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*Attorneys for Plaintiffs Eli Lilly and Company
And ICOS Corporation*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ELI LILLY AND COMPANY and ICOS)	
CORPORATION,)	
)	CIVIL ACTION NO.
Plaintiffs,)	
)	
v.)	
)	
HETERO USA INC., HETERO LABS LIMITED)	
UNIT-III, and HETERO LABS LIMITED)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Eli Lilly and Company (“Lilly”) and ICOS Corporation (“ICOS”) (collectively “Plaintiffs”) file this Complaint for patent infringement against Defendants Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (collectively “Hetero” or “Defendant”) under 35 U.S.C. § 271(e)(2) for infringement of U.S. Patent No. 6,943,166 (“the ’166 patent”).

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant. This action relates to Abbreviated New Drug Application No. 209908 (“tadalafil ANDA”) submitted by Defendant to the U.S. Food and

Drug Administration (“FDA”) for approval to market a generic version of Lilly’s Cialis[®] (tadalafil) tablets (“proposed tadalafil ANDA product”) prior to the expiration of the ’166 patent. Defendant’s tadalafil ANDA includes a “Paragraph IV certification” asserting that the ’166 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Defendant’s proposed tadalafil ANDA product, which constitutes an act of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

THE PARTIES

2. Lilly is an Indiana Corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. ICOS is a Delaware corporation having its corporate office at Lilly Corporate Center, Indianapolis, Indiana 46825. ICOS is a wholly owned subsidiary of Lilly.

4. Upon information and belief, Hetero USA Inc. is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1035 Centennial Ave, Piscataway, New Jersey 08854.

5. Upon information and belief, Hetero USA Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in the State of New Jersey, and including as an agent of Hetero Labs Limited Unit-III and Hetero Labs Limited.

6. Upon information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Limited.

7. Upon information and belief, Hetero Labs Limited Unit-III is an India corporation and has its principle place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, A.P. India.

8. Upon information and belief, Hetero Labs Limited Unit-III is a division of Hetero Labs Limited.

9. Upon information and belief, Hetero Labs Limited Unit-III manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in the State of New Jersey, and including through its agent Hetero USA Inc.

10. Upon information and belief, Hetero Labs Limited is an India corporation and has its principle place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, A.P. India.

11. Upon information and belief, Hetero Labs Limited manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in the State of New Jersey, and including through its agent Hetero USA Inc.

JURISDICTION AND VENUE

12. Each of the preceding paragraphs 1 to 11 is re-alleged and re-incorporated as if fully set forth herein.

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

15. On information and belief, Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited collaborate to develop, manufacture, import, market, and distribute, and/or

sell pharmaceutical products, including generic drug products manufactured and sold pursuant to the tadalafil ANDA, throughout the United States and the State of New Jersey.

16. On information and belief, Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

17. On information and belief, Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the State of New Jersey and throughout the United States.

18. On information and belief, Hetero USA Inc. is the agent of Hetero Labs Limited Unit-III and Hetero Labs Limited. Upon information and belief, Hetero USA Inc. is acting as the agent of Hetero Labs Limited Unit-III and Hetero Labs Limited with respect to ANDA No. 209908.

19. Hetero USA Inc. is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District.

20. On information and belief, Hetero USA Inc. has its principal place of business in New Jersey and has a registered agent for service of process in this Judicial District.

21. On information and belief, Hetero USA Inc., directly or through its affiliates Hetero Labs Limited Unit-III and Hetero Labs Limited, manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Hetero USA Inc. purposefully has conducted and continues to conduct business, directly or through its affiliates Hetero Labs Limited Unit-III and Hetero Labs Limited, in New Jersey, and this Judicial District is a destination for Hetero USA Inc.'s generic products.

22. On information and belief, Hetero USA Inc. has previously consented to personal jurisdiction in this District. *See, e.g., BTG Int'l Ltd. v. Actavis Labs. Fl, Inc. et al.*, Civ. Action No. 2:15-cv-5909-KM-JBC (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Hetero Drugs Limited et al.*, Civ. Action No. 1:15-cv-0161-JBS-KMW (D.N.J.).

23. On information and belief, Hetero USA Inc. has availed itself of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Symed Labs Limited et al. v. Amneal Pharmaceuticals LLC*, Civ. Action No. 2:15-cv-8307-MCA-MAH (D.N.J.).

24. Hetero Labs Limited Unit-III is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District. On information and belief, Hetero Labs Limited Unit-III, directly or through its affiliates Hetero USA Inc. and Hetero Labs Limited, manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Hetero Labs Limited Unit-III purposefully has conducted and continues to conduct business, directly or through its affiliates Hetero USA Inc. and Hetero Labs Limited, in New Jersey, and this Judicial District is a destination for Hetero Labs Limited Unit-III's generic products.

25. On information and belief, Hetero Labs Limited Unit-III has previously consented to personal jurisdiction in this District. *See, e.g., Takeda GmbH et al. v. Hetero USA Inc. et al.*, Civ. Action No. 3:16-cv-1280-FLW-DEA (D.N.J.); *Janssen Products, LP et al. v. Hetero Labs, Ltd. et al.*, Civ. Action No. 2:13-cv-01444-WHW-SCM (D.N.J.).

26. Hetero Labs Limited is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District. On information and belief, Hetero Labs Limited, directly or through its affiliates Hetero USA Inc.

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