

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OTSUKA PHARMACEUTICAL CO., LTD.
AND H. LUNDBECK A/S,

Plaintiffs,

v.

HETERO LABS LTD., HETERO LABS LTD.
UNIT-V, HETERO USA, INC., HETERO
DRUGS LTD. AND HONOUR LAB LTD.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) and H. Lundbeck A/S (“Lundbeck”) (collectively, “Plaintiffs”), by way of Complaint against Defendants Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero USA, Inc., Hetero Drugs Ltd. and Honour Lab Ltd. (collectively, “Hetero”), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 (“the RE’059 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Hetero’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the RE’059 patent.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Hetero Drugs Ltd. is a corporation organized under the laws of India and its principal place of business is located at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

6. Upon information and belief, Hetero Labs Ltd. is a corporation organized under the laws of India and its principal place of business is located at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

7. Upon information and belief, Hetero Labs Ltd. Unit-V is a division of Hetero Labs Ltd. and its principal place of business is located at Polepally, Jadcherla, Mahabubnagar 509 301, Andhra Pradesh, India.

8. Upon information and belief, Hetero USA, Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 1035 Centennial Avenue, Piscataway, NJ 08854. Upon information and belief, Hetero USA, Inc. is the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, Hetero Labs Ltd. and Hetero Drugs Ltd.

9. Upon information and belief, Hetero Drugs Ltd. and Hetero Labs Ltd. each own a 50% share of Hetero USA, Inc.

10. Upon information and belief, Honour Lab Ltd. is a corporation organized under the laws of India and its principal place of business is located at 8-3-166/7/1, Hetero House, Erragadda, Hyderabad 500 018, Telangana, India.

11. Upon information and belief, Honour Lab Ltd. is a subsidiary or affiliate of the Hetero group companies, including Hetero Drugs Ltd. and Hetero Labs Ltd.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Hetero Drugs Ltd. Upon information and belief, Hetero Drugs Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Drugs Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

14. Upon information and belief, Hetero Drugs Ltd. admits it "is one of India's leading generic pharmaceutical companies" and it "has a strong global presence in over 126 countries[.]" <https://www.heteroworld.com/company-profile.php> (accessed Nov. 11, 2020). Upon information and belief, Hetero Drugs Ltd. admits "our R&D has been able to develop niche generics, . . . ANDAs and FTFs[.]" <https://www.heteroworld.com/research.php> (accessed Nov. 11, 2020).

15. This Court has personal jurisdiction over Hetero Labs Ltd. Upon information and belief, Hetero Labs Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Labs Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs

throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

16. Upon information and belief, Hetero Labs Ltd. "is a research based global pharmaceutical company focused on development, manufacturing and marketing of Active Pharmaceutical Ingredients (APIs), Intermediate Chemicals & Finished Dosages." <https://www.indiamart.com/heterolabs-limited/aboutus.html> (Hetero Labs Ltd. Profile, accessed Nov. 11, 2020).

17. Upon information and belief, Hetero Drugs Ltd. and Hetero Labs Ltd. share more than one common corporate director. *See* <https://www.zaubacorp.com/company/HETERO-DRUGS-LIMITED/U24230TG1993PLC015582> (Hetero Drugs Ltd. Profile, accessed Nov. 11, 2020); <https://www.zaubacorp.com/company/HETERO-LABS-LIMITED/U24110TG1989PLC009723> (Hetero Labs Ltd. Profile, accessed Nov. 11, 2020) (naming five common corporate directors).

18. This Court has personal jurisdiction over Hetero Labs Ltd. Unit-V. Upon information and belief, Hetero Labs Ltd. Unit-V is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Labs Ltd. Unit-V directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Ltd. Unit-V purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

19. Upon information and belief, Hetero Labs Ltd. Unit-V is the drug manufacturing

facility for Hetero Labs Ltd. and manufactures Hetero's generic products. *See, e.g.*, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017> (letter from the FDA to Hetero Labs Ltd. Unit-V, accessed Nov. 11, 2020).

20. This Court has personal jurisdiction over Hetero USA, Inc. Upon information and belief, Hetero USA, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero USA, Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero USA, Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

21. Upon information and belief, Hetero USA, Inc. admits it is "the US representation of HETERO, a privately owned; research based global pharmaceutical company" and that it has "a significant presence in the development and marketing of finished dosages (comprising of various dosage forms of wide range of therapeutic categories), active pharmaceutical ingredients (API's), over-the-counter products." <https://www.linkedin.com/company/hetero-usa-inc/about/> (Hetero USA, Inc. LinkedIn Profile, accessed Nov. 11, 2020).

22. This Court has personal jurisdiction over Honour Lab Ltd. Upon information and belief, Honour Lab Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Honour Lab Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Honour Lab Ltd. purposefully has conducted and continues to conduct business in this judicial district, and

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