IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA, and ARES TRADING SA, Plaintiffs, v. AUROBINDO PHARMA USA, INC. and AUROBINDO PHARMA LIMITED, Defendants.	C.A. No. 23-39 (GBW)

DEFENDANTS AUROBINDO PHARMA U.S.A., INC. AND AUROBINDO PHARMA LIMITED'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT

Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited (collectively, "Aurobindo"), by and through their counsel, hereby respond to the allegations set forth in Plaintiffs Merck KGaA, Merck Serono SA, and Ares Trading SA's (collectively, "Merck") Complaint against Aurobindo. This response is based on Aurobindo's current knowledge as to its respective own activities, and on information and belief as to the activities of others. If not specifically admitted herein by Aurobindo, the allegations of the Complaint are denied. The headings in Merck's Complaint are copied herein for convenience only, and any allegations in such headings are denied.

NATURE OF THE ACTION

1. Aurobindo admits that this action purports to arise under the United States Patent Laws, Title 35 of the United States Code, involving U.S. Patent Nos. 7,713,947 ("the '947 patent"), U.S. Patent No. 8,377,903 ("the '903 patent"), and U.S. Patent No. 10,849,919 ("the '919 patent")

(collectively, the "patents-in-suit"). Aurobindo admits that it filed its Abbreviated New Drug Application ("ANDA") No. 217924 with the U.S. Food and Drug Administration ("FDA") seeking approval to market its generic version of Merck's MAVENCLAD® prior to the expiration of the patents-in-suit. Aurobindo denies any remaining allegations in this paragraph.

PARTIES

2. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint and therefore denies them.

3. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint and therefore denies them.

4. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint and therefore denies them.

5. Aurobindo Pharma Limited admits that Aurobindo Pharma Limited's corporate office is located at: Galaxy, Floors 22-24, Plot No. 1, Survey No.83/1, Hyderabad Knowledge City, Raidurg Ranga Reddy District, Hyderabad – 500032, Telangana, India. Aurobindo Pharma Limited also admits that Aurobindo Pharma Limited's registered office is located at: Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India. Aurobindo denies any remaining allegations in this paragraph.

6. Admitted.

7. Admitted.

8. Aurobindo is in the generic pharmaceutical business in the U.S. market. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations in this paragraph.

9. Admitted.

10. Aurobindo admits that it filed its ANDA No. 217924 with the FDA seeking approval to market its ANDA product in the United States prior to the expiration of the patents-in-suit. Aurobindo denies any remaining allegations in this paragraph.

11. Aurobindo admits that Merck purports to refer in the Complaint (subsequent to paragraph 11 thereof) to defendants Aurobindo Pharma and Aurobindo USA collectively as "Aurobindo" or "Defendants." Aurobindo denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. Aurobindo will not contest subject matter jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations in this paragraph.

13. Paragraph 13 of the Complaint states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations in this paragraph.

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. Aurobindo will not contest venue for the limited purpose of this action only.

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations in this paragraph.

16. Paragraph 16 of the Complaint states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations in this paragraph.

17. Paragraph 17 of the Complaint states a legal conclusion to which no response is required. Aurobindo will not contest personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations in this paragraph.

PATENTS-IN-SUIT

18. Aurobindo admits that the purported copy of the '947 patent in Ex. A to Merck's Complaint bears a title of "Cladribine Regimen For Treating Multiple Sclerosis" and an issuance date of May 11, 2010. Aurobindo denies that the '947 patent was "duly and legally" issued. Aurobindo denies any remaining allegations in this paragraph.

19. Aurobindo admits that the purported copy of the '903 patent in Ex. B to Merck's Complaint bears a title of "Cladribine Regimen For Treating Multiple Sclerosis" and an issuance date of February 19, 2013. Aurobindo denies that the '903 patent was "duly and legally" issued. Aurobindo denies any remaining allegations in this paragraph.

20. Aurobindo admits that the purported copy of the '919 patent in Ex. C to Merck's Complaint bears a title of "Cladribine Regimen For Treating Progressive Forms of Multiple Sclerosis" and an issuance date of December 1, 2020. Aurobindo denies that the '919 patent was "duly and legally" issued. Aurobindo denies any remaining allegations in this paragraph.

21. Aurobindo admits that, according to the purported patent covers, the '947 patent and '903 patents are purportedly assigned to Merck Serono SA. Aurobindo admits that, according to the purported patent cover, the '919 patent is purportedly assigned to Merck Patent GmbH. Upon information and belief, Aurobindo admits that the United States Patent and Trademark Office patent assignment database lists a purported assignment of the '919 patent to Ares Trading S.A. Aurobindo denies any remaining allegations in this paragraph.

