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Plaintiffs Aurobindo Pharma Limited,
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Aurobindo Pharma USA Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

AUROBINDO PHARMA USA INC.,
AUROMEDICS PHARMA LLC, and
AUROBINDO PHARMA LTD.,

Defendants.

Civil Action No. 3:20-cv-10444 (BRM) (TJB)

ANSWER TO COMPLAINT

Defendants Aurobindo Pharma USA Inc., AuroMedics Pharma LLC, and Aurobindo Pharma Ltd. (together, "Aurobindo" or "Defendants"), by and through their undersigned attorneys, hereby respond to the allegations set forth by Plaintiff Merck Sharp & Dohme Corp. ("Merck" or "Plaintiff") in Merck's Complaint, dated August 13, 2020, as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 9,023,790 (the "'790 Patent'") and 9,358,297 (the "'297 Patent'") arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular under 35 U.S.C. § 271(e). Aurobindo notified Merck pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "Notice Letter") that Aurobindo is the owner of Abbreviated New Drug Application ("ANDA") No. 214842, (the "Aurobindo ANDA"), which Aurobindo filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of a generic version of Merck's NOXAFIL® (posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL), which is sold in the United States. The Aurobindo posaconazole intravenous solution product described in the Aurobindo ANDA is referred to herein as the "Generic Posaconazole IV Solution Product."

ANSWER: Aurobindo admits that Plaintiff has brought an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100 et seq., and that Aurobindo filed ANDA No. 214842 (the "Aurobindo ANDA") under 21 U.S.C. §355(j) with the United States Food and Drug Administration ("FDA"). Aurobindo admits that Plaintiff has asserted that this action arises from Aurobindo's Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of NOXAFIL® (posaconazole) intravenous (infusion) solution ("Aurobindo's Generic Posaconazole IV Solution Product"), but denies any remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health.

ANSWER: Aurobindo admits, upon information and belief, that Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, and that it has a place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Except as so admitted, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of the remaining allegations in paragraph 2 of the Complaint and therefore denies them.

3. On information and belief, Defendant Aurobindo Pharma USA Inc. ("Aurobindo USA") is a company organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Rd, East Windsor, New Jersey 08520-1401, USA. On information and belief Aurobindo USA develops, formulates, manufactures, markets and sells pharmaceutical drug products in the United States.

ANSWER: Aurobindo admits that Defendant Aurobindo Pharma USA Inc. ("Aurobindo USA") is a company organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Rd, East Windsor, New Jersey 08520-1401, USA. Aurobindo admits that Aurobindo USA in conjunction with APL and Auromedics Pharma LLC is in the business of developing, formulating, manufacturing, marketing, and selling pharmaceutical drug products in the United States.

4. On information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Pharma Ltd. ("APL").

ANSWER: Admitted.

5. On information and belief, Defendant AuroMedics Pharma LLC ("AuroMedics") is a company organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Rd, East Windsor, New Jersey 08520-1401, USA. On information and belief AuroMedics develops, formulates, manufactures, markets and sells injectable pharmaceutical drug products in the United States.

ANSWER: Aurobindo admits that Defendant AuroMedics Pharma LLC ("AuroMedics") is a company organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Rd, East Windsor, New Jersey 08520-1401, USA. Aurobindo admits that AuroMedics in conjunction with APL and Aurobindo USA is in the business of developing, formulating, manufacturing, marketing, and selling pharmaceutical drug products in the United States.

6. On information and belief, AuroMedics is a wholly-owned subsidiary of APL.

ANSWER: Admitted.

7. On information and belief, APL is a corporation organized and existing under the laws of India with a principle place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hi-Tech City, Hyderabad – 500084, Telangana, India. Further on information and belief, APL is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating subsidiaries, including Aurobindo USA and AuroMedics.

