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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHIESI USA INC. and CHIESI FARMACEUTICI S.P.A Plaintiffs, v. EUGIA PHARMA SPECIALITIES LIMITED (A.K.A. EUGIA PHARMA SPECIALTIES LIMITED), EUGIA US LLC, and AUROBINDO PHARMA LIMITED, Defendants.	Civil Action No. _____ *Document Filed Electronically*

COMPLAINT

Plaintiffs Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. (collectively, "Chiesi" or "Plaintiffs") by its undersigned attorneys, for its Complaint against Defendants Eugia Pharma Specialities Limited (a.k.a. Eugia Pharma Specialties Limited), Eugia US LLC ("Eugia US"), and Aurobindo Pharma Limited ("APL") (collectively, "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 8,680,052 ("the '052 patent") (attached as Exhibit A hereto), U.S. Patent No. 9,295,687 ("the '687 patent") (attached as Exhibit B hereto), U.S. Patent No. 9,427,448 ("the '448 patent") (attached as Exhibit C hereto), U.S. Patent No. 9,439,921 ("the '921 patent") (attached as Exhibit D hereto), U.S. Patent No. 9,700,575 ("the '575 patent") (attached as Exhibit E hereto), U.S. Patent No. 9,925,265 ("the '265 patent") (attached as Exhibit F hereto), and U.S. Patent No. 10,039,780 ("the '780 patent") (attached as Exhibit G hereto) (collectively, the "patents-in-suit").

2. This action relates to the submission of an Abbreviated New Drug Application ("ANDA") No. 217986 by Defendants to the United States Food and Drug Administration ("FDA"), seeking approval to market a proposed generic version of Kengreal® (the "ANDA Product") prior to the expiration of the patents-in-suit.

THE PARTIES

3. Chiesi USA Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518. Chiesi USA Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

4. Chiesi USA Inc. is the owner of New Drug Application ("NDA") No. 204958, which was approved by the FDA for the manufacture and sale of Kengreal® (cangrelor) for injection.

5. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having a principal place of business at Via Palermo, 26 A, 43122 Parma, Italy.

6. Chiesi Farmaceutici S.p.A. is the current owner and assignee of each of the eight (8) patents listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Chiesi's Kengreal®, of which seven (7) are the patents-in-suit. The seven (7) patents-in-suit were previously owned by The Medicines Company, on assignment from the inventors, who were employees of The Medicines Company. Upon information and belief, The Medicines Company is a corporation having its principal place of business in Parsippany, New Jersey. Upon information and belief, one or more of the inventors of the patents-in-suit are located in New Jersey.

7. Upon information and belief, Eugia is a corporation organized under the laws of India, having its principal place of business at either its registered office at Maitrivihar, Plot #2, Ameerpet, Hyderabad, Telangana 500038, India ("Maitrivihar" address) or its corporate office at Galaxy, Floors: 22-24, Plot No.1, Sy No.83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Hyderabad, Telangana 500032, India ("Galaxy" address). Upon information and belief, Eugia is in the business of, among other things, the development, manufacture, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey.

8. Upon information and belief, Eugia has on some occasions identified itself as Eugia Pharma "Specialities," and on other occasions as Eugia Pharma "Specialties," including, for example, in Answers that Eugia filed in the following cases: *Pfizer Inc. et al. v. Aurobindo Pharma, Ltd*. et al., No. 20-cv-01528, Answer (D. Del. Dec 4, 2020) ("Eugia Pharma Specialities Ltd."; principal place of business at the "Maitrivihar" address), *Medicure International, Inc. v. Aurobindo Pharma Limited et al*., No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) ("Eugia

Pharma Specialties Limited"; principal place of business at the "Galaxy" address), and *Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al*., No. 22-cv-00227, Answer (D. Del. Mar 17, 2022).

9. Upon information and belief, Eugia is the holder of over two hundred ANDAs that have been submitted to the FDA, seeking approval to market generic pharmaceutical products throughout the United States, including in New Jersey.

10. Upon information and belief, Eugia is the manufacturer of generic pharmaceutical products that are the subject of ANDAs that have been approved by the FDA for sale and distribution throughout the United States, including in New Jersey. Upon information and belief, Eugia manufactures such generic pharmaceutical products for distribution by its affiliates and other wholly owned subsidiaries of APL, including Eugia US (e.g., Pemetrexed for Injection, USP (100 mg per vial)); AuroMedics Pharma LLC (e.g., Docetaxel Injection, USP (10 mg/mL), Esmolol Hydrochloride Injection (10 mg/mL), and Vasopressin Injection, USP (1 mL vial)); and Aurobindo Pharma USA, Inc. (e.g., Exemestane Tablets, USP (25 mg) and Erlotinib Tablets (25 mg, 100 mg, 150 mg)).

