in the Complaint that is not specifically admitted herein is hereby denied.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE: NON-INFRINGEMENT OF U.S. PATENT NO. 7,713,947

Hopewell does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '947 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE: INVALIDITY OF U.S. PATENT NO. 7,713,947

Each claim of the '947 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

THIRD DEFENSE: NON-INFRINGEMENT OF U.S. PATENT NO. 8,377,903

Hopewell does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '903 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE: INVALIDITY OF U.S. PATENT NO. 8,377,903

Each claim of the '903 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and any judicially created bases for invalidation.

FIFTH DEFENSE: NON-INFRINGEMENT OF U.S. PATENT NO. 10,849,919

Hopewell does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '919 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SIXTH DEFENSE: INVALIDITY OF U.S. PATENT NO. 10,849,919

Each claim of the '919 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and any judicially created bases for invalidation.

SEVENTH DEFENSE: UNENFORCEABILITY OF U.S. PATENT NO. 10,849,919 DUE TO INEQUITABLE CONDUCT

The '919 patent is unenforceable because of inequitable conduct, as detailed in Hopewell's counterclaims below, which Hopewell incorporates by reference.

RESERVATION OF DEFENSES

Hopewell reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Defendant and Counterclaim-Plaintiff Hopewell Pharma Ventures, Inc. ("Hopewell") asserts the following counterclaims against Plaintiffs and Counterclaim-Defendants Merck KGaA, Merck Serono SA, and Ares Trading SA (collectively, "Counterclaim-Defendants").

NATURE OF THE COUNTERCLAIMS

1. These counterclaims include claims for declaratory judgment that U.S. Patent Nos. 7,713,947 (the "'947 patent"), 8,377,903 (the "'903 patent"), and 10,849,919 (the "'919 patent") (collectively, the "Patents-in-Suit") are invalid and that the '919 patent is unenforceable due to inequitable conduct.

THE PARTIES

2. Hopewell Pharma Ventures, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1201 North Orange Street, Suite 717, Wilmington, Delaware, 19801-1186.

3. On information and belief, and as alleged in Counterclaim-Defendants' Complaint, Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Hessen, Germany.

4. On information and belief, and as alleged in Counterclaim-Defendants' Complaint, 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.

5. On information and belief, and as alleged in Counterclaim-Defendants' Complaint, 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, and is a wholly owned subsidiary of Merck KGaA.

JURISDICTION AND VENUE

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, 2202.

7. This Court has subject-matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

8. Counterclaim-Defendants have availed themselves of this forum in this action and are therefore subject to personal jurisdiction in this District for purposes of these counterclaims.

9. Venue is proper for these counterclaims under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

10. The ’947 patent is titled “Cladribine Regimen for Treating Multiple Sclerosis” and issued on May 11, 2010.

11. The ’903 patent is titled “Cladribine Regimen for Treating Multiple Sclerosis” and issued on February 19, 2013.

12. The ’919 patent is titled “Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis” and issued on December 1, 2020.

13. On information and belief, and as alleged in Counterclaim-Defendants’ Complaint, Merck Serono SA owns rights, title, and interests in and to the ’947 and ’903 patents.

14. On information and belief, and as alleged in Counterclaim-Defendants’ Complaint, Ares Trading SA owns rights, title, and interests in and to the ’919 patent.

15. The Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists EMD Serono, Inc. as the holder of the New Drug Application (“NDA”) No. 022561 for MAVENCLAD. On information and belief, the active ingredient in MAVENCLAD is cladribine.

16. Hopewell submitted ANDA No. 215547 under 21 U.S.C. § 355(j) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, or importation of cladribine tablets, 10 mg ("Hopewell's ANDA Product"), prior to the expiration of the '947 and '903 patents.

17. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Hopewell submitted a certification in ANDA No. 215547 stating that the claims of the '947 and '903 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Hopewell's ANDA Product.

