IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HETERO LABS LTD. UNIT V and HETERO USA, INC., *Plaintiffs*, v. PHARMACIA & UPJOHN COMPANY LLC, *Defendant*.	Civil Action No. _____

COMPLAINT

Plaintiffs Hetero Labs Ltd. Unit V and Hetero USA, Inc. (collectively, "Hetero"), by their attorneys, for their complaint against Pharmacia & Upjohn Company LLC ("Defendant") allege as follows:

NATURE OF THE ACTION

1. Hetero bring claims for declaratory relief under the Declaratory Judgment Act, 29 U.S.C. §§ 2201, 2202, and the provision of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act ("FDCA") establishing civil actions for patent certainty, 21 U.S.C. § 355(j)(5)(C), that U.S. Patent Nos. 6,514,529 ("the '529 patent") and 6,559,305 ("the '305 patent") are not infringed by Hetero so that the U.S. Food & Drug Administration ("FDA") can provide Hetero final approval to market its Linezolid Tablets, which are generic equivalents of Defendant's Zyvox® drug product.

PARTIES

2. Hetero Labs Ltd. Unit V is a corporation under the laws of India, with its principal place of business at 22-110, IDA, Jeedimetla, Hyderabad-500055, India.

3. Hetero USA Inc. is a Delaware corporation with a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

4. On information and belief, Pharmacia & Upjohn Company LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, with offices located at 7000 Portage Road, Kalamazoo, Michigan 49001.

JURISDICTION AND VENUE

5. This is a declaratory judgment action is under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., the FDCA, 21 U.S.C. § 301 *et seq*. (as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C § 355)), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. Subject matter jurisdiction is proper under 28 U.S.C. § 1331 and 1338(a).

7. Personal jurisdiction as to Pharmacia & Upjohn Company is proper in this district because it has consented to personal jurisdiction by filing in this district *Pharmacia & Upjohn Co., LLC v. Apotex, Inc.,* Civil Action No. 1:13-cv-02034, which involved the ‘305 and the ‘529 patents, which are the same patents that are the subject of the instant action.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

BACKGROUND--FDA Approval of Brand Name and Generic Drugs

9. Under the FDCA, 21 U.S.C. § 301 *et seq*., an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by the FDA. 21 U.S.C. § 355(a).

10. The NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §§ 355(b)(1), 355(c)(2).

11. Upon approval of the NDA, the FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. 21 U.S.C. § 355(j)(7)(A)(iii).

12. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e).

13. Under the Hatch-Waxman Amendments, a generic manufacturer submits an Abbreviated New Drug Application ("ANDA") and to receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is bioequivalent to the listed reference drug. 21 U.S.C. § 355(j)(2)(A).

14. An ANDA must contain a certification to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the listed reference drug. 21 U.S.C. § 355(j)(2)(A)(vii).

15. An ANDA containing a paragraph IV certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. 21 U.S.C. §

355(j)(2)(B)(i)-(iii).

17. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

18. The patent holder's filing of a lawsuit prior to the expiration of 45 days prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. 21 U.S.C. § 355(j)(5)(B)(iii).

19. If the patent holder does not file a lawsuit within the 45 days after receiving notice of the ANDA applicant's paragraph IV certification, the applicant's ANDA is to be approved immediately (subject to any 180-day marketing exclusivity). 21 U.S.C. §§ 355(j)(5)(B)(iii), 355(j)(5)(B)(iv)(I).

First-to-File ANDA Applicant's 180-day Generic Market Exclusivity and Forfeiture

20. If an ANDA applicant is the "first-to-file" a substantially complete ANDA with a paragraph IV certification to an Orange Book-listed patent and provides appropriate notice to the FDA, the NDA holder, and all patent owner(s) for a particular generic product, that first-to-file ANDA applicant may be awarded a 180-day period of marketing exclusivity against other companies that subsequently file ANDAs referencing the same branded drug product. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

21. An ANDA with a paragraph IV certification shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug by any first-to-file ANDA applicant. See 21 U.S.C. §355(j)(5)(B)(iv)(I).

22. The first-to-file ANDA applicant can forfeit its 180-day marketing exclusivity period under certain circumstances, including if the ANDA is not marketed within 75 days after

a final and non-appealable court decision finding an Orange Book listed patent invalid or not infringed in an infringement or declaratory judgment action, wherein such declaratory judgment action was brought by either a first-to-file ANDA applicant or any other ANDA applicant, and such action relates to the Orange Book listed patent for which the ANDA applicant submitted and lawfully maintained a paragraph IV certification. See 21 U.S.C. § 355(j)(5)(D)(i)(I).

