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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME LLC,

Plaintiff,

v.

HETERO USA INC.; HETERO LABS LIMITED UNIT-III; and HETERO LABS LIMITED,

Defendants.

Civil Action No. 23-22954

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme LLC ("Merck") brings this Complaint for patent infringement against defendants Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited, and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited, (collectively, "Hetero" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 218374 ("Raltegravir ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of Merck's ISENTRESS HD® (raltegravir) drug product prior to expiration of Merck's U.S. Patent No. 7,754,731 (**Exhibit 1**; "the '731 patent"), U.S. Patent No. 8,771,733 (**Exhibit 2**; "the '733 patent"), U.S. Patent No. 9,649,311 (**Exhibit 3**; "the '311 patent"), and U.S. Patent No. 10,772,888 (**Exhibit 4**; "the '888 patent") that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for ISENTRESS HD®.

THE PARTIES

2. Plaintiff Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065. Merck is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve health.

3. On information and belief, defendant Hetero USA Inc. ("Hetero USA") is a corporation organized under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA is the United States regulatory agent for Hetero Labs Limited Unit-III and Hetero Labs Limited, including for ANDA No. 218374.

4. On information and belief, defendant Hetero Labs Limited Unit-III ("Hetero Unit-III") is a corporation organized and existing under the laws of India, having a principal place of business at #22-110, IDA Jeedimetla, Hyderabad – 500 055, Telangana, India. On information

and belief, Hetero Unit-III is a division of Hetero Labs Limited. On information and belief, Hetero Unit-III itself and through its affiliates and subsidiaries, including Hetero USA and Hetero Labs Limited, formulates, manufactures, packages, and markets generic versions of branded pharmaceutical drugs for distribution in the District of New Jersey and throughout the United States.

5. On information and belief, defendant Hetero Labs Limited ("Hetero Labs") is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India. On information and belief, Hetero Labs is the parent corporation of Hetero USA and Hetero Unit-III. On information and belief, Hetero Labs itself and through its affiliates and subsidiaries, including Hetero USA and Hetero Unit-III, formulates, manufactures, packages, and markets generic versions of branded pharmaceutical drugs for distribution in the District of New Jersey and throughout the United States.

JURISDICTION AND VENUE

6. Each of the preceding paragraphs 1–5 is re-alleged and re-incorporated as if fully set forth herein.

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

8. On information and belief, Hetero Labs and its subsidiaries Hetero USA and Hetero Unit-III hold themselves out as a unitary entity where Hetero Labs directs and controls its subsidiaries in the manufacture, importation, offer for sale, sale, and distribution of generic products in the United States, including New Jersey.

9. On information and belief, Hetero USA is an agent of Hetero Labs and acts at the direction, and for the benefit, of Hetero Labs, and is controlled and/or dominated by Hetero Labs. For instance, on information and belief, Hetero USA is the U.S. Regulatory Agent for Hetero Labs Limited Unit-III, which, on information and belief, is a division of Hetero Labs. Hetero Labs' website explains: "Hetero USA Inc, a group company of Hetero is the sales and marketing arm of Hetero's Active Pharmaceutical Ingredients (API) and Custom Pharmaceutical Services (CPS) business in USA." **Exhibit 5** at 2.

10. On information and belief, Hetero Unit-III is an agent of Hetero Labs and acts at the direction, and for the benefit, of Hetero Labs, and is controlled and/or dominated by Hetero Labs. For instance, Hetero's 2021 sustainability report notes "Hetero Labs Limited, Unit-3" is one of Hetero's manufacturing facilities in Jeedimelta, India. *See* **Exhibit 6** at 25.