ANSWER: Aurobindo admits that Defendant Aurobindo Pharma Ltd. ("APL") is a company organized and existing under the laws of India, having a principal place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hi-Tech City, Hyderabad – 500084, Telangana, India. Aurobindo admits that, among other things, APL in conjunction with Aurobindo USA and AuroMedics Pharma LLC is in the business of developing, formulating, manufacturing, marketing, and selling pharmaceutical drug products in the United States.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

ANSWER: Paragraph 9 contains conclusions of law for which no response is required. To the extent that a response is required, Aurobindo admits for purposes of this case only that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a) and 2201-02. With respect to any remaining allegations of Paragraph 9, Aurobindo denies the same.

9. This Court has personal jurisdiction over Aurobindo USA by virtue of its presence in New Jersey, having conducted business in New Jersey, having its principal place of business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV Solution Product, if approved, in this judicial district and to residents of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit. *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759–60 (Fed. Cir. 2016), *cert. denied sub nom. Mylan Pharm. v. Acorda Therapeutics*, 137 S. Ct. 625 (2017).

ANSWER: Paragraph 9 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it is qualified to do business in New Jersey and sells some of its generic products in New Jersey. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 9, Aurobindo denies the same.

10. This Court has personal jurisdiction over AuroMedics by virtue of its presence in New Jersey, having conducted business in New Jersey, having its principal place of business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV

Solution Product, if approved, in this judicial district and to residents of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit. *Id.*

ANSWER: Paragraph 10 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it is qualified to do business in New Jersey and sells some of its generic products in New Jersey. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 10, Aurobindo denies the same.

11. This Court has personal jurisdiction over APL by virtue of its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV Solution Product, if approved, in this judicial district and to residents of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit. *Id.*

ANSWER: Paragraph 11 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it is qualified to do business in New Jersey and sells some of its generic products in New Jersey. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 11, Aurobindo denies the same.

12. Although this Court has personal jurisdiction over APL for at least the reasons set forth in Paragraph 11, in the absence of such personal jurisdiction in any single

state, a foreign entity such as APL is subject to jurisdiction throughout the United States. See Fed. R. Civ. P. 4(k)(2); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1293–94 (Fed. Cir. 2012).

ANSWER: Paragraph 12 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 12, Aurobindo denies the same.

13. Venue is proper in this judicial district as to Aurobindo USA under 28 U.S.C. § 1400(b) because, *inter alia*, it has committed an act of infringement—including having sent or caused to have sent the Notice Letter to Merck this judicial district—and has a regular and established place of business in this judicial district.

ANSWER: Paragraph 13 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it sent the Notice Letter to Merck in this judicial district, and although Aurobindo does not admit that venue is proper, it will not contest venue in the District of New Jersey for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 13.

14. Venue is proper in this judicial district as to AuroMedics under 28 U.S.C. § 1400(b) because, *inter alia*, it has committed an act of infringement—including having sent or caused to have sent the Notice Letter to Merck this judicial district—and has a regular and established place of business in this judicial district.

ANSWER: Paragraph 14 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it sent the Notice Letter to Merck in this judicial district, and although Aurobindo does not admit that venue is proper, it will not contest venue in the District of New Jersey for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 14.

15. Venue is proper as to APL in this judicial district under 28 U.S.C. § 1391(c)(3) because APL is a foreign entity who may be sued in any judicial district. See *In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

ANSWER: Paragraph 15 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it sent the Notice Letter to Merck in this judicial district, and although Aurobindo does not admit that venue is proper, it will not contest venue in the District of New Jersey for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 15.

NOXAFIL®

16. Merck is the holder of New Drug Application ("NDA") N205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells under the registered trademark NOXAFIL® ("NOXAFIL® for Injection"). NOXAFIL® for Injection is approved for the prophylaxis of invasive fungal infections in high risk patients.

ANSWER: Aurobindo admits, upon information and belief, that Merck is the holder of New Drug Application ("NDA") No. 205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells under the brand name NOXAFIL®. Aurobindo directs Merck to the FDA-approved label for NOXAFIL® the best description of NOXAFIL®'s use.

