IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DUCHESNAY INC., SHIONOGI INC., and QUATRX PHARMACEUTICALS COMPANY, Plaintiffs, v. HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, and HETERO USA INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Duchesnay Inc. ("Duchesnay"), Shionogi Inc. ("Shionogi"), and QuatRx Pharmaceuticals Company ("QuatRx") (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), Hetero Drugs Limited ("Hetero Drugs"), and Hetero USA Inc. ("Hetero USA") (collectively, "Hetero"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of United States Patent Nos. 6,245,819 ("the '819 patent") and 8,236,861 ("the '861 patent") (collectively, "the patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 215574, which Hetero filed or caused to be filed under 21 U.S.C. § 355(j) with the U.S. Food and Drug Administration (the "FDA") for approval to market in the United States a generic copy of Plaintiffs' Osphena® product prior to the expiration of the patents-in-suit.

THE PARTIES

2. Duchesnay is a Canadian corporation with its headquarters at 950 Boulevard Michele-Bohec, Blainville, Quebec, Canada J7C 5E2.

3. Duchesnay is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for women's health.

4. Shionogi is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

5. Shionogi is engaged in the business of researching, developing, and bringing to market innovative pharmaceutical products.

6. QuatRx is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

7. On information and belief, Hetero Labs is a corporation organized and existing under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India.

8. On information and belief, Hetero Unit-V is a division of Hetero Labs, with its principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

9. On information and belief, Hetero Drugs is a corporation organized under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India.

10. On information and belief, Hetero USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

11. On information and belief, Hetero USA is the U.S. Regulatory Agent for Hetero Labs, Hetero Unit-V, and Hetero Drugs.

12. On information and belief, Hetero Drugs and Hetero Labs each own a 50% share of Hetero USA.

JURISDICTION AND VENUE

13. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

14. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero USA is incorporated in the State of Delaware.

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Labs and Hetero Drugs are incorporated in India and may be sued in any judicial district in the United States.

18. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Unit-V is a division of Hetero Labs, which is incorporated in India and may be sued in any judicial district in the United States.

19. On information and belief, venue is also proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero is an ANDA submitter and its connections to this forum are sufficiently related to the ANDA submission.

20. This Court has personal jurisdiction over Hetero Labs. On information and belief, Hetero Labs is in the business of, *inter alia*, manufacturing, marketing, importing, and selling

generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero Labs directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Labs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

21. On information and belief, Hetero Labs "is a research based global pharmaceutical company focused on development, manufacturing and marketing of Active Pharmaceutical Ingredients (APIs), Intermediate Chemicals & Finished Dosages." https://www.indiamart.com/heterolabs-limited/aboutus.html (Hetero Labs Ltd. Profile, accessed July 31, 2021).

22. This Court has personal jurisdiction over Hetero Unit-V. On information and belief, Hetero Unit-V is in the business of, *inter alia*, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero Unit-V directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Unit-V purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

23. On information and belief, Hetero Unit-V is the drug manufacturing facility for Hetero Labs and manufactures Hetero's generic products. *See, e.g.*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017 (letter from the FDA to recipient Hetero

Unit-V, accessed July 31, 2021).

24. This Court has personal jurisdiction over Hetero Drugs. On information and belief, Hetero Drugs is in the business of manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero Drugs, directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Drugs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

25. On information and belief, Hetero Drugs admits it "is a globally renowned vertically integrated pharmaceutical player engaged in research and development, manufacturing, and marketing of high-quality chemical and biologic medicines across diverse therapeutic areas" and it "has a strong global presence in over 126 countries[.]" https://www.heteroworld.com/company-profile.php (accessed July 31, 2021). On information and belief, Hetero Drugs admits that "our R&D has been able to develop niche generics" and that "ANDAs and FTFs accredited to us showcase our strength in R&D." https://www.heteroworld.com/research.php (accessed July 31, 2021).

26. This Court has personal jurisdiction over Hetero USA. On information and belief, Hetero USA is organized and existing under the laws of the State of Delaware. On information and belief, Hetero USA is in the business of, *inter alia*, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero USA directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this

judicial district. On information and belief, Hetero USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

27. On information and belief, Hetero USA, Inc. admits it is "the US representation of HETERO, a privately owned; research based global pharmaceutical company" and that "[w]e have a significant presence in the development and marketing of finished dosages." *See* https://h1bdata.com/pin/hetero-usa/ (accessed July 31, 2021).

