UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, Plaintiff, v. MYLAN PHARMACEUTICALS INC. and JAI PHARMA LIMITED, Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC, by its undersigned attorneys, brings this action against Defendants Mylan Pharmaceuticals Inc. ("Mylan Pharma") and Jai Pharma Limited ("Jai Pharma") (collectively "Mylan" or "Defendants"), and hereby alleges as follows:

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott") is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico. Warner Chilcott maintains its United States corporate office in the State of New Jersey at 100 Enterprise Drive, Rockaway, New Jersey 07866.

2. Upon information and belief, Defendant Mylan Pharma is a corporation organized and existing under the laws of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharma is a wholly-owned subsidiary of Mylan Inc. and is primarily responsible for marketing, distributing, and selling Mylan Inc.'s products in the United States, including in this judicial district. Upon

information and belief, Mylan Pharma filed as the registered U.S. agent for Jai Pharma's Abbreviated New Drug Application ("ANDA") No. 206120. Mylan Pharma and Jai Pharma's Paragraph IV notice letter to Warner Chilcott, in fact, states that Mylan Pharma is "the U.S. Agent for Jai Pharma Limited" for ANDA No. 206120.

3. Upon information and belief, Mylan Pharma is in the business of developing, manufacturing, marketing, distributing, and/or directly or indirectly selling generic pharmaceutical products throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Jai Pharma is a corporation organized and existing under the laws of India, having a principal place of business at Brady House, 3rd Floor, 12114, Veer Nariman Road, Fort, Mumbai - 400 001. Maharashtra, India. Upon information and belief, Jai Pharma is a wholly-owned subsidiary of Mylan N.V., of which Mylan Inc. is a wholly-owned subsidiary, of which Mylan Pharma is a wholly-owned subsidiary.

5. Upon information and belief, Jai Pharma is in the business of developing, manufacturing, marketing, distributing, and/or directly or indirectly selling generic pharmaceutical products throughout the

United States, including in this judicial district, via its agents and affiliate Mylan Pharma.

JURISDICTION AND VENUE

6. Warner Chilcott re-alleges and incorporates paragraphs 1–5.

7. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355. This Court has subject matter jurisdiction over this action based on 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendants because, among other things, they have maintained continuous and systematic contacts with the State of New Jersey and this judicial district.

9. On information and belief, Defendants have collaborated to develop, market, and sell generic pharmaceutical products, pursuant to the ANDA process, throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. Defendants derive substantial

revenue from goods used or consumed or services rendered in this judicial district.

10. This Court has personal jurisdiction over Mylan Pharma, at least, because it has purposefully availed itself of the rights and benefits of New Jersey law, has substantial, continuous, and systematic contacts with the State of New Jersey, and is essentially at home in New Jersey, and also because, through such contacts, it has consented to jurisdiction in this District. Upon information and belief, Mylan Pharma:

- is registered with the State of New Jersey Division of Revenue and Enterprise Services and maintains a Business Registration Certificate under entity identification No. 0100214277;
- has appointed The Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey, 08628, as its registered agent for service of process in New Jersey;
- is registered with the New Jersey Department of Health Food and Drug Safety Program as a manufacturer and wholesale drug establishment and maintains a Drug and Medical Device Certificate of Registration under the trade name Mylan

Pharmaceuticals Inc. and parent company name Mylan Inc. under Registration No. 5003762;

- has registered prescription drug products in the New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services;
- performed the acts complained of here at the direction, authorization, or cooperation, participation, or assistance of Jai Pharma, and were done, at least in part, to directly benefit Jai Pharma;
- is affiliated with, controls or is controlled by, at least, seven other corporations registered with the State of New Jersey Division of Revenue and Enterprise Services, including: (1) Mylan Inc. (Registration No. 0100971292); (2) Mylan Bertek Pharmaceuticals Inc. (Registration No. 100203569); (3) Mylan Institutional Inc. (Registration No. 100616877); (4) Mylan Pharmaceuticals Inc. (Registration No. 100214277); (5) Mylan Specialty L.P. (Registration No. 600349249); (6) Mylan Technologies, Inc. (Registration No. 100545825); and (7) Agila Specialties Inc. (Registration No. 100791546);