11. Upon information and belief, Eugia is a wholly owned subsidiary of APL. Upon information and belief, Eugia acts at the direction and for the benefit of APL, and is controlled and/or dominated by APL.

12. Upon information and belief, Eugia US is a corporation organized and existing under the laws of Delaware, having its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Upon information and belief, Eugia US is in the business of, among other things, the development, manufacture, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey.

13. Upon information and belief, Eugia US is the U.S. agent with respect to ANDA No. 217986.

14. Upon information and belief, Eugia US is registered with New Jersey's Department of Health as a drug manufacturer and drug wholesaler.

15. Upon information and belief, Eugia US is formerly known as AuroMedics Pharma LLC.

16. Upon information and belief, Eugia US is a wholly owned subsidiary of APL. Upon information and belief, Eugia US acts at the direction and for the benefit of APL, and is controlled and/or dominated by APL.

17. Upon information and belief, APL is a corporation organized and existing under the laws of the Republic of India, having a place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India. Upon information and belief, APL is, by itself and/or through its wholly owned subsidiaries such as Eugia and Eugia US, in the business of, among other things, the development, manufacture, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey.

18. Upon information and belief, APL is, by itself and/or through its wholly owned subsidiaries such as Eugia and Eugia US, is in the business of seeking and obtaining FDA approval for the marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey. Upon information and belief, APL derives substantial revenue from the sale of such generic pharmaceutical products throughout the United States, including in New Jersey.

19. Upon information and belief, Eugia, Eugia US, and APL cooperate, collaborate, or act in concert for the purposes of the development, manufacture, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey.

20. Upon information and belief, Eugia, Eugia US, and APL operate as a single, integrated business with respect to regulatory approval, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey.

21. Upon information and belief, Eugia, Eugia US, and APL cooperated, collaborated, or acted in concert for purposes of submitting ANDA No. 217986 to the FDA.

22. Upon information and belief, following any FDA approval of ANDA No. 217986, Eugia, Eugia US, and APL will act in concert to make, import, market, sell, offer to sell, and/or distribute the ANDA Product throughout the United States, including in New Jersey.

23. Upon information and belief, following any FDA approval of ANDA No. 217986, Eugia, Eugia US, and APL will benefit from the commercial offering for sale and/or sale of the ANDA Product throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

24. 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.

25. This Court has personal jurisdiction over Eugia at least because, upon information and belief: (i) Eugia manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States and thus avails itself of the privileges and benefits of the laws and commerce of the United States and New Jersey; (ii) Eugia, through its

affiliates including at least Eugia US, is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Eugia is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, and in partnership or agency with its affiliates including at least Eugia US for importation, sale, and/or distribution in New Jersey; (iv) Eugia derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District; (v) Eugia has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (vi) Eugia has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal protections in at least eleven (11) prior litigations and/or consented to personal jurisdiction and venue in this Judicial District.[1]

26. This Court has personal jurisdiction over Eugia at least because, upon information and belief, if ANDA No. 217986 receives final approval, the ANDA Product will be manufactured, sold, distributed, and/or used by Eugia, by itself and/or together with Eugia US and APL, in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

[1] *Aragon Pharmaceuticals, Inc. et al v. Eugia Pharma Specialities Limited et al.*, No. 2-22-cv-03186 (D.N.J. filed May. 26, 2022); *Bristol-Myers Squibb Company v. Eugia Pharma Specialities Ltd.*, No. 2-21-cv-20409 (D.N.J. filed Dec. 8, 2021); *Medicure International, Inc. v. Aurobindo Pharma Limited et al.*, No. 2-21-cv-17534 (D.N.J. filed Sep. 24, 2021); *Celgene Corporation v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-00624 (D.N.J. filed Jan. 12, 2021); *Merck Sharp & Dohme BV et al v. Aurobindo Pharma USA, Inc. et al*., No. 2-20-cv-02576 (D.N.J. filed Mar. 10, 2020); *Celgene Corporation v. Aurobindo Pharma Limited et al*., No. 2-20-cv-02606 (D.N.J. filed Mar. 10, 2020); *Celgene Corporation v. Aurobindo Pharma Ltd. et al.*, No. 2-20-cv-00315 (D.N.J. filed Jan. 8, 2020); *Celgene Corporation v. Aurobindo Pharma Limited et al*., No. 2-19-cv-05799 (D.N.J. filed Feb. 14, 2019); *Celgene Corporation v. Aurobindo Pharma Limited et al.*, No. 2-19-cv-00143 (D.N.J. filed Jan. 4, 2019); *Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Aurobindo Pharma USA Inc. et al.*, No. 3-17-cv-07887 (D.N.J. filed Oct. 4, 2017); and *Celgene Corporation v. Hetero Labs Limited et al.*, No. 2-17-cv-03387 (D.N.J. filed May 11, 2017).

