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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA PHARMACEUTICALS U.S.A., INC., and ARIAD PHARMACEUTICALS INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Civil Action No. 22-7454

COMPLAINT

(Filed Electronically)

Plaintiffs Takeda Pharmaceuticals America, Inc. ("TPA"), Takeda Pharmaceuticals U.S.A., Inc. ("TPUSA"), and ARIAD Pharmaceuticals Inc. ("Ariad") (collectively, "Plaintiffs"), by their attorneys, for their complaint against Teva Pharmaceuticals, Inc. ("Teva Inc."), Teva

Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Limited ("Teva Ltd.") (Teva Inc., Teva USA, and Teva Ltd. together, "Teva" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 9,493,470 (the "'470 patent"), 11,192,895 (the "'895 patent"), 11,192,897 (the "'897 patent"), and 11,384,086 (the "'086 patent"), (collectively, the "Patents-in-Suit") under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* This action arises from Teva's submission of Abbreviated New Drug Application ("ANDA") No. 217825 ("the Teva ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell generic versions of Plaintiffs' 15 mg and 45 mg ICLUSIG® drug product ("the Teva ANDA Product") prior to the expiration of the Patents-in-Suit.

THE PARTIES

2. TPA is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 95 Hayden Avenue, Lexington, MA 02421.

3. TPUSA is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 95 Hayden Avenue, Lexington, MA 02421.

4. Ariad is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at 40 Lansdowne Street, Cambridge, MA 02139.

5. On information and belief, defendant Teva Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Defendant Teva Pharmaceutical Industries Limited is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

8. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

9. On information and belief, Teva Inc. is a wholly owned subsidiary of Teva Ltd.

THE PATENTS-IN-SUIT

10. On November 15, 2016, the United States Patent and Trademark Office duly and lawfully issued the ’470 patent, entitled “Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-(trifluoromethyl)phenyl}benzamide and its mono hydrochloride salt.” A copy of the ’470 patent is attached as Exhibit A.

11. On December 7, 2021, the United States Patent and Trademark Office duly and lawfully issued the ’895 patent, entitled “Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-(trifluoromethyl)phenyl}benzamide and its mono hydrochloride salt.” A copy of the ’895 patent is attached as Exhibit B.

12. On December 7, 2021, the United States Patent and Trademark Office duly and lawfully issued the ’897 patent, entitled “Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-

(trifluoromethyl)phenyl}benzamide and its mono hydrochloride salt." A copy of the '897 patent is attached as Exhibit C.

13. On July 12, 2022, the United States Patent and Trademark Office duly and lawfully issued the '086 patent, entitled "Crystalline forms of 3-(imidazo[1,2-B] pyridazin-3-ylethynyl)-4-methyl-N-{4-[(4-methylpiperazin-1-yl) methyl]-3-(trifluoromethyl)phenyl}benzamide and its mono hydrochloride salt." A copy of the '086 patent is attached as Exhibit D.

THE ICLUSIG® DRUG PRODUCT

14. TPUSA holds approved New Drug Application No. 203469 for ponatinib hydrochloride tablets, which are prescribed and sold under the trademark ICLUSIG®. ICLUSIG® is indicated for the treatment of adult patients with (1) chronic phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors, (2) accelerated phase or blast phase chronic myeloid leukemia or Philadelphia chromosome positive acute lymphoblastic leukemia for whom no other kinase inhibitors are indicated, and (3) T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia.

15. The claims of the Patents-in-Suit describe, *inter alia*, crystalline forms of ponatinib hydrochloride, compositions comprising crystalline forms of ponatinib hydrochloride, and methods of treating chronic myeloid leukemia, or Philadelphia chromosome-positive acute lymphoblastic leukemia.

16. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ICLUSIG®.

17. The FDA-approved labeling for ICLUSIG® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer ICLUSIG® for the treatment of, *inter alia*, adult patients with chronic phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors.

18. The FDA-approved labeling for ICLUSIG® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer ICLUSIG® for the treatment of, *inter alia*, adult patients with accelerated phase or blast phase chronic myeloid leukemia or Philadelphia chromosome positive acute lymphoblastic leukemia for whom no other kinase inhibitors are indicated.

19. The FDA-approved labeling for ICLUSIG® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer ICLUSIG® for the treatment of, *inter alia*, adult patients with T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia.

JURISDICTION AND VENUE

20. 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.

