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IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Alexandria Division 2007 APR 17 P 12: 11

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THREE RIVERS PHARMACEUTICALS, LLC 301 Commerce Park Cranberry Township, PA 16066,	CLERK US DETRICT COURT ALEXABERIA, VIRGINIA)
Plaintiff,)
v.) Civil Action No. 2:07cv / 7 ?
ZYDUS PHARMACEUTICALS (USA) INC. 508 Carnegie Center, Suite 101 Princeton, NJ 08540; and	RAI))
CADILA HEALTHCARE LIMITED d/b/a ZYDUS-CADILA Zydus Tower, Satellite Cross Roads,) JURY TRIAL DEMANDED))
Ahmadabad 380015, India,)
Defendants.)))

COMPLAINT

Plaintiff Three Rivers Pharmaceuticals, LLC ("Three Rivers"), by its undersigned counsel, brings this action against Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited, d/b/a Zydus-Cadila and alleges as follows:

- 1. Plaintiff Three Rivers is a Pennsylvania limited liability corporation having a principal place of business at 301 Commerce Park, Cranberry Township, Pennsylvania, 16066.
- 2. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 508 Carnegie Center, Suite 101, Princeton, New Jersey, 08540.

- 3. On information and belief, Cadila Healthcare Limited, d/b/a Zydus-Cadila is an Indian corporation having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmadabad 380015, India.
- 4. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Zydus-Cadila. On information and belief, as to the facts and events alleged herein, Zydus Pharmaceuticals (USA) Inc. and Zydus-Cadila have acted together and are hereafter referred to collectively as Zydus.

Jurisdiction and Venue

- 5. This action is for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and seeks damages and injunctive relief. This court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331(a) and 1338. The courts of Virginia have personal jurisdiction over Zydus pursuant to Va. Code Ann. § 8.01-328.1.
- 6. On information and belief, Zydus transacts business within this judicial district, has sold, offered to sell and/or imported pharmaceutical products in this judicial district, including ribavirin drug products and more particularly 200 mg ribavirin capsules and/or tablets.
- 7. Zydus is subject to personal jurisdiction by the courts of the Commonwealth of Virginia.
 - 8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

Background

9. Donald J. Kerrish, John R. Bergeron and Lawrence H. Augsburger conceived and reduced to practice the invention disclosed and claimed in United States Patent No. 6,720,000 (hereinafter the "000 patent") for a new, useful and non-obvious process for manufacturing

ribavirin drug products. The '000 patent complies with all of the requirements of 35 U.S.C. § 1 et seq.

- 10. On April 13, 2004, the United States Patent and Trademark Office (the "PTO") duly and lawfully issued the '000, patent entitled "Process for Producing Wet Ribavirin Pellets."
- 11. Three Rivers owns all right, title, and interest in the '000 patent. A copy of the '000 patent is attached as Exhibit A.
- 12. On information and belief, Zydus has sold, offered to sell and/or imported ribavirin drug products, including 200 mg ribavirin capsules and/or tablets, that have been and/or will be made by a process that infringes the '000 patent.
- 13. On March 16, 2007, the United States Food and Drug Administration ("FDA") approved Zydus's production of 400 and 600 mg tablets of ribavirin. On information and belief, the 400 mg and 600 mg tablets will be made by the same infringing process as the 200 mg ribavirin tablets and/or capsules. A copy of the FDA's on-line Orange Book indicating such approval is attached as Exhibit B.

Count for Infringement of U.S. Patent No. 6,720,000

- 14. Three Rivers hereby realleges and incorporates by reference the allegations of paragraphs 1-13 of this complaint.
- 15. On information and belief, Zydus, without authority or license from Plaintiff, has directly infringed and continues to directly infringe the '000 patent either literally or under the doctrine of equivalents by manufacturing ribavirin drug products, including the 200 mg ribavirin capsules and/or tablets, by a process claimed by the '000 patent and thereafter selling, offering to sell or importing those drug products in this judicial district and elsewhere throughout the United States.

- 16. On information and belief, Zydus, without authority or license from Plaintiff, actively induced others to directly infringe the '000 patent and/or contributorily infringed the '000 patent.
- 17. On information and belief, Zydus has committed such acts of infringement with knowledge of the '000 patent.
- 18. Such acts of infringement by Zydus have been, and continue to be, willful and deliberate, and Plaintiff believes such acts will continue in the future unless enjoined by this Court.
- 19. By reason of Zydus's acts of infringement, Plaintiff has suffered and continues to suffer irreparable harm and damages, including, but not limited to, diminution in the value of the rights granted under the '000 patent.

PRAYER FOR RELIEF

WHEREFORE, Three Rivers prays for judgment in its favor and against Defendants as follows:

- A) Entering judgment for Plaintiff that Zydus directly and/or indirectly infringes the '000 patent;
- B) Entering judgment preliminarily and permanently enjoining Zydus from making, using, selling, offering to sell, or importing any product produced by a process that infringes the '000 patent;
- C) Awarding damages under 35 U.S.C. § 284 including costs and prejudgment interest;
- D) Determining that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiff its reasonable attorneys' fees, costs and expenses;

- E) Awarding Plaintiff treble damages by reason of Zydus's willful infringement; and
 - Awarding Plaintiff such other relief as the Court deems just and proper. F)

Respectfully submitted,

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Dated: April 17, 2007