17. NOXAFIL® for Injection is an embodiment of one or more claims of the '790 Patent and the '297 Patent (collectively, the "Patents-in-Suit"). The Patents-in-Suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NOXAFIL®.

ANSWER: Paragraph 17 sets forth legal conclusions based on alleged activities to which no response is required. Aurobindo admits, upon information and belief, that the '790 and '297 Patents (collectively, the "Patents-in-Suit") are listed in the FDA's Approved Drugs with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NOXAFIL®. Aurobindo denies the remaining allegations of Paragraph 17.

PATENTS-IN-SUIT

18. The '790 Patent, entitled "Posaconazole Intravenous Solution Formulations Stabilized by Substituted f3-Cyclodextrin," was duly and legally issued by the USPTO on May 5, 2015. The Orange Book lists the expiration date of the '790 Patent as July 4, 2031. Merck is the owner of all title, right and interest in and to the '790 Patent by assignment. A copy of the '790 Patent is attached as Exhibit A.

ANSWER: Paragraph 18 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '790, as set forth at Exhibit A to the Complaint, the '790 patent was issued on May 5, 2015 with such title, the patent is in the Orange Book and an expiration date of July 4, 2031 is appended therein. With respect to any remaining allegations of Paragraph 18, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

19. The '297 Patent, entitled "Posaconazole Intravenous Solution Formulations Stabilized by Substituted f3-Cyclodextrin" was duly and legally issued by the USPTO on June 7, 2016. The Orange Book lists the expiration date of the '297 Patent as June 24, 2031. Merck is the owner of all title, right and interest in and to the '297 Patent by assignment. A copy of the '297 Patent is attached as Exhibit B.

ANSWER: Paragraph 19 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '297, as set forth at Exhibit B to the Complaint, the '297 patent was issued on June 7, 2016 with such title, that such patent is in the Orange Book, and that the expiration date is listed therein as June 24, 2031. With respect to any remaining allegations of Paragraph 19, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

AUROBINDO'S ANDA

20. Aurobindo filed or caused to be filed the Aurobindo ANDA with the FDA, seeking FDA approval to market and sell within the United States the Generic Posaconazole IV Solution Product before the expiration of the Patents-in-Suit.

ANSWER: Admitted.

21. On information and belief, the Aurobindo ANDA identified Merck's NOXAFIL® for Injection product and included a written certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the Patents-in-Suit are invalid or otherwise will not be infringed by the Generic Posaconazole IV Solution Product.

ANSWER: Aurobindo admits that the Aurobindo Notice Letter contained a written certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the Patents in suit are invalid or otherwise will not be infringed by Aurobindo's Generic Posaconazole IV Solution Product.

22. On or about July 2, 2020, Merck received the Notice Letter from Aurobindo, dated July 1, 2020, stating that pursuant to § 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(ii), Aurobindo had submitted the Aurobindo ANDA to the FDA.

ANSWER: Aurobindo admits, upon information and belief, that Merck received the Notice Letter from Aurobindo dated July 1, 2020 on July 2, 2020, notifying Merck of Aurobindo's submission of the Aurobindo ANDA to the FDA. Aurobindo denies the remaining allegations of Paragraph 22.

23. In its letter to Merck, Aurobindo stated its allegation that the claims of the Patents-in-Suit are invalid.

ANSWER: Admitted.

24. Aurobindo does not contest that Claims 1–19 of the '790 Patent and Claims 1–34 of the '297 Patent would be infringed by the manufacture, use, or sale of the Generic Posaconazole IV Solution Product, unless those claims are found to be invalid.

ANSWER: Denied.

25. By filing or causing to be filed the Aurobindo ANDA, Aurobindo necessarily represented to the FDA that the Generic Posaconazole IV Solution Product has the same active ingredient as NOXAFIL® for Injection, has the same method of administration, dosage form, and strength as NOXAFIL® for Injection and is bioequivalent to NOXAFIL® for Injection.

