IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SHILPA MEDICARE LIMITED and MAIA PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genentech, Inc. ("Genentech") and InterMune, Inc. ("InterMune") (Genentech and InterMune, collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants, Shilpa Medicare Limited and Maia Pharmaceuticals, Inc. (collectively, "Shilpa" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, concerning Defendants' submission of Abbreviated New Drug Application No. 212606, which seeks approval from the U.S. Food and Drug Administration ("FDA") to market a generic copy of Plaintiffs' drug Esbriet® (pirfenidone) 267 and 801 mg tablets, in violation of Plaintiffs' exclusive rights held under numerous patents that Plaintiffs have listed with the FDA for Esbriet®.

2. Plaintiffs seek a judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A), and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4), including, but not limited to, the specific remedy provided in 35 U.S.C. § 271(e)(4)(A), which

provides that the Court "shall order the effective date of any approval of the drug … involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

PARTIES

3. Plaintiff Genentech is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, CA 94080. Genentech develops and commercializes pharmaceutical products throughout the United States, including within this judicial district, on its own behalf and on behalf of its affiliates within the Roche group of companies, including InterMune. Genentech holds New Drug Applications ("NDAs") in the United States for (i) Esbriet® capsules, 267 mg and (ii) Esbriet® tablets, 267, 534, and 801 mg. Genentech is also exclusively licensed by InterMune under the below-listed Asserted Patents, which cover Esbriet® FDA-approved formulations and its FDA-approved uses for safely and effectively treating Idiopathic Pulmonary Fibrosis.

4. Plaintiff InterMune is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, CA 94080. InterMune owns the United States patents that have been listed with the FDA in connection with the NDAs held by Genentech for Esbriet®, including, but not limited to, all the Asserted Patents listed below.

5. On information and belief, Defendant Shilpa Medicare Limited ("Shilpa Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at 12-6-214/A-1 Hyderabad Road, Raichur – 584 135, Karnataka, India.

6. On information and belief, Shilpa Ltd. controls and directs a joint venture in the United States named Maia Pharmaceuticals, Inc. ("Maia"). Maia is a Delaware corporation having a principal place of business at 707 State Rd #104, Princeton, New Jersey 08540.

7. On information and belief, Shilpa Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and joint ventures, including Maia, from which Shilpa Ltd. derives a substantial portion of its revenue.

8. On information and belief, Shilpa Ltd. acted in concert with Maia to prepare and submit ANDA No. 212606 (the "Shilpa ANDA") for Shilpa Ltd.'s 267 and 801 mg pirfenidone tablets (the "Shilpa ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Shilpa Ltd. Following FDA approval of the Shilpa ANDA, Shilpa Ltd. will manufacture and supply the approved generic product to Maia, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Shilpa Ltd.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 101, *et seq.,* seeking a finding and declaratory judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A) and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4). Jurisdiction exists under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

10. Venue is proper in this Court because, among other things, Maia is incorporated in the State of Delaware and therefore "resides" in this judicial district. 28 U.S.C. § 1400(b). Shilpa Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

PERSONAL JURISDICTION OVER SHILPA LTD.

11. Plaintiffs reallege paragraphs 1-10 as if fully set forth herein.

12. On information and belief, Shilpa Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

13. This Court has personal jurisdiction over Shilpa Ltd. because, *inter alia*, Shilpa Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its joint ventures or agents; (2) intends to market, sell, and/or distribute the Shilpa ANDA Products to residents of this State upon approval of ANDA No. 212606, either directly or through at least one of its joint ventures or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Maia, which is a Delaware corporation; and (4) controls and directs Maia, which is a Delaware corporation.

14. Alternatively, to the extent the above facts do not establish personal jurisdiction over Shilpa Ltd., this Court may exercise jurisdiction over Shilpa Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Shilpa Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Shilpa Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products through its U.S.

subsidiaries that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Shilpa Ltd. satisfies due process.

PERSONAL JURISDICTION OVER MAIA

15. Plaintiffs reallege paragraphs 1-14 as if fully set forth herein.

16. On information and belief, Maia develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

17. This Court has personal jurisdiction over Maia because, *inter alia*, Maia, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute the Shilpa ANDA Products to residents of this State; (3) is controlled by Defendant Shilpa Ltd.; (4) makes its generic drug products available in this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

BACKGROUND FACTS

18. Esbriet®, which contains pirfenidone as its active ingredient, is a drug used for treating patients afflicted with a rare, fatal lung disease called Idiopathic Pulmonary Fibrosis ("IPF").

19. IPF results in scarring of the lungs, which makes breathing difficult and prevents the heart, muscles, and vital organs from receiving enough oxygen to work properly. The disease can advance quickly or slowly, but eventually the lungs will harden and stop working altogether. The prognosis for IPF patients is extremely poor, with patients experiencing significant progressive worsening of disease, and median survival of 2-5 years after diagnosis. IPF is irreversible and fatal. The cause is unknown, and there is no cure.

20. Prior to Esbriet®, no drug had been approved in the United States as safe and effective for treating IPF. Approval in the United States came only after extensive clinical

research by Plaintiff InterMune, which demonstrated that Esbriet® slows progression of the disease. The FDA's approval of Esbriet® would not have been possible without the twelve years of effort by InterMune, a biopharmaceutical company that dedicated itself to developing medicines for treating IPF.

21. The FDA approved the first NDA for Esbriet® on October 15, 2014, shortly after Plaintiff InterMune was acquired by Plaintiff Genentech. This approval did not come easily. The FDA initially denied approval in 2010 following many years of research & development and multiple clinical trials. This necessitated further large-scale clinical trials and resubmission of the NDA in 2014. The clinical experimentation spanned over a decade and these combined results ultimately convinced the FDA that Esbriet® could be used safely and effectively to treat IPF patients.

22. When it first approved Esbriet®, the FDA accorded it status as a Breakthrough Therapy, and awarded Esbriet® Orphan Drug Exclusivity for treating IPF, which runs until October 15, 2021.

23. Shilpa now seeks to piggy-back on Plaintiffs' hard work by seeking FDA approval of the Shilpa ANDA that cross-references and relies upon Plaintiffs' clinical trial data. In so doing, Shilpa has not conducted any of the clinical trials needed to demonstrate effectiveness and safe conditions of use for its proposed Shilpa ANDA Product. Rather, Shilpa asks that the FDA permit the Shilpa ANDA to rely on proprietary clinical data submitted by Plaintiffs InterMune and Genentech.

24. This action arose when Shilpa sent a letter notifying Plaintiffs that (i) it had filed the Shilpa ANDA seeking to rely on Plaintiffs' safety and efficacy data without consent, and (ii)

it is seeking FDA approval to commercially launch the Shilpa ANDA Product before Plaintiffs' exclusive patent rights to Esbriet® have expired.

THE ASSERTED PATENTS

- U.S. Patent No. 8,383,150

25. U.S. Patent No. 8,383,150 ("the '150 patent"), entitled "Granulate Formulation of Pirfenidone and Pharmaceutically Acceptable Excipients," was duly and legally issued by the Patent Office on February 26, 2013, and has not expired.

26. Plaintiffs have maintained the entire right, title, and interest in the '150 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '150 patent is attached as Exhibit 1.

- U.S. Patent No. 8,778,947

27. U.S. Patent No. 8,778,947 ("the '947 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on July 15, 2014, and has not expired.

28. Plaintiffs have maintained the entire right, title, and interest in the '947 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '947 patent is attached as Exhibit 2.

29. The '150 and '947 patents are referred to collectively herein as the "Asserted Patents."

ACTS GIVING RISE TO THIS ACTION

30. Plaintiff Genentech is the holder of NDA No. 208780 (the "Genentech NDA") by which the FDA granted approval for 267, 534, and 801 mg pirfenidone tablets for treating IPF.

Genentech holds the exclusive right to market these tablets in the United States under the trademark Esbriet®.

31. Esbriet® tablets and the use of Esbriet® tablets in accordance with its FDA-approved label are covered by one or more claims of the Asserted Patents.

32. The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Asserted Patents in connection with Esbriet® tablets.

33. By letter dated December 10, 2018 (the "Notice Letter") Shilpa notified Plaintiffs that it had submitted the Shilpa ANDA to the FDA, seeking approval for commercial manufacture, use, and sale of the Shilpa ANDA Product in the United States prior to the expiration of the Asserted Patents.

34. In the Notice Letter, Shilpa notified Plaintiffs that, as a part of its ANDA, it had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents (the "Paragraph IV Certification"), that those patents are allegedly invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Shilpa ANDA Product in the United States.

35. By filing the Shilpa ANDA, Shilpa has necessarily represented to the FDA that the Shilpa ANDA Product will have the same pirfenidone active ingredient, route of administration, dosage form, and dosage strengths as Plaintiffs' FDA-approved Esbriet® tablets, and will be bioequivalent.

