IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

LUPIN LIMITED, Plaintiff, v. ABBOTT LABORATORIES and ASTELLAS PHARMA INC., Defendants.	Civil Action No. 3:06cv400 Judge James R. Spencer
ABBOTT LABORATORIES and ASTELLAS PHARMA INC., Counterclaim-Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Counterclaim-Defendants.	

LUPIN PHARMACEUTICALS, INC.'S REPLY, AFFIRMATIVE DEFENSES AND COUNTERCLAIM TO COUNTERCLAIM/THIRD-PARTY COMPLAINT BY ASTELLAS PHARMA INC.

Counterclaim-Defendant Lupin Pharmaceuticals, Inc. ("LPI") hereby submits its Reply to the Counterclaim/Third-Party Complaint by Counterclaim-Plaintiff Astellas Pharma Inc. ("Astellas"), for which every allegation not expressly admitted is denied, as follows:

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ASTELLAS'S COUNTERCLAIM

Nature of the Case

1. This is a civil action for infringement of United States Patents No. 4,935,507 ("the '507 patent") (Exhibit A).

REPLY: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, LPI admits that this action purports to be an action for alleged infringement of U.S. Patent No. 4,935,507 ("the '507 patent"). LPI denies all remaining allegations of Paragraph 1.

2. The '507 patent is directed to cephalosporin antibiotics and pharmaceutical compounds including such cephalosporin antibiotics. These antibiotics are known by the generic name cefdinir.

REPLY: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer is required, LPI admits that the '507 patent speaks for itself, and that the subject matter of the '507 patent is set forth in the specification and claims thereof. LPI denies all remaining allegations of Paragraph 2.

Jurisdiction and Venue

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§1331, 1332 and 1338. Venue is believed to be proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

REPLY: Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, LPI admits that subject matter jurisdiction and venue for purposes of this action only are proper. LPI denies all remaining allegations of Paragraph 3.

The Parties and Patents

4. Counterclaim Plaintiff Astellas Pharma Inc. ("Astellas") is a corporation organized and existing under the laws of Japan, having its principal place of business at 3-11, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo, Japan. Astellas is the owner by assignment of the '507 patent.

REPLY: On information and belief, LPI admits the allegations of Paragraph 4.

5. Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is the exclusive licensee of the '507 patent.

REPLY: On information and belief, LPI admits that Abbott Laboratories has a place of business at 100 Abbott Park Road, Abbott Park, Illinois, and that Abbott is the exclusive licensee of the '507 patent. LPI denies all remaining allegations of Paragraph 5.

6. Upon information and belief, Counterclaim Defendant Lupin Ltd. ("Lupin Ltd.") is a corporation organized and existing under the laws of India, having its principal place of business at Laxmi Towers, 'B' Wing, Bandra Kurla Complex, Bandra (East), Mumbai, India. Upon information and belief, Lupin Ltd. transacts business in this judicial district.

REPLY: LPI admits that Lupin Limited is a corporation organized and existing under the laws of the Sovereign Nation of India, having a place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India. LPI denies all remaining allegations of Paragraph 6.

7. Upon information and belief, Counterclaim Defendant Lupin Pharmaceuticals, Inc. ("Lupin Inc.") is a corporation organized and existing under the laws of the State of Maryland, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland. Lupin Inc. is a wholly owned subsidiary of Lupin Ltd. Upon information and belief, Lupin Inc. is the agent of Lupin Ltd. before the U.S. Food and Drug Administration ("FDA"). Upon information and belief, Lupin Inc. transacts business in this judicial district.

REPLY: LPI admits that it has a place of business at 111 South Calvert Street, Baltimore, Maryland, and that it is the U.S. agent of Lupin Limited in connection with Lupin Limited's ANDA Nos. 65-259 and 65-264 for Cefdinir for Oral Suspension, 125 mg/5 mL and Cefdinir Capsules, 300 mg, respectively. LPI denies all remaining allegations of Paragraph 7.