ANSWER: Admitted.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,023,790

26. Merck incorporates by reference Paragraphs 1–25 of this Complaint as if fully set forth herein.

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 25 of the Complaint with the same force and effect as if hereinafter set forth at length.

27. By filing or causing to be filed the Aurobindo ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Posaconazole IV Solution Product before the expiration of the '790 Patent, Aurobindo committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

28. If Aurobindo commercially makes, uses, offers to sell or sells the Generic Posaconazole IV Solution Product within the United States, or imports the Generic Posaconazole IV Solution Product into the United States, or induces or contributes to any such conduct during the term of the '790 Patent, Aurobindo would further infringe the '790 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

29. Aurobindo's commercial manufacture, use, offer to sell, or sale of the Generic Posaconazole IV Solution Product within the United States, or importation of the Generic Posaconazole IV Solution Product into the United States, during the term of the '790 Patent, would infringe the '790 Patent.

ANSWER: Denied.

30. Upon approval of the Aurobindo ANDA, and the commercial marketing of the Generic Posaconazole IV Solution Product, Aurobindo would actively induce and/or contribute to infringement of the '790 Patent. At least in light of the prescribing instructions Aurobindo proposes to provide in connection with the Generic Posaconazole IV Solution Product, Aurobindo will induce health care professionals, resellers, pharmacies, and end users of the Generic Posaconazole IV Solution Product to directly infringe one or more claims of the '790 Patent. Aurobindo will encourage acts of direct infringement with knowledge of the '790 Patent and knowledge that it is encouraging infringement.

ANSWER: Denied.

31. Aurobindo had actual and constructive knowledge of the '790 Patent prior to filing the Aurobindo ANDA, and was aware that the filing of the Aurobindo ANDA with the request for FDA approval before the expiration of the '790 Patent would constitute an act of infringement of the '790 Patent.

ANSWER: Denied.

32. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

ANSWER: Denied.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,358,297

33. Merck incorporates by reference Paragraphs 1–25 of this Complaint as if fully set forth herein.

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 25 of the Complaint with the same force and effect as if hereinafter set forth at length.

34. By filing or causing to be filed the Aurobindo ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Posaconazole IV Solution Product before the expiration of the '297 Patent, Aurobindo committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

35. If Aurobindo commercially makes, uses, offers to sell or sells the Generic Posaconazole IV Solution Product within the United States, or imports the Generic Posaconazole IV Solution Product into the United States, or induces or contributes to any such conduct during the term of the '297 Patent, Aurobindo would further infringe the '297 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

36. Aurobindo's commercial manufacture, use, offer to sell, or sale of the Generic Posaconazole IV Solution Product within the United States, or importation of the Generic Posaconazole IV Solution Product into the United States, during the term of the '297 Patent, would infringe the '297 Patent.

ANSWER: Denied.

37. Upon approval of the Aurobindo ANDA, and the commercial marketing of the Generic Posaconazole IV Solution Product, Aurobindo would actively induce and/or contribute to infringement of the '297 Patent. At least in light of the prescribing instructions Aurobindo proposes to provide in connection with the Generic Posaconazole IV Solution Product, Aurobindo will induce health care professionals, resellers, pharmacies, and end

users of the Generic Posaconazole IV Solution Product to directly infringe one or more claims of the '297 Patent. Aurobindo will encourage acts of direct infringement with knowledge of the '297 Patent and knowledge that it is encouraging infringement.

ANSWER: Denied.

38. Aurobindo had actual and constructive knowledge of the '297 Patent prior to filing the Aurobindo ANDA, and was aware that the filing of the Aurobindo ANDA with the request for FDA approval before the expiration of the '297 Patent would constitute an act of infringement of the '297 Patent.

ANSWER: Denied.

39. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

ANSWER: Denied.