11. This Court has jurisdiction over Hetero USA.

12. On information and belief, Hetero USA directly and/or indirectly through, and/or in concert with Hetero Unit-III and/or Hetero Labs, has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 218374 with the intent to make, use, sell, offer for sale, and/or import the generic raltegravir product(s) in or into this judicial district, prior to the expiration of the '731, '733, '311, and '888 patents. Hetero USA sent the Notice Letter for ANDA No. 218374 to Merck at 126 East Lincoln Avenue, Rahway, New Jersey 07065. On information and belief, Hetero USA directly and/or indirectly through, and/or in concert with Hetero Unit-III and/or Hetero Labs, will engage in marketing, sale, and distribution of the generic raltegravir product(s) in New Jersey upon approval of its ANDA. On information and belief, such generic raltegravir product(s) will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey.

Additionally, on information and belief, Hetero USA directly and/or indirectly through, and/or in concert with Hetero Unit-III and/or Hetero Labs, will offer its generic raltegravir product(s) for sale and place them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in New Jersey and/or purchased by consumers in New Jersey.

13. On information and belief, Hetero USA has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Hetero USA has a registered agent for service of process in New Jersey and directly and/or indirectly through, and/or in concert with Hetero Unit-III and/or Hetero Labs, operates a facility at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA actively contracts with, *inter alia*, Hetero Unit-III and/or Hetero Labs, which operate in New Jersey, to develop, manufacture, import, market, distribute, offer for sale, and/or sell generic drugs throughout the United States, including New Jersey.

14. Further, on information and belief, Hetero USA directly and/or indirectly through, and/or in concert with Hetero Unit-III and/or Hetero Labs, has established distribution channels for its generic drug products in New Jersey and derives substantial revenue from the sale of drug products in New Jersey. For instance, on information and belief, Hetero USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826. On information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

15. On information and belief on information and belief, Hetero USA has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the

following District of New Jersey actions: *Merck Sharp & Dohme LLC v. Hetero USA, Inc., et al.*, Civil Action No. 22-6820 (D.N.J.); *Rigel Pharma., Inc. v. Annora Pharma Private Ltd., et al.*, Civil Action No. 22-4732 (D.N.J.); and *Celgene Corporation v. Hetero Labs Ltd., et al.*, Civil Action No. 20-14389 (D.N.J.).

16. On information and belief, Hetero USA has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See, e.g., Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 19-15449 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 19-5797 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 18-17463 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 18-14111 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil No. 17-3387 (D.N.J.); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, Civil Action No. 15-161 (D.N.J.); *AstraZeneca AB, et al v. Hetero USA Inc., et al.*, Civil Action No. 16-2442 (D.N.J.); and *BTG Int'l Ltd., et al v. Actavis Lab'ys FL, Inc., et al.*, Civil Action No. 15-5909 (D.N.J.).

17. This Court has personal jurisdiction over Hetero Unit-III.

18. On information and belief, Hetero Unit-III directly and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Labs, has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 218374 with the intent to make, use, sell, offer for sale, and/or import the generic raltegravir product(s) in or into this judicial district, prior to the expiration of the '731, '733, '311, and '888 patents. Hetero Unit-III sent the Notice Letter for ANDA No. 218374 to Merck at 126 East Lincoln Avenue, Rahway, New Jersey 07065. On information and belief, Hetero Unit-III directly and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Labs, will engage in marketing, sale, and distribution of the generic raltegravir product(s) in New Jersey upon approval of its ANDA. On

information and belief, such generic raltegravir product(s) will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Additionally, on information and belief, Hetero Unit-III directly and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Labs, will offer its generic raltegravir product(s) for sale and place them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in New Jersey and/or purchased by consumers in New Jersey.

19. On information and belief, Hetero Unit-III has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, Hetero Unit-III directly and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Labs, operates a facility at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero Unit-III actively contracts with, *inter alia*, Hetero USA and/or Hetero Labs, which operate in New Jersey, to develop, manufacture, import, market, distribute, offer for sale, and/or sell generic drugs throughout the United States, including New Jersey.

20. Further, on information and belief, Hetero Unit-III directly and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Labs, has established distribution channels for its generic drug products in New Jersey and derives substantial revenue from the sale of drug products in New Jersey. For instance, on information and belief, Hetero USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826. On information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

21. In the alternative, this Court has jurisdiction over Hetero Unit-III pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (a) Merck's claims arise under federal law; (b) Hetero Unit-III is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Unit-III has substantial contacts with the United States as a whole, including, but not limited to participating in the preparation and submission of the Raltegravir ANDA and/or manufacturing, importing, offering for sale, and selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Unit-III satisfies due process.

