IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD., Plaintiff, v. WATSON LABS., INC., Defendant.	C.A. No. 15-1159-GMS **CONSOLIDATED**
ALCON RESEARCH, LTD., Plaintiff, v. LUPIN LTD., & LUPIN PHARMA., INC., Defendants.	

MEMORANDUM

I. INTRODUCTION

In this patent infringement action, Alcon Research, Ltd. alleges that Watson Labs., Inc., Lupin Ltd., and Lupin Pharma. Inc., (collectively, "the Defendants") infringes the asserted claims of the patents-in-suit. The court held a four-day bench trial in this matter beginning on October 2, 2017. Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patents-in-suit, specifically whether the asserted claims are invalid as obvious under 35 U.S.C. § 103. (D.I. 149; D.I. 150.)

Pursuant to Federal Rule of Civil Procedure 52(a), having considered the entire record in this case and the applicable law, the court concludes that the asserted claims of the patents-in-suit

are not invalid due to obviousness. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT[1]

A. The Parties

1. Plaintiff Alcon Research, Ltd. ("Alcon") 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.

2. Defendant Watson Laboratories, Inc. ("Watson") is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, California 92880, and a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Defendant Lupin Ltd. ("Lupin") 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 €, Mumbai 400 051, India.

4. Lupin Pharmaceuticals, Inc. ("Lupin Pharms") is a corporation organized and existing under the laws of Delaware having a principal place of business at Harborplace Tower, 111 South Calbert Street, Baltimore, Maryland 21202.

5. Lupin Pharms is an indirectly wholly-owned subsidiary of Lupin Ltd. (collectively, "Lupin").

6. The court has subject matter jurisdiction and personal jurisdiction over all parties.

B. Background

7. On January 30, 2015, Novartis Pharmaceuticals Corp., an affiliate of Alcon, received approval from the FDA to market olopatadine hydrochloride ophthalmic solution (0.7%) under the trade name Pazeo® for the treatment of ocular allergic conjunctivitis.

8. Alcon has asserted claims 4-6, 8-10, 12-14, and 20-27 of the '154 Patent.

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[1] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 131, Ex. 1.) The court takes most of its findings of fact from the parties' uncontested facts. The court has also reordered and renumbered some paragraphs and made minor edits for the purpose of concision and clarity that it does not believe alters the meaning of the paragraphs from the Pretrial Order. Otherwise, any differences between this section and the parties' statement of uncontested facts are unintentional.

The court's findings of fact with respect to matters that were the subject of dispute between the parties are included in Part III this opinion ("Discussion and Conclusions of Law"), preceded by the phrase "the court finds" or "the court concludes."

9. The Prescribing Information for Patanol® (Olopatadine Hydrochloride Opthalmic Solution) 0.1% (Revised August 2002) ("Patanol® Label") was publicly available before October 19, 2010, and meets the requirements of 35 U.S.C. § 102(b) as prior art, but Alcon does not concede that it is relevant prior art.

10. Highlights of Prescribing Information for Pataday® (Olopatadine Hycdrochloride Opthalmic Solution) 0.2% (Revised August 2010) ("Pataday® Label") was publicly available before October 19, 2010, and meets the requirements of 35 U.S.C. § 102(b) as prior art, but Alcon does not concede that it is relevant prior art.

11. Alcon Highlights of Prescribing Information and Labeling for Patanase® (Olopatadine Hydrochloride) Nasal Spray (Revised March 2008) ("Patanase® Label") was publicly available before October 19, 2010, and meets the requirements of 35 U.S.C. § 102(b) as prior art, but Alcon does not concede that it is relevant prior art.

12. Each of Alcon's Patanol®, Pataday®, and Patanase® olopatadine products were commercially available in the United States prior to October 19, 2010, and meets the requirements of 35 U.S.C. § 102(b) as prior art, but Alcon does not concede that it is relevant prior art.

C. The Patents-in-Suit

13. The '154 Patent may be referred to as the "Patent-in-suit."

14. United States Patent No. 8,791,154 ("the '154 Patent") issued on July 29, 2014 and is entitled "High Concentration Olopatadine Ophthalmic Composition." The '154 Patent names Daniel A. Gamache, Laman Alani, Malay Ghosh, Francisxo Javier Galán, Núria Carreras Perdiguer, and Onkar N. Singh as inventors.

