

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC. and WYETH)	
PHARMACEUTICALS INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
INTAS PHARMACEUTICALS LIMITED,)	
ASTRON RESEARCH LIMITED, ACCORD)	
HEALTHCARE LIMITED and ACCORD)	
HEALTHCARE, INC. USA,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, and Wyeth Pharmaceuticals Inc. (collectively “Pfizer”), for their Complaint against Defendants, Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA (collectively “Accord”), allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,362,718 (“the ‘718 Patent”). Pfizer institutes this action to enforce its patent rights covering Torisel[®] (Temsirolimus) Injection dosage form 25 mg/mL, 1.8 mL vial, that is approved in the United States by the U.S. Food and Drug Agency (“FDA”) for the treatment of advanced renal cell carcinoma. This action relates to Abbreviated New Drug Application (“ANDA”) No. 203-153 filed by Accord with the FDA for approval to market generic copies of Pfizer’s Torisel[®] pharmaceutical products that are sold in the United States.

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Wyeth LLC is a company organized and existing under the laws of the State of Delaware with its principal place of business at Five Giralda Farms, Madison, NJ 07940.

4. Plaintiff Wyeth Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 500 Arcola Road, Collegeville, PA 19426.

5. On information and belief, Defendant Intas Pharmaceutical Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 2nd Floor, Chinubhai Centre, Ashram Road, Ahmedabad – 380 009, India.

6. On information and belief, Defendant Astron Research Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 2nd Floor, Premier House-1, opp. Gurudwara, Gandhinagar, Sarkhej Highway, Ahmedabad – 380 009 India.

7. On information and belief, Astron Research Ltd. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

8. On information and belief, Defendant Accord Healthcare Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 2nd Floor, Chinubhai Centre, Ashram Road, Ahmedabad – 380 009 India.

9. On information and belief, Accord Healthcare Ltd. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

10. On information and belief, Defendant Accord Healthcare, Inc. USA is a corporation organized and existing under the laws of the State of North Carolina with its principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina, 27703.

11. On information and belief, Accord Healthcare, Inc. USA is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, generally, and 35 U.S.C. § 271(e)(2) specifically and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Accord by virtue of the fact that, *inter alia*, Accord has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Pfizer, which manufactures numerous drugs for sale and use throughout the United States, including this judicial district.

14. This Court also has personal jurisdiction over Accord by virtue of Accord's systematic and continuous contact with Delaware. Upon information and belief, Accord regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware. Accordingly, Accord has purposefully availed itself of the privilege of

conducting business in the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

15. On information and belief, the acts of Intas Pharmaceuticals Ltd. complained of herein were done at the direction or, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of Astron Research Ltd., Accord Healthcare Ltd. and Accord Healthcare, Inc. USA.

16. On information and belief, the acts of Astron Research Ltd. complained of herein were done at the direction or, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of Intas Pharmaceuticals Ltd., Accord Healthcare Ltd. and Accord Healthcare, Inc. USA.

17. On information and belief, the acts of Accord Healthcare Ltd. complained of herein were done at the direction or, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of Intas Pharmaceuticals Ltd., Astron Research Ltd. and Accord Healthcare, Inc. USA.

18. On information and belief, the acts of Accord Healthcare, Inc. USA complained of herein were done at the direction or, with the authorization of, and/or with the cooperation, participation and assistance of, and at least in part for the benefit of Intas Pharmaceuticals Ltd., Astron Research Ltd. and Accord Healthcare Ltd.

19. On information and belief, Intas Pharmaceuticals Ltd. is in the business of formulating, manufacturing, and commercializing pharmaceutical products. For example, in New Jersey, Intas Pharmaceuticals Ltd. is registered as a manufacturer, and doing business under the trade name Accord Healthcare, Inc. *See* New Jersey Drug Registration and Verification,

available at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx>. Intas Pharmaceuticals Ltd. maintains a website at the uniform resource locator (“URL”) <http://www.intaspharma.com/>. The website states that Intas Pharmaceuticals Ltd. is “one of the leading players in chronic therapy areas, also having presence in central nervous system (CNS), cardiovascular system (CVS), diabetology, gastroenterology and pain management...gynecology, infertility and respiratory care.” http://www.intaspharma.com/index.php?option=com_content&view=article&id=47&Itemid=34.

20. On information and belief, Intas Pharmaceuticals Ltd., either directly or through one or more of its wholly-owned subsidiaries, agents or distributors, markets, sells and or distributes drug products in this judicial district.