MERCK'S PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '790 Patent under 35 U.S.C. § 271(e)(2) by submitting the Aurobindo ANDA;

B. A judgment that Defendants have infringed one or more claims of the '297 Patent under 35 U.S.C. § 271(e)(2) by submitting the Aurobindo ANDA;

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from making, using, selling, offering to sell, or importing any product that infringes the '790 Patent, including the product described in the Aurobindo ANDA, prior to the expiration of the '790 Patent, including any extensions;

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, parents,

subsidiaries, divisions, affiliates, from making, using, selling, offering to sell, or importing any product that infringes the '297 Patent, including the product described in the Aurobindo ANDA, prior to the expiration of the '297 Patent, including any extensions;

E. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Aurobindo ANDA, or inducing or contributing to such conduct, would constitute infringement of the '790 Patent by Defendants pursuant to 35 U.S.C. § 271;

F. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Aurobindo ANDA, or inducing or contributing to such conduct, would constitute infringement of the '297 Patent by Defendants pursuant to 35 U.S.C. § 271;

G. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Aurobindo ANDA be a date that is not earlier than the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

H. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Aurobindo ANDA be a date that is not earlier than the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

I. If Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them commercially manufactures, uses, offers to sell, sells or imports the product described in the Aurobindo ANDA prior to the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

J. If Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, or those persons in active concert or participation with any

of them commercially manufactures, uses, offers to sell, sells or imports the product described in the Aurobindo ANDA prior to the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

K. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and awarding reasonable attorneys' fees, costs and disbursement incurred as a result of this action; and

L. Such other and further relief as the Court deems just and proper.

ANSWER TO PRAYER FOR RELIEF: The "WHEREFORE" paragraphs following Paragraph 39 states Plaintiff's prayer for relief for which no response is required. To the extent a response is required, Aurobindo denies the allegations contained in the "WHEREFORE" paragraphs following Paragraph 39 of the Complaint and denies that Plaintiff is entitled to any of the relief required, or to any relief whatsoever. Aurobindo specifically denies that Plaintiff is entitled to the general or specific relief requested against Aurobindo, or to any relief whatsoever, and pray for judgment in favor of Aurobindo dismissing this action with prejudice, and awarding Aurobindo its reasonable attorneys' fees.

AFFIRMATIVE DEFENSES

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

FIRST AFFIRMATIVE DEFENSE (FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole or in part, fails to state claims upon which relief may be granted.

**SECOND AFFIRMATIVE DEFENSE
(INVALIDITY AND UNENFORCEABILITY)**

United States Patent No. 9,023,790 (the "'790 patent") and United States Patent No. 9,358,297 (the "'297 patent") (together, the "Patents-In-Suit") and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability, as more particularly set forth in the July 1, 2020 Notice Letter ("Aurobindo's Notice Letter") sent in respect Aurobindo's Paragraph IV Certifications ("Aurobindo's Paragraph IV Certification").

**THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)**

As set forth in the Detailed Statement of Aurobindo's Notice Letter, Aurobindo does not infringe literally any valid and enforceable claim of the Patents-In-Suit and thus cannot be said to literally infringe the same. As no equivalent can be found in Aurobindo's proposed product for the missing elements of any of the claims of the Patents-In-Suit, there can be no infringement under the doctrine of equivalents.

**FOURTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)**

Aurobindo has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the Aurobindo ANDA product does not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit.

FIFTH AFFIRMATIVE DEFENSE
(NO COSTS)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE CLAIM OF WILFULNESS)

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 §§ 271(e)(4) and 285, or otherwise.