Pharmacia's NDA

23. Pharmacia holds the approved New Drug Application No. 21-130 for Zyvox® linezolid tablets.

24. Pharmacia sells and distributes a pharmaceutical product under the trade name Zyvox® that is a linezolid tablet.

25. The '529 patent is listed in the Orange Book in connection with NDA No. 21-130 and the brand name drug Zyvox®.

26. The '305 patent is listed in the Orange Book in connection with NDA No. 21-130 and the brand name drug Zyvox®.

27. Pharmacia, as holder of NDA No. 21-130, listed or caused to be listed the '529 patent and the '305 patent in the Orange Book for NDA No. 21-130.

28. Pharmacia's linezolid tablets, 600 mg, are the only linezolid tablets currently commercially available in the United States.

Hetero's ANDA

29. Hetero Labs Ltd. Unit V, through Hetero USA Inc. acting as its U.S. Regulatory Agent, submitted ANDA No. 20-4239 to the FDA under section 505(j) of the FDCA, seeking approval for Linezolid Tablets, 600 mg, as defined in ANDA No. 20-4239 ("Hetero's Proposed

ANDA Product").

30. Hetero's ANDA No. 20-4239 includes paragraph IV certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '529 patent and the '305 patent are invalid, unenforceable, and/or will not be infringed by Hetero's Proposed ANDA Product.

First-to-File ANDA Applicant for Linezolid Tablets 600 mg

31. After reasonable opportunity for further investigation and discovery, the first substantially complete generic drug application for linezolid tablets containing a paragraph IV certification to the '529 patent and the '305 patent was submitted to the FDA on December 21, 2005, resulting in an ANDA applicant other than Hetero being awarded 180-days of marketing exclusivity for linezolid tablets ("Linezolid first-to-file ANDA applicant").

32. Hetero filed its ANDA No. 20-4239 on or about May 16, 2012 with the FDA seeking approval for Linezolid Tablets, 600 mg, as defined its ANDA, and is not the Linezolid first-to-file ANDA applicant.

33. Hetero has not been awarded first-to-file status by the FDA for linezolid tablets and as such, is precluded from obtaining final approval and entering the market due to the delay in FDA final approval of its ANDA application caused by Pharmacia's listing of the '529 and '305 patents in the Orange Book.

34. On April 3, 2015, FDA tentatively approved Hetero's ANDA 20-4239, concluding that Hetero's Proposed ANDA Product is safe and effective for use as recommended in the proposed labeling.

35. On information and belief, Pharmacia's listing of the '529 patent and the '305 patent in the Orange Book for NDA 21-130, and the associated 180-day exclusivity held by the Linezolid first-to-file ANDA applicant, is the only obstacle preventing FDA from granting final

approval to Hetero's ANDA 20-4239, which would permit Hetero to begin marketing its Proposed ANDA Product as a generic equivalent to Zyvox® tablets.

36. As there are no other unexpired patents or other exclusivities listed in the Orange Book for NDA 21-130, had Pharmacia not listed the '529 patent and the '305 patent in the Orange Book for NDA 21-130, there would no 180-day exclusivity at present for the Linezolid first-to-file ANDA applicant.

37. By listing the '529 patent and the '305 patent in the Orange Book for NDA 21-130, Pharmacia is causally responsible for the current existence of 180-day exclusivity period for the Linezolid first-to-file ANDA applicant.

38. Hetero may market its Proposed ANDA Product before the expiration of the 180-day exclusivity period held by the Linezolid first-to-file ANDA applicant if that exclusivity period is forfeited by a triggering event defined by 21 U.S.C. § 355(j)(5)(D)(i)(I), including a final court decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '529 patent and the '305 patent are not infringed.

39. If the 180-day exclusivity period held by the Linezolid first-to-file ANDA applicant is not forfeited or otherwise extinguished, then that exclusivity period will continue to prevent Hetero from marketing its Proposed ANDA Product until the '529 patent and the '305 patent expire.

The '529 Patent

40. The '529 patent is entitled "Oxazolidinone Tablet Formulation" and lists Pharmacia & Upjohn Company on its face as the assignee. The Orange Book lists the '529 patent's expiration date as March 15, 2021. The Orange Book also lists a period of pediatric exclusivity related to the '529 patent that expires on September 15, 2021.

41. After a reasonable opportunity for further investigation or discovery, Pharmacia & Upjohn Company owns the right, title, and interest in the '529 patent. A true and correct copy of the '529 patent is attached hereto as Exhibit A.