21. On information and belief, Astron Research Ltd., a wholly owned subsidiary of Intas Pharmaceuticals Ltd., is in the business of formulating, manufacturing and commercializing Accord generic drug products throughout the United States. *See* http://www.intaspharma.com/index.php?option=com_content&view=article&id=50&Itemid=57; Intas Pharmaceuticals Ltd. Draft Red Herring Prospectus, 163 (March 25, 2011), *available at* <http://www.sebi.gov.in/dp/intaspharma.pdf> (hereinafter “Intas Prospectus”). Astron Research Ltd. maintains a website at <http://astron-research.com/> stating that “[t]he Company has products and technology that are sold in over 50 countries, which includes ... US...” and that “45 ANDAs [were] filed in US.”

22. On information and belief, Astron Research Ltd. formulates and manufactures the drug products marketed or sold by Intas Pharmaceuticals Ltd. in this judicial district. In its Paragraph IV Notice letter regarding its submission of ANDA No. 203-153 to the

FDA, Accord Healthcare, Inc. USA listed Astron Research Ltd.'s formulation of temsirolimus injection as the one submitted to the FDA. *See* Paragraph IV Notice letter, p. 22 (Nov. 4, 2011).

23. On information and belief, Accord Healthcare Ltd., a wholly owned subsidiary of Intas Pharmaceuticals Ltd., is in the business of marketing and distributing Accord generic drug products throughout the United States. *See* http://www.intaspharma.com/index.php?option=com_content&view=article&id=50&Itemid=57; Intas Prospectus, 164. Accord Healthcare Ltd. maintains a website at <http://www.accord-healthcare.com/> stating that it is “[a] wholly owned subsidiary and the marketing arm of Intas Pharmaceuticals Ltd. ... engaged in all the licensing related activities and pharmaceutical product trading in various Therapeutic Segments in the regulatory markets. The company leverages the manufacturing support from INTAS. Accord Healthcare has its global matrix spread to USA ...” http://www.accord-healthcare.com/corporate_profile.htm.

24. On information and belief, Accord Healthcare Ltd. markets and distributes Accord generic products formulated and manufactured by Intas Pharmaceuticals Ltd. and Astron Research Ltd. throughout the United States.

25. On information and belief, Accord Healthcare, Inc. USA, a wholly owned subsidiary of Intas Pharmaceuticals Ltd., is in the business of exporting, importing and wholesale of Accord generic drug products throughout the United States. *See* http://www.intaspharma.com/index.php?option=com_content&view=article&id=56&Itemid=63. *See also* Intas Prospectus, 170-71. According to Intas Pharmaceuticals Ltd.'s website, Accord Healthcare Inc. USA is “the preferred supplier for leading distributors and retail pharma chains.” http://www.accord-healthcare.com/corporate_profile.htm.

26. On information and belief, Accord Healthcare, Inc. USA markets and distributes Accord generic products formulated and manufactured by Intas Pharmaceuticals Ltd. and Astron Research Ltd. throughout the United States.

27. On information and belief, Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA operate as an integrated unitary business. For example, Intas Pharmaceuticals Ltd. states in its red herring prospectus dated March 25, 2011, and submitted to the Securities and Exchange Board of India, that “References to the “Company,” “we,” “our” or “us” are to our Company, and where the context requires, our Company, our Subsidiaries and other entities which are consolidated in the financial statements of our Company.” Further, Intas Prospectus, viii. Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA have common board members, *e.g.*, Binish Chudgar and Nimish Chudgar. *See* Intas Prospectus, 65, 163-64, 170-71.

28. On information and belief, Intas Pharmaceuticals Ltd.’s website, www.intaspharma.com, serves as the website for all of Intas Pharmaceutical’s subsidiaries, including Astron Research Ltd, Accord Healthcare Ltd., and Accord Healthcare, Inc. USA. On Intas Pharmaceuticals Ltd.’s website, the activities of Astron Research Ltd, Accord Healthcare Ltd., and Accord Healthcare, Inc. USA are attributed to Intas Pharmaceuticals Ltd. For example, Intas Pharmaceuticals Ltd. states that

Intas’s forte in delivering world-class products has earned it reputable presence in over 50 countries on the International pharmaceutical horizon ... It has successfully augmented its R & D and manufacturing competency to enter into product alliances and strategic tie-ups and build business efficiencies for its partner companies. Intas customer base in Europe and US is multinational generic companies, retail pharma chains, distributors and hospitals. A territory specific marketing approach i.e. a mix of own marketing in select countries and tie ups with multinational companies in other markets, helps leverage its strong product basket and pipeline...

http://www.intaspharma.com/index.php?option=com_content&view=article&id=55&Itemid=62.