8. The '507 patent was duly and legally issued by the United States Patent and Trademark Office on June 19, 1990, and its term was duly and properly extended under 35 U.S.C. § 156 for a period of 1,213 days. The '507 patent is currently in force and is valid.

REPLY: LPI admits that the United States Patent and Trademark Office ("PTO") issued the '507 patent on June 19, 1990. LPI denies that the '507 patent was "duly and legally issued,"

and further denies that such patent was "duly and properly extended." LPI denies all remaining allegations of Paragraph 8.

Defendants' Infringement of the '507 patent

9. Upon information and belief, Lupin Ltd. and Lupin Inc. received approval from the FDA for an Abbreviated New Drug Application ("ANDA") to market generic cefdinir on May 19, 2006 (ANDA No. 65-264) and on May 31, 2006 (ANDA No. 65-259). (Exhibits B and C). Upon filing these ANDAs, they were technically infringing at least one claim of the '507 patent.

REPLY: LPI admits that, by letters dated May 19 and May 31, 2006, the United States Food and Drug Administration ("FDA") approved Lupin Limited's ANDA No. 65-264 for Cefdinir Capsules, 300 mg, and Lupin Limited's ANDA No. 65-259 for Cefdinir for Oral Suspension, 125 mg/5 mL, respectively. LPI further admits that copies of FDA's letters, dated May 19 and May 31, 2006, are attached as Exhibits B and C, respectively, to Astellas' Counterclaim. LPI denies all remaining allegations of Paragraph 9.

10. Upon information and belief, Counterclaim Defendants intend to manufacture, sell, offer for sale, import, or distribute products in the United States that will infringe at least one claim of the '507 patent and that such activities are imminent.

REPLY: Denied.

11. Upon information and belief, Counterclaim Defendants have in fact manufactured or imported into the United States a product that infringes at least one claim of the '507 patent.

REPLY: Denied.

12. Upon information and belief, Lupin Inc. aided and abetted Lupin Ltd.'s infringement of at least one claim of the '507 patent in the United States by acting as Lupin Ltd.'s agent before the FDA. (Exhibits B and C).

REPLY: Denied.

13. Counterclaim Defendants' actions as alleged in paragraphs 9-12 are without the consent of Astellas and violate 35 U.S.C. § 271.

REPLY: Denied.

14. Upon information and belief, Counterclaim Defendants intend to and will continue their infringing activities unless enjoined by this Court.

REPLY: Denied.

15. As a result of Counterclaim Defendants' infringing activities, Astellas will be seriously damaged and irreparably injured unless Counterclaim Defendants are enjoined by this Court.

REPLY: Denied.

16. Astellas gives notice to Counterclaim Defendants of the infringement of the '507 patent by the filing of this complaint.

REPLY: Denied.

17. Upon information and belief, the infringement of the '507 patent by the Counterclaim Defendants has been willful.

REPLY: Denied.

Count 1: Direct Infringement of the '507 Patent

18. Astellas repeats the allegations of paragraphs 1-17 as if set forth at length herein.

REPLY: LPI restates and incorporates by reference its responses to the allegations of the foregoing Paragraphs 1 through 17, as though fully set forth herein.

19. Upon information and belief, Counterclaim Defendants intend to commence imminently the manufacture, sell, offer for sale, import, and/or distribute products in the United States that will infringe at least one claim of the '507 patent.

REPLY: Denied.

20. Upon information and belief, Counterclaim Defendants have in fact manufactured or imported into the United States a product that infringes at least one claim of the '507 patent.

REPLY: Denied.

21. Lupin Ltd. filed an ANDA for products that infringe at least one claim of the '507 patent.

REPLY: Denied.

22. Counterclaim Defendants' conduct constitutes infringement of at least one claim of the '507 patent.

REPLY: Denied.

23. Counterclaim Defendants' conduct violates 35 U.S.C. § 271.

REPLY: Denied.

Count 2: Indirect Infringement of the '507 Patent

24. Astellas repeats the allegations of paragraphs 1-23 as if set forth at length herein.

REPLY: LPI restates and incorporates by reference its responses to the allegations of the foregoing Paragraphs 1 through 23, as though fully set forth herein.