SEVENTH AFFIRMATIVE DEFENSE
(RESERVATION OF RIGHTS)

Aurobindo reserves the right to assert additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Aurobindo Pharma USA, Inc., AuroMedics Pharma LLC, and Aurobindo Pharma Ltd. ("Aurobindo" or "Counterclaim-Plaintiffs"), through their undersigned attorneys, for their Counterclaims against Merck Sharp & Dohme Corp. ("Merck" or "Counterclaim-Defendant"), hereby allege as follows:

1. Counterclaim-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of Aurobindo's (Defendants') Answer and Additional Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of United States Patent No. 9,023,790 (the "'790 patent") and United States Patent No. 9,358,297 (the "'297 patent") (together, the "Patents-In-Suit"). Upon information and belief, a true and correct copy of the '790 patent is attached to the Complaint as Exhibit A. Upon information and belief, a true and correct copy of the '297 patent is attached to the Complaint as Exhibit B.

THE PARTIES

3. Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA.

4. Counterclaim-Plaintiff AuroMedics LLC is a corporation organized and existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA

5. Counterclaim-Plaintiff Aurobindo Pharma Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andra Pradesh, India.

6. On information and belief, based on the complaint filed by Plaintiff/Counterclaim-Defendant in this case, Counterclaim-Defendant Merck is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

JURISDICTION AND VENUE

7. 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 Counterclaim-Plaintiffs, on the one hand, and the Counterclaim-Defendant on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court has personal jurisdiction over Counterclaim-Defendant based, *inter alia*, on the filing by Counterclaim-Defendant of this lawsuit in this jurisdiction and because Counterclaim-Defendant is doing business in this jurisdiction.

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

ORANGE BOOK LISTING OF THE PATENTS

10. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

11. On information and belief, on May 5, 2015, the U.S. Patent and Trademark Office ("PTO") issued the '790 Patent. On information and belief, a true and correct copy of the '790 Patent is attached to the complaint as Exhibit A.

12. On information and belief, on June 7, 2016, the U.S. Patent and Trademark Office ("PTO") issued the '297 Patent. On information and belief, a true and correct copy of the '297 Patent is attached to the complaint as Exhibit B.

13. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(1), Counterclaim-Defendant caused the FDA to list the Patents-In-Suit in the Orange Book in connection with NDA No. 205596 in respect of the brand name product NOXAFIL® (generic name posaconazole) ("Noxafil NDA").

14. By maintaining the listings of the Patents-In-Suit in the Orange Book, Counterclaim-Defendant represents to the world that the Patents-In-Suit could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(1)) of the respective brand name product before the expiration of the Patents-in-Suit.

AUROBINDO'S ABBREVIATED NEW DRUG APPLICATION

15. Aurobindo filed ANDA No. 214842 ("Aurobindo's ANDA") with the FDA seeking approval to market a generic posaconazole intravenous solution, intended to be a generic version

of NOXAFIL®. Aurobindo's ANDA included a Paragraph IV Certification to the Patents-In-Suit, certifying that to the best of its knowledge that all of the claims of the Patents-In-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in Aurobindo's ANDA.

THE PRESENCE OF A CASE OR CONTROVERSY

16. By maintaining the Orange Book listing of the Patents-In-Suit in connection with the NOXAFIL®, Counterclaim-Defendant represents that the Patents-In-Suit could reasonably be asserted against anyone making, using or selling generic posaconazole tablets, intended to be generic version of NOXAFIL®, without a license from the Counterclaim-Defendant prior to the expiration of the Patents-In-Suit.

17. Counterclaim-Defendant has filed an infringement action under Title 35, United States Code, Sections 100 et seq., asserting the Patents-In-Suit against Counterclaim-Plaintiffs and seeking a declaration of infringement regarding the Patents-In-Suit. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiffs on the one hand, and Counterclaim-Defendant, on the other hand, as to whether the products disclosed in Aurobindo's ANDA infringe the Patents-In-Suit, and whether any valid, enforceable claim in the Patents-In-Suit exists.

18. Aurobindo seeks to market generic posaconazole solution that is the subject of Aurobindo's ANDA in the United States prior to the expiration of the Patents-In-Suit.