- intentionally markets and provides its generic pharmaceutical products to residents of the State of New Jersey;
- maintains a broad sales, marketing, and/or distribution network in the State of New Jersey;
- enjoys substantial income from the State of New Jersey;
- intends to manufacture, market, sell, or distribute to residents of New Jersey — either directly or via one of its subsidiaries, agents, or affiliates — Mylan's ANDA Product (defined below);
- is the U.S. registered agent for Jai Pharma with respect to Defendants' ANDA No. 206120;
- has, within the past two years, advertised and sought employees in New Jersey; and
- has initiated lawsuits in this judicial district and routinely consents to this Court's jurisdiction and avails itself of the protections afforded by this Court by asserting counterclaims against plaintiffs in this judicial district, including in an action for infringement of an oral contraceptive product filed by Warner Chilcott. *See* Answer, Defenses, and Counterclaims of Mylan Inc. and Mylan Pharmaceuticals Inc. to Plaintiff's

Complaint for Patent Infringement, *Warner Chilcott Company, LLC v. Mylan Inc.*, No. 13-cv-6560 (D.N.J. May 20, 2014) (ECF No. 19); *see also, e.g.*, *Mylan Inc. and Mylan Pharmaceuticals Inc. v. Apotex Inc. and Apotex Corp.*, No. 14-cv-4560 (D.N.J. July 18, 2014); *Mylan Pharmaceuticals Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014); Defendants Mylan Pharmaceuticals Inc.'s and Mylan Inc.'s Answer and Counterclaims, *Aptalis Pharma US Inc. v. Mylan Pharmaceuticals Inc.*, No. 13-cv-4158 (D.N.J. Aug. 23, 2013) (ECF No. 11).

In addition, this Court has previously expressly found that Mylan Pharma is subject to personal jurisdiction in this judicial district. *See* Memorandum Op. at 2, *Boehringer Ingelheim Pharma GMBH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-cv-7811 (July 16, 2015) (ECF No. 76); *Otsuka Pharm. Co., Ltd. v. Mylan Inc.*, No. 14-cv-4508, 2015 WL 1305764 (D.N.J. Mar. 23, 2015).

11. In addition, this Court also has specific personal jurisdiction over Mylan Pharma under traditional notions of fair play and substantial justice by virtue of the fact that, as noted below, on or about

September 23, 2015, Jai Pharma and Mylan Pharma sent a Paragraph IV notice letter to Warner Chilcott's United States corporate office in New Jersey alleging that Warner Chilcott's U.S. Patent No. 6,667,050 (the "'050 Patent") is invalid and/or not infringed, and informing Warner Chilcott that Mylan Pharma and Jai Pharma seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to Minastrin® 24 Fe, which is covered by the '050 Patent, prior to the expiration of the '050 Patent. By doing so, Mylan Pharma — alone and in coordination with Jai Pharma, for whom Mylan Pharma is the registered U.S. agent with respect to ANDA No. 206120 — purposefully directed activities to New Jersey, giving rise to a tortious act of patent infringement that results from, and relates to, Mylan Pharma's contact with Warner Chilcott in New Jersey. Upon information and belief, Jai Pharma and Mylan Pharma's contacts with Warner Chilcott in New Jersey was in furtherance of and directly related to their ongoing substantial conduct of business in New Jersey and plans to expand that business via the distribution, marketing, and sale of Mylan's ANDA Product (defined below). In addition, because Mylan Pharma is the registered U.S. agent for Jai Pharma with respect

to ANDA No. 206120 and because the acts of Jai Pharma were done at the direction of, or in coordination with, Mylan Pharma or for the direct benefit of Mylan Pharma, the acts of Jai Pharma should be imputed to Mylan Pharma for purposes of personal jurisdiction, and vice versa.

