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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GLAXOSMITHKLINE PLC; PFIZER, INC.; and ENCYSIVE PHARMACEUTICALS, INC.,	
Plaintiffs,	**CIVIL CASE NO.**
MITSUBISHI CHEMICAL CORP. and MITSUBISHI TANABE PHARMA CORP.,	
Involuntary Plaintiffs,	**COMPLAINT AND JURY DEMAND**
vs.	
HIKMA PHARMACEUTICAL CO., LTD. and WEST-WARD PHARMACEUTICAL CORP.,	
Defendants.	

Plaintiffs GlaxoSmithKline plc ("GSK"), Pfizer, Inc. ("Pfizer"), and Encysive Pharmaceuticals, Inc. ("Encysive") (collectively, "Plaintiffs"), along with Involuntary Plaintiffs Mitsubishi Chemical Corporation ("MCC"), Mitsubishi Tanabe Pharma Corporation ("MTPC") (collectively, "Mitsubishi"), by their undersigned counsel, allege the following against Defendants Hikma Pharmaceutical Co., Ltd. ("Hikma") and West-Ward Pharmaceutical Corp. ("West-Ward") (collectively, "Hikma"):

THE PARTIES

1. GSK is a British company, having its registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England. GSK is a worldwide, research-based pharmaceutical and healthcare company, producing and marketing a variety of medicines, vaccines, and consumer products.

2. Pfizer is a Delaware corporation, having its principal place of business at 235 East 42nd Street, New York, NY 10017. Pfizer is a pharmaceutical and biotechnology company applying science and global resources to improve health and well-being, focusing on quality, safety, and value in the discovery, development, and manufacturing of medicines for people and animals.

3. Encysive is a Delaware corporation having its corporate headquarters and principal place of business in Houston, Texas. Encysive is a biopharmaceutical company engaged in the discovery, development, and commercialization of novel compounds to address unmet medical needs. Pfizer acquired Encysive in 2008.

4. MCC, joined as an involuntary plaintiff, is a Japanese corporation, having its headquarters and principal place of business in Tokyo, Japan. MCC is

engaged in the business of employing the science of chemistry to create, develop, and improve products with a particular focus on the areas of petrochemicals, performance and functional products, and healthcare.

5. MTPC, joined as an involuntary plaintiff, is a Japanese corporation having its headquarters and principal place of business in Osaka, Japan. MTPC is a pharmaceutical company that engages in the development, manufacture, and marketing of a broad spectrum of innovative pharmaceutical products.

6. Upon information and belief, Hikma is a Jordanian company, having its registered address at Bayader Wadi El-Seer, Industrial Area, P.O. Box 182400, Amman, Jordan, 11118. Hikma is a worldwide pharmaceutical company in the business of developing and manufacturing injectables and branded and generic drugs. Hikma is the wholly-owned subsidiary of Hikma Pharmaceutical PLC, a U.K. holding company.

7. Upon information and belief, West-Ward is a Delaware corporation, having its principal place of business at 401 Industrial Way West, Eatontown, NJ 07724-2206. West-Ward is in the business of generic pharmaceutical manufacturing and distribution. West-Ward is an agent and wholly-owned subsidiary of Hikma Pharmaceutical PLC.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under the patent laws of the United States, specifically 35 U.S.C. §§ 271(e)(2), 271(b), 271(c), and 281-283.

9. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

11. Defendant West-Ward is properly subject to personal jurisdiction in the State of New Jersey (the "State") because West-Ward has its headquarters and principal place of business within the State.

12. Upon information and belief, West-Ward and Hikma are agents of each other and/or operate in concert as integrated parts of Hikma's generic business.

13. Upon information and belief, Hikma has knowingly placed its products in New Jersey's stream of commerce by acting in concert with West-Ward to market and sell generic drug products throughout the United States, including in New Jersey.

14. Upon information and belief, and according to Hikma's website, http://www.hikma.com, West-Ward was acquired by Hikma in 1991 in order to establish its presence in the United States. This was prior to the formation of the Hikma Pharmaceutical PLC holding company, which is now the parent of both wholly-owned subsidiaries Hikma and West-Ward.

15. Upon information and belief, and according to West-Ward's website, http://www.west-ward.com, West-Ward is "one of the top 20 generic prescription medication providers in the US, providing pharmaceuticals to a growing number of chain stores, wholesalers, distributors, health systems and government agencies. We are the US agent and subsidiary of Hikma PLC."

16. Upon information and belief, and according to Hikma's website, Hikma's generics business is focused entirely on the United States market, and operates as West-Ward, which manufactures and/or markets over 50 generic

compounds in the United States and New Jersey.

17. Upon information and belief, Hikma has filed New Drug Applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"), requesting permission to market, throughout the United States (including in New Jersey), a number of generic drugs, including a generic copy of GSK's Argatroban Injection (the "Proposed Hikma Product").

18. Upon information and belief, West-Ward is the distributor of drugs for which Hikma is the named applicant on the FDA's Approved Drug Product List. Upon information and belief, West-Ward, acting as the agent of Hikma, markets Hikma's drug products in New Jersey and elsewhere in the United States.