19. If Counterclaim-Plaintiffs succeed in proving that their generic posaconazole solution that is the subject of Aurobindo's ANDA does not infringe the Patents-In-Suit or all asserted claims are invalid or unenforceable, and thus non-infringing, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendant's maintenance of the Patents-In-Suit in the Orange Book in connection with the NOXAFIL® NDA.

20. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendant and Counterclaim-Plaintiffs as to whether the claims of the Patents-In-Suit are invalid and/or not infringed by Counterclaim-Plaintiffs.

COUNT I
(DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE PATENTS-IN-SUIT)

21. Counterclaim-Plaintiffs repeat and incorporates by reference Paragraphs 1-20 of their Counterclaims, above, as if fully set forth herein.

22. This counterclaim arises 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. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendant concerning the Patents-In-Suit and the claims of the Patents-In-Suit.

23. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic posaconazole solution that is the subject of Aurobindo's ANDA infringes one or more claims of the Patents-In-Suit.

24. Counterclaim-Plaintiffs assert that no valid claim of the Patents-In-Suit is infringed by the manufacture, use, offer for sale, sale, and/or importation of generic posaconazole solution that is the subject of Aurobindo's ANDA.

25. Counterclaim-Plaintiffs are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiff's' generic posaconazole solution that is the subject of Aurobindo's ANDA, does not infringe any valid claim of the Patents-In-Suit.

COUNT II
(DECLARATORY JUDGMENT OF
INVALIDITY OF THE PATENTS-IN-SUIT)

26. Counterclaim-Plaintiffs repeat and incorporates by reference Paragraphs 1-25 of Counterclaim-Plaintiffs' Counterclaims, above, as if fully set forth herein.

27. This counterclaim arises 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. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendant concerning the claims of the Patents-In-Suit.

28. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic posaconazole solution that is the subject of Aurobindo's ANDA, infringes one or more claims of the Patents-In-Suit.

29. Counterclaim-Plaintiffs assert that the manufacture, use, offer-for-sale, sale, and/or importation of Counterclaim-Plaintiffs' generic posaconazole solution that is the subject of Aurobindo's ANDA do not infringe any valid claim of the Patents-In-Suit, and that the claims of the Patents-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation for all the reasons set forth in Aurobindo's July 1, 2020 Notice Letter (which Counterclaim-Plaintiffs can resupply if needed).

30. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the Patents-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request that the Court enter judgment in their favor and against Counterclaim-Defendant as follows:

- a. Denying Counterclaim-Defendant's claims and dismissing Plaintiff's Complaint with prejudice.
- b. Declaring that the claims of the Patents-In-Suit are invalid;
- c. Declaring that the claims of the Patents-In-Suit are not, and will not be, infringed by Counterclaim-Plaintiffs' manufacture, use, sale, offer for sale, or importation of the generic posaconazole solution that is the subject of Aurobindo's ANDA;
- d. Preliminarily and permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from utilizing the Patents-In-Suit to block, hamper, hinder or obstruct FDA approval of Counterclaim-Plaintiffs' proposed product;
- e. Permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce the Patents-In-Suit against Counterclaim-Plaintiffs or anyone in privity with Counterclaim-Plaintiffs;
- f. Declaring this case exceptional and awarding Counterclaim-Plaintiffs their attorneys' fees pursuant to 35 U.S.C. § 285, the inherent power of this Court, or otherwise;
- g. Awarding costs to Counterclaim-Plaintiffs; and
- h. Awarding to Counterclaim-Plaintiffs any other such and further relief as is just and proper.

Dated: October 13, 2020



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Aurobindo Pharma USA Inc.

CERTIFICATE OF SERVICE

I certify that, on October 13, 2020 I caused the foregoing Answer and Counterclaims of Defendants/Counterclaim-Plaintiffs Aurobindo Pharma USA, Inc., Auromedics Pharma LLC and Aurobindo Pharma LTD. to be served upon plaintiffs' counsel of record by email, who shall also receive a copy simultaneously through the Court's ECF system.

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Dated: November 8, 2019



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