25. Upon information and belief, Lupin Inc. aided and abetted Lupin Ltd.'s filing of an ANDA for products that directly infringe at least one claim of the '507 patent.

REPLY: Denied.

26. Lupin Inc.'s conduct constitutes infringement of at least one claim of the '507 patent.

REPLY: Denied.

27. Lupin Inc.'s conduct violates 35 U.S.C. § 271.

REPLY: Denied.

Relief Sought

Wherefore, Astellas prays for a judgment against Counterclaim Defendants:

A. that Counterclaim Defendants, their officers, directors, employees, agents, attorneys, privies, successors, and assigns, and all persons and entities acting in concert or participation with them, under their authority or control, or on their behalf, be preliminarily and permanently enjoined from further inducement of and direct infringement of the '507 patent;

B. that Counterclaim Defendants have directly infringed, contributed to the infringement of, and induced the infringement of the '507 patent;

C. that Counterclaim Defendants' infringement of the '507 patent has been willful;

D. that the Court issue an order under 35 U.S.C. § 154 to exclude Counterclaim Defendants from making, using, offering for sale, or selling products that infringe the '507 patent or from importing products that infringe the '507 patent into the United States;

E. that Astellas be awarded monetary damages for all damages incurred as a result of Counterclaim Defendants' infringement of the '507 patent, increased threefold for willful infringement, pursuant to 35 U.S.C. § 284;

F. that Astellas be awarded reasonable attorney fees pursuant to 35 U.S.C. § 285;

G. that Astellas be awarded its costs in this action; and

H. that Astellas be awarded such other relief as this Court may deem just and proper.

REPLY: LPI denies that Defendant/Counterclaim-Plaintiff Astellas is entitled to any of the relief requested in Paragraphs A through H of the Counterclaim, or to any relief whatsoever. LPI respectfully requests that the Court: (a) dismiss the Counterclaim with prejudice; (b) enter judgment in favor of LPI; (c) award LPI the reasonable attorneys' fees and costs of defending the Counterclaims pursuant to 35 U.S.C. § 285; and (d) award LPI such further relief as the Court deems just and appropriate. LPI further denies each allegation not specifically admitted herein.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Reply, without admitting any allegations of the Counterclaim not otherwise admitted, and without undertaking any of the burdens imposed by law on Astellas, LPI and asserts the following defenses to the Counterclaim:

First Defense

Astellas' Counterclaim fails to state a claim upon which relief can be granted.

Second Defense

The activities taken in conjunction with the preparation, submission and development of ANDA Nos. 65-529 and 65-264, and/or otherwise acting as an agent on behalf

of Lupin Limited in connection with such preparation, submission and development of ANDA Nos. 65-529 and 65-264, are immune from infringement liability under 35 U.S.C. § 271(e)(1).

Third Defense

The manufacture, sale, offer for sale, use, importation and/or distribution of Lupin Limited's cefdinir products that are the subject of ANDA Nos. 65-529 and 65-264 will not and do not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of United States Patent No. 4,935,507 ("the '507 patent").

Fourth Defense

The '507 patent, entitled "CRYSTALLINE 7-(2-(2-AMINOTHIAZOL-4-YL)-2-HYDROXYIMINOACETAMIDO)-3-VINYL-3-CEPHEM-4-CARBOXYLIC ACID (SYN ISOMER)," which purportedly issued on June 19, 1990, to Takao Takaya, Fumiyuki Shirai, Hitoshi Nakamura, and Yasunobu Inaba, is invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. § 1 *et seq.* and/or for obviousness-type double patenting.

Fifth Defense

The patent term extension for the '507 patent is invalid.

* * *

LPI reserves the right to amend this pleading at any time to assert additional defenses as necessary and/or appropriate in accordance with the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the Eastern District of Virginia.

COUNTERCLAIMS BY LUPIN PHARMACEUTICALS, INC.