12. This Court has personal jurisdiction over Jai Pharma, at least, because it has purposefully availed itself of the rights and benefits of New Jersey law, has substantial, continuous, and systematic contacts with the State of New Jersey, and is essentially at home in New Jersey. Upon information and belief, Jai Pharma:

- acted in concert with, or at the direction of, Mylan Pharma in connection with Mylan Pharma — as Jai Pharma's registered U.S. agent — in submitting ANDA No. 206120 for generic contraceptive products and to market, sell, or supply those products to customers in the United States, including in this judicial district;
- intends to manufacture, market, sell, or distribute to residents of New Jersey — either directly or via one of its agents or affiliates, such as Mylan Pharma — Mylan's ANDA Product (defined below);

- has or intends to make its generic drug products available in the State of New Jersey;
- has or intends to derive substantial profit from the sale or distribution of its generic pharmaceutical products in the State of New Jersey;
- has been sold to, or is in currently in the process of being sold to, Mylan N.V., of which Mylan Inc. is a wholly-owned subsidiary, which in turn is the parent of Mylan Pharma;
- performed the acts complained of here at the direction, authorization, or cooperation, participation, or assistance of Mylan Pharma, and were done, at least in part, to directly benefit Mylan Pharma; and
- identified Mylan Pharma as it registered U.S. agent with respect to ANDA No. 206120, and so the contacts of Mylan Pharma should be imputed to Jai Pharma for purposes of personal jurisdiction, and vice versa.

13. In addition, this Court also has specific personal jurisdiction over Jai Pharma under traditional notions of fair play and substantial justice by virtue of the fact that on or about September 23, 2015, Jai

Pharma sent a Paragraph IV notice letter to Warner Chilcott's United States corporate office in New Jersey alleging that Warner Chilcott's '050 Patent is invalid and/or not infringed, and informing Warner Chilcott that Jai Pharma seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to Minastrin® 24 Fe, which is covered by the '050 Patent, prior to the expiration of the '050 Patent. By doing so, Jai Pharma — alone and in coordination with, or under the direction of, Mylan Pharma, its registered U.S. agent with respect to ANDA No. 206120 — purposefully directed activities to New Jersey, giving rise to a tortious act of patent infringement that results from, and relates to, Jai Pharma's contact with Warner Chilcott in New Jersey. Upon information and belief, Jai Pharma and Mylan Pharma's contacts with Warner Chilcott in New Jersey was in furtherance of and directly related to their ongoing substantial conduct of business in New Jersey and plans to expand that business via the distribution, marketing, and sale of Mylan's ANDA Product (defined below). In addition, because Mylan Pharma is the registered U.S. agent for Jai Pharma with respect to ANDA No. 206120, the acts of Mylan Pharma

(and its consent to jurisdiction) should be imputed to Jai Pharma for purposes of personal jurisdiction, and vice versa.

14. Consistent with due process, if the above facts do not establish this Court's personal jurisdiction over Jai Pharma, this Court has jurisdiction over Jai Pharma under Federal Rule of Civil Procedure 4(k)(2), at least, because:

(a) Warner Chilcott's claims arise under federal law;

(b) Jai Pharma would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and

(c) Jai Pharma has sufficient contacts with the United States as a whole, including, at least, by filing ANDA 206120 via its registered U.S. agent Mylan Pharma, with the intent to manufacture, distribute, or sell generic pharmaceuticals throughout the United States, including in this judicial district.

15. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I: CLAIM FOR INFRINGEMENT OF THE '050 PATENT

Regulatory Requirements for New and Generic Drugs

16. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

17. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by submitting an Abbreviated New Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

18. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

19. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C.§ 355(j)(2)(A)(i).

The Approved Drug Product

20. Warner Chilcott is the holder of NDA No. 203667 for Minastrin® 24 Fe, which contains the active ingredients ethinyl estradiol and norethindrone acetate. Minastrin® 24 Fe was approved by the FDA on May 8, 2013, and is indicated for use by women to prevent pregnancy. Minastrin® 24 Fe is sold as a 28-day oral contraceptive regimen that includes 24 chewable tablets comprising 1.0 mg norethindrone acetate and 0.020 mg ethinyl estradiol, and 4 chewable ferrous fumarate tablets (placebo).

21. The FDA has listed the '050 Patent in the Orange Book—formally known as *Approved Drug Products with Therapeutic Equivalence Evaluations*—in connection with NDA No. 203667.