21. This Court has personal jurisdiction over Teva USA by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva USA's principal place of business is in Parsippany, New Jersey. On information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100250184. On information and belief, Teva USA is registered with the State of New Jersey's Department of

Health as a drug manufacturer and wholesaler under Registration Nos. 5000583 and 5003436. On information and belief, Teva USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Teva USA.

22. On information and belief, Teva USA is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Teva's ANDA. On information and belief, Teva USA also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

23. This Court has personal jurisdiction over Teva USA because Teva USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Teva USA regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Teva USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Teva USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District. For example, upon information and belief, Teva USA states on their website that "Teva is the leading generic drug company in the United States." Teva USA Website, https://www.tevausa.com/globalassets/us/usa-files---global/teva-in-the-usa_fact-sheet_17.08.20.pdf (last visited December 20, 2022).

24. This Court has personal jurisdiction over Teva Ltd. because, inter alia, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Teva USA, a company registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Teva USA.

25. Teva Ltd.'s Securities and Exchange Commission Form 10-K filing states that it is "one of the leading generic pharmaceutical companies in the United States" and that it markets "over 550 generic prescription products in more than 1,600 dosage strengths, packaging sizes and forms, including oral solid dosage forms, injectable products, inhaled products, transdermal patches, liquids, ointments and creams." Teva Ltd. Securities and Exchange Commission Form 10-K (for the fiscal year ended December 31, 2021) ("Teva Ltd. Form 10-K") at 3. The Teva Ltd. Form 10-K further states that its annual revenues of generic products in the United States were $3.769 billion. *Id.* at 56. It further states that, "[i]n 2021, our total prescriptions were approximately 301 million (based on trailing twelve months), representing 8.3% of total U.S. generic prescriptions . . . ." *Id.* at 60.

26. This Court has personal jurisdiction over Teva Inc. by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Inc.'s principal place of business is in Parsippany, New Jersey. On information and belief, Teva Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0450614134. On information and belief, Teva Inc. purposefully has conducted and continues to conduct business

in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Teva Inc.

27. On information and belief, Teva Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Teva's ANDA. On information and belief, Teva Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

28. This Court has personal jurisdiction over Teva because, *inter alia*, Teva has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Teva ANDA, Teva will make, use, import, sell, and/or offer for sale the Teva ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

29. On information and belief, Teva Inc., Teva USA, and Teva Ltd. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

30. On information and belief, Teva Inc. and Teva USA act at the direction, and for the benefit, of Teva Ltd., and are controlled and/or dominated by Teva Ltd.

31. On information and belief, Teva Inc., Teva USA, and Teva Ltd. operate as a single integrated business.

32. On information and belief, Teva has a regular and established, physical place of business in New Jersey.

33. On information and belief, Teva has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

34. On information and belief, Teva Inc., Teva USA, and Teva Ltd. have previously been sued in this Judicial District and have availed themselves of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey and have not challenged personal jurisdiction. *See, e.g.*, *Horizon Orphan LLC, et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 22-1382 (RMB)(AMD); *Biomarin Pharmaceutical Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 21-15392 (ES)(CLW); *Evoke Pharma, Inc. v. Teva Pharmaceuticals, Inc., et al.*, Civil Action No. 22-2019 (RMB)(SAK) *Merck Sharp & Dohme B.V. and Organon USA Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-2751 (CCC)(MF); *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-3485 (BRM)(ESK); *Horizon Medicines LLC v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-8188 (SRC)(CLW); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 19-8758 (ES)(MAH); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 18-14366 (ES)(MAH); *Celgene Corporation v. Par Pharm., Inc., et al.*, Civil Action No. 17-3159 (ES)(MAH); *Boehringer Ingelheim Pharma GMBH & Co., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-7811 (BRM)(TJB); *Janssen Prods., L.P., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 13-7576 (WHW)(CLW).

35. Teva USA and Teva Ltd. have further availed themselves of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g.*, *Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd.*, and *Teva Neuroscience, Inc. v.*

Sandoz Inc., et al., Civil Action No. 17-275 (FLW)(DEA); *Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 17-517 (FLW)(DEA); *Teva Neuroscience, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceutical USA, Inc., and Yeda Research and Development Co., Ltd. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 14-5672 (MAS)(TJB).