MERCK'S MAVENCLAD® PRODUCT

22. Aurobindo admits that EMD Serono, Inc. is the applicant holder of the New Drug Application ("NDA) No. 022561, which the FDA approved on March 29, 2019. Aurobindo admits that EMD Serono Inc. markets 10mg strength cladribine tablets under the name

"MAVENCLAD®." Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and therefore denies them.

23. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint and therefore denies them.

24. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24, but admits that the Electronic version of the Approved Drug Products with Therapeutic Equivalence Evaluations contains entry for MAVENCLAD®.

INFRINGEMENT BY AUROBINDO

25. Aurobindo admits that it filed its ANDA No. 217924 with the FDA seeking approval to market its ANDA product in the United States prior to the expiration of the patents-in-suit. Aurobindo admits that, according to the Electronic Orange Book, the '947 patent expires on October 16, 2026; the '903 patent expires on May 31, 2026; and the '919 patent expires on November 23, 2038. Aurobindo denies any remaining allegations in this paragraph.

26. Aurobindo admits that Aurobindo's proposed ANDA product has an active ingredient cladribine and a dosage strength of 10 mg. Aurobindo also admits that its proposed ANDA product is bioequivalent to MAVENCLAD for purposes of the FDA's requirements for an ANDA product. Aurobindo denies any remaining allegations in this paragraph.

27. Aurobindo admits that the currently proposed prescribing information for Aurobindo's proposed ANDA product does not carve out any indication pursuant to 21 U.S.C. § 355(j)(2)(A)(viii). Aurobindo denies any remaining allegations in this paragraph.

28. Admitted.

29. Admitted.

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

30. Aurobindo incorporates each of the preceding paragraphs as if fully set forth herein.

31. Denied. Filing an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

32. Denied.

33. Admitted.

34. Denied.

35. Aurobindo admits that it filed its ANDA No. 217924 with the FDA seeking approval to market its ANDA product in the United States prior to the expiration of the patents-in-suit. Aurobindo denies any remaining allegations in this paragraph.

36. Denied.

37. Aurobindo admits that there is a judiciable controversy between the parties as to Merck's allegation that Aurobindo infringes the '947 patent based on Aurobindo's proposed ANDA product suitable for resolution under the Declaratory Judgment Act. Aurobindo denies any remaining allegations in this paragraph.

38. Denied.

39. Denied.

40. Denied.

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

41. Aurobindo incorporates each of the preceding paragraphs as if fully set forth herein.

42. Denied. Filing an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

43. Denied.

44. Admitted.

45. Denied.

46. Aurobindo admits that it filed its ANDA No. 217924 with the FDA seeking approval to market its ANDA product in the United States prior to the expiration of the patents-in-suit. Aurobindo denies any remaining allegations in this paragraph.

47. Denied.

48. Aurobindo admits that there is a judiciable controversy between the parties as to Merck's allegation that Aurobindo infringes the '903 patent based on Aurobindo's proposed ANDA product suitable for resolution under the Declaratory Judgment Act. Aurobindo denies any remaining allegations in this paragraph.

49. Denied.

50. Denied.

51. Denied.

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

52. Aurobindo incorporates each of the preceding paragraphs as if fully set forth herein.

53. Denied. Filing an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c).

54. Denied.

55. Admitted.

56. Denied.

57. Aurobindo admits that it filed its ANDA No. 217924 with the FDA seeking approval to market its ANDA product in the United States prior to the expiration of the patents-in-suit. Aurobindo denies any remaining allegations in this paragraph.

58. Denied.

59. Aurobindo admits that there is a judiciable controversy between the parties as to Merck's allegation that Aurobindo infringes the '919 patent based on Aurobindo's proposed ANDA product suitable for resolution under the Declaratory Judgment Act. Aurobindo denies any remaining allegations in this paragraph.

60. Denied.

61. Denied.

62. Denied.

RESPONSE TO MERCK'S PRAYER FOR RELIEF

Aurobindo denies that Merck is entitled to any of the relief sought in their Prayer for Relief (a)-(g).

ADDITIONAL DEFENSES

63. An allegation of any defense below is not an admission that Aurobindo bears the burden of proof or persuasion on any claim or issue.

First Additional Defense – Non-Infringement

64. Aurobindo has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claim of any of the patents-in-suit.

Second Additional Defense – Invalidity or Unenforceability

65. The claims of the patents-in-suit are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and 116 and/or for double patenting.

Third Additional Defense – Failure to State a Claim

66. Plaintiff's Complaint fails to state a claim upon which relief can be granted.

Fourth Additional Defense – Estoppel

67. Plaintiff's claims are barred, in whole or in part, by estoppel, including prosecution history estoppel and/or collateral estoppel.