42. The '529 patent states that "[t]he present invention is a novel tablet formulation which permits high drug load and does not use lactose." *See* col. 1, lines 13-14.

43. In stating that "[t]he present invention is a novel tablet formulation which permits high drug load and does not use lactose" (col. 1, lines 13-14), the patent applicants clearly disavowed any tablet formulation containing lactose.

44. The claims of the '529 patent are directed to a compressed tablet having a specific formulation, or a method of using such a tablet.

45. None of the claims of the '529 patent recite lactose.

46. In contrast, all of the claims of the '529 patent recite a compressed tablet containing at least (1) starch or corn starch, (2) microcrystalline cellulose, (3) hydroxypropylcellulose, and (4) disintegrants selected from sodium starch glycolate, crosscarmellose sodium, crospovidone, and low substituted hydroxypropylcellulose.

47. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.95, Hetero sent a letter on October 16, 2012, (the "Notice Letter"), to Pharmacia & Upjohn Company, LLC, as well as to Pfizer, Inc., stating Hetero had certified the '529 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the new drug for which ANDA No. 20-4239 is submitted. A true and correct copy of the Notice Letter is attached hereto as Exhibit B.

48. Hetero's Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero had filed ANDA No. 20-4239 with the FDA, seeking approval for its Linezolid Tablets,

600 mg, prior to the expiration of the ‘529 patent.

49. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero’s Proposed ANDA Product includes lactose, and for at least that reason does not infringe the ‘529 patent.

50. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero’s Proposed ANDA Product does not include starch or corn starch or its equivalent, and for at least that reason does not infringe the ‘529 patent.

51. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero’s Proposed ANDA Product does not include microcrystalline cellulose or its equivalent, and for at least that reason does not infringe the ‘529 patent.

52. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero’s Proposed ANDA Product does not include hydroxypropylcellulose or its equivalent, and for at least that reason does not infringe the ‘529 patent.

53. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero’s Proposed ANDA Product does not include a disintegrant selected from sodium starch glycolate, crosscarmellose sodium, crospovidone, and low substituted hydroxypropylcellulose, or an equivalent thereof, and for at least that reason does not infringe the ‘529 patent.

54. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc), the Notice Letter contained an Offer of Confidential Access, as defined by 21 U.S.C. § 355(j)(5)(C)(i)(III).

55. Neither Pharmacia & Upjohn Company nor Pfizer brought a civil action against Hetero for infringement of the ‘529 patent before the expiration of forty-five days after which they received notice that Hetero had submitted ANDA No. 20-4239 to the FDA seeking approval for Linezolid Tablets, 600 mg, prior to expiration of the ‘529 patent.

56. Under the framework of the Hatch-Waxman Amendments, Hetero is being restrained from selling a non-infringing product because Pharmacia's action of listing the '529 patent in the Orange Book delays FDA final approval of Hetero's ANDA and excludes Hetero from the market.

57. Pharmacia's listing of the '529 patent creates an independent barrier to the drug market that deprives Hetero of an opportunity to compete with its non-infringing product.

58. After a reasonable opportunity for further investigation or discovery, a final and non-appealable court decision relating to Hetero's non-infringement of the '529 patent would ensure that Hetero is able to obtain final approval of its ANDA No. 20-4239 before the expiration of the '529 patent absent a launch by the Linezolid first-to-file ANDA applicant (*i.e*. the court decision would operate as a forfeiture event of the Linezolid first-to-file ANDA applicant's 180-day marketing exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)).

59. A real, actual and justiciable controversy exists between Hetero on the one hand, and Pharmacia on the other hand, regarding Hetero's non-infringement of the '529 patent, constituting a case of actual controversy to ensure that Hetero's Proposed ANDA Product can freely enter the market earlier than it otherwise would absent a final and non-appealable order relating to the '529 patent. This actual controversy regarding patent certainty is defined by 21 U.S.C. §355(j)(5)(C)(i)(II) and is within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

The '305 Patent

60. The '305 patent is entitled "Linezolid – Crystal Form II" and lists Pharmacia & Upjohn Company on its face as the assignee. The Orange Book lists the '305 patent's expiration date as January 29, 2021. The Orange Book also lists a period of pediatric exclusivity related to

the ‘305 patent that expires on July 29, 2021.

61. After a reasonable opportunity for further investigation and discovery, Pharmacia & Upjohn Company owns the right, title, and interest in the ‘305 patent. A true and correct copy of the ‘305 patent is attached hereto as Exhibit C.

