UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

GILEAD SCIENCES, INC.
333 Lakeside Drive
Foster City, California 94404;

HOFFMANN-La ROCHE INC.
150 Clove Road, Suite 8
Little Falls, New Jersey 07424;

F. HOFFMANN-La ROCHE LTD.
CH 4070
Basel, Switzerland;

and

GENENTECH, INC.
1 DNA Way
South San Francisco, California 94080-4490;

Plaintiffs,

v.

LUPIN PHARMACEUTICALS, INC.
111 S. Calvert Street
21st Floor
Baltimore, MD 21202
Baltimore City;

LUPIN ATLANTIS HOLDINGS S.A.
Mülentalstrasse 2
8200 Schaffhausen
Schaffhausen, Switzerland;

and

LUPIN LTD.
B/4 Laxmi Towers
Bandra Kurla Complex, Bandra (E)
Mumbai 400 051 India;

Defendants.

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd., and Genentech, Inc. (collectively "Plaintiffs"), for their Complaint against Defendants, Lupin Atlantis Holdings S.A. ("Lupin Atlantis"), Lupin Limited ("Lupin Ltd."), and Lupin Pharmaceuticals, Inc. ("Lupin Pharma") (collectively "Lupin"), to the best of their knowledge, information and belief, 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, for infringement of United States Patent No. 5,763,483 ("the '483 Patent") (attached as Exhibit A hereto). Plaintiffs institute this action to enforce their patent rights covering TAMIFLU® (oseltamivir phosphate) 6 mg base/mL suspension dosage form ("suspension"), that is approved by the United States Food and Drug Administration ("FDA") for the treatment of uncomplicated acute illness due to influenza infection in patients one year or older who have been symptomatic for no more than two days and for the prophylaxis of influenza in patients one year or older.

PARTIES

2. Plaintiff Gilead Sciences, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Plaintiff Hoffmann-La Roche Inc. is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

4. Plaintiff F. Hoffmann-La Roche Ltd. is a company organized and existing under the laws of Switzerland with its principal place of business at CH 4070 Basel, Switzerland.

5. Plaintiff Genentech, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 1 DNA Way, South San Francisco, California 94080-4490.

6. Upon information and belief, Defendant Lupin Atlantis is a corporation organized and existing under the laws of Switzerland and has a principal place of business at Mülentalstrasse 2, 8200 Schaffhuasen, Switzerland. Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

7. Upon information and belief, Defendant Lupin Pharma is a wholly-owned subsidiary of Lupin Ltd. and is a corporation organized and existing under the laws of the Commonwealth of Virginia. Upon information and belief, Lupin Pharma has a principal place of business located at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

8. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India. Upon information and belief, Lupin Ltd. has its principal place of business located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, Maharashtra, India.

9. Upon information and belief, Lupin Ltd. is the parent company of twenty-three subsidiaries worldwide, including Lupin Atlantis and Lupin Pharma.

10. Upon information and belief, Lupin Atlantis has engaged in continuous and systemic contacts with the United States by, among other things, filing with the United States Food and Drug Administration ("FDA") Abbreviated New Drug Applications ("ANDAs") to sell various products in the United States.

11. Upon information and belief, Lupin Ltd., Lupin Atlantis, and Lupin Pharma are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic pharmaceutical products. Upon information and belief, Lupin Ltd. and

Lupin Pharma, through their affiliate and agent Lupin Atlantis, filed with the FDA the ANDA that is at issue in this patent infringement suit. Upon information and belief, the acts of Lupin Atlantis complained of herein were done and are being done with the cooperation, participation, and assistance of, and at least in part for the benefit of, Lupin Ltd. and Lupin Pharma.

JURISDICTION AND VENUE

12. 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 over this action based on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Lupin Atlantis. On information and belief, Lupin Atlantis, Lupin Ltd., and Lupin Pharma are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to Plaintiffs' TAMIFLU® (oseltamivir phosphate) suspension for which they have sought approval from the FDA. Upon information and belief, Lupin Atlantis purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Lupin Ltd. and Lupin Pharma, in the United States through its filing of an ANDA. Upon information and belief, Lupin Ltd. and Lupin Pharma, through their affiliate and agent, Lupin Atlantis, filed the ANDA with the FDA that is at issue in this patent infringement suit.