22. On information and belief on information and belief, Hetero Unit-III has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following District of New Jersey action: *AstraZeneca AB et al v. Hetero Labs Ltd., et al.*, Civil Action No. 15-03385 (D.N.J.).

23. On information and belief, Hetero Unit-III has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See, e.g., Eisai Co., Ltd., et al. v. Hetero USA Inc., et al.*, Civil Action No. 22-1795 (D.N.J); *Eli Lilly & Co. et al v. Hetero USA Inc., et al.*, Civil Action No. 17-1951 (D.N.J.); *IVUS, Inc., et al. v. Hetero USA Inc., et al.*, Civil Action No. 16-4560 (D.N.J.); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 16-2442 (D.N.J.).

24. This court has personal jurisdiction over Hetero Labs.

25. On information and belief, Hetero Labs directly and/or indirectly through, and/or in concert with Hetero USA and Hetero Unit-III, has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 218374 with the intent to make, use, sell, offer for sale, and/or import the generic raltegravir product(s) in or into this judicial district, prior to the expiration of the '731, '733, '311, and '888 patents. On

information and belief, Hetero Labs will benefit directly if the Raltegravir ANDA is approved by participating in the manufacture, importation, marketing, distribution, and/or sale, of generic raltegravir products in New Jersey. On information and belief, such generic raltegravir product(s) will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Additionally, on information and belief, Hetero Labs directly, and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Unit-III, will offer the generic raltegravir product(s) for sale and place them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in New Jersey and/or purchased by consumers in New Jersey.

26. On information and belief, Hetero Labs has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Hetero Labs directly, and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Unit-III, operates a facility at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero Labs directly, and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Unit-III, manufactures, markets, distributes, and sells generic drug products, throughout the United States, including in this judicial district. On information and belief, Hetero Labs, directly or indirectly, derives substantial revenue from selling generic pharmaceutical products/and or active pharmaceutical ingredients used in generic pharmaceutical products in New Jersey.

27. Further, on information and belief, Hetero Labs directly and/or indirectly through, and/or in concert with Hetero USA and/or Hetero Unit-III, has established distribution channels for its generic drug products in New Jersey and derives substantial revenue from the sale of drug products in New Jersey. For instance, on information and belief, Hetero USA is registered with

the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826. On information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

28. In the alternative, this Court has jurisdiction over Hetero Labs pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (a) Merck's claims arise under federal law; (b) Hetero Labs is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs has substantial contacts with the United States as a whole, including, but not limited to participating in the preparation and submission of the Raltegravir ANDA and/or manufacturing, importing, offering for sale, and selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs satisfies due process.

29. On information and belief on information and belief, Hetero Labs has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following District of New Jersey actions: *Merck Sharp & Dohme LLC v. Hetero USA, Inc., et al.*, Civil Action No. 22-6820 (D.N.J.); *Rigel Pharma., Inc. v. Annora Pharma Private Ltd., et al.*, Civil Action No. 22-4732 (D.N.J.); and *Celgene Corporation v. Hetero Labs Ltd., et al.*, Civil Action No. 20-14389 (D.N.J.).

30. On information and belief, Hetero Labs has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See, e.g.*, *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 19-15449 (D.N.J.);*Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 19-5797 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 18-17463 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 18-14111 (D.N.J.); *Celgene*

Corp. v. Hetero Labs Ltd., et al., Civil No. 17-3387 (D.N.J.); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, Civil Action No. 15-161 (D.N.J.); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 16-2442 (D.N.J.); *BTG Int'l Ltd., et al. v. Actavis Lab'ys FL, Inc., et al.*, Civil Action No. 15-5909 (D.N.J.).

31. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

32. Hetero USA, Hetero Unit-III, and Hetero Labs did not contest venue in this judicial district in at least the following actions: *Merck Sharp & Dohme LLC v. Hetero USA, Inc., et al.*, Civil Action No. 22-6820 (D.N.J.); *Eisai Co., Ltd., et al. v. Hetero USA Inc.*, Civil Action No. 22-01795 (D.N.J) (Hetero USA, Hetero Unit-III, Hetero Labs); *Eli Lilly & Co., et al. v. Hetero USA Inc., et al.*, Civil Action No. 17-01951 (D.N.J.) (Hetero USA, Hetero Unit-III, Hetero Labs); *Rigel Pharms., Inc. v. Annora Pharma Priv. Ltd., et al.*, Civil Action No. 22-4732 (D.N.J.) (Hetero Labs, Hetero USA); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 19-15449 (D.N.J.) (Hetero USA, Hetero Labs); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 19-5797 (D.N.J.) (Hetero USA, Hetero Labs); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 18-17463 (D.N.J.) (Hetero USA, Hetero Labs); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 18-14111 (D.N.J.) (Hetero USA, Hetero Labs); *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 17-3387 (D.N.J.) (Hetero USA, Hetero Labs); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, Civil Action No. 15-161 (D.N.J.) (Hetero USA, Hetero Labs); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 16-2442 (D.N.J.) (Hetero USA, Hetero Labs); and *BTG Int'l Ltd., et al. v. Actavis Lab'ys FL, Inc., et al.*, Civil Action No. 15-5909 (D.N.J.) (Hetero USA, Hetero Labs).

33. On information and belief, venue is proper against Hetero USA in the District of New Jersey because, *inter alia*, it maintains a regular and established place of business in this judicial district and has committed an act of infringement in this judicial district.

34. Venue is proper in the District of New Jersey for Hetero Unit-III because it is an Indian corporation not resident in the United States, and thus venue is proper in any judicial district that has personal jurisdiction, including the District of New Jersey.

35. Venue is proper in the District of New Jersey for Hetero Labs because it is an Indian corporation not resident in the United States, and thus venue is proper in any judicial district that has personal jurisdiction, including the District of New Jersey.

PATENTS-IN-SUIT

36. On July 13, 2010, the U.S. Patent and Trademark Office duly and legally issued the '731 patent, entitled "Potassium Salt of an HIV Integrase Inhibitor." A true and correct copy of the '731 patent is attached hereto as **Exhibit 1**. The claims of the '731 patent are valid and enforceable. Merck is the owner of the '731 patent by assignment and has the right to enforce it.

37. On July 8, 2014, the U.S. Patent and Trademark Office duly and legally issued the '733 patent, entitled "Pharmaceutical Composition Containing an Anti-Nucleating Agent." A true and correct copy of the '733 patent is attached hereto as **Exhibit 2**. The claims of the '733 patent are valid and enforceable. Merck is the owner of the '733 patent by assignment and has the right to enforce it.

38. On May 16, 2017, the U.S. Patent and Trademark Office duly and legally issued the '311 patent, entitled "Solid Pharmaceutical Compositions Containing an Integrase Inhibitor." A true and correct copy of the '311 patent is attached hereto as **Exhibit 3**. The claims of the '311 patent are valid and enforceable. Merck is the owner of the '311 patent by assignment and has the right to enforce it.

39. On September 15, 2020, the U.S. Patent and Trademark Office duly and legally issued the '888 patent, entitled "Solid Pharmaceutical Compositions Containing an Integrase Inhibitor." A true and correct copy of the '888 patent is attached hereto as **Exhibit 4**. The claims of the '888 patent are valid and enforceable. Merck is the owner of the '888 patent by assignment and has the right to enforce it.

40. Merck is the holder of NDA No. 022145 by which the FDA granted approval for the marketing and sale of raltegravir tablets in 400 mg and 600 mg dosage strengths for the treatment of HIV. Merck markets raltegravir tablets in the United States under the trade names "ISENTRESS®" and "ISENTRESS HD®". The FDA's official publication of approved drugs, the Orange Book, includes ISENTRESS HD® at a 600 mg dosage strength together with, *inter alia*, the '731, '733, '311, and '888 patents.