36. In the alternative, this Court has personal jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

37. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

TEVA'S INFRINGING ANDA SUBMISSION

38. On or about November 11, 2022, Plaintiffs received from Teva a letter dated November 10, 2022 ("Teva Letter"), stating that Teva had submitted the Teva ANDA to the FDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Teva ANDA Product before the expiration of the Patents-in-Suit.

39. On information and belief, in connection with the submission of its ANDA as described above, Teva provided a written certification to the FDA as called for by Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

40. On information and belief, in connection with the submission of its ANDA as described above, Teva provided a written certification to the FDA as called for by Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(III), wherein Teva does not seek FDA approval of Teva's ANDA until after the Orange Book Patents, U.S. Patent Nos. 8,114,874 and 9,029,533, have expired.

41. On information and belief, following FDA approval of the Teva ANDA, Teva will make, use, offer for sale, or sell the Teva ANDA Product throughout the United States, or import such generic products into the United States.

42. The Teva ANDA Product is intended to be a generic version of ICLUSIG®.

43. On information and belief, discovery will show that the Teva ANDA Product infringes one or more claims of the Patents-in-Suit.

COUNT I
Infringement of U.S. Patent No. 9,493,470 by Teva

44. Plaintiffs repeat and reallege the preceding paragraphs above as if fully set forth herein.

45. By submitting the Teva ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Teva ANDA Product before the expiration of the '470 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

46. On information and belief, the Teva ANDA Product is a pharmaceutical composition that includes one or more crystalline form(s) of ponatinib hydrochloride recited in one or more claims of the '470 patent (e.g., claims 1-7, 10, and 12-15) and Teva seeks FDA approval for the Teva ANDA Product for one or more claimed methods of treatment (e.g., claims 8-9, 11, and 16-17), and discovery will show that if Teva commercially makes, uses, offers to

sell, or sells the Teva ANDA Product within the United States, or imports the Teva ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '470 patent, it would further infringe one or more claims of the '470 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Claim 1 of the '470 patent recites:

> Crystalline Form A of ponatinib hydrochloride characterized by an x-ray powder diffraction pattern comprising at least five 2θ values (±0.3) chosen from 5.9, 7.1, 10.0, 12.5, 16.4, 19.3, 21.8, 23.8, and 26.1.

48. Claim 8 of the '470 patent recites:

> A method for treating chronic myeloid leukemia or Philadelphia chromosome-positive acute lymphoblastic leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition [comprising crystalline Form A ponatinib hydrochloride according to claim 1 and at least one pharmaceutically acceptable carrier, vehicle or excipient].

49. On information and belief, the Teva ANDA Product will infringe at least claims 1 and 8 of the '470 patent.

50. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will infringe one or more claims of the '470 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States.

51. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will induce infringement of one or more claims of the '470 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, upon FDA approval of the Teva ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '470 patent and knowledge that its acts are encouraging infringement.

52. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will contributorily infringe one or more claims of the '470 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, Teva has had and continues to have knowledge that the Teva ANDA Product is especially adapted for a use that infringes one or more claims of the '470 patent and that there is no substantial non-infringing use for the Teva ANDA Product.

53. Teva has had knowledge of the '470 patent since at least the date it submitted the Teva ANDA.

54. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '470 patent. Plaintiffs do not have an adequate remedy at law.

55. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
Infringement of U.S. Patent No. 11,192,895 by Teva

56. Plaintiffs repeat and reallege the preceding paragraphs above as if fully set forth herein.

57. By submitting the Teva ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Teva ANDA Product before the expiration of the '895 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

58. On information and belief, Teva seeks FDA approval for its ANDA Product for one or more claimed methods of treatment (e.g., claims 1-24 of the '895 patent), and discovery will show that if Teva commercially makes, uses, offers to sell, or sells the Teva ANDA Product within the United States, or imports the Teva ANDA Product into the United

States, or induces or contributes to any such conduct during the term of the '895 patent, it would further infringe one or more claims of the '895 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