18. In accordance with 21 U.S.C. § 355(j)(2)(B), Hopewell notified Merck KGaA, Merck Serono SA, and EMD Serono, Inc. in writing that Hopewell's ANDA was filed with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '947 and '903 patents are invalid, unenforceable, and/or will not be infringed by Hopewell's ANDA Product ("Hopewell's Notice Letter"). In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(ii), Hopewell's Notice Letter included a detailed statement of the factual and legal basis for the certification that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by Hopewell's ANDA Product.

19. On October 17, 2022, Counterclaim-Defendants sued Hopewell in the District of Delaware, alleging infringement of the Asserted Patents.

COUNT I: DECLARATORY JUDGMENT OF INVALIDITY OF THE '947 PATENT

20. Hopewell incorporates by reference, as though fully set forth herein, paragraphs 1 through 19 of the counterclaims.

21. Counterclaim-Defendants have alleged in this action that Hopewell infringed the '947 patent by filing ANDA No. 215547 and that Hopewell's manufacture, use, offer for sale, or

sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 215547 would infringe the '947 patent.

22. The '947 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

23. Accordingly, a present, genuine, and justiciable controversy exists between Hopewell and Counterclaim-Defendants regarding the validity of the claims of the '947 patent.

24. Hopewell is entitled to a declaration by the Court that one or more of the claims of the '947 patent are invalid.

25. Hopewell is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '903 PATENT

26. Hopewell incorporates by reference, as though fully set forth herein, paragraphs 1 through 25 of the counterclaims.

27. Counterclaim-Defendants have alleged in this action that Hopewell infringed the '903 patent by filing ANDA No. 215547 and that Hopewell's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 215547 would infringe the '903 patent.

28. The '903 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

29. Accordingly, a present, genuine, and justiciable controversy exists between Hopewell and Counterclaim-Defendants regarding the validity of the claims of the '903 patent.

30. Hopewell is entitled to a declaration by the Court that one or more of the claims of the '903 patent are invalid.

31. Hopewell is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT III: DECLARATORY JUDGMENT OF INVALIDITY OF THE '919 PATENT

32. Hopewell incorporates by reference, as though fully set forth herein, paragraphs 1 through 31 of the counterclaims.

33. Counterclaim-Defendants have alleged in this action that Hopewell infringed the '919 patent by filing ANDA No. 215547 and that Hopewell's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 215547 would infringe the '919 patent.

34. The '919 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

35. Accordingly, a present, genuine, and justiciable controversy exists between Hopewell and Counterclaim-Defendants regarding the validity of the claims of the '919 patent.

36. Hopewell is entitled to a declaration by the Court that one or more of the claims of the '919 patent are invalid.

37. Hopewell is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT IV: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '919 PATENT DUE TO INEQUITABLE CONDUCT

38. The '919 patent is unenforceable because the named inventors of the '919 patent—Fernando Dangond and Matthias Dotzauer—and the prosecuting attorney for the '919 patent—Kirsten Grueneberg—violated their duty of candor and good faith in dealing with the United States Patent and Trademark Office (the "PTO") by intentionally and deceptively failing to disclose material information to the PTO during prosecution of the '919 patent. Specifically,

the '919 patent asserts that the claimed invention was based on "new and surprisingly advantageous clinical results" from a study called the "ONWARD Study." *See* '919 patent, 3:25-67. However, Dr. Dangond, Mr. Dotzauer, and Dr. Grueneberg failed to disclose to the PTO that the relevant details of the ONWARD Study, including both its methodology and results, were disclosed in the prior art more than one year before the earliest possible November 24, 2017 effective filing date of the '919 patent—namely, within at least: (1) the public clinicaltrials.gov webpage for the ONWARD study posted on July 2, 2013 as captured by The Wayback Machine and titled "A Phase II, Multicenter, Randomized, Double Blind, Placebo Controlled, Safety, Tolerability and Efficacy Study of Add-on Cladribine Tablet Therapy With Interferon-beta (IFN-β) Treatment in Multiple Sclerosis Subjects With Active Disease (ONWARD)" ("ONWARD Webpage") (a copy of which is attached as Exhibit A), as well as (2) the abstract of Xavier Montalban, et al., *Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Rules from the Phase II ONWARD Study (P3.029)*, published in the journal *Neurology* on April 4, 2016 ("Montalban 2016 Abstract") (a copy of which is attached as Exhibit B).