Lupin Pharmaceuticals, Inc. ("LPI") asserts the following counterclaims against Counterclaim/Third-Party-Plaintiff/Counterclaim-Defendant Astellas Pharma, Inc. ("Astellas"):

The Parties

1. LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

2. Lupin Limited is a corporation organized and existing under the laws of the Sovereign Nation of India, having a place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India.

3. On information and belief, Counterclaim-Plaintiff Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the State of Illinois, having a place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. On information and belief, Abbott manufactures and sells pharmaceutical products throughout the United States, including within the State of Virginia and this District.

4. On information and belief, Counterclaim-Plaintiff/Counterclaim-Defendant Astellas Pharma Inc. ("Astellas") is a corporation organized and existing under the laws of the Sovereign Nation of Japan, having a place of business at 2-3-11, Nihonbashi-Honcho 2-Chome, Chuo-Ku, Tokyo 103-8411, Japan. On information and belief, Astellas manufactures and sells pharmaceutical products throughout the United States, including within the State of Virginia and this District.

Jurisdiction and Venue

5. This Counterclaim arises under, *inter alia*, the Patent Laws of the United States 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. The Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. § 1 *et seq.*), and under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202), because this action involves an actual controversy concerning the infringement and validity of the patent-in-suit.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

8. This Court has personal jurisdiction over Abbott and Astellas because they regularly conduct business in, and have regular and systematic contact with, the State of Virginia, including this District, and because Abbott and Astellas sued LPI in this State and District.

Patent-in-Suit

9. On or about June 19, 1990, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,935,507 ("the '507 patent"), entitled "Crystalline 7-(2-(2-aminothiazol-4-YL)-2-Hydroxyiminoacetamido)-3-Vinyl-3-Cephem-4-Carboxylic Acid (Syn Isomer)," to Takao Takaya, Fumiyuki Shirai, Hitoshi Nakamura, and Yasunobu Inaba. A true and correct copy of the '507 patent is attached to this Counterclaim as Exhibit A.

10. According to the records of the PTO, Astellas is the assignee and record owner of the '507 patent.

11. On information and belief, Astellas purports and claims to own, and to have the right to enforce, the '507 patent.

12. On information and belief, Abbott is the exclusive licensee of the '507 patent.

13. On information and belief, Abbott purports and claims to have the right to enforce the '507 patent.

14. On or about November 1, 2006, Astellas sued LPI in this District alleging infringement and induced and contributory infringement of the '507 patent under 35 U.S.C. § 271, based on the manufacture, use, sale, offer for sale, importation and/or distribution of Lupin Limited's generic Cefdinir Capsules 300 mg, and Lupin Limited's generic Cefdinir for Oral Suspension, 125 mg/5 mL, which drug products are the subject of Lupin Limited's ANDA Nos. 65-264 and 65-259, respectively.

COUNT I
(Declaratory Judgment of Non-Infringement of the '507 Patent)

15. LPI repeats each of the foregoing paragraphs as if fully set forth herein.

16. There is an actual, substantial, and continuing justiciable case or controversy between Astellas and LPI regarding the infringement and validity of the '507 patent.

17. The manufacture, use, sale, offer for sale, importation and/or distribution of Lupin Limited's generic Cefdinir Capsules 300 mg, which are the subject of ANDA No. 65-264, and Lupin Limited's generic Cefdinir for Oral Suspension, 125 mg/5 mL, which is the subject of Lupin Limited's ANDA No. 65-259, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '507 patent.

18. LPI has not infringed and will not infringe the '507 patent.

19. LPI has not induced or contributed to, and will not induce or contribute to, infringement of the '507 patent.

20. LPI is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation and/or distribution of Lupin Limited's generic Cefdinir Capsules 300 mg, which are the subject of ANDA No. 65-264, and Lupin Limited's generic Cefdinir for Oral Suspension, 125 mg/5 mL, which is the subject of Lupin Limited's ANDA No. 65-259, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '507 patent.