59. Claim 1 of the '895 patent recites:

> A method for treating chronic phase chronic myeloid leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising at least one crystalline form of ponatinib hydrochloride characterized by:
>
> a) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 5.9, 7.1, 10.0, 12.5, 13.6, 14.1, 15.0, 16.4, 17.7, 18.6, 19.3, 20.4, 21.8, 22.3, 23.8, 24.9, 26.1, 27.0, 28.4, 30.3, 31.7, and 35.1;
>
> b) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 15.4, 16.2, 17.4, 18.0, 20.4, 23.2, 24.4, 26.1, and 26.9;
>
> c) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 17.4, 18.0, 20.6, 22.0, 23.0, 25.5, 26.5, 27.4, 28.4, and 29.0;
>
> d) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.2, 10.1, 10.9, 14.9, 16.0, 16.3, 16.8, 17.7, 18.7, 20.2, 22.9, 24.0, 25.6, 26.7, and 28.5;
>
> e) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl1 + HCl4 (GRP1.1);
>
> f) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 7.9, 8.7, 9.7, 11.4, 15.6, 16.5, and 25.8;
>
> g) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl5b (VDS28.2);
>
> h) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.0, 10.2, 10.9, 11.8, 14.1, 15.4, 16.3, 19.9, 22.3, 23.7, 25.0, and 28.2;
>
> i) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.0, 13.3, 16.4, 20.7, 22.2, 23.9, 25.5, and 29.1; or

j) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.4, 13.5, 17.4, 18.5, 20.7, 23.9, and 28.3.

60. Claim 7 of the '895 patent recites:

A method for treating accelerated phase chronic myeloid leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising at least one crystalline form of ponatinib hydrochloride characterized by:

a) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 5.9, 7.1, 10.0, 12.5, 13.6, 14.1, 15.0, 16.4, 17.7, 18.6, 19.3, 20.4, 21.8, 22.3, 23.8, 24.9, 26.1, 27.0, 28.4, 30.3, 31.7, and 35.1;

b) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 15.4, 16.2, 17.4, 18.0, 20.4, 23.2, 24.4, 26.1, and 26.9;

c) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 17.4, 18.0, 20.6, 22.0, 23.0, 25.5, 26.5, 27.4, 28.4, and 29.0;

d) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.2, 10.1, 10.9, 14.9, 16.0, 16.3, 16.8, 17.7, 18.7, 20.2, 22.9, 24.0, 25.6, 26.7, and 28.5

e) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl1 + HCl4 (GRP1.1);

f) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 7.9, 8.7, 9.7, 11.4, 15.6, 16.5, and 25.8;

g) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl5b (VDS28.2);

h) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.0, 10.2, 10.9, 11.8, 14.1, 15.4, 16.3, 19.9, 22.3, 23.7, 25.0, and 28.2;

i) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.0, 13.3, 16.4, 20.7, 22.2, 23.9, 25.5, and 29.1; or

j) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.4, 13.5, 17.4, 18.5, 20.7, 23.9, and 28.3.

61. Claim 13 of the ’895 patent recites:

A method of treating blast phase chronic myeloid leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising at least one crystalline form of ponatinib hydrochloride characterized by:

a) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 5.9, 7.1, 10.0, 12.5, 13.6, 14.1, 15.0, 16.4, 17.7, 18.6, 19.3, 20.4, 21.8, 22.3, 23.8, 24.9, 26.1, 27.0, 28.4, 30.3, 31.7, and 35.1;

b) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 15.4, 16.2, 17.4, 18.0, 20.4, 23.2, 24.4, 26.1, and 26.9;

c) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 17.4, 18.0, 20.6, 22.0, 23.0, 25.5, 26.5, 27.4, 28.4, and 29.0;

d) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.2, 10.1, 10.9, 14.9, 16.0, 16.3, 16.8, 17.7, 18.7, 20.2, 22.9, 24.0, 25.6, 26.7, and 28.5;

e) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl1 + HCl4 (GRP1.1);

f) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 7.9, 8.7, 9.7, 11.4, 15.6, 16.5, and 25.8;

g) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl5b (VDS28.2);

h) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.0, 10.2, 10.9, 11.8, 14.1, 15.4, 16.3, 19.9, 22.3, 23.7, 25.0, and 28.2;

i) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.0, 13.3, 16.4, 20.7, 22.2, 23.9, 25.5, and 29.1; or

j) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.4, 13.5, 17.4, 18.5, 20.7, 23.9, and 28.3.

62. Claim 19 of the ’895 patent recites:

A method of treating Philadelphia chromosome positive acute lymphoblastic leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising at least one crystalline form of ponatinib hydrochloride characterized by:

a) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 5.9, 7.1, 10.0, 12.5, 13.6, 14.1, 15.0, 16.4, 17.7, 18.6, 19.3, 20.4, 21.8, 22.3, 23.8, 24.9, 26.1, 27.0, 28.4, 30.3, 31.7, and 35.1;

b) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 15.4, 16.2, 17.4, 18.0, 20.4, 23.2, 24.4, 26.1, and 26.9;

c) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 3.1, 6.5, 12.4, 13.8, 17.4, 18.0, 20.6, 22.0, 23.0, 25.5, 26.5, 27.4, 28.4, and 29.0;

d) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.2, 10.1, 10.9, 14.9, 16.0, 16.3, 16.8, 17.7, 18.7, 20.2, 22.9, 24.0, 25.6, 26.7, and 28.5;

e) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl1 + HCl4 (GRP1.1);

f) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 7.9, 8.7, 9.7, 11.4, 15.6, 16.5, and 25.8;

g) an x-ray powder diffraction pattern substantially as shown in FIG. 41 labelled HCl5b (VDS28.2);

h) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 8.0, 10.2, 10.9, 11.8, 14.1, 15.4, 16.3, 19.9, 22.3, 23.7, 25.0, and 28.2;

i) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.0, 13.3, 16.4, 20.7, 22.2, 23.9, 25.5, and 29.1; or

> j) an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 6.1, 7.4, 13.5, 17.4, 18.5, 20.7, 23.9, and 28.3.

63. On information and belief, the Teva ANDA Product will infringe at least claims 1, 7, 13, and 19 of the '895 patent.

64. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will infringe one or more claims of the '895 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States.

65. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will induce infringement of one or more claims of the '895 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, upon FDA approval of the Teva ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '895 patent and knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will contributorily infringe one or more claims of the '895 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, Teva has had and continues to have knowledge that the Teva ANDA Product is especially adapted for a use that infringes one or more claims of the '895 patent and that there is no substantial non-infringing use for the Teva ANDA Product.

67. Teva has had knowledge of the claims of the '895 patent since at least the date it submitted the Teva ANDA.

68. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '895 patent. Plaintiffs do not have an adequate remedy at law.

69. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
Infringement of U.S. Patent No. 11,192,897 by Teva

70. Plaintiffs repeat and reallege the preceding paragraphs above as if fully set forth herein.

71. By submitting the Teva ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Teva ANDA Product before the expiration of the '897 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

72. On information and belief, the Teva ANDA Product is a pharmaceutical composition that includes one or more crystalline form(s) of ponatinib hydrochloride recited in one or more claims of the '897 patent (e.g., claims 1-14 of the '897 patent) and Teva seeks FDA approval for its ANDA Product for one or more claimed methods of treatment (e.g., claims 15-23 of the '897 patent), and discovery will show that if Teva commercially makes, uses, offers to sell, or sells the Teva ANDA Product within the United States, or imports the Teva ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '897 patent, it would further infringe one or more claims of the '897 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

73. Claim 1 of the '897 patent recites:

> A crystalline form of ponatinib hydrochloride characterized by an x-ray powder diffraction pattern comprising at least three 2θ values (±0.3) chosen from 5.9, 7.1, 10.0, 12.5, 13.6, 14.1, 15.0, 16.4, 17.7, 18.6, 19.3, 20.4, 21.8, 22.3, 23.8, 24.9, 26.1, 27.0, 28.4, 30.3, 31.7, and 35.1.

74. Claim 5 of the '897 patent recites:

A crystalline form of ponatinib hydrochloride, wherein the crystalline form

(a) does not change as measured by XRPD and undergoes no apparent degradation as measured by HPLC after exposure to 70 °C for up to 72 hours;
(b) does not change as measured by XRPD and undergoes no apparent degradation as measured by HPLC after exposure to 220 °C for 5 minutes;
(c) does not change as measured by XPRD and the DVS isotherm does not change after exposure to DVS cycling of 0-95-0% RH followed by 0-45% RH; and/or
(d) does not change as measured by XPRD and DSC after exposure to 75% RH for 6 days.

75. Claim 11 of the ’897 patent recites:

A crystalline form of ponatinib hydrochloride having an onset melting temperature of 262 °C to 264 °C.

76. Claim 13 of the ’897 patent recites:

A pharmaceutical composition comprising at least two crystalline forms of ponatinib hydrochloride and a pharmaceutically acceptable carrier.

77. Claim 15 of the ’897 patent recites:

A method for treating chronic myeloid leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of the crystalline form of ponatinib hydrochloride according to claim 1 or the pharmaceutical composition according to claim 13.