22. Warner Chilcott is the sole owner of the '050 Patent.

ANDA No. 206120

23. Upon information and belief, Jai Pharma and Mylan Pharma, as U.S. agent for Jai Pharma, submitted ANDA No. 206120 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Minastrin® 24 Fe before the expiration of the '050 Patent ("Mylan's ANDA Product"). Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of such product would infringe the claims of the '050 Patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

24. On information and belief, Defendants acted in concert to develop, prepare, and file ANDA No. 206120, and to seek regulatory approval from the FDA to market and sell Mylan's ANDA Product throughout the United States, including within this judicial district.

25. As part of its ANDA submission, Defendants purportedly provided written certification ("Paragraph IV certification") to the FDA that the claims of the '050 Patent are invalid or will not be infringed by the manufacture, use, or sale of Mylan's ANDA Product.

26. By letter dated September 23, 2015, Defendants gave written notice of the certification of invalidity and non-infringement of the '050 Patent, alleging that all of the claims of the '050 Patent are invalid, and that claims 19–60 are not infringed by Mylan's ANDA Product. The letter also informed Warner Chilcott that Defendants intend to engage in the commercial manufacture, use, and sale of a product bioequivalent to Minastrin® 24 Fe before the '050 Patent expires.

Patent Infringement of the '050 Patent

27. Warner Chilcott incorporates by reference the allegations contained in paragraphs 1 through 26 above.

28. The '050 Patent, entitled "Chewable Oral Contraceptive," was lawfully issued by the United States Patent and Trademark Office on December 23, 2003. A copy of the '050 Patent is attached as Exhibit A.

29. The '050 Patent claims, among other things, chewable, palatable oral contraceptive tablets; methods of administering said tablets to a human female; and methods of enhancing compliance with the oral contraception regimen. Minastrin® 24 Fe and its use in

accordance with the FDA-approved labeling are covered by the claims of the '050 Patent.

30. Upon information and belief, Mylan submitted ANDA No. 206120 to the FDA seeking approval to engage in the commercial manufacturer, use, offer for sale, and sale of a generic version of Minastrin® 24 Fe before the '050 Patent expires.

31. By submitting Mylan's ANDA under 21 U.S.C. § 355(j), with a paragraph IV certification, for the purpose of obtaining approval to engage in the manufacture, use, offer-for-sale, or sale of Mylan's ANDA Product before the '050 Patent expires, Defendants have committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). Further, the manufacture, use, offer-for-sale, or sale of Mylan's ANDA Product would infringe (directly or indirectly) one or more claims of the '050 Patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

32. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic Minastrin® 24 Fe product for which approval is sought in ANDA No. 206120 would actively induce and contribute to infringement of the '050

Patent, and Mylan would be liable under one or more 35 U.S.C. §§ 271(b) and (c).

33. Upon information and belief, the acts of Mylan Pharma and Jai Pharma complained of herein were done and are being done at the direction of, with the authorization of, and with the cooperation, participation and assistance of, and at least in part for the direct benefit of each other.

34. This case is an exceptional one, and Warner Chilcott is entitled to its reasonable attorneys' fees under 35 U.S.C. § 285.

35. Warner Chilcott will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '050 Patent. Warner Chilcott does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Warner Chilcott respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '050 Patent by submitting ANDA No. 206120;

B. A permanent injunction restraining and enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '050 Patent, including the product described in ANDA No. 206120;

C. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 206120, or inducing or contributing to such conduct, would constitute infringement of the '050 Patent by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. An order that the effective date of any approval of Defendants' ANDA No. 206120 be a date that is not earlier than the expiration of the '050 Patent or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled to;

E. A finding that this is an exceptional case, and awarding Warner Chilcott its attorneys' fees under 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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

Dated: November 4, 2015

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I certify that this action alleges infringement of the same patent at issue in the consolidated matters *Warner Chilcott Co., LLC v. Mylan Inc. et al.*, 3:11–cv–06844 (D.N.J.), and *Warner Chilcott Co., LLC v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, 3:11–cv–07228 (D.N.J.) (Appeal No. 14–1582 (Fed. Cir.)); and that this action alleges infringement of the same patent at issue in *Warner Chilcott Co., LLC v. Lupin Atlantis Holdings SA et al.*, 1:14–cv–01827-RWT (D. Md.) and in *Warner Chilcott Co. LLC. v. Amneal Pharmaceuticals LLC*, 3:15–cv–03590 (D.N.J.).

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