27. This Court has personal jurisdiction over Eugia US at least because, upon information and belief: (i) Eugia US is incorporated in Delaware and has its principal place of business in East Windsor, New Jersey; (ii) Eugia US regularly does or solicits business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Eugia US, together with Eugia and/or APL, is in the business of developing and manufacturing generic pharmaceutical product for importation, sale, and/or distribution in New Jersey; and (iv) Eugia US, together with Eugia and/or APL, has committed, induced, or contributed to acts of patent infringement in New Jersey.

28. This Court has personal jurisdiction over Eugia US at least because, upon information and belief, if ANDA No. 217986 receives final approval, the ANDA Product will be manufactured, sold, distributed, and/or used by Eugia US, by itself and/or together with Eugia and APL, in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

29. This Court has personal jurisdiction over APL at least because, upon information and belief: (i) APL manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States and thus avails itself of the privileges and benefits of the laws and commerce of the United States and New Jersey; (ii) APL is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) APL is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, and in partnership or agency with its subsidiaries, including at least Eugia and Eugia US for importation, sale, and/or distribution in New Jersey; (iv) APL derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in New Jersey; (v) APL, together with Eugia and Eugia US has committed, induced, or contributed to

acts of patent infringement in New Jersey; and (vi) APL has previously submitted to the jurisdiction of this Court and/or has availed itself of New Jersey's legal protections in at least nine (9) prior litigations.[2]

30. This Court has personal jurisdiction over APL at least because, upon information and belief, if ANDA No. 217986 receives final approval, the ANDA Product will be manufactured, sold, distributed, and/or used by APL, by itself and/or together with Eugia and Eugia US, in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

31. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

32. Federal venue rules do not restrict the locations in which alien corporations, like APL and Eugia, may be sued. *In re HTC Corp.*, 889 F.3d 1349, 1354– 61 (Fed. Cir. 2018) (citing *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); *In re Hohorst*, 150 U.S. 653 (1893)). For that reason, venue is proper in this Court as to Eugia and APL.

[2] *Eisai Co. Ltd., et al. v. Aurobindo Pharma Ltd.*, No. 1:22-cv-03610 (D.N.J. filed June 8, 2022); *Eisai Co., Ltd., et al. v. Aurobindo Pharma Ltd.*, No. 1:21-cv-20723 (D.N.J. filed Dec. 28, 2021); *Medicure Int'l, Inc. v. Aurobindo Pharma Ltd.*, No. 2:21-v-17534 (D.N.J. filed Sept. 24, 2021); *Teva Branded Pharma. Prods. R&D, Inc. et al. v. Aurobindo Pharma Ltd. et al*., No. 3:21-cv-13240 (D.N.J. filed July 1, 2021); *Celgene Corp. v. Aurobindo Pharma Ltd. et al*., No. 2:21-cv- 0624 (D.N.J. filed Jan. 12, 2021); *Chiesi USA, Inc. et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 3:19-cv-18756 (D.N.J. filed Oct. 7, 2019); *Celgene Corp. v. Aurobindo Pharma Ltd. et al*., No. 2:19-cv-05799 (D.N.J. filed Feb. 14, 2019); *Sumitomo Daonippon Pharma Co. et al v. Aurobindo Pharma Ltd. et al*., No. 2:18-cv-02620 (D.N.J. filed Feb, 23, 2018); *Janssen Prods., L.P. et al. v. Aurobindo Pharma Ltd. et al.*, No. 2:17-cv-06872 (D.N.J. filed Sept. 7, 2017).

33. Venue is proper in this Court under 28 U.S.C. § 1400(b), because Eugia US has committed an act of infringement and has a regular and established place of business in this Judicial District.

FACTS AS TO ALL COUNTS

34. Chiesi's Kengreal® is sold and marketed under NDA No. 204958, which was approved by FDA as a New Chemical Entity ("NCE") on June 22, 2015.

