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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.	)	
	)	
DR. REDDY’S LABORATORIES, INC. and DR.	)	
REDDY’S LABORATORIES, LTD.	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiffs Eli Lilly and Company (“Lilly”) and ICOS Corporation (“ICOS”) (collectively “Plaintiffs”) file this Complaint for patent infringement against Defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. (collectively “DRL” 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 DRL. This action relates to Abbreviated New Drug Application No. 210069 (“tadalafil ANDA”) submitted by DRL to the U.S. Food and Drug

Administration (“FDA”) for approval to market a generic version of Lilly’s Cialis<sup>®</sup> (tadalafil) tablets (“proposed tadalafil ANDA product”) prior to the expiration of the ’166 patent. DRL’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 DRL’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, Dr. Reddy’s Laboratories, Inc. is a corporation organized under the laws of the State of New Jersey and has its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

5. Upon information and belief, Dr. Reddy’s Laboratories, 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 Dr. Reddy’s Laboratories, Ltd.

6. Upon information and belief, Dr. Reddy’s Laboratories, Inc. is a subsidiary of Dr. Reddy’s Laboratories, Ltd.

7. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is an India corporation and has its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, India.

8. Upon information and belief, Dr. Reddy's Laboratories, Ltd. 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 Dr. Reddy's Laboratories, Inc.

### **JURISDICTION AND VENUE**

9. Each of the preceding paragraphs 1 to 8 is re-alleged and re-incorporated as if fully set forth herein.

10. 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.

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

12. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. 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.

13. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

14. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. 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.

15. On information and belief, Dr. Reddy's Laboratories, Inc. is the agent of Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Inc. is acting as the agent of Dr. Reddy's Laboratories, Ltd. with respect to ANDA No. 210069.

16. Dr. Reddy's Laboratories, Inc. is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District.

17. On information and belief, Dr. Reddy's Laboratories, Inc. has its principal place of business in New Jersey and has a registered agent for service of process in this Judicial District.

18. On information and belief, Dr. Reddy's Laboratories, Inc., directly or through its affiliate Dr. Reddy's Laboratories, Ltd., manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Dr. Reddy's Laboratories, Inc. purposefully has conducted and continues to conduct business, directly or through its affiliate Dr. Reddy's Laboratories, Ltd., in New Jersey, and this Judicial District is a destination for Dr. Reddy's Laboratories, Inc.'s generic products.

19. On information and belief, Dr. Reddy's Laboratories, Inc. has previously consented to personal jurisdiction in this District. *See, e.g., AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8267-MLC-TJB (D.N.J.); *Helsinn Healthcare SA, et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8662-MLC-DEA (D.N.J.).

20. On information and belief, Dr. Reddy's Laboratories, Inc. has availed itself of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Dr. Reddy's*

*Laboratories, Inc. et al. v. Purdue Pharmaceutical Products LP et al.*, Civ. Action No. 2:14-cv-3230-JLL-JAD (D.N.J.).

21. Dr. Reddy's Laboratories, Ltd. 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, Dr. Reddy's Laboratories, Ltd., directly or through its agent Dr. Reddy's Laboratories, Inc., manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Dr. Reddy's Laboratories, Ltd. purposefully has conducted and continues to conduct business, directly or through its agent Dr. Reddy's Laboratories, Inc., in New Jersey, and this Judicial District is a destination for Dr. Reddy's Laboratories, Ltd.'s generic products.

22. On information and belief, Dr. Reddy's Laboratories, Ltd. has previously consented to personal jurisdiction in this District. *See, e.g., AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8267-MLC-TJB (D.N.J.); *Helsinn Healthcare SA, et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8662-MLC-DEA (D.N.J.).

23. On information and belief, Dr. Reddy's Laboratories, Ltd. has availed itself of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products LP et al.*, Civ. Action No. 2:14-cv-3230-JLL-JAD (D.N.J.).

24. DRL is subject to specific jurisdiction in this District based on the filing of its tadalafil ANDA with a Paragraph IV certification regarding the '166 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

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