15. The application that matured into the '154 Patent was filed on May 18, 2012 and claims priority to a provisional patent application (No. 61/487,789) that was filed on October 19, 2011.

16. The priority date for the asserted claims is October 19, 2011.

17. The '154 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") at the U.S. Food and Drug Administration ("FDA") in connection with Pazeo®.

18. Alcon is the assignee of and owns the '154 Patent.

19. It is stipulated that the products that are the subject of Defendants' Abbreviated New Drug Applications infringe asserted claims 8-9 and 21-24 of the '154 Patent. (D.I. 73); (D.I. 93); (D.I. 131-1, ¶ 96.)

1. The Asserted Claims

20. Alcon has asserted infringement of claims 8, 9, and 21-24 of the '154 Patent against Watson.

21. Alcon has asserted infringement of claims 8, 9, and 21-24 of the the '154 Patent against Lupin.

i. '154 Patent, Claim 8

22. Claim 8 of the '154 Patent claims:

"[a]n aqueous ophthalmic solution for treatment of allergic conjunctivitis, the solution comprising:
at least 0.67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution;
2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500;
2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone;
at least 0.5% w/v% but no greater than 2.0 w/v% hydroxypropyl-γ-cyclodextrin; and
water."

ii. '154 Patent, Claim 9

23. Claim 9 of the '154 Patent claims: [a] solution as in claim 8 further comprising borate at a concentration of at least 0.18 w/v% but less than 0.5 w/v%."

iii. '154 Patent, Claim 21

24. Claim 21 of the '154 Patent claims: "[a]n aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising:
At least 0.67 w/v% but no greater that 1.0 w/v% olopatadine dissolved in the silution;
2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500;
2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone;
at least 0.5 w/v% but no greater than 2.0 w/v% hydroxypropyl-γ-cyclodextrin;
greater than 0.003 w/v% but less than 0.03 w/v% benzalkonium chloride; and
water.;
wherein the pH of the solution is 6.0 to 7.8 and the osmolality of the solution is 200 to 400 mOsm/kg."

iv. '154 Patent, Claim 22

25. Claim 22 of the '154 Patent claims: "[a] solution as in claim 21 further comprising at least 0.15 w/v% but no greater than 1.0 w/v% hydroxypropylinethyl cellulose."

v. '154 Patent, Claim 23

26. Claim 23 of the '154 Patent claims: "[a] solution as in claim 22 wherein:
i) the concentration of PEG is at least 3.0 w/v% but no greater than 5.0 w/v%;

ii) the concentration of polyvinylprrolidone is at least 3.0 w/v% but no greater than 5.0 w/v%; and
iii) the concentration of hydroxypropyl methylcellulose is at least 0.3 w/v% but no greater than 0.5 w//v%."

vi. '154 Patent, Claim 24

27. Claim 24 of the '154 Patent claims: "[a] solution as in claim 23 further comprising: at least 0.18 w/v% but less than 0.4 w/v% boric acid and at least 0.05 w/v% but no greater than 0.5 w/v% mannitol.

2. The Accused Products

i. ANDA No. 20-8637 Submitted by Watson

28. Watson submitted an Abbreviated New Drug Application ("ANDA") No. 208637 to the Food and Drug Administration ("FDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a generic olopatadine ophthalmic solution ("Watson's ANDA Product") prior to the expiration of the '154 Patent. .

29. Watson sent Alcon a letter dated November 3, 2015 ("Watson '154 Notice Letter"), stating that Watson had submitted an ANDA No. 208637 to the FDA seeking approval of the Watson's ANDA product.

30. Watson's '154 Notice Letter stated that the claims of the '154 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the product described in ANDA No. 208637.

31. Alcon brought suit against Watson alleging infringement of the '154 patent under 35 U.S.C. § 100 et seq., including § 271(e)(2)(A), on December 16, 2015, within 45 days of receipt of Watson's '154 Notice Letter.

32. Watson had submitted an Abbreviated New Drug Application ("ANDA") No. 208637 to the Food and Drug Administration ("FDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a generic olopatadine ophthalmic solution ("Watson's ANDA Product") prior to the expiration of the '154 Patent.

33. Watson's '154 Notice Letter stated that the claims of the '154 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the product described in ANDA No. 208637.

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