78. Claim 22 of the ’897 patent recites:

A method for treating Philadelphia chromosome positive acute lymphoblastic leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of the crystalline form of ponatinib hydrochloride according to claim 1 or the pharmaceutical composition according to claim 13.

79. On information and belief, the Teva ANDA Product will infringe at least claims 1, 5, 11, 13, 15, and 22 of the ’897 patent.

80. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will infringe one or more claims of the '897 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States.

81. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will induce infringement of one or more claims of the '897 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, upon FDA approval of the Teva ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '897 patent and knowledge that its acts are encouraging infringement.

82. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will contributorily infringe one or more claims of the '897 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, Teva has had and continues to have knowledge that the Teva ANDA Product is especially adapted for a use that infringes one or more claims of the '897 patent and that there is no substantial non-infringing use for the Teva ANDA Product.

83. Teva has had knowledge of the claims of the '897 patent since at least the date it submitted the Teva ANDA.

84. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '897 patent. Plaintiffs do not have an adequate remedy at law.

85. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
Infringement of U.S. Patent No. 11,384,086 by Teva

86. Plaintiffs repeat and reallege the preceding paragraphs above as if fully set forth herein.

87. By submitting the Teva ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Teva ANDA Product before the expiration of the '086 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

88. On information and belief, the Teva ANDA Product is a pharmaceutical composition that includes one or more crystalline form(s) of ponatinib hydrochloride recited in one or more claims of the '086 patent (e.g., claims 1-6 of the '086 patent) and Teva seeks FDA approval for its ANDA Product for one or more claimed methods of treatment (e.g., claims 7-19 of the '086 patent), and discovery will show that if Teva commercially makes, uses, offers to sell, or sells the Teva ANDA Product within the United States, or imports the Teva ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '086 patent, it would further infringe one or more claims of the '086 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

89. Claim 1 of the '086 patent recites:

> Crystalline anhydrous ponatinib hydrochloride, characterized by an X-ray diffraction pattern comprising 2θ values (±0.3) at 5.9, 7.1, 12.5, 19.3, 23.8 and 26.1.

90. Claim 7 of the '086 patent recites:

> A method for treating chronic myeloid leukemia in a subject in need thereof comprising administering to the subject a therapeutically effective amount of crystalline anhydrous ponatinib hydrochloride characterized by an X-ray diffraction pattern comprising 2θ values (±0.3) at 5.9, 7.1, 12.5, 19.3, 23.8 and 26.1 or a pharmaceutical composition comprising the crystalline anhydrous ponatinib hydrochloride and a pharmaceutically acceptable carrier.

91. On information and belief, the Teva ANDA Product will infringe at least claims 1 and 7 of the ’086 patent.

92. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will infringe one or more claims of the ’086 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States.

93. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will induce infringement of one or more claims of the ’086 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, upon FDA approval of the Teva ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the ’086 patent and knowledge that its acts are encouraging infringement.

94. Unless enjoined by this Court, upon FDA approval of the Teva ANDA, Teva will contributorily infringe one or more claims of the ’086 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling and/or importing the Teva ANDA Product in the United States. On information and belief, Teva has had and continues to have knowledge that the Teva ANDA Product is especially adapted for a use that infringes one or more claims of the ’086 patent and that there is no substantial non-infringing use for the Teva ANDA Product.

95. Teva has had knowledge of the ’086 patent since at least the date it submitted the Teva ANDA.

96. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the ’086 patent. Plaintiffs do not have an adequate remedy at law.

97. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Teva has infringed one or more claims of the ’470 patent by submitting ANDA No. 217825;

B. A Judgment that Teva has infringed, and that Teva’s making, using, selling, offering to sell, or importing the Teva ANDA Product would constitute infringement of one or more claims of the ’470 patent, and/or induce or contribute to infringement of one or more claims of the ’470 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

C. A preliminary and permanent injunction restraining and enjoining Teva, and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Teva ANDA Product until after the expiration of the ’470 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any compounds, crystalline forms of ponatinib hydrochloride, compositions, or methods as claimed in the ’470 patent, or from actively inducing or contributing to the infringement of any claim of the ’470 patent, until after the expiration of the ’470 patent, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

E. An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 217825 relating to the Teva ANDA Product be a date that is not earlier than the later of the expiration of the ’470 patent, or any later expiration to which Plaintiffs are or become entitled;