The website also states that “Intas is supported in its endeavours through its extensive network of branch offices and subsidiaries spanning USA, Canada, Europe, Central & Latin America, Africa, Asia-Pacific as well as CIS countries.” *See id.* (emphasis added).

29. On information and belief, by virtue of, *inter alia*, Accord’s sales-related activities in Delaware, including, but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Delaware, this Court has personal jurisdiction over Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA.

30. On information and belief, Accord Healthcare, Inc. USA has previously been sued in this district and has not challenged personal jurisdiction. *See Aventis Pharma S.A. v. Accord Healthcare, Inc. USA*, C.A. No. 11-018 (D. Del.). On further information and belief, Accord Healthcare, Inc. USA has also submitted to the jurisdiction of this Court by asserting counterclaims in civil actions initiated in this jurisdiction. *See id.*

31. On information and belief, Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA acted in concert to develop the Accord generic copies of Pfizer’s Torisel[®] (Temsirolimus) Injection, and to seek approval from the FDA to sell Accord’s generic copies of Pfizer’s Torisel[®] (Temsirolimus) Injection throughout the United States and in this judicial district.

32. On information and belief, Accord Healthcare, Inc. USA, under the direction of and/or guidance from Intas Pharmaceuticals Ltd., Astron Research Ltd., and Accord Healthcare Ltd., filed ANDA No. 203-153 with the FDA.

33. On information and belief, Accord Healthcare, Inc. USA stated in its Paragraph IV Notice letter to Pfizer that it had submitted ANDA No. 203-153. On information and belief, Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA acted jointly as a single entity in connection with preparing and filing ANDA No. 203-153.

34. On information and belief, by virtue of, *inter alia*, Intas Pharmaceuticals Ltd.'s, Astron Research Ltd.'s, and Accord Healthcare Ltd.'s relationship with Accord Healthcare, Inc. USA in connection with the preparation and/or filing of ANDA No. 203-153, and the associated systematic and continuous activities within the state of Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, this Court has personal jurisdiction over Intas Pharmaceuticals Ltd., Astron Research Ltd., and Accord Healthcare Ltd.

35. On information and belief, by virtue of, *inter alia*, Accord's continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, this Court has general and specific personal jurisdiction over Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA. These activities satisfy due process and confer personal jurisdiction over Intas Pharmaceuticals Ltd., Astron Research Ltd., Accord Healthcare Ltd., and Accord Healthcare, Inc. USA consistent with the Delaware Long Arm Statute.

36. On information and belief, Accord caused tortious injury in Delaware to Pfizer, all of who are Delaware corporations, by filing ANDA No. 203-153, further supporting specific and/or general jurisdiction over Accord.

37. Accord has consented to jurisdiction in this Court for the purposes of this case.

38. Venue is proper in this district under 28 U.S.C. §§ 1391(b), (c), and (d) and/or 1400(b).

BACKGROUND

U.S. Patent 5,362,718

39. On November 8, 1994, the United States and Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 5,362,718 (the “‘718 patent”) entitled, “Rapamycin Hydroxyesters.” A true and correct copy of the ‘718 patent is attached hereto as Exhibit A.

40. The ‘718 patent claims rapamycin hydroxyesters, pharmaceutical compositions thereof, and methods of treatment using such compositions.

41. The ‘718 patent covers Pfizer’s product Torisel[®], which contains temsirolimus, a rapamycin hydroxyester, and is indicated for the treatment of advanced renal cell carcinoma.

42. The ‘718 patent is assigned to Wyeth LLC, which is a wholly owned subsidiary of Pfizer Inc.

43. A patent term extension (“PTE”) application was filed under 35 U.S.C. § 156 on July 24, 2007 for the ‘718 patent requesting an extension of 1,764 days.

44. On January 7, 2008, the USPTO forwarded the PTE application to the FDA with a letter indicating that the ‘718 patent would not be eligible for PTE because the approval of Torisel[®] did not comply with 35 U.S.C. § 156(a)(5)(A), *i.e.*, Torisel[®] was an ester of a previously approved compound.

45. On November 4, 2010, Pfizer Inc. sent a letter to the USPTO asking that the PTE be granted based on a May 2010 Federal Circuit decision, *Photocure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010), where the Court held that an ester of a previously approved human drug product could support term extension even in light of a previous approval of a product containing the same “active moiety.” In other words, “product,” as used in § 156(a), means the product that is present in the drug for which federal approval was obtained, thus an ester of a previously approved drug substance formulated as a salt may still be eligible for a PTE.