19. Upon information and belief, Hikma intends to engage in the commercial manufacture, use, offering for sale, and sale of the Proposed Hikma Product imminently, actions that will directly or indirectly infringe GSK's intellectual property rights within the State of New Jersey.

20. Upon information and belief, West-Ward is the intended U.S. distributor for the Proposed Hikma Product, and is thereby acting in concert with Hikma to market and/or sell the infringing generic product within the boundaries of New Jersey, and thus to commit tortious acts therein.

21. Upon information and belief, Hikma earns revenue from West-Ward's marketing and distribution in New Jersey of generic pharmaceutical products that are manufactured by Hikma or for which Hikma is the named applicant on approved NDAs or ANDAs.

22. Upon information and belief, upon launch, the Proposed Hikma Product charged with infringing the patent-in-suit, will, among other things, be

marketed and distributed by West-Ward, acting as the U.S. agent of Hikma, in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by hospital pharmacies located within New Jersey, all of which would have a substantial effect on the State.

23. Hikma is subject to personal jurisdiction in the State of New Jersey, under N.J. Ct. R. 4:4-4(b)(1), because, *inter alia*, it has maintained systematic and continuous contacts with the State, including through its relationship with West-Ward.

24. Hikma also is subject to personal jurisdiction in the State of New Jersey because it has purposefully availed itself of the legal protections of the State by admitting jurisdiction and asserting counterclaims in a lawsuit filed in 2003, *Glaxo Group Ltd. v. West-Ward Pharmaceuticals, Inc.*, No. 03-CV-4791(JLL) (D.N.J. 2003), seeking a declaratory judgment that the asserted patents in that case were invalid, unenforceable, and not infringed.

GENERAL ALLEGATIONS

25. This case involves United States Patent No. 5,214,052 (the "'052 Patent"), entitled "Method for Dissolving Arginineamides and Pharmaceutical Compositions Containing Them," a true and correct copy of which is attached hereto as **Exhibit A**. The '052 Patent was duly issued on May 25, 1993 to inventors Kunihiko Ofuchi and Tatsuo Nomura, and assigned to MCC (then known as Mitsubishi Kasei Corporation).

26. The '052 Patent claims, *inter alia*, a novel injectable pharmaceutical composition comprising 1-[5-[(aminoiminomethyl)amino]-1-oxo-2-[[(1,2,3,4-tetrahydro-3-methyl-8-quinolinyl)sulfonyl]amino]pentyl]-4-methyl-2-

piperidinecarboxylic acid, monohydrate ("argatroban"), dissolved in a solvent containing ethanol, water, and a saccharide, as well as a method of preparing such a composition.

27. The claims of the '052 Patent are valid and enforceable. The United States District Court for the Southern District of New York held that the '052 Patent was not invalid and enjoined another generic company from launching a generic version of GSK's Argatroban Injection. *See Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 718 F. Supp. 2d 382 (S.D.N.Y. 2010), *aff'd*, 435 F. App'x 927 (Fed. Cir. 2011).

28. MCC has been and is the owner and assignee of the '052 Patent, which is set to expire on June 30, 2014, having received a patent term extension pursuant to 35 U.S.C. § 156.

29. Upon information and belief, MTPC is the successor-in-interest to certain rights in MCC's pharmaceutical business, including rights relating to Argatroban Injection. MTPC holds an exclusive license to the '052 Patent, with the right to sublicense, as well as certain rights through a license agreement between MCC and Encysive relating to Argatroban Injection.

30. In 1997, MCC granted Encysive (then Texas Biotechnology Company) an exclusive license to the '052 Patent for the United States. Encysive's exclusive license included the right to further sublicense to GSK's predecessor. Encysive also was the holder of the approved NDA for Argatroban Injection, No. 020833, which was approved on June 30, 2000 by the FDA. By way of acquisition of Encysive, Pfizer now holds an exclusive license to the '052 Patent in the United States and also holds NDA No. 020833 for Argatroban Injection.

31. GSK is the exclusive sublicensee of Pfizer and is the exclusive distributor of Argatroban Injection under NDA No. 020833 in the United States.

32. Under NDA No. 020833, GSK's Argatroban Injection is approved for use as an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia ("HIT"), and also as an anticoagulant in adult patients with or at risk for HIT and undergoing percutaneous coronary intervention ("PCI").

33. HIT can arise in some patients who receive heparin (an anticoagulant) to prevent clot formation following, among other things, thrombotic events such as heart attacks, occlusions, or strokes; serious trauma resulting in extended periods of bed-rest; or any extracorporeal bypass such as dialysis. Within two weeks of receiving heparin, a sensitized patient may experience an immune response that seriously damages platelets and releases clotting factors into the bloodstream. If the fragmented platelets and clotting factors spread significantly throughout the body, a more serious condition, known as heparin-induced thrombocytopenia and thrombosis ("HITT"), can result.