14. This Court has personal jurisdiction over Lupin Ltd. Upon information and belief, Lupin Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Lupin Ltd., directly or through its wholly-owned subsidiaries, including Lupin Pharma located in Baltimore, Maryland, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. According to Lupin Ltd.'s Annual Report, with an effective date

of March 31, 2014, Lupin Ltd. "has 93 ANDAs pending for approval and launch, addressing a total market size of over USD 80 billion." Upon information and belief, Lupin Ltd. is "the 7th largest generic pharmaceutical company in the world by market capitalization and the 10th largest generic pharmaceutical company by revenues" and its "global formulations business contributes 90% of Lupin's global revenues with formulations sales in excess of USD 1.65 billion." *See* http://lupin.com/formulations.php. Upon information and belief, Lupin Ltd. "has significant market share in key markets." *See* http://lupinworld.com/corporate-overview.htm. Upon information and belief, Lupin Ltd. is the manufacturer of Lupin products sold in the United States, and will do the same with respect to Plaintiffs' TAMIFLU® (oseltamivir phosphate) drug product, which it seeks approval to sell in the form of a suspension. *See* http://www.lupinpharmaceuticals.com/manufacture.htm.

15. This Court has jurisdiction over Lupin Pharma at least because it has its principal place of business in Baltimore, Maryland.

16. Upon information and belief, Lupin Pharma is an affiliate and agent of Lupin Atlantis and Lupin Ltd. in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district and will do the same with respect to Plaintiffs' TAMIFLU® (oseltamivir phosphate) suspension. Upon information and belief, since 2003 Lupin Pharma has "received more than 75 FDA approvals and ha[s] become one of the fastest growing pharmaceutical companies in the US." *See* http://www.lupinpharmaceuticals.com/generics.htm. Upon information and belief, Lupin Pharma is "the 5th largest and fastest growing top 5 generics player in the US with a 5.4% market share by prescriptions" and as of March 2014, "31 of [its] 63 generic products marketed . . . in the US ranked No. 1 by market share and 53 of [its] 63 are

in the top 3 by Market share[.]" *See* http://lupin.com/business-usa.php#global2 ("US Generics" tab).

17. Upon information and belief, Lupin Pharma "is the wholly owned subsidiary of Lupin Limited" that was "founded on the strengths of our parent company Lupin Limited, [and] intends to bring a portfolio of generics as well as branded products to the U.S. market." *See* http://www.lupinpharmaceuticals.com/about.htm. Upon information and belief, "[Lupin Pharma] is the exclusive US distributor for all of the products developed and manufactured by its parent company, Lupin Ltd., and other affiliate companies." *See* http://www.pharmacytimes.com/publications/supplement/2014/Generic-Supplement-2014/Lupin-Pharmaceuticals-Inc.

18. Alternatively, assuming that the above facts do not establish personal jurisdiction over Lupin Atlantis, this Court may exercise jurisdiction over Lupin Atlantis pursuant to Federal Rule of Civil Procedure 4(k)(2).

19. Alternatively, assuming that the above facts do not establish personal jurisdiction over Lupin Ltd., this Court may exercise jurisdiction over Lupin Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2).

20. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b) because substantial events giving rise to acts of infringement occurred within this judicial district.

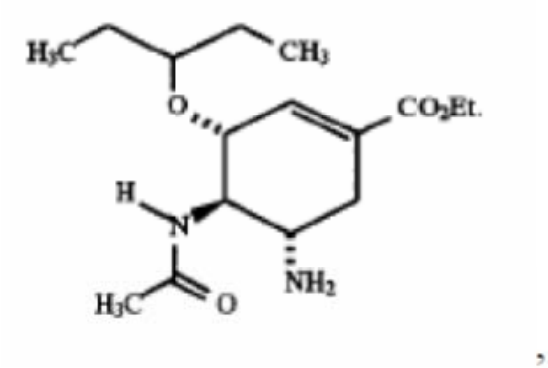
BACKGROUND

21. Hoffmann-La Roche Inc. is the holder of New Drug Application ("NDA") No. 21-246 which relates to, *inter alia*, a suspension of oseltamivir phosphate in a dosage of eq. 6 mg base/ml as the active ingredient, formulated as the TAMIFLU® brand for the treatment of uncomplicated acute illness due to influenza infection in patients one year or older who have

been symptomatic for no more than two days and for the prophylaxis of influenza in patients one year or older. On March 21, 2011, the FDA approved plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension product for marketing in the United States pursuant to section 505(b) of the Federal Food, Drug, and Cosmetics Act, ("FFDCA"), 21 U.S.C. § 355(b).