DEFENDANT'S INFRINGING ACTIVITIES

41. Each of the preceding paragraphs 1–40 is re-alleged and re-incorporated as if fully set forth herein.

42. By letter dated October 24, 2023, addressed to Merck ("Notice Letter"), Hetero notified Merck that Hetero had submitted its Raltegravir ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter states that Hetero is seeking approval from the FDA to engage in the commercial manufacture, use, and sale of generic raltegravir product(s) before the expiration of the '731, '733, '311, and '888 patents. On information and belief, the Raltegravir ANDA seeks approval of Hetero's generic raltegravir product(s) that are the same, or substantially the same, as Merck's ISENTRESS HD®.

43. On information and belief, Hetero USA, Hetero Unit-III, and Hetero Labs, through their own actions and/or the actions of their agents, affiliates, and subsidiaries, intend to engage in the importation, commercial manufacture, offer for sale, and sale of generic raltegravir product(s)

after receiving FDA approval to do so. On information and belief, if the FDA approves Hetero's Raltegravir ANDA, Hetero USA, Hetero Unit-III, and Hetero Labs, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of generic raltegravir product(s) in or into the United States.

44. In the Notice Letter, Hetero notified Merck that its Raltegravir ANDA contained a "Paragraph IV certification" asserting that the '731, '733, '311, and '888 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's generic raltegravir product(s).

45. Counsel for Merck contacted counsel for Hetero listed in the Notice Letter regarding the Notice Letter's Offer for Confidential Access to Hetero's Raltegravir ANDA. On November 20, 2023, counsel for Hetero confirmed receipt of the correspondence and indicated it would "provide a response after the Thanksgiving weekend." As of the filing of this complaint, counsel for Hetero has not provided a response on the terms of access.

46. Upon information and belief, Hetero's actions related to the Raltegravir ANDA complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Hetero USA, Hetero Unit-III, and Hetero Labs.

COUNT I
INFRINGEMENT OF THE '731 PATENT

47. Each of the preceding paragraphs 1–46 is re-alleged and re-incorporated as if fully set forth herein.

48. Defendant's submission of the Raltegravir ANDA with a Paragraph IV certification against the '731 patent to obtain approval to engage in the commercial manufacture, use, offer to

sell, or sale of generic raltegravir product(s) prior to the expiration of the '731 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

49. On information and belief, Defendant had actual knowledge of the '731 patent since the filing of the Raltegravir ANDA and at least since October 24, 2023, the date on the Notice Letter that was sent to Merck.

50. Upon information and belief, Defendant's generic raltegravir product(s) will, if approved and marketed, infringe at least one claim of the '731 patent.

51. On information and belief, upon FDA approval of Defendant's Raltegravir ANDA, Defendant will further infringe, literally or under the doctrine of equivalents, at least one claim of the '731 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), contributorily under 35 U.S.C. § 271(c), and/or under 35 U.S.C. § 271(g) by making, using, offering to sell, marketing, and selling its generic raltegravir product(s) in the United States and/or importing such product(s) into the United States, unless enjoined by the Court.

52. If Defendant's marketing and sale of generic raltegravir product(s) prior to expiration of the '731 patent and all other relevant exclusivities is not enjoined, Merck will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II
INFRINGEMENT OF THE '733 PATENT

53. Each of the preceding paragraphs 1–52 is re-alleged and re-incorporated as if fully set forth herein.

54. Defendant's submission of the Raltegravir ANDA with a Paragraph IV certification against the '733 patent to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic raltegravir product(s) prior to the expiration of the '733 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

55. On information and belief, Defendant had actual knowledge of the ’733 patent since the filing of the Raltegravir ANDA and at least since October 24, 2023, the date on the Notice Letter that was sent to Merck.

56. Upon information and belief, Defendant’s generic raltegravir product(s) will, if approved and marketed, infringe at least one claim of the ’733 patent.