28. On information and belief, Hetero USA maintains continuous and systematic contacts with Delaware through its authorized Delaware registered agent, W/K Incorporating Services, Inc., located at 3500 South DuPont Highway, Dover, DE 19901.

29. On information and belief, the acts of Hetero complained of herein were done with the cooperation, participation, and assistance of Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA.

30. On information and belief, and consistent with Hetero's practice with respect to other generic products, following FDA approval of ANDA No. 215574, Hetero will act in concert to distribute and sell the generic product described in ANDA No. 215574 ("Hetero's Generic Product") throughout the United States, including the State of Delaware.

31. This Court has personal jurisdiction over Hetero Labs, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Labs is organized under the laws of India.

32. This Court has personal jurisdiction over Hetero Unit-V, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Unit-V is organized under the laws of India.

33. This Court has personal jurisdiction over Hetero Drugs, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Labs is organized under the laws of India.

34. This Court has personal jurisdiction over Hetero USA because, *inter alia*, Hetero USA is organized and existing under the laws of the State of Delaware.

35. This Court also has personal jurisdiction over Hetero because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Hetero satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), and § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State").

36. On information and belief, the effort to seek approval for ANDA No. 215574 and to manufacture, import, market, and/or sell Hetero's Generic Product upon approval has been a cooperative and joint enterprise and venture between Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA.

37. On information and belief, Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 215574 and in commercializing Hetero's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 215574 upon approval.

38. On information and belief, Hetero Labs, Hetero Labs Unit-V, Hetero Drugs, and Hetero USA hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic

pharmaceutical products throughout the United States, including in this judicial district.

39. On information and belief, Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 215574.

40. This Court has personal jurisdiction over Hetero by virtue of the fact that it has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

41. This Court also has personal jurisdiction over Hetero because Hetero has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Hetero, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Hetero's website states that its "[b]randed generics division is intended to bring access to high-quality medicines within affordable reach of markets across the globe" and identifies the United States as part of its global footprint. *See* https://www.heteroworld.com/branded-generics.php, https://www.heteroworld.com/global-footprint.php (accessed July 31, 2021). On information and belief, Hetero derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

42. This Court also has personal jurisdiction over Hetero because it has availed itself of this forum previously for the purpose of litigating a patent dispute, including in a related case involving the same parties, ANDA No. 215574, and Hetero's Generic Product. For example, Hetero has previously invoked this Court's jurisdiction by asserting counterclaims in at least seven

cases in the last four years. *See, e.g.*, *Duchesnay Inc. v. Hetero Labs Limited*, No. 538-LPS (D. Del. Apr. 14, 2021) (pending related case involving the same parties, ANDA No. 215574, and Hetero's Generic Product), *Gilead Sciences, Inc. v. Apotex, Inc.*, No. 20-189 (D. Del. Apr. 13, 2020), *Novartis Pharm. v. Dr. Reddy's Labs., Inc.*, No. 19-2053 (D. Del. Jan. 27, 2020), *Genentech, Inc. v. Hetero Labs Ltd*, No. 19-178 (D. Del. Apr. 1, 2019), *Biogen Int'l GMBH v. Amneal Pharm. LLC*, No. 17-823 (D. Del. Mar. 21, 2019), *Novartis Pharm. v. Accord Healthcare Inc.*, No. 18-1043 (D. Del. Aug. 9, 2018), *Biogen Int'l GMBH v. Hetero USA Inc.*, No. 17-825 (D. Del. Oct. 16, 2017).

43. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Hetero.

FACTUAL BACKGROUND

THE NDA

44. Duchesnay is the holder of New Drug Application ("NDA") No. 203505 for Osphena® (ospemifene) tablets.

45. The FDA approved NDA No. 203505 on February 26, 2013, for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause, and on January 25, 2019, for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.

THE PATENTS-IN-SUIT

46. The '819 patent, titled "Method for the Treatment of Vaginal Dryness and Sexual Dysfunction in Women During or After the Menopause," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on June 12, 2001. A true and correct copy of the '819 patent is attached as Exhibit A.