The ONWARD Webpage and Montalban 2016 Abstract

39. On information and belief, beginning in or about November 2006, EMD Serono, Inc.—which, on information and belief, is a wholly owned subsidiary of Plaintiff Merck KGaA—commenced the ONWARD Study, a 2-year, randomized, placebo-controlled, double-blind clinical study whose goal was "to evaluate the safety, tolerability and effectiveness of oral cladribine when taken in combination with Interferon-beta (IFN-beta) therapy for the treatment of multiple sclerosis (MS)." Exhibit A at 1, 3. On information and belief, the ONWARD Study was completed in or about March 2012. *Id.* at 3 (U.S. National Library of Medicine, *A Phase 2*

Study of Cladribine Add-on to Interferon-beta (IFN-beta) Therapy in Multiple Sclerosis (MS) Subjects With Active Disease (ONWARD) (ONWARD), https://clinicaltrials.gov/ct2/show/NCT00436826 (last updated Oct. 12, 2020).).

40. By no later than July 2, 2013, the purpose, outcome measures, eligibility criteria, and methodology for the ONWARD Study, as well as the fact that the study had been completed, were posted publicly on the clinicaltrials.gov website, as captured by the Wayback Machine.[1] *See generally* ONWARD Webpage. For context, clinicaltrials.gov is a public website maintained by the National Library of Medicine (NLM) and serves as a "Web-based resource that provides . . . the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions." (U.S. National Library of Medicine, *ClinicalTrials.gov Background* (May 2021), https://clinicaltrials.gov/ct2/about-site/background.). The interested public can learn more about a particular clinical study by visiting clinicaltrials.gov and searching for the profile page of the clinical study. There they will find detailed information about the clinical study (e.g., the study's objectives, its treatment protocol, etc.), which is provided by the entity that is sponsoring the study.

41. The ONWARD Webpage disclosed that the ONWARD study would include around 200 subjects between the ages of 18 to 65 years of age, and specifically include subjects suffering from both relapsing-remitting multiple sclerosis (RRMS) as well as secondary progressive multiple sclerosis (SPMS). Ex. A at 1, 5. The ONWARD Webpage further disclosed

[1] This information about the ONWARD Study was also publicly available on the ONWARD Study Webpage on August 4, 2013, as indicated by the "History of Changes" section of the ONWARD Study Webpage. (U.S. National Library of Medicine, *History of Changes for Study: NCT00436826*, https://clinicaltrials.gov/ct2/history/NCT00436826?A=18&B=18&C=merged#StudyPageTop (last updated Oct. 8, 2020).)

that the subjects were to be randomly divided into a placebo group and a treatment group, and during the course of a 96-week treatment period, participants in the treatment group—including those participants with SPMS—would "receive cladribine tablets orally as [a] cumulative dose of 0.875 milligram per kilogram (mg/kg) over a course of 4-5 consecutive days at Week 1, 5, 48, and 52 resulting in [a] total cladribine dose of 3.5 mg/kg." *Id.* at 4. The ONWARD Webpage also noted that patients in both the treatment and placebo group were to be further administered interferon-beta (IFN-beta or IFN-β) during the treatment period. *Id.*

