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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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Case No. IPR2018-01675  
U.S. Patent No. 8,603,044

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**DECