IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSI PHARMACEUTICALS, LLC and GENENTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SHILPA MEDICARE LIMITED,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs OSI Pharmaceuticals, LLC ("OSI") and Genentech, Inc. ("Genentech") (OSI and Genentech, collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Shilpa Medicare Limited ("Shilpa"). This action relates to Abbreviated New Drug Application ("ANDA") No. 211960 filed by Shilpa with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 211960, Shilpa seeks approval to market 25 mg, 100 mg, and 150 mg tablets of erlotinib hydrochloride, generic versions of Plaintiffs' Tarceva® drug product (the "Shilpa ANDA product"), prior to expiration of U.S. Patent No. 6,900,221 (the "'221 patent" or "patent-in-suit").

PARTIES

3. OSI is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062.

4. 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.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for non-small cell lung cancer ("NSCLC"). Plaintiffs sell Tarceva in this judicial district and throughout the United States.

6. Upon information and belief, Shilpa is a corporation organized and existing under the laws of India, with a principal place of business at 12-6-214/A1 Hyderabad Road, Raichur – 584 135, Karnataka, India.

JURISDICTION AND VENUE

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

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), and this Court has personal jurisdiction over Shilpa. Shilpa, through its counsel, by e-mail dated June 21, 2018, agreed that it does not contest jurisdiction or venue in this Court in this matter.

PATENT-IN-SUIT

9. On May 31, 2005, the U.S. Patent and Trademark Office duly and legally issued the '221 patent, titled "Stable polymorph on N-(3-ethynylphenyl)-6, 7-bis (2methoxyethoxy)-4-quinazolinamine hydrochloride, methods of production, and pharmaceutical uses thereof." A true and correct copy of the '221 patent is attached hereto as Exhibit A. The claims of the '221 patent are valid, enforceable, and not expired. OSI is the owner of the '221 patent and Genentech is a co-exclusive licensee of the '221 patent.

10. On January 8, 2018, the U.S. Patent Trial and Appeal Board ("the Board") issued a Final Written Decision finding claims 44-46 and 53 of the '221 patent unpatentable under a preponderance of the evidence standard. On May 4, 2018, OSI filed a timely notice of appeal to the Court of Appeals for the Federal Circuit (No. 18-1925) challenging the Board's patentability determination. OSI's appeal remains pending.

11. OSI is the holder of New Drug Application ("NDA") No. 021743, by which the FDA granted approval for the marketing and sale of 25 mg, 100 mg, and 150 mg strength erlotinib hydrochloride tablets. Plaintiffs market erlotinib hydrochloride tablets in the United States, under the trade name "Tarceva®." The FDA's official publication of approved drugs (the "Orange Book") includes Tarceva together with the patent-in-suit. Tarceva is a kinase inhibitor indicated for: (1) the treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen, and (2) first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. A copy of the complete prescribing information for Tarceva approved in NDA No. 021743 is attached as Exhibit B.

INFRINGEMENT BY SHILPA

12. By letter dated June 13, 2018, Shilpa notified Plaintiffs that Shilpa had submitted ANDA No. 211960 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Tarceva Notice Letter"). Plaintiffs received the Tarceva Notice Letter no earlier than June 14, 2018.

13. The Tarceva Notice Letter states that Shilpa has submitted an ANDA under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, importation, offer for sale, or

sale of the Shilpa ANDA product before the expiration of the patent-in-suit. Upon information and belief, Shilpa intends to—directly or indirectly—engage in the commercial manufacture, use, and sale of the Shilpa ANDA product.

14. By filing ANDA No. 211960, Shilpa has necessarily represented to the FDA that the Shilpa ANDA product has the same active ingredient as Tarceva, has the same dosage form and strength as Tarceva, and is bioequivalent to Tarceva.

15. Upon information and belief, Shilpa is seeking approval to market the Shilpa ANDA product for the same approved indications as Tarceva.

16. In the Tarceva Notice Letter, Shilpa states that the patent-in-suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Shilpa ANDA product.

17. In the Tarceva Notice Letter, Shilpa offered confidential access to portions of its ANDA No. 211960 on terms and conditions set forth in the Tarceva Notice Letter ("the Shilpa Offer"). Shilpa requested that Plaintiffs accept the Shilpa Offer before receiving access to Shilpa's ANDA No. 211960. The Shilpa Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Shilpa Offer contained a broad patent prosecution and regulatory work bar, which, among other things, does not have a carve-out for *inter partes* reviews or other adversarial proceedings. The Shilpa Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside scientific consultants without written permission from Shilpa's designated counsel; and Shilpa had broad authority to reject any request by Plaintiffs to seek outside expert access to the Shilpa ANDA. The restrictions Shilpa has placed on access to ANDA No. 211960 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).

18. The Complaint was filed before the expiration of forty-five days from the date Plaintiffs received the Tarceva Notice Letter, which triggered a stay of FDA approval of Shilpa's ANDA No. 211960, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), for 30 months from the date of the receipt of the notice letter on June 14, 2018.

COUNT I

(INFRINGEMENT OF THE '221 PATENT)

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth herein.

20. Shilpa's submission of ANDA No. 211960 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Shilpa ANDA product prior to the expiration of the '221 patent constituted a technical act of infringement of at least one of the claims of the '221 patent, either literally or under the doctrine of equivalents, including but not limited to claims 44-46 and 53, under 35 U.S.C. § 271(e)(2)(A).

21. Shilpa's commercial manufacture, use, offer to sell, sale, or importation of the Shilpa ANDA product prior to the expiration of the '221 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '221 patent, either literally or under the doctrine of equivalents, including but not limited to claims 44-46 and 53, under 35 U.S.C. §§ 271(a), (b) and/or (c).

22. Upon FDA approval of Shilpa's ANDA No. 211960, Shilpa will infringe one or more claims of the '221 patent, either literally or under the doctrine of equivalents, including but not limited to claims 44-46 and 53, by making, using, offering to sell, and selling the Shilpa ANDA product in the United States and/or importing said product into the United States, and/or by

actively inducing and contributing to infringement of the '221 patent by others, under 35 U.S.C. § 271(a), (b) and/or (c), unless enjoined by the Court.

23. If Shilpa's marketing and sale of the Shilpa ANDA product prior to expiration of the '221 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

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

1. A judgment that the claims of the patent-in-suit are not invalid, are not unenforceable, and are infringed by Shilpa's submission of ANDA No. 211960, either literally or under the doctrine of equivalents, and that Shilpa's 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 patent-in-suit, 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 ANDA No. 211960 shall be a date which is not earlier than the latest expiration date of the patent-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Shilpa, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Shilpa ANDA product until after the latest expiration date of the patent-in-suit, 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 Shilpa engages 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 patent-in-suit, 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

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