42. By April 18, 2016, the Montalban 2016 Abstract was published in the journal *Neurology*, disclosing the results of the ONWARD study. *See* Ex. B. Specifically, the Montalban 2016 Abstract disclosed that "14.5[percent] of patients (N=172) had SPMS at baseline" and that the "mean number of qualifying relapses . . . was lower (0.23) in patients treated with cladribine 3.5mg/kg plus IFN-β (N=124) vs. patients who received placebo plus IFN-β (0.56; N=48)." *Id.* at 1. It further disclosed that "cladribine-treated patients were 63[percent] less likely to have a qualifying relapse (P<0.001)." *Id.* Based on these results, Montalban 2016 Abstract concluded that "treatment with cladribine tablets added on to IFN-β demonstrated significant efficacy benefits**"** for "patients with active relapsing MS . . . including [patients with] SPMS with ongoing relapses." *Id.* Notably, Montalban 2016 Abstract lists named inventor Dr. Dangond as co-author, and further notes that the ONWARD study was "supported by" Plaintiff Merck KGaA. *Id.*

Intentional and Material Failure to Disclose that the ONWARD Study Methodology and Results Were Disclosed in the Prior Art

43. The '919 patent explicitly points to the results of the ONWARD study as forming the basis for the invention recited in the asserted claims. For example, the '919 patent

specification states that "there is clearly a high unmet medical need for therapeutics that are effective in the field of progressive forms of MS" and accordingly, "[b]ased on new and surprisingly advantageous clinical results discussed herein in detail . . . it is believed that specific oral dosings, specific oral dosage forms and/or specific oral dose regimens described herein comprising the active ingredient Cladribine, newly approved for the treatment of RRMS . . . are also effective in the treatment of progressive forms of MS, clearly beyond the treatment of [another type of MS, called] ESPMS, and especially effective for the treatment of PPMS and/or SPMS." '919 patent, 3:22-34. The '919 patent specification then "go[es] into more detail" regarding these "surprisingly advantageous clinical results" by specifically citing "the results from the ONWARD Study, which contained both RRMS and SPMS patients." *Id.* at 3:35-37.

44. Additionally, during prosecution of the '919 patent, the named inventors and their prosecution counsel relied on these results regarding the treatment of SPMS to successfully traverse the Examiner's rejection of the claims in view of a prior Merck patent (the "De Luca '903 patent") filed before the completion of the ONWARD study that disclosed the same cladribine dosing regimen as the one claimed but for the treatment of two other forms of MS (RRMS and ESPMS) rather than for a progressive form of MS, like SPMS. Notably, Merck did not contest that the prior art De Luca '903 patent disclosed the claimed cladribine dosing regimen, but instead asserted that the De Luca '903 patent failed to teach that the progressive form of MS treated by that dosing regimen was "SPMS, PPMS, and PRMS, but not ESPMS," as recited by the claims. Ex. C ('919 Patent File History, April 14, 2020 Office Action) at 5-9; Ex. D ('919 Patent File History, May 15, 2020 Applicant-Initiated Interview Summary); Ex. E ('919 Patent File History, July 7, 2020 Reply to Office Action) at 15, 17-19; Ex. F ('919 Patent File History, July 23, 2020 Notice of Allowance).

45. Even though the '919 patent explicitly states that the purported invention was based on the results of Merck's ONWARD study and the named inventors and their prosecution counsel relied on those results during prosecution to distinguish from the prior art of record by asserting that the claimed dosing regimen successfully treated progressive forms of MS, such as SPMS, neither named inventors nor their prosecution counsel ever informed the PTO that the methodology and results of that exact study were publicly disclosed in the prior art. Nor did they disclose the ONWARD Webpage or the Montalban 2016 Abstract to the Patent Office during prosecution. Thus, on information and belief, and as explained in further detail below, the named inventors and their prosecution counsel failed to disclose this "but-for" material information and prior art with the specific intent to deceive the PTO.

The ONWARD Webpage and Montalban 2016 Abstract Are "But-For" Material

46. The fact that the ONWARD study methodology and results were disclosed in the prior art is "but-for" material to the patentability of the asserted claims: the PTO would not have allowed the asserted claims of the '919 patent had the named inventors or their prosecution counsel disclosed this information or the ONWARD Webpage and the Montalban 2016 Abstract during prosecution.