35. Kengreal® is supplied as single-use 10 mL vial containing 50 mg Kengreal® as a lyophilized powder for reconstitution. Cangrelor, the active ingredient in Kengreal®, is a $P2Y_{12}$ platelet inhibitor indicated as an adjunct to percutaneous coronary intervention ("PCI") for reducing the risk of periprocedural myocardial infarction ("MI"), repeat coronary revascularization, and stent thrombosis ("ST") in patients in who have not been treated with a $P2Y_{12}$ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

36. NDA No. 204958 pertains to Kengreal®'s 50 mg/vial presentation.

37. Kengreal®'s recommended dosage is 30 mcg/kg administered through intravenous ("IV") bolus prior to PCI followed immediately by a 4 mcg/kg/min (IV) infusion for at least 2 hours or the duration of the procedure, whichever is longer. Kengreal®'s prescribing information also recommends that in order to maintain platelet inhibition after discontinuation of Kengreal® infusion, an oral $P2Y_{12}$ platelet inhibitor should be administered.

38. FDA's Orange Book lists eight (8) patents as covering Chiesi's Kengreal®. Pursuant to 21 U.S.C. § 355(b)(1), these eight (8) patents were submitted to FDA with NDA No. 204958. These eight (8) patents were subsequently listed in the Orange Book as covering Kengreal®.

39. Defendants sent a letter addressed to Chiesi USA, Inc. and Chiesi Farmaceutici S.p.A. dated November 21, 2022, purportedly pursuant to § 505(j)(2)(B)(ii) and §

505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act ("FDCA") and § 314.95 of Title 21 of the Code of Federal Regulations, regarding ANDA No. 217986 (the "Notice Letter").

40. The Notice Letter states that FDA has received ANDA No. 217986, which seeks FDA approval to engage in the commercial manufacture, use or sale of the ANDA Product before the expiration of the '052 patent, the '687 patent, the '448 patent, the '921 patent, the '575 patent, the '265 patent, and the '780 patent.

41. The Notice Letter states that Eugia and Eugia US filed ANDA No. 217986 with the FDA, and that Eugia US is the "U.S. agent" of Eugia.

42. Upon information and belief, ANDA No. 217986 has been submitted under § 505(j)(2) of the FDCA with certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the '052, '687, '448, '921, '575, '265, and '780 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

43. The Notice Letter includes an attachment which purports to provide a detailed statement of legal and factual bases, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), for the paragraph IV certification contained in ANDA No. 217986.

44. Upon information and belief, the prescribing information for the ANDA Product will have the same Indications and Usage as Kengreal®.

45. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Dosage and Administration as Kengreal®.

46. Upon information and belief, administration of the ANDA Product will be used to inhibit platelet aggregation in a patient in need thereof.

47. The ’052 patent, titled “Methods of Treating, Reducing the Incidence of, and/or Preventing Ischemic Events,” was duly and legally issued by the U.S. Patent and Trademark Office on March 25, 2014, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell, Simona Skerjanec, Jayne Prats, and David J. Schneider. Subsequently, The Medicines Company assigned the ’052 patent to Chiesi Farmaceutici S.p.A.

48. The ’687 patent, titled “Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on March 29, 2016, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the ’687 patent to Chiesi Farmaceutici S.p.A.

49. The ’448 patent, titled “Methods of Treating, Reducing the Incidence of, and/or Preventing Ischemic Events” was duly and legally issued by the U.S. Patent and Trademark Office on August 30, 2016, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell, Simona Skerjanec, and Jayne Prats. Subsequently, The Medicines Company assigned the ’448 patent to Chiesi Farmaceutici S.p.A.

50. The ’921 patent, titled “Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on September 13, 2016, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the ’921 patent to Chiesi Farmaceutici S.p.A.

51. The ’575 patent, titled “Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same,” was duly and legally issued by the U.S. Patent and Trademark Office on July 11, 2017, to The Medicines Company on assignment

from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '575 patent to Chiesi Farmaceutici S.p.A.

52. The '265 patent, titled "Methods of Treating or Preventing Stent Thrombosis," was duly and legally issued by the U.S. Patent and Trademark Office on March 27, 2018, to The Medicines Company on assignment from inventors Clive Arthur Arculus-Meanwell and Simona Skerjanec. Subsequently, The Medicines Company assigned the '265 patent to Chiesi Farmaceutici S.p.A.

53. The '780 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the U.S. Patent and Trademark Office on August 7, 2018, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '780 patent to Chiesi Farmaceutici S.p.A.