47. QuatRx owns the rights to the ’819 patent. Duchesnay and Shionogi are exclusive licensees in the United States of the ’819 patent. The ’819 patent currently expires on July 21, 2025. This expiration date includes a 5-year patent term extension granted by the PTO pursuant to 35 U.S.C. § 156. A true and correct copy of the Certificate Adjusting Patent Term is attached as Exhibit B.

48. The ’819 patent is listed in the FDA Orange Book in connection with NDA No. 203505 for Osphena® (ospemifene) tablets.

49. The ’861 patent, titled “Method for Enhancing the Bioavailability of Ospemifene,” was duly and legally issued by the PTO on August 7, 2012. A true and correct copy of the ’861 patent is attached as Exhibit C.

50. QuatRx owns the rights to the ’861 patent. Duchesnay and Shionogi are exclusive licensees in the United States of the ’861 patent. The ’861 patent currently expires on August 11, 2026. This expiration date includes a 910-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b).

51. The ’861 patent is listed in the FDA Orange Book in connection with NDA No. 203505 for Osphena® (ospemifene) tablets.

THE ANDA

52. On information and belief, Hetero filed ANDA No. 215574 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of ospemifene tablets, which is a generic version of Plaintiffs’ Osphena® (ospemifene) tablets.

53. On information and belief, ANDA No. 215574 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certifications”), alleging that the claims of the

patents-in-suit are invalid, unenforceable, and/or would not be infringed by Hetero's Generic Product.

54. On March 1, 2021, Duchesnay received a letter sent by Hetero, dated February 26, 2021, purporting to be a "Notice of Certification" for ANDA No. 215574 ("Hetero's First Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Hetero's First Notice Letter notified Duchesnay that Hetero had filed ANDA No. 215574, seeking approval to market Hetero's Generic Product prior to the expiration of United States Patent No. 8,642,079 ("the '079 patent").

55. In response to Hetero's First Notice Letter, Plaintiffs previously filed a separate action in this Court against Hetero for patent infringement, which included a count of infringement of the '079 patent. *See Duchesnay Inc., et al. v. Hetero Labs Limited, et al.*, No. 538-LPS (D. Del. Apr. 14, 2021).

56. On or about June 22, 2021, Plaintiffs each received a letter sent by Hetero, dated June 21, 2021, purporting to be a "Notice of Certification" for ANDA No. 215574 ("Hetero's Second Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Hetero's Second Notice Letter notified Plaintiffs that Hetero had filed ANDA No. 215574, seeking approval to market Hetero's Generic Product prior to the expiration of the patents-in-suit.

57. Plaintiffs commenced this action within 45 days of receiving Hetero's Second Notice Letter.

COUNT I
INFRINGEMENT OF THE '819 PATENT

58. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

59. On information and belief, Hetero filed ANDA No. 215574 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '819 patent.

60. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.95(c)(2), a certification that the claims of the '819 patent are purportedly invalid, unenforceable, and/or not infringed.

61. On information and belief, in its ANDA No. 215574, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' Osphena® (ospemifene) tablets.

62. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 215574 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '819 patent, constitutes infringement, either literally or under the doctrine of equivalents.

63. In Hetero's Second Notice Letter, Hetero did not allege noninfringement of claims 1-6 of the '819 patent, and therefore admits infringement of those claims.

64. Upon FDA approval of ANDA No. 215574, Hetero will infringe one or more claims of the '819 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215574 shall be no earlier than the expiration of the '819 patent and any additional periods of exclusivity.

65. On information and belief, Hetero has knowledge of the '819 patent and has filed

ANDA No. 215574 seeking authorization to commercially manufacture, use, offer for sale, and sell Hetero's Generic Product in the United States. On information and belief, if the FDA approves ANDA No. 215574, physicians, health care providers, and/or patients will use Hetero's Generic Product according to Hetero's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '819 patent in violation of Plaintiffs' patent rights.

66. On information and belief, Hetero knows and intends that physicians, health care providers, and/or patients will use Hetero's Generic Product according to Hetero's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '819 patent with the requisite intent under 35 U.S.C. § 271(b).

67. On information and belief, if the FDA approves ANDA No. 215574, Hetero will sell or offer to sell Hetero's Generic Product specifically labeled for use in practicing one or more claims of the '819 patent, wherein Hetero's Generic Product is a material part of the invention claimed in the '819 patent, wherein Hetero knows that physicians will prescribe and patients will use Hetero's Generic Product for practicing one or more claims in the '819 patent, and wherein Hetero's Generic Product are especially adapted for a use that infringes the '819 patent and are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants will thus contribute to the infringement of the '819 patent under 35 U.S.C. § 271(c).