22. Gilead Sciences, Inc. is the owner of the '483 Patent (copy attached as Exhibit A), titled "Carbocyclic Compounds," which was duly and legally issued by the United States Patent and Trademark Office on June 9, 1998.

23. The '483 Patent claims a compound having the following chemical structure:



which is the active ingredient in the TAMIFLU® (oseltamivir phosphate) product described in NDA No. 21-246, as well as methods for the treatment or prophylaxis of influenza infection using such a compound.

24. Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc. are the exclusive licensees of the '483 Patent.

25. This action arises because of the efforts of Lupin Atlantis, Lupin Pharma and Lupin Ltd. to gain approval from the FDA to market generic copies of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug products prior to the expiration of patent rights and regulatory exclusivity covering same.

26. With passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several important respects. One provision requires innovator drug companies to submit patent information to the FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA then lists the patent information in the "Approved Drug Products with Therapeutic equivalence Evaluations" (commonly referred to as the "Orange Book").

27. Plaintiffs submitted patent information to the FDA in connection with NDA No. 21-246 for TAMIFLU® (oseltamivir phosphate) suspension drug product, and the FDA has published the same for the 6 mg dosage forms in the Orange Book.

28. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called the "reference drug") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources as the innovator. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C.§ 355(j). When filing an ANDA, generic drug companies are required to review the patent information that the FDA has published in the Orange Book for the reference drug and make a statutory certification (commonly called a "patent certification") with respect to each listed patent.

29. The generic drug company may, *inter alia*, state that it does not seek FDA approval to market its generic drug product prior to patent expiration (a "Paragraph III certification"). *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug product prior to patent expiration by alleging

in its ANDA that one or more patents listed in the Orange Book is "invalid or will not be infringed" (commonly called a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

30. The '483 Patent, identified in paragraph 1 of this Complaint, is listed in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

31. On information and belief, Lupin Atlantis, Lupin Pharma and Lupin Ltd., acting jointly, filed ANDA No. 208347 with the FDA seeking approval to market generic copies of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product prior to expiration of the '483 Patent.

32. On or about August 4, 2015, Lupin Atlantis sent to Plaintiffs a letter purporting to be a notice of Lupin Atlantis's filing of an ANDA seeking to market a generic copy of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product. The letter contained the Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(ii) with respect to the '483 Patent listed in the Orange Book for TAMIFLU® ("Paragraph IV Notice").

33. In particular, the Paragraph IV Notice purportedly sent by Lupin Atlantis states that Lupin Atlantis is seeking FDA approval to market generic copies of the TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product prior to expiration of the '483 Patent listed in the Orange Book for TAMIFLU®. Notwithstanding the United States Patent and Trademark Office's grant of patent protection, in its Paragraph IV Notice, Lupin Atlantis asserts that the '483 Patent is invalid, unenforceable, and/or would not be infringed by its proposed generic products.

34. The efforts of Lupin Atlantis, Lupin Pharma and Lupin Ltd. to seek FDA approval to market generic copies of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product prior to expiration of the '483 Patent constitute acts of infringement pursuant to 21 U.S.C. § 271(e)(2) and, thus, create a justiciable controversy between the parties with respect to the subject matter of Lupin's ANDA and the '483 Patent which has been challenged in Lupin Atlantis's Paragraph IV Notice.

COUNT I
INFRINGEMENT OF THE '483 PATENT UNDER 35 U.S.C. § 271(e)(2)

35. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

36. On information and belief, Lupin Atlantis, Lupin Ltd. and Lupin Pharma, acting jointly, filed ANDA No. 208347 in order to obtain approval to market Lupin's generic copy of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product in the United States before the expiration of the '483 Patent.

37. On information and belief, Lupin Atlantis, Lupin Ltd., and Lupin Pharma, acting jointly, also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Section 505(j)(2)(A)(vii)(IV) of the FFDCA), a certification alleging that the claims of the '483 Patent are invalid and/or will not be infringed by their manufacture, use or sale of generic copies of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product.