21. LPI is entitled to a judicial declaration that it has not infringed and will not infringe the '507 patent.

22. LPI is entitled to a judicial declaration that it has not induced or contributed to, and will not induce or contribute to, infringement of the '507 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '507 Patent)

23. LPI repeats each of the foregoing paragraphs as if fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy between Astellas and LPI regarding the validity of the '507 patent.

25. The claims of the '507 patent are invalid for failure to satisfy one or more of the conditions for patentability in 35 U.S.C. § 1 *et seq*. and/or for obviousness-type double patenting.

26. LPI is entitled to a judicial declaration that the claims of the '507 patent are invalid.

COUNT III
(Declaratory Judgment of Invalidity of PTE for the '507 Patent)

27. LPI repeats each of the foregoing paragraphs as if fully set forth herein.

28. There is an actual, substantial, and continuing justiciable case or controversy between Astellas and LPI regarding the validity of the patent term extension ("PTE") for the '507 patent.

29. The requirements for a PTE under Hatch-Waxman is found in 35 U.S.C. § 156.

30. The '507 patent was extended by 1,213 days under 35 U.S.C. § 156.

31. U.S. Patent No. 4,559,334 ("the '334 patent") received a PTE under 35 U.S.C. § 156.

32. But for the PTE for the '507 patent, the '507 patent would expire at midnight on August 7, 2008.

33. But for the PTE for the '334 patent, the '334 patent would have expired as of the present day.

34. 35 U.S.C. § 156(c)(4) states that "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product." Subsection (c)(4) thus limits the authority of the PTO to issue a PTE based on time lost for the "same" regulatory review period for "any product."

35. 35 U.S.C. § 156 does not permit the issuance of more than one PTE for a regulatory review period involving the same active ingredient.

36. On or about January 27, 1998, Warner-Lambert filed a request for a PTE of the '507 patent.

37. In filing the PTE for the '507 patent, Warner-Lambert was acting at the time on behalf of Fujisawa, then the assignee of the '507 patent.

38. Fujisawa authorized Warner-Lambert to submit the PTE application for the '507 patent.

39. Astellas is the successor-in-interest to Fujisawa. The company Astellas was formed when Fujisawa merged with Yamanouchi Pharmaceuticals.

40. In the application for PTE for the '507 patent that Warner-Lambert filed, Warner-Lambert informed the PTO that the '507 patent fulfilled the statutory requirements of 35 U.S.C. § 156 rendering it eligible for extension.

41. As part of the PTE that Warner-Lambert filed for the '507 patent, Warner-Lambert represented to the PTO that the '507 patent claims cefdinir.

42. According to Warner-Lambert's statements in the PTE application, the '507 patent's crystalline form was the ingredient used by Warner-Lambert in the clinical trials for Omnicef® oral suspension. The January 27, 1998 PTE application at page 8 specifically states:

> Claim 1 reads, in part, 'Crystalline [cefdinir] (syn isomer) ....' This is the active ingredient in Omnicef® (cefdinir suspension).

43. Also in the '507 patent's PTE application, Warner-Lambert stated that "[n]either cefdinir, as the free acid, nor any salt or ester of cefdinir free acid, has previously been approved." (1/27/1998 PTE Application at 4). Warner-Lambert did not disclose that it was simultaneously seeking a PTE for the '334 patent. (*Id.*)

44. Warner-Lambert also informed the PTO that the original IND submission that started the regulatory review period was assigned IND No. 34,738. (*See* 1/27/1998 PTE Application at 9-10).

45. Also, with its PTE application for the '507 patent, Warner-Lambert submitted a declaration by Charles Ashbrook stating:

> I believe the patent is eligible for extension pursuant to 37 C.F.R. § 1.710; I believe that the length of extension claimed in this Application is fully justified under [Section] 156 and the applicable regulations; and I believe the patent for which this

> extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. § 1.720.

(1/27/1998 PTE Application at 23). Fujisawa confirmed that Warner-Lambert was acting as its agent in seeking the PTE, and that Charles Ashbrook had power of attorney "for purposes of filing and prosecuting the application for extension." (*Id.*, Ex. 1 at 1).