46. The ‘718 will expire on February 15, 2019, if the patent term extension is granted. If the patent term extension is not granted, then the ‘718 patent will expire on April 18, 2014.

Torisel®

47. Wyeth Pharmaceuticals Inc. (a wholly owned subsidiary of Pfizer Inc.) is the holder of approved New Drug Application (“NDA”) No. 22-088 for Torisel® (Temsirrolimus) Injection, 25 mg/mL, 1.8 mL vial, for the treatment of advanced renal cell carcinoma.

48. Torisel® is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations database (“Orange Book”) as having New Chemical Exclusivity until May 30, 2012 and Orphan Drug Exclusivity until May 30, 2014.

49. On information and belief, Accord filed with the FDA ANDA No. 203-153 under 21 U.S.C. § 355(j), seeking approval to market Temsirrolimus Injection, dosage form 25 mg/mL, 1.8 mL vial (“Accord’s Temsirrolimus Injection”), which are generic copies of Pfizer’s Torisel® (Temsirrolimus) Injection, 25 mg/mL, 1.8 mL vial.

50. By a letter dated November 4, 2011, Accord Healthcare, Inc. USA notified Pfizer that it had filed ANDA No. 203-153, seeking approval to market Accord's Temsirolimus Injection, and that it was providing information to Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii). Pfizer received the letter on or about November 4, 2011.

CLAIM FOR INFRINGEMENT

Infringement of U.S. Patent No. 5,362,718

51. Pfizer incorporates by reference paragraphs 1-50 of this Complaint as if fully set forth herein.

52. Accord has infringed the '718 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 203-153, by which Accord seeks FDA approval to engage in the commercial manufacture, use, or sale of Accord's Temsirolimus Injection for the treatment of advanced renal cell carcinoma prior to the expiration of the '718 patent.

53. If Accord commercially manufactures, uses, offers to sell, or sells the Accord product within the United States, or imports Accord's Temsirolimus Injection into the United States, for the treatment of advanced renal cell carcinoma, or induces or contributes to any such conduct during the term of the '718 patent, it would further infringe the '718 patent under 35 U.S.C. § 271(a), (b), and/or (c).

54. On information and belief, Accord's Temsirolimus Injection, 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 '718 patent either literally or under the doctrine of equivalents.

55. On information and belief, the use of Accord's Temsirolimus Injection constitutes a material part of at least one of the claims of the '718 patent; Accord knows that its Temsirolimus Injection is especially made or adapted for use in infringing at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents; and its Temsirolimus Injection is not a staple article of commerce or commodities of commerce suitable for substantial noninfringing use.

56. On information and belief, the offering to sell, sale, and/or importation of Accord's Temsirolimus Injection would contributorily infringe at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents.

57. On information and belief, Accord had knowledge of the '718 patent and, by its promotional activities and package insert for Accord's Temsirolimus Injection, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents.

58. On information and belief, the offering to sell, sale, and/or importation of Accord's Temsirolimus Injection would actively induce infringement of at least one of the claims of the '718 patent, either literally or under the doctrine of equivalents.

59. Pfizer will be irreparably harmed if Accord's infringement is not enjoined. Pfizer does not have an adequate remedy at law.

60. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Pfizer's reasonable attorney fees.

RELIEF SOUGHT

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

A) That pursuant to 35 U.S.C. § 271(e)(2)(A), Accord has infringed the ‘718 patent;

B) That judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States, of the Accord product described in ANDA No. 203-153 for the treatment of advanced renal cell carcinoma, will infringe the ‘718 patent;

C) The effective date of any FDA approval of the Accord product for the treatment of advanced renal cell carcinoma not be earlier than the expiration of the ‘718 patent, including extensions;

D) That Accord, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Accord product described in ANDA No. 203-153 for the treatment of advanced renal cell carcinoma, and any other product that infringes or induces or contributes to the infringement of the ‘718 patent, prior to the expiration of the ‘718 patent, including any extensions;

E) That Pfizer be awarded monetary relief if Accord commercially uses, offers to sell, or sells its proposed generic version of Torisel[®] for the treatment of advanced renal cell carcinoma, or any other product that infringes or induces or contributes to the infringement of the ‘718 patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Pfizer with prejudgment interest;

F) That judgment be entered that this is an exceptional case under 35 U.S.C. § 285;

G) That pursuant to 35 U.S.C. § 285, Pfizer recover its reasonable attorney fees incurred in connection with this action;

H) For an assessment of costs and expenses against Accord; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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