54. The Notice Letter does not indicate that a paragraph IV certification has been submitted for U.S. Patent No. 6,130,208 ("The '208 patent").

55. Upon information and belief, Defendants have submitted ANDA No. 217986 with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("paragraph III certification") for the '208 patent.

56. Upon information and belief, Defendants are not seeking final FDA approval of ANDA No. 217986 before the patent expiration of the '208 patent. As indicated in the Orange Book, the patent expiration for the '208 patent is June 29, 2023.

57. As indicated in the Orange Book, the patent expiration for the '780 patent is July 10, 2035; the patent expiration for the '052 patent is May 09, 2033; the patent expiration for the '687 patent is July 10, 2035; the patent expiration for the '448 patent is November 10, 2030; the

patent expiration for the ’921 patent is July 10, 2035; the patent expiration for the ’575 patent is July 10, 2035; and the patent expiration for the ’265 patent is May 13, 2029.

COUNT I

Defendants’ Infringement of the ’052 Patent

58. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

59. Upon information and belief, Defendants prepared ANDA No. 217986.

60. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

61. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

62. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the ’052 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the ’052 patent.

63. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a “detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or

will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

64. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

65. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

66. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '052 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '052 patent is an act of infringement of the '052 patent.

67. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

68. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '052 patent's claims under 35 U.S.C. § 271.

69. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

70. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '052 patent under 35 U.S.C. § 271.

71. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

72. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

COUNT II

Defendants' Infringement of the '687 Patent

73. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

74. Upon information and belief, Defendants prepared ANDA No. 217986.

75. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

76. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

77. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the '687 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '687 patent.

78. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

79. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

80. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

81. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '687 patent for the purpose of obtaining approval to

engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '687 patent is an act of infringement of the '687 patent.

82. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

83. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe literally or under the doctrine of equivalents, directly and/or indirectly, one or more of the '687 patent's claims under 35 U.S.C. § 271.

84. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

85. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '687 patent under 35 U.S.C. § 271.

86. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

87. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

COUNT III

Defendants' Infringement of the '448 Patent

88. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

89. Upon information and belief, Defendants prepared ANDA No. 217986.

90. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

91. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

92. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the ’448 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the ’448 patent.

93. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a “detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include: “For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

94. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

95. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

96. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '448 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '448 patent is an act of infringement of the '448 patent.

97. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

98. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '448 patent's claims under 35 U.S.C. § 271.

99. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

100. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '448 patent under 35 U.S.C. § 271.

101. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

102. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

COUNT IV

Defendants' Infringement of the '921 Patent

103. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

104. Upon information and belief, Defendants prepared ANDA No. 217986.

105. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

106. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

107. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the '921 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '921 patent.

108. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

109. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

110. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

111. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '921 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '921 patent is an act of infringement of the '921 patent.

112. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

113. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe literally or under the doctrine of equivalents, directly and/or indirectly, one or more of the '921 patent's claims under 35 U.S.C. § 271.

114. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

115. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '921 patent under 35 U.S.C. § 271.

116. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

117. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

COUNT V

Defendants' Infringement of the '575 Patent

118. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

119. Upon information and belief, Defendants prepared ANDA No. 217986.

120. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

121. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

122. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the '575 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '575 patent.

123. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

124. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

125. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

126. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '575 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '575 patent is an act of infringement of the '575 patent.

127. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

128. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe literally or under the doctrine of equivalents, directly and/or indirectly, one or more of the '575 patent's claims under 35 U.S.C. § 271.

129. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

130. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '575 patent under 35 U.S.C. § 271.

131. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

132. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

COUNT VI

Defendants' Infringement of the '265 Patent

133. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

134. Upon information and belief, Defendants prepared ANDA No. 217986.

135. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

136. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

137. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the '265 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '265 patent.

138. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

139. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

140. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

141. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '265 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '265 patent is an act of infringement of the '265 patent.

142. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

143. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '265 patent's claims under 35 U.S.C. § 271.

144. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

145. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '265 patent under 35 U.S.C. § 271.

146. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

147. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

COUNT VII

Defendants' Infringement of the '780 Patent

148. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

149. Upon information and belief, Defendants prepared ANDA No. 217986.

150. Upon information and belief, Defendants submitted ANDA No. 217986 to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents-in-suit. Upon information and belief, ANDA No. 217986 is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

151. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

152. Upon information and belief, Defendants submitted ANDA No. 217986 with a paragraph IV certification to the '780 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '780 patent.

153. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

154. Upon information and belief, as of the date of Notice Letter, Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

155. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

156. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 217986 with a paragraph IV certification to the '780 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '780 patent is an act of infringement of the '780 patent.

157. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217986 ever receives final FDA approval.

158. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe literally or under the doctrine of equivalents, directly and/or indirectly, one or more of the '780 patent's claims under 35 U.S.C. § 271.

159. Upon information and belief, Defendants will all benefit from the commercial offering for sale and/or sale of the ANDA Product within the United States if ANDA No. 217986 ever receives final FDA approval.

160. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '780 patent under 35 U.S.C. § 271.

161. This case is "exceptional," and Chiesi is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

162. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment declaring that the '052 patent is valid;

(B) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '052 patent by submitting to FDA ANDA No. 217986 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '052 patent;

(C) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '052 patent (including any regulatory extension), would infringe the '052 patent;

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the '052 patent expires (including any regulatory extension);

(E) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and

any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '052 patent (including any regulatory extension);

(F) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '052 patent (including any regulatory extension);

(G) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '052 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '052 patent (including any regulatory extension);

(H) A judgment declaring that the '687 patent is valid;

(I) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '687 patent by submitting to FDA ANDA No. 217986 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '687 patent;

(J) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '687 patent (including any regulatory extension), would infringe the '687 patent;

(K) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the ’687 patent expires (including any regulatory extension);

(L) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the ’687 patent (including any regulatory extension);

(M) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the ’687 patent (including any regulatory extension);

(N) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants’ infringement of the ’687 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the ’687 patent (including any regulatory extension);

(O) A judgment declaring that the ’448 patent is valid;

(P) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the ’448 patent by submitting to FDA ANDA No. 217986 with a paragraph IV

certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the ’448 patent;

(Q) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the ’448 patent (including any regulatory extension), would infringe the ’448 patent;

(R) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the ’448 patent expires (including any regulatory extension);

(S) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the ’448 patent (including any regulatory extension);

(T) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the ’448 patent (including any regulatory extension);

(U) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants’ infringement of the ’448 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or

imports into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '448 patent (including any regulatory extension);

(V) A judgment declaring that the '921 patent is valid;

(W) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '921 patent by submitting to FDA ANDA No. 217986 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '921 patent;

(X) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '921 patent (including any regulatory extension), would infringe the '921 patent;

(Y) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the '921 patent expires (including any regulatory extension);

(Z) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '921 patent (including any regulatory extension);

(AA) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject

of ANDA No. 217986, prior to the expiration of the ’921 patent (including any regulatory extension);

(BB) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants’ infringement of the ’921 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the ’921 patent (including any regulatory extension);

(CC) A judgment declaring that the ’575 patent is valid;

(DD) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the ’575 patent by submitting to FDA ANDA No. 217986 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the ’575 patent;

(EE) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the ’575 patent (including any regulatory extension), would infringe the ’575 patent;

(FF) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the ’575 patent expires (including any regulatory extension);

(GG) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or

importation into the United States of the ANDA Product until the expiration of the '575 patent (including any regulatory extension);

(HH) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '575 patent (including any regulatory extension);

(II) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '575 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '575 patent (including any regulatory extension);

(JJ) A judgment declaring that the '265 patent is valid;

(KK) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '265 patent by submitting to FDA ANDA No. 217986 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '265 patent;

(LL) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '265 patent (including any regulatory extension), would infringe the '265 patent;

(MM) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the ’265 patent expires (including any regulatory extension);

(NN) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the ’265 patent (including any regulatory extension);

(OO) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the ’265 patent (including any regulatory extension);

(PP) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants’ infringement of the ’265 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the ’265 patent (including any regulatory extension);

(QQ) A judgment declaring that the ’780 patent is valid;

(RR) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the ’780 patent by submitting to FDA ANDA No. 217986 with a paragraph IV

certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '780 patent;

(SS) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '780 patent (including any regulatory extension), would infringe the '780 patent;

(TT) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 217986 shall be no earlier than the date on which the '780 patent expires (including any regulatory extension);

(UU) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '780 patent (including any regulatory extension);

(VV) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '780 patent (including any regulatory extension);

(WW) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '780 patent is willful and awarding Chiesi enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or

import into the United States any product that is the subject of ANDA No. 217986, prior to the expiration of the '780 patent (including any regulatory extension);

(XX) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Chiesi its attorneys' fees and costs;

(YY) Such other and further relief as this Court may deem just and proper.

Dated: January 4, 2023

By: s/ Charles H. Chevalier

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