47. Specifically, as exemplified in the below chart for independent claim 1, the ONWARD Webpage and the Montalban 2016 Abstract references, taken either alone or together, teach and disclose each and every limitation of the asserted independent claims of the '919 patent. Thus, the Examiner would have concluded that each of the asserted claims were invalid as anticipated or obvious in view of the ONWARD Webpage and the Montalban 2016 Abstract:

Claim Element	U.S. Patent No. 10,849,919 – Claim 1	ONWARD Webpage	Montalban 2016 Abstract
1.1	"A method of treating a progressive form of	"The goal of this study [was] to evaluate the	"Objective: To assess the efficacy of cladribine

	Multiple Sclerosis, said method comprising:"	safety, tolerability and effectiveness of oral cladribine when taken in combination with Interferon-beta (IFN-beta) therapy for the treatment of multiple sclerosis." Ex. A at 1. "Secondary progressive multiple sclerosis (SPMS) subjects, who [were] still experiencing relapses . . . may also be enrolled." *Id.*	tablets (3.5mg/kg) as an add-on to IFN-β in patients with active relapsing MS." Ex. B at 1. "14.5[percent] of patients (N=172) had SPMS at baseline." *Id.*
1.2	"[O]rally administering Cladribine to a patient in need thereof at fixed dose per patient, per body weight and per treatment year, wherein said fixed dose is in a range of 1.5 mg/kg to 4.0 mg/kg,"	"Subjects will receive cladribine tablets orally as cumulative dose of 0.875 milligram per kilogram (mg/kg) over a course of 4-5 consecutive days at Week 1, 5, 48, and 52 resulting in total cladribine dose of 3.5 mg/kg during the [DB] [i.e., Double Blind] period of 96 weeks." *Id.* at 4.	"Objective: To assess the efficacy of cladribine tablets (3.5mg/kg) as an add-on to IFN-β in patients with active relapsing MS." *Id.* "ONWARD was a 2-year, randomized, double-blind Phase IIb study in patients aged 18-65 years, with ≥ 1 relapse during the prior 48 weeks while on IFN-β therapy." *Id.*
1.3	"[W]herein the progressive form of Multiple Sclerosis is selected from the group consisting of Secondary Progressive Multiple Sclerosis (SPMS), Primary Progressive Multiple Sclerosis (PPMS), and Progressive Relapsing Multiple Sclerosis (PRMS), and wherein the progressive form of Multiple Sclerosis does not include Early	"Inclusion Criteria . . . Have definite MS, as confirmed by the revised McDonald criteria 2005, and have relapsing forms of MS, such as relapsing-remitting multiple sclerosis (RRMS) or SPMS with superimposed relapses." *Id.* at 5. "Secondary progressive multiple sclerosis (SPMS) subjects, who [were] still experiencing relapses . . .	"14.5[percent] of patients (N=172) had SPMS at baseline." *Id.* "In patients with active relapsing MS with breakthrough disease while on IFN-β therapy (including SPMS with ongoing relapses), treatment with cladribine tablets added on to IFN-β demonstrated significant efficacy benefits." *Id.*

	Secondary Progressive Multiple Sclerosis (ESPMS)."	may also be enrolled." *Id.* at 1.	

48. The ONWARD Webpage and the Montalban 2016 Abstract are also not cumulative over the prior art and information that was before the Examiner during prosecution of the '919 patent. As discussed above, the '919 patent asserts that the ONWARD study demonstrated that the claimed dosing regimen could be used to treat progressive forms of MS like SPMS, rather than just RRMS or ESPMS. Moreover, the Examiner allowed the claims in view of Merck's assertion that the prior art of record did not teach using the claimed dosing regimen to treat "SPMS, PPMS, and PRMS, but not ESPMS," as recited by the claims. However, as shown above, the ONWARD Webpage and Montalban 2016 Abstract references disclose the methodology and results of the ONWARD study, and explicitly supply the supposedly missing limitations of using the claimed dosing regimen to treat progressive forms of MS, like SPMS. Indeed, none of the prior art of record during prosecution mentioned or disclosed anything regarding the ONWARD study, let alone its results regarding treatment of progressive forms of MS. Thus, the ONWARD Webpage and the Montalban 2016 Abstract plainly provide non-cumulative disclosures as compared to the prior art of record.