Fifth Additional Defense – Unenforceability of the '919 Patent Due to Inequitable Conduct/Unclean Hands

68. The '919 patent is unenforceable because the named inventors of the '919 patent Fernando Dangond and Matthias Dotzauer, in addition to 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 allegedly "new and surprisingly advantageous clinical results" from a study called the "ONWARD Study." '919 patent at 3:25-67. However, Drs. Dangond, Grueneberg, and Mr. Dotzauer failed to disclose to the PTO that certain material details of the ONWARD Study, including both its methodology and results, were in fact disclosed in the prior art more than one year before the earliest date of November 24, 2017 to which the '919 patent could take priority. These material disclosures occurred least at: (1) the publicly accessible 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 (IFNf3)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 published 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

69. 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).).

70. 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*

[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,*

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), which is provided by the entity that is sponsoring the study.

71. 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). **Exhibit A** at 1, 5. The ONWARD Webpage further disclosed 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-f3) during the treatment period. *Id.*

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https://clinicaltrials.gov/ct2/history/NCT00436826?A=18&B=18&C=merged#StudyPageTop (last updated Oct. 8, 2020).)

72. By April 18, 2016, the Montalban 2016 Abstract was published in the journal *Neurology*, disclosing the results of the ONWARD study. *See* **Exhibit B.** Specifically, the Montalban 2016 Abstract disclosed that "14.5[percent] of patients (N=l 72) 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-f3 (N=124) vs. patients who received placebo plus IFN-f3 (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-f3 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

73. 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.

74. 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. **Exhibit C** ('919 Patent File History, April 14, 2020 Office Action) at 5-9; **Exhibit D** ('919 Patent File History, May 15, 2020 Applicant-Initiated Interview Summary); **Exhibit E** ('919 Patent File History, July 7, 2020 Reply to Office Action) at 15, 17-19; **Exhibit F** ('919 Patent File History, July 23, 2020 Notice of Allowance).

75. 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

76. At least based on the assertion in the '919 patent that the alleged invention of the '919 patent was based on or supported by the results of the ONWARD study, and/or at least to the extent that the claims are construed to cover treatment of the SPMS patients within the study, 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.

77. Specifically, as exemplified in the below chart for independent claim 1, at least based on the assertion in the '919 patent that the alleged invention of the '919 patent was based on or supported by the results of the ONWARD study, and/or at least to the extent that the claims are construed to cover treatment of the SPMS patients within the study, 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 Multiple Sclerosis, said method comprising:"	"The goal of this study [was] to evaluate the safety, tolerability and effectiveness of oral cladribine when taken in combination with Interferon-beta (IFN-beta) therapy for the treatment	"Objective: To assess the efficacy of cladribine 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 multiple sclerosis." Ex. A at 1. "Secondary progressive multiple sclerosis (SPMS) subjects, who [were] still experiencing relapses… may also be enrolled." *Id.*	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 Secondary Progressive Multiple Sclerosis (ESPMS)."	"Inclusion Criteria . . . Have definite MS, as confirmed by the revised McDonald criteria 2005, and have relapsing forms of MS, such as relapsingremitting multiple sclerosis (RRMS) or SPMS with superimposed relapses." *Id.* at 5. "Secondary progressive multiple sclerosis (SPMS) subjects, who [were] still experiencing relapses . . . may also be enrolled." *Id.* at 1.	"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.*

78. 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

79. 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.

80. ***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/fernandodangond-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.

81. 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." **Exhibit 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.

82. ***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.

83. 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." **Exhibit 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.

84. ***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.

85. 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. **Exhibit 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.

86. To the extent that Merck argues that no inequitable conduct exists because the claims of the '919 patent do not encompass treatment of SPMS with ongoing relapses, or otherwise do not encompass treatment of SPMS disclosed in the ONWARD study, such claims would not be infringed by Aurobindo's proposed ANDA product for at least that reason.

RESERVATION OF ADDITIONAL DEFENSES

87. Aurobindo reserves the right to assert such other defenses and damages, if such defenses or and damages are discovered during the course of this litigation.

AUROBINDO'S PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully prays that this Court enter judgement in Aurobindo's favor and grant the following relief:

A. Dismiss Merck's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Aurobindo does not infringe the claims of the patents-in-suit against Aurobindo;

C. A declaration that the claims of the patents asserted against Aurobindo are invalid or unenforceable;

D. Assess the costs of this action against Merck;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Aurobindo is entitled to recover reasonable attorney fees and costs upon prevailing in this action;

F. That the effective date of any FDA approval of Aurobindo's proposed ANDA product shall not be stayed thirty months from the date of its Notice Letter, in accordance with 21

U.S.C. § 355(j)(5)(B)(iii);

G. An award to Aurobindo of such further and other relief as this Court deems necessary, just, and proper.

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Dated: February 3, 2023

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