57. On information and belief, upon FDA approval of Defendant’s Raltegravir ANDA, Defendant will further infringe, literally or under the doctrine of equivalents, at least one claim of the ’733 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), contributorily under 35 U.S.C. § 271(c), and/or under 35 U.S.C. § 271(g) by making, using, offering to sell, marketing, and selling its generic raltegravir product(s) in the United States and/or importing such product(s) into the United States, unless enjoined by the Court.

58. If Defendant’s marketing and sale of generic raltegravir product(s) prior to expiration of the ’733 patent and all other relevant exclusivities is not enjoined, Merck will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III
INFRINGEMENT OF THE ’311 PATENT

59. Each of the preceding paragraphs 1–58 is re-alleged and re-incorporated as if fully set forth herein.

60. Defendant’s submission of the Raltegravir ANDA with a Paragraph IV certification against the ’311 patent to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic raltegravir product(s) prior to the expiration of the ’311 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

61. On information and belief, Defendant had actual knowledge of the ’311 patent since the filing of the Raltegravir ANDA and at least since October 24, 2023, the date on the Notice Letter that was sent to Merck.

62. Upon information and belief, Defendant’s generic raltegravir product(s) will, if approved and marketed, infringe at least one claim of the ’311 patent.

63. On information and belief, upon FDA approval of Defendant’s Raltegravir ANDA, Defendant will further infringe, literally or under the doctrine of equivalents, at least one claim of the ’311 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), and/or contributorily under 35 U.S.C. § 271(c) by making, using, offering to sell, marketing, and/or selling its generic raltegravir product(s) in the United States, unless enjoined by the Court.

64. If Defendant’s marketing and sale of generic raltegravir product(s) prior to expiration of the ’311 patent and all other relevant exclusivities is not enjoined, Merck will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV
INFRINGEMENT OF THE ’888 PATENT

65. Each of the preceding paragraphs 1–64 is re-alleged and re-incorporated as if fully set forth herein.

66. Defendant’s submission of the Raltegravir ANDA with a Paragraph IV certification against the ’888 patent to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic raltegravir product(s) prior to the expiration of the ’888 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

67. On information and belief, Defendant had actual knowledge of the ’888 patent since the filing of the Raltegravir ANDA and at least since October 24, 2023, the date on the Notice Letter that was sent to Merck.

68. Upon information and belief, Defendant's generic raltegravir product(s) will, if approved and marketed, infringe at least one claim of the '888 patent.

69. On information and belief, upon FDA approval of Defendant's Raltegravir ANDA, Defendant will further infringe, literally or under the doctrine of equivalents, at least one claim of the '888 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), and/or contributorily under 35 U.S.C. § 271(c) by making, using, offering to sell, marketing, and/or selling its generic raltegravir product(s) in the United States, unless enjoined by the Court.

70. If Defendant's marketing and sale of generic raltegravir product(s) prior to expiration of the '888 patent and all other relevant exclusivities is not enjoined, Merck will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully requests that this Court enter judgment in its favor and against Defendant and grant the following relief:

A. A judgment that the claims of the '731, '733, '311, and '888 patents are not invalid, not unenforceable, and are infringed by Defendant's submission of its Raltegravir ANDA, and that Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic raltegravir product(s) will infringe the claims of the '731 , '733, '311, and '888 patents.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's Raltegravir ANDA shall be a date which is not earlier than the latest expiration date of the '731, '733, '311, and '888 patents, including any extensions and/or additional periods of exclusivity to which Merck is or becomes entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from

making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic raltegravir product(s) until after the latest expiration date of the '731, '733, '311, and '888 patents, including any extensions and/or additional periods of exclusivity to which Merck is or becomes entitled.

D. Damages or other monetary relief to Merck if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's generic raltegravir product(s) prior to the latest expiration date of the '731, '733, '311, and '888 patents, including any extensions and/or additional periods of exclusivity to which Merck is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: December 7, 2023

Respectfully submitted,

s/ William P. Deni, Jr.
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