38. Under 35 U.S.C. § 271(e)(2)(A), Lupin's submission to the FDA of ANDA No. 208347 to obtain approval for the commercial manufacture, use, or sale of Lupin's generic copies of Plaintiffs' TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product before the expiration date of the '483 Patent and any additional periods of exclusivity constitutes

infringement of one or more claims of the ’483 Patent, either literally or under the doctrine of equivalents.

39. Plaintiffs will be irreparably harmed by Lupin’s infringing activities unless such activities are enjoined by the Court as Plaintiffs do not have an adequate remedy at law. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order by this Court that the effective date of any FDA approval of Lupin’s ANDA shall be no earlier than the expiration date of the ’483 Patent and any additional periods of exclusivity.

COUNT II
INFRINGEMENT OF THE ’483 PATENT UNDER 35 U.S.C. § 271(a), (b) and/or (c)

40. Plaintiffs incorporate by reference paragraphs 1-39 of this Complaint as if fully set forth herein.

41. On information and belief, Lupin Atlantis, Lupin Ltd., and Lupin Pharma acted jointly to submit ANDA No. 208347 in order to obtain approval to engage in the commercial manufacture, use or sale of generic copies of Plaintiffs’ TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product in the United States before the expiration date of the ’483 Patent and any additional periods of exclusivity.

42. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic copies of Plaintiffs’ TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product will infringe the ’483 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

43. Upon FDA approval of Lupin’s ANDA No. 208347, Lupin will directly infringe one or more claims of the ’483 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin’s generic copies of Plaintiffs’ TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c),

unless this Court orders that the effective date of any FDA approval of Lupin's ANDA shall be no earlier than the expiration date of the '483 Patent and any additional periods of exclusivity.

44. On information and belief, Lupin's generic oseltamivir phosphate suspension drug 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 '483 Patent, either literally or under the doctrine of equivalents.

45. On information and belief, the use of Lupin's generic oseltamivir phosphate suspension drug product constitutes a material part of at least one of the claims of the '483 Patent; Lupin knows that its generic oseltamivir phosphate suspension drug product is especially made or adapted for use in infringing at least one of the claims of the '483 Patent, either literally or under the doctrine of equivalents; and Lupin's generic oseltamivir phosphate suspension drug product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

46. On information and belief, the offering to sell, sale, and/or importation of Lupin's generic oseltamivir phosphate suspension drug product would contributorily infringe at least one of the claims of the '483 Patent, either literally or under the doctrine of equivalents.

47. On information and belief, Lupin had knowledge of the '483 Patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '483 Patent, either literally or under the doctrine of equivalents.

48. On information and belief, the offering to sell, sale, and/or importation of Lupin's generic oseltamivir phosphate suspension drug product would actively induce infringement of at least one of the claims of the '483 Patent, either literally or under the doctrine of equivalents.

49. Plaintiffs will be substantially and irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

A) a judgment that Lupin has infringed the '483 Patent under 21 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 208347 with a Paragraph IV certification seeking to market Lupin's generic copies of TAMIFLU® (oseltamivir phosphate) 6 mg suspension drug product prior to the expiration date of said patent and any additional periods of exclusivity;

B) a judgment and decree that the '483 Patent is valid and enforceable;

C) an Order pursuant to 21 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin's ANDA No. 208347 be a date that is not earlier than the expiration date of the '483 Patent and any additional periods of exclusivity;

D) a judgment that Lupin would infringe and induce infringement of the '483 Patent upon marketing its generic copies of TAMIFLU® (oseltamivir phosphate) suspension drug products prior to the expiration date of said patent and any additional periods of exclusivity;

E) a judgment declaring that if Lupin, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, and/or importation of Lupin's generic copies of TAMIFLU® (oseltamivir phosphate) suspension drug product prior to the expiration date the '483 Patent and

any additional periods of exclusivity, it will constitute acts of infringement of the '483 Patent under 35 U.S.C. §§ 271(a)(b) and/or (c);

F) a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Lupin and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of its generic copies of TAMIFLU® (oseltamivir phosphate) suspension drug product and any other drug products that infringe or induce or contribute to the infringement of the '483 Patent prior to the expiration date of the '483 Patent and any additional periods of exclusivity;

G) a judgment that this is an exceptional case and that Plaintiffs are entitled to an award of attorneys fees from Lupin under 35 U.S.C. § 285; and

H) such other and further relief as the Court may deem just and proper.

Date: September 16, 2015

Respectfully submitted,

/s/ Cheryl Zak Lardieri

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