46. The '507 patent received a PTE based on a regulatory review period involving Omnicef® oral suspension.

47. Omnicef® oral suspension contains cefdnir as the active ingredient.

48. Warner-Lambert also filed a request for a PTE of the '334 patent.

49. In filing the PTE for the '334 patent, Warner-Lambert was acting at the time on behalf of Fujisawa, then the assignee of the '334 patent.

50. Fujisawa authorized Warner-Lambert to submit the PTE application for the '334 patent.

51. As part of the PTE that Warner-Lambert filed for the '334 patent, Warner-Lambert represented to the PTO that the '334 patent claims cefdinir.

52. The '334 patent received a PTE based on a regulatory review period involving Omnicef® capsules.

53. Omnicef® capsules contain cefdnir as the active ingredient.

54. The PTO issued two PTEs, one for the '507 patent, and one for the '334 patent, based on regulatory review periods involving Omnicef® drug products.

55. The PTO issued two PTEs, one for the '507 patent, and one for the '334 patent, based on regulatory review periods involving drug products, which each contained cefdinir as the active ingredient.

56. Abbott contends that both the '507 and '334 PTEs were duly and legally issued.

57. Abbott contends that both the '507 and '334 PTEs were duly and properly extended.

58. Astellas contends that both the '507 and '334 PTEs were duly and legally issued.

59. Astellas contends that both the '507 and '334 PTEs were duly and properly extended.

60. Both Abbott and Astellas have asserted that the '507 PTE permits the enforcement of the patent past its original expiration date.

61. Both Abbott and Astellas have asserted that the '334 PTE permits the present enforcement of the '334 patent.

62. At least one of the PTEs for the '507 and/or '334 patent was improper. The issuance of two PTEs for regulatory review periods involving cefdinir as the active ingredient was not authorized under 35 U.S.C. § 156.

63. The PTE for the '507 patent is invalid because Astellas already received a PTE on an earlier patent for cefdinir. Section 156 does not permit the additional PTE for the '507 patent.

64. LPI is entitled to a judicial declaration that the PTE for the '507 patent is invalid and that the term of such patent expires no later than August 8, 2008.

PRAYER FOR RELIEF

Wherefore, Lupin Pharmaceuticals, Inc. respectfully requests entry of judgment:

A. Declaring that the manufacture, use, sale, offer for sale, importation and/or distribution of Lupin Limited's generic Cefdinir Capsules 300 mg, which are the subject of ANDA No. 65-264, have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '507 patent;

B. Declaring that the manufacture, use, sale, offer for sale, importation and/or distribution of Lupin Limited's generic Cefdinir for Oral Suspension, 125 mg/5 mL, which is the subject of ANDA No. 65-259, have not infringed, do not infringe, and will not infringe (either literally or under the doctrine

of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '507 patent;

C. Declaring that Lupin Pharmaceuticals, Inc. has not infringed and will not infringe the '507 patent;

D. Declaring that Lupin Pharmaceuticals, Inc. has not induced or contributed to, and will not induce or contribute to, infringement of the '507 patent;

E. Declaring that the claims of the '507 patent are invalid;

F. Declaring that the PTE for the '507 patent is invalid and that such patent expires August 8, 2008;

G. Declaring this an exceptional case and awarding Lupin Pharmaceuticals, Inc. its reasonable attorneys' fees under 28 U.S.C. § 285;

H. Awarding Lupin Pharmaceuticals, Inc. its reasonable costs and expenses of this action; and

I. Awarding Lupin Pharmaceuticals, Inc. such further necessary or proper relief as the Court may deem just.

JURY DEMAND

Counterclaim-Defendant/Counterclaim-Plaintiff Lupin Pharmaceuticals, Inc. hereby demands a trial by jury on all issues so triable.

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CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2006, a true copy of the foregoing Lupin Pharmaceuticals, Inc.'s Reply, Affirmative Defenses and Counterclaim to Counterclaim/Third-Party Complaint by Astellas Pharma Inc. was sent *via* overnight delivery to:

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