62. The ‘305 patent has two claims, both of which are limited to Form II of linezolid.

63. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.95, Hetero sent the Notice Letter to Pharmacia & Upjohn Company, LLC, as well as to Pfizer, Inc., stating Hetero had certified the ‘305 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the new drug for which ANDA No. 20-4239 is submitted.

64. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero had filed ANDA No. 20-4239 with the FDA, seeking approval for its Linezolid Tablets, 600 mg, prior to the expiration of the ‘305 patent.

65. Hetero’s Notice Letter notified Pharmacia & Upjohn Company and Pfizer that Hetero’s Proposed ANDA Product does not contain Form II of linezolid, and for at least that reason does not infringe the ‘305 patent.

66. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc), the Notice Letter contained an Offer of Confidential Access, as defined by 21 U.S.C. § 355(j)(5)(C)(i)(III).

67. Neither Pharmacia & Upjohn Company nor Pfizer brought a civil action against Hetero for infringement of the ‘305 patent before the expiration of forty-five days after which they received notice that Hetero had submitted ANDA No. 20-4239 to the FDA seeking approval for Linezolid Tablets, 600 mg, prior to expiration of the ‘305 patent.

68. Under the framework of the Hatch-Waxman Amendments, Hetero is being restrained from selling a non-infringing product because Pharmacia’s action of listing the ‘305

patent in the Orange Book delays FDA final approval of Hetero's ANDA and excludes Hetero from the market.

69. Pharmacia's listing of the '305 patent creates an independent barrier to the drug market that deprives Hetero of an opportunity to compete with its non-infringing product.

70. After a reasonable opportunity for further investigation or discovery, a final and non-appealable court decision relating to Hetero's non-infringement of the '305 patent would ensure that Hetero is able to obtain final approval of its ANDA No. 20-4239 before the expiration of the '305 patent absent a launch by the Linezolid first-to-file ANDA applicant (*i.e.* the court decision would operate as a forfeiture event of the Linezolid first-to-file ANDA applicant's 180-day marketing exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)).

71. A real, actual and justiciable controversy exists between Hetero on the one hand, and Pharmacia on the other hand, regarding Hetero's non-infringement of the '305 patent, constituting a case of actual controversy to ensure that Hetero's Proposed ANDA Product can freely enter the market earlier than it otherwise would absent a final and non-appealable order relating to the '305 patent. This actual controversy regarding patent certainty is defined by 21 U.S.C. § 355(j)(5)(C)(i)(II) and is within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '529 PATENT

72. Hetero adopts by reference, repeats, and realleges Paragraphs 1-71 above as though set forth fully herein.

73. Hetero does not, and would not if it were to market its Proposed ANDA Product, infringe, contribute to the infringement of, or induce the infringement of any valid claim of the

‘529 patent.

COUNT II: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ‘305 PATENT

74. Hetero adopts by reference, repeats, and realleges Paragraphs 1-73 above as though set forth fully herein.

75. Hetero does not, and would not if it were to market its Proposed ANDA Product, infringe, contribute to the infringement of, or induce the infringement of any valid claim of the ‘305 patent.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Hetero Labs Ltd. Unit V and Hetero USA, Inc. respectfully pray for judgment in their favor and against Pharmacia:

a) ordering that judgment be entered in favor of Hetero Labs Ltd. Unit V and Hetero USA, Inc.;

b) declaring that the manufacture, use, sale, offer for sale, or importation of the linezolid tablet that is the subject of ANDA No. 20-4239 does not infringe, directly or indirectly, either literally or under the doctrine of equivalents, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘529 patent;

c) declaring that the manufacture, use, sale, offer for sale, or importation of the linezolid tablet that is the subject of ANDA No. 20-4239 does not infringe, directly or indirectly, either literally or under the doctrine of equivalents, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘305 patent;

d) declaring this case exceptional and awarding Hetero Labs Ltd. Unit V and Hetero USA, Inc. their costs, expenses, and attorneys’ fees under 35 U.S.C. § 285; and

e) awarding Hetero Labs Ltd. Unit V and Hetero USA, Inc. such other and further relief as the Court may deem just and proper.

Dated: June 18, 2015

s/ Stephen R. Auten

Stephen R. Auten (ARDC 6242454)
Richard T. Ruzich (ARDC 6238004)
Roger Kiley (ARDC 6283248)
Brian P. Murray (ARDC 6305864)
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
aalul@taftlaw.com
rkiley@taftlaw.com
bmurray@taftlaw.com

Attorneys for Plaintiffs
Hetero Labs Ltd. Unit V and Hetero USA, Inc.