36. Shilpa's Notice Letter contained an offer of confidential access ("OCA"), the terms of which the parties attempted to negotiate in good faith in an effort to reach a mutually acceptable agreement, and under which the Shilpa ANDA would be provided to Plaintiffs. The parties were not able to reach an agreement on the OCA terms because Shilpa's proposed OCA

contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the proposed Shilpa OCA contained a broad patent prosecution and regulatory work bar (including both a patent-related bar and an FDA bar) which, among other things, does not have a carve-out for inter partes reviews or other adversarial proceedings. The restrictions Shilpa placed on access to ANDA No. 212606 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, **as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information**" (emphasis added). Plaintiffs have not been able to evaluate the Shilpa ANDA. Plaintiffs require discovery from Shilpa in this action.

37. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letter.

COUNT I

INFRINGEMENT OF THE '150 PATENT

38. Plaintiffs reallege paragraphs 1 to 37 as if fully set forth herein.

39. Defendants' submission of the Shilpa ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Shilpa ANDA Product in the United States prior to the expiration of the '150 patent infringed at least one of the claims of the '150 patent, including but not limited to claims 1 and 27, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

40. Defendants' manufacture, use, offer to sell, or sale of the Shilpa ANDA Product in the United States or importation of the Shilpa ANDA Product into the United States during the

term of the '150 patent would further infringe at least one claim of the '150 patent, including but not limited to claims 1 and 27, under 35 U.S.C. §§ 271 (a), (b), and/or (c), either literally or under the doctrine of equivalents because, *inter alia*, the Shilpa ANDA Product contains the same components recited in claim 1 and use of the Shilpa ANDA product in accordance with its associated labeling would infringe at least claim 27.

41. On information and belief, the Shilpa ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '150 patent either literally or under the doctrine of equivalents.

42. On information and belief, the use of the Shilpa ANDA Product constitutes a material part of at least one of the claims of the '150 patent; Defendants know that the Shilpa ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents; and the Shilpa ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

43. On information and belief, the offering to sell, sale, and/or importation of the Shilpa ANDA Product would contributorily infringe at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents.

44. On information and belief, Shilpa had knowledge of the '150 patent and, by its promotional activities and package inserts for the Shilpa ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '150 patent.

45. On information and belief, the offering to sell, sale, and/or importation of the Shilpa ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents.

46. If Defendants' marketing and sale of the Shilpa ANDA Product prior to expiration of the '150 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

INFRINGEMENT OF THE '947 PATENT

47. Plaintiffs reallege paragraphs 1 to 46 as if fully set forth herein.

48. Shilpa's Notice Letter regarding its Paragraph IV Certification does not deny that the Shilpa ANDA Product will infringe claims 1-3 and 5-18 of the '947 patent.

49. On information and belief, Shilpa does not deny that the Shilpa ANDA Product will infringe at least certain claims of the '947 patent.

50. Defendants' submission of the Shilpa ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Shilpa ANDA Product in the United States prior to the expiration of the '947 patent infringed at least one of the claims of the '947 patent, including but not limited to claims 1-3 and 5-18, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

51. Defendants' manufacture, use, offer to sell, or sale of the Shilpa ANDA Product in the United States or importation of the Shilpa ANDA Product into the United States during the term of the '947 patent would further infringe at least one claim of the '947 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

52. On information and belief, the Shilpa ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '947 patent either literally or under the doctrine of equivalents.

53. On information and belief, the use of the Shilpa ANDA Product constitutes a material part of at least one of the claims of the '947 patent; Defendants know that the Shilpa ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents; and the Shilpa ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

54. On information and belief, the offering to sell, sale, and/or importation of the Shilpa ANDA Product would contributorily infringe at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents.

55. On information and belief, Shilpa had knowledge of the '947 patent and, by its promotional activities and package inserts for the Shilpa ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '947 patent.

56. On information and belief, the offering to sell, sale, and/or importation of the Shilpa ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents.

57. If Defendants' marketing and sale of the Shilpa ANDA Product prior to expiration of the '947 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

* * *

58. Defendants' activities, as alleged herein, were undertaken with knowledge of the Asserted Patents and without a good faith belief that they are not infringing those patents. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the Asserted Patents were infringed by Defendants' submission of the Shilpa ANDA, either literally or under the doctrine of equivalents, and are not invalid or unenforceable, and that Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States the Shilpa ANDA Product will infringe the claims of the Asserted Patents, either literally or under the doctrine of equivalents.

2. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Shilpa ANDA shall be a date which is not earlier than the latest expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An Order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Shilpa ANDA Product until after the latest expiration date of the Asserted

Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Shilpa ANDA Product prior to the latest expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

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

MORRIS NICHOLS ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Karen Jacobs (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Attorneys for Plaintiffs Genentech, Inc. and InterMune, Inc.

OF COUNSEL:

Mark E. Waddell
Warren K. MacRae
Ryan Hagglund
LOEB & LOEB LLP
345 Park Avenue
New York, NY 10154
(212) 407-4000

January 23, 2019