68. On information and belief, Hetero's actions relating to Hetero's ANDA No. 215574 complained of herein were done by and for the benefit of Hetero.

69. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero as to liability for infringement of the '819

patent claims. Hetero's actions have created in Plaintiffs a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Hetero's threatened imminent actions, unless those actions are enjoined by this Court.

70. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '819 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT II
INFRINGEMENT OF THE '861 PATENT

71. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

72. On information and belief, Hetero filed ANDA No. 215574 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '861 patent.

73. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.95(c)(2), a certification that the claims of the '861 patent are purportedly invalid, unenforceable, and/or not infringed.

74. On information and belief, in its ANDA No. 215574, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' Osphena® (ospemifene) tablets.

75. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 215574 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '861 patent, constitutes infringement, either literally or under the doctrine of equivalents.

76. In Hetero's Second Notice Letter, Hetero did not allege noninfringement of claims 1-3, 7-14, and 18-20 of the '861 patent, and therefore admits infringement of those claims.

77. Upon FDA approval of ANDA No. 215574, Hetero will infringe one or more claims of the '861 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215574 shall be no earlier than the expiration of the '861 patent and any additional periods of exclusivity.

78. On information and belief, Hetero has knowledge of the '861 patent and has filed ANDA No. 215574 seeking authorization to commercially manufacture, use, offer for sale, and sell Hetero's Generic Product in the United States. On information and belief, if the FDA approves ANDA No. 215574, physicians, health care providers, and/or patients will use Hetero's Generic Product according to Hetero's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '861 patent in violation of Plaintiffs' patent rights.

79. On information and belief, Hetero knows and intends that physicians, health care providers, and/or patients will use Hetero's Generic Product according to Hetero's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '861 patent with the requisite intent under 35 U.S.C. § 271(b).

80. On information and belief, if the FDA approves ANDA No. 215574, Hetero will sell or offer to sell Hetero's Generic Product specifically labeled for use in practicing one or more claims of the '861 patent, wherein Hetero's Generic Product is a material part of the invention

claimed in the '861 patent, wherein Hetero knows that physicians will prescribe and patients will use Hetero's Generic Product for practicing one or more claims in the '861 patent, and wherein Hetero's Generic Product are especially adapted for a use that infringes the '861 patent and are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants will thus contribute to the infringement of the '861 patent under 35 U.S.C. § 271(c).

81. On information and belief, Hetero's actions relating to Hetero's ANDA No. 215574 complained of herein were done by and for the benefit of Hetero.

82. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero as to liability for infringement of the '861 patent claims. Hetero's actions have created in Plaintiffs a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Hetero's threatened imminent actions, unless those actions are enjoined by this Court.

83. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '861 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A declaration that the '819 patent remains valid and is enforceable;

B. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim of the '819 patent through Hetero's submission of ANDA No. 215574 to the FDA

to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '819 patent;

C. The entry of judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Hetero's making, using, offering to sell, selling or importing Hetero's Generic Product prior to the expiration of the '819 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '819 patent under 35 U.S.C. § 271(a), (b), and/or (c);

D. The issuance of an order that the effective date of any FDA approval of Hetero's Generic Product shall be no earlier than the expiration date of the '819 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, or selling Hetero's Generic Product within the United States, or importing Hetero's Generic Product into the United States, until the expiration of the '819 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '819 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

G. A declaration that the '861 patent remains valid and is enforceable;

H. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim of the '861 patent through Hetero's submission of ANDA No. 215574 to the FDA

to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '861 patent;

I. The entry of judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Hetero's making, using, offering to sell, selling or importing Hetero's Generic Product prior to the expiration of the '861 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '861 patent under 35 U.S.C. § 271(a), (b), and/or (c);

J. The issuance of an order that the effective date of any FDA approval of Hetero's Generic Product shall be no earlier than the expiration date of the '861 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

K. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, or selling Hetero's Generic Product within the United States, or importing Hetero's Generic Product into the United States, until the expiration of the '861 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

L. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '861 patent, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

M. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

N. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

O. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Dated: August 3, 2021

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