Dr. Dangond, Mr. Dotzauer, and Dr. Grueneberg Knew the ONWARD Methodology and Results were Disclosed in the Prior Art, and Withheld Them With the Specific Intent to Deceive

49. On information and belief, each of Dr. Dangond, Mr. Dotzauer, and Dr. Grueneberg knew that the methodology and results of the ONWARD study were publicly disclosed in the prior art within the ONWARD Webpage and Montalban 2016 Abstract, and further knew that these disclosures were but-for material to the patentability of the claims. Yet,

on information and belief, each of them failed to disclose this known material information to the PTO with the specific intent to deceive.

50. ***Dr. Dangond***. On information and belief, Dr. Dangond knew of the Montalban 2016 Abstract and its disclosures regarding the results of the ONWARD study, as he is listed as a co-author of the reference. Additionally, on information and belief, Dr. Dangond also knew that the methodology of the ONWARD study was publicly disclosed on the ONWARD Webpage on clinicaltrials.gov by no later than July 2, 2013. Specifically, according to Mr. Dangond's LinkedIn profile, from March 2008 to September 2015, Dr. Dangond served as Senior Medical Director and Head of US Medical Affairs for EMD Serono, which was the sponsor of the ONWARD Study. (Fernando Dangond, LinkedIn, https://www.linkedin.com/in/fernando-dangond-b11b1b4.). Thus, on information and belief, Dr. Dangond would have been involved with and/or responsible for the ONWARD study and drafting, revising, and supplementing the ONWARD Webpage with the ONWARD study methodology.

51. On information and belief, Dr. Dangond also knew of the materiality of the public disclosures regarding the ONWARD Study within the ONWARD Webpage and Montalban 2016 Abstract references, yet deliberately chose to withhold them with the specific intent to deceive the PTO. Specifically, Dr. Dangond, as a named inventor of the '919 patent, was involved with the prosecution of the '919 patent. Thus, on information and belief, Dr. Dangond was aware that the '919 patent stated that the results of the ONWARD Study provided the basis for the purported inventive method of treating progressive forms of MS, like SPMS, and was also aware of the statements made to the Examiner during prosecution asserting that the prior art failed to disclose such a method of treating such progressive forms of MS. Dr. Dangond further executed a declaration pursuant to 37 C.F.R. § 1.63, requiring that "a person may not execute" such a

declaration "unless that person … is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56." Ex. G ('919 Patent File History, December 14, 2018 Dangond Declaration (37 CFR 1.63) For Utility or Design Application Using an Application Data Sheet (37 CFR 1.76) and Assignment for Single Assignee). Yet Dr. Dangond knowingly violated his duty of disclosure by failing to inform the PTO that the ONWARD Study and its results (namely, the use of the claimed dosing regimen to treat progressive forms of MS like SPMS) were disclosed within the prior-art ONWARD Webpage and Montalban 2016 Abstract.

52. ***Mr. Dotzauer.*** Along with Dr. Dangond, Mr. Dotzauer is named as a co-inventor of the '919 patent, which as discussed above, contains extensive disclosures regarding the ONWARD Study and its results. Additionally, according to Mr. Dotzauer's LinkedIn profile, he is Senior Patent Counsel for Plaintiff Merck KGaA. (Matthias Dotzauer, LinkedIn, https://de.linkedin.com/in/matthias-dotzauer-647600233.). Therefore, on information and belief, Mr. Dotzauer would have been aware that the ONWARD Study methodology, as well as its results were published, and therefore publicly available, almost 5, and almost 2 years, respectively, before the earliest possible effective filing date of the '919 patent.