34. Both HIT and HITT can result in clot formation throughout the body, and if undiagnosed or untreated, can lead to amputation or death. The diagnosis of HIT and HITT can be very difficult because both conditions present with thrombocytopenia (low platelet count), a symptom that can result from a number of other disorders. Furthermore, HIT and HITT are generally asymptomatic until a morbidity or mortality event occurs.

35. GSK's Argatroban Injection is the preferred treatment among healthcare providers for HIT and HITT because, among other reasons, it is excreted by the liver and not the kidneys. Other drugs are excreted through the

kidneys, making them less suitable as a treatment for those patients undergoing kidney dialysis. Furthermore, GSK's Argatroban Injection is sold in high concentration and can be diluted for intravenous delivery in lower amounts of fluids, making it more suitable for patients on liquid volume restrictions.

36. Upon information and belief, Defendant Hikma submitted an NDA to the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "Act") along with a certification under Section 505(b)(2)(A)(IV) ("Paragraph IV"), requesting approval to market the Proposed Hikma Product in the United States. The FDA assigned NDA No. 203049 to the application.

37. Upon information and belief, Defendant Hikma sent a letter, dated June 3, 2011, providing Paragraph IV Notice of NDA No. 203049 to MCC, Encysive, and Pfizer (the "Paragraph IV Notice").

38. Upon information and belief, Defendant Hikma received notification on January 5, 2012 of the FDA's approval of NDA No. 203049 (the "Approval"), allowing the Proposed Hikma Product to be used for prophylaxis or treatment of thrombosis in adult patients with HIT and as an anticoagulant in adult patients with or at risk for HIT undergoing PCI. The FDA also published Hikma's label for the Proposed Hikma Product.

39. Upon information and belief, the Proposed Hikma Product has been given an "AP" rating by the FDA, which means that the FDA has deemed it bioequivalent to GSK's Argatroban Injection.

40. Upon information and belief, Hikma intends to engage in the commercial manufacture, use, importation, offering for sale, and sale of the Proposed Hikma Product imminently.

41. As the owner and licensor of the ‘052 Patent, Mitsubishi is an indispensible party to this action. Upon information and belief, Mitsubishi has an obligation under certain licensing agreements to cooperate with and join in infringement actions brought by Encysive/Pfizer and GSK as its exclusive licensee and exclusive sublicense, respectively, to enforce and protect the ‘052 Patent and GSK’s Argatroban Injection. GSK and Encyzive/Pfizer have requested that Mitsubishi voluntarily cooperate with Plaintiffs in this action and join as a plaintiff. To date, Mitsubishi has refused to authorize GSK or Encyzive/Pfizer to name MCC and MTPC as plaintiffs in this action.

COUNT I - INFRINGEMENT OF U.S. PATENT NO. 5,214,052

42. Plaintiffs repeat and incorporate by reference herein the allegations contained in Paragraphs 1-41 above.

43. Upon information and belief, Defendant Hikma filed and received FDA approval for NDA No. 203049 to manufacture and market the Proposed Hikma Product.

44. Hikma’s submission of NDA No. 203049 to obtain approval to market the Proposed Hikma Product prior to the expiration of the ‘052 Patent constitutes infringement of one or more of the claims of the ‘052 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon launch of the Proposed Hikma Product, Defendants will further infringe the ‘052 Patent through the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Hikma Product in or into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

46. Upon information and belief, Defendants had actual and constructive knowledge of the ‘052 Patent prior to filing NDA No. 203049 and were aware that filing of the aforementioned NDA with the FDA constituted an act of infringement of the ‘052 Patent.

47. Unless Defendants are enjoined from infringing the ‘052 Patent, Plaintiffs will suffer substantial and irreparable injury, for which there is no adequate remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiffs request the following relief:

(a) a judgment that one or more claims of the ‘052 Patent are infringed by Hikma’s submission of NDA No. 203049, and that Defendants’ making, using, selling, offering to sell and/or importing in or into the United States the Proposed Hikma Product will infringe, directly or indirectly, one or more claims of the ‘052 Patent;

(b) a preliminary and permanent injunction restraining and enjoining against any infringement, direct or indirect, of the ‘052 Patent by Defendants, each of their subsidiaries, affiliates, officers, agents, servants, and employees, and those acting in privity or concert with all or any of them, through the commercial manufacture, use, sale, offer for sale or importation in or into the United States of the Proposed Hikma Product;

(c) damages or other monetary relief to Plaintiffs if Defendants engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Proposed Hikma Product prior to the

expiration date of the ‘052 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(d) attorneys’ fees in this action under 35 U.S.C. § 285; and

(e) such further and other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

Dated: March 30, 2012

CONNELL FOLEY LLP
Attorneys for Plaintiffs, GlaxoSmithKline plc, Pfizer, Inc. and Encysive Pharmaceuticals, Inc.

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: March 30, 2012

/s Liza M. Walsh
Liza M. Walsh

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that declaratory and injunctive relief is sought.

Dated: March 30, 2012

/s Liza M. Walsh
Liza M. Walsh