IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Alcon Research, Ltd. ("Alcon"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Lupin's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of PAZEO® ophthalmic solution, a drug product containing olopatadine hydrochloride, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent No. 9,533,053 (the "'053 patent").

2. By letter dated March 15, 2017 (the "Notice Letter"), Lupin notified Alcon that it had submitted to the FDA an ANDA, No. 208896, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic olopatadine ophthalmic solution ("Lupin's ANDA Product") prior to the expiration of the '053 patent. Upon

information and belief, Lupin's ANDA Product is a drug product that is a generic version of PAZEO®, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

3. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon information and belief, defendant Lupin Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

5. Upon information and belief, defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. Upon information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

6. Upon information and belief, Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Ltd.

7. Upon information and belief, and consistent with their practice with respect to other generic products, Lupin Ltd. and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 208896.

8. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals contemplate that, upon approval of ANDA No. 208896, they directly or indirectly manufacture, market, sell, and distribute Lupin's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Lupin's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Lupin Pharmaceuticals participated in, assisted, and cooperated with Lupin Ltd. in the acts complained of herein. Lupin Ltd. and Lupin Pharmaceuticals are collectively referred to herein as "Lupin."

9. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 208896, Lupin Ltd. and Lupin Pharmaceuticals will act in concert to distribute and sell Lupin's ANDA Product throughout the United States, including within Delaware.

10. Upon information and belief, following any FDA approval of ANDA No. 208896, Lupin Ltd. and Lupin Pharmaceuticals know and intend that Lupin's ANDA Product will be distributed and sold throughout the United States, including in Delaware.

JURISDICTION AND VENUE

11. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391 and 1400(b), and 2201 and 2202.

12. This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharmaceuticals.

13. Lupin Ltd. is subject to personal jurisdiction in Delaware because, among other things, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals,

has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Lupin Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Lupin Pharmaceuticals and therefore the activities of Lupin Pharmaceuticals in this jurisdiction are attributed to Lupin Ltd.

14. Lupin Pharmaceuticals is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Lupin Pharmaceuticals develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, upon information and belief, Lupin Pharmaceuticals is qualified to do business in Delaware and has appointed a registered agent for service of process, and therefore has consented to general jurisdiction in Delaware.

15. Upon information and belief, Lupin earns substantial revenue from generic pharmaceutical products that are distributed, sold, used and/or consumed in Delaware which are manufactured by Lupin and/or for which Lupin Ltd. or Lupin Pharmaceuticals is the named

applicant on approved ANDAs. Upon information and belief, various products for which Lupin Ltd. or Lupin Pharmaceuticals is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

16. Upon information and belief, if ANDA No. 208896 is approved, Lupin will directly or indirectly manufacture, market, and/or sell Lupin's ANDA Product within the United States, including in Delaware, consistent with Lupin's practices for the manufacturing, marketing and distribution of other generic pharmaceutical products. Upon information and belief, Lupin regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Lupin's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

17. Upon information and belief, Lupin's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Alcon's patent in the event that Lupin's ANDA Product is approved before the '053 patent expires.

18. Lupin has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

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