53. On information and belief, Mr. Dotzauer also knew of the materiality of the public disclosures regarding the ONWARD Study, yet deliberately chose to withhold them with the specific intent to deceive the PTO. Specifically, Mr. Dotzauer, as a named inventor of the '919 patent, and on information and belief, was involved with the prosecution of the '919 patent. Thus, on information and belief, Mr. Dotzauer was aware that the '919 patent stated that the results of the ONWARD Study provided the basis for the purported inventive method of treating progressive forms of MS, like SPMS, and was also aware of the statements made to the

Examiner during prosecution asserting that the prior art failed to disclose such a method of treating such progressive forms of MS. Mr. Dotzauer further executed an oath pursuant to 37 C.F.R. § 1.63, requiring that a person executing such an oath must be "aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56." Ex. H ('919 Patent File History, December 17, 2018 Dotzauer Declaration (37 CFR 1.63) For Utility or Design Application Using an Application Data Sheet (37 CFR 1.76) and Assignment for Single Assignee). Yet Mr. Dotzauer violated his known duty of disclosure by failing to inform the PTO that the ONWARD Study and its results (namely, the use of the claimed dosing regimen to treat progressive forms of MS like SPMS) were disclosed in the prior art.

54. ***Dr. Grueneberg.*** Dr. Grueneberg was named as attorney of record of the '919 patent, which, as discussed above, contains extensive disclosures regarding the ONWARD Study and its results. Therefore, on information and belief, Dr. Grueneberg would have been aware that the ONWARD Study and its results were published, and therefore publicly available, almost 5 years before the earliest possible effective filing date of the '919 patent.

55. On information and belief, Dr. Grueneberg also knew of the materiality of the public disclosures regarding the ONWARD Study, yet deliberately chose to withhold them with the specific intent to deceive the PTO. Specifically, Dr. Grueneberg, as attorney of record of the '919 patent, was involved with the prosecution of the '919 patent. Thus, on information and belief, Dr. Grueneberg was aware that the '919 patent stated that the results of the ONWARD Study provided the basis for the purported inventive method of treating progressive forms of MS, like SPMS. Moreover, Dr. Grueneberg signed the Reply to Office Action containing the statements made to the Examiner during prosecution asserting that the prior art failed to disclose

a method of treating such progressive forms of MS. Ex. E ('919 Patent File History, July 7, 2020 Reply to Office Action) at 20. Lastly, as attorney of record for the '919 patent, Dr. Grueneberg would have been well aware of her duty to disclose to the PTO all information known to her to be material to the patentability of the claims pursuant to 37 C.F.R. § 1.56. Yet Dr. Grueneberg violated her known duty of disclosure by failing to inform the PTO that the ONWARD Study and its results (namely, the use of the claimed dosing regimen to treat progressive forms of MS like SPMS) were disclosed in the prior art.

PRAYER FOR RELIEF

WHEREFORE, Hopewell requests that the Court enter judgment in its favor against Plaintiffs/Counterclaim-Defendants as follows:

(a) Declaring that the filing of Hopewell's ANDA No. 215547 has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the '947 patent;

(b) Declaring that the filing of Hopewell's ANDA No. 215547 has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the '903 patent;

(c) Declaring that the filing of Hopewell's ANDA No. 215547 has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the '919 patent;

(d) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hopewell's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '947 patent;

(e) Declaring that the manufacture, use, offer to sell, sale, and/or importation

into the United States of Hopewell's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '903 patent;

(f) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hopewell's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '919 patent;

(g) Declaring that the claims of the '947 patent are invalid;

(h) Declaring that the claims of the '903 patent are invalid;

(i) Declaring that the claims of the '919 patent are invalid;

(j) Declaring that the claims of the '919 patent are unenforceable due to inequitable conduct;

(k) If the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Hopewell reasonable attorneys' fees and costs reasonably incurred in prosecuting this action; and

(l) Granting Hopewell such other and further relief as the Court deems just and appropriate.

/s/ Nathan R. Hoeschen

Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 5486)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Defendant

OF COUNSEL:
J.C. Rozendaal
Chandrika Vira
STERNE KESSLER GOLDSTEIN & FOX
1100 New York Ave. NW
Suite 600
Washington, D.C. 20005

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