F. To the extent that Teva has committed any acts with respect to the compounds, crystalline forms of ponatinib hydrochloride, compositions, or methods claimed in the '470 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

G. If Teva engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Teva ANDA Products prior to the expiration of the '470 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

H. A Judgment declaring that the '470 patent remain valid;

I. A Judgment that Teva has infringed one or more claims of the '895 patent by submitting ANDA No. 217825;

J. A Judgment that Teva has infringed, and that Teva's making, using, selling, offering to sell, or importing the Teva ANDA Product would constitute infringement of one or more claims of the '895 patent, and/or induce or contribute to infringement of one or more claims of the '895 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

K. A preliminary and permanent injunction restraining and enjoining Teva, and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Teva ANDA Product until after the expiration of the '895 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

L. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity

and/or concert with them, from practicing methods as claimed in the ’895 patent, or from actively inducing or contributing to the infringement of any claim of the ’895 patent, until after the expiration of the ’895 patent, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

M. An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 217825 relating to the Teva ANDA Product be a date that is not earlier than the later of the expiration of the ’895 patent, or any later expiration to which Plaintiffs are or become entitled;

N. To the extent that Teva has committed any acts with respect to the methods claimed in the ’895 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

O. If Teva engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Teva ANDA Products prior to the expiration of the ’895 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

P. A Judgment declaring that the ’895 patent remain valid;

Q. A Judgment that Teva has infringed one or more claims of the ’897 patent by submitting ANDA No. 217825;

R. A Judgment that Teva has infringed, and that Teva’s making, using, selling, offering to sell, or importing the Teva ANDA Product would constitute infringement of one or more claims of the ’897 patent, and/or induce or contribute to infringement of one or more claims of the ’897 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

S. A preliminary and permanent injunction restraining and enjoining Teva, and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Teva ANDA Product until after the expiration of the ’897 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

T. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any crystalline forms of ponatinib hydrochloride, compositions, or methods as claimed in the ’897 patent, or from actively inducing or contributing to the infringement of any claim of the ’897 patent, until after the expiration of the ’897 patent, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

U. An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 217825 relating to the Teva ANDA Product be a date that is not earlier than the later of the expiration of the ’897 patent, or any later expiration to which Plaintiffs are or become entitled;

V. To the extent that Teva has committed any acts with respect to the crystalline forms of ponatinib hydrochloride, compositions, or methods claimed in the ’897 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

W. If Teva engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Teva ANDA Products prior to the expiration of

the ’897 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

X. A Judgment declaring that the ’897 patent remain valid;

Y. A Judgment that Teva has infringed one or more claims of the ’086 patent by submitting ANDA No. 217825;

Z. A Judgment that Teva has infringed, and that Teva’s making, using, selling, offering to sell, or importing the Teva ANDA Product would constitute infringement of one or more claims of the ’086 patent, and/or induce or contribute to infringement of one or more claims of the ’086 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

AA. A preliminary and permanent injunction restraining and enjoining Teva, and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Teva ANDA Product until after the expiration of the ’086 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

BB. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any crystalline forms of ponatinib hydrochloride, or methods as claimed in the ’086 patent, or from actively inducing or contributing to the infringement of any claim of the ’086 patent, until after the expiration of the ’086 patent, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

CC. An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 217825 relating to the Teva ANDA Product be a date that is not

earlier than the later of the expiration of the ’086 patent, or any later expiration to which Plaintiffs are or become entitled;

DD. To the extent that Teva has committed any acts with respect to the crystalline forms of ponatinib hydrochloride, or methods claimed in the ’086 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

EE. If Teva engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Teva ANDA Products prior to the expiration of the ’086 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

FF. A Judgment declaring that the ’086 patent remains valid;

GG. A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs its attorneys’ fees incurred in this action;

HH. A Judgment awarding Plaintiffs its costs and expenses incurred in this action; and

II. Such other and further relief as the Court may deem just and proper.

Dated: December 21, 2022

By: s/ Charles H. Chevalier

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I, Charles H. Chevalier, hereby certify that the matter in controversy is a related case to a separate matter pending in the United States District Court for the District of New Jersey, namely *Takeda Pharmaceuticals America, Inc. v. Apotex, Inc.*, Case No. 2:21-cv-12998 (KM)(AME).

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: December 21, 2022

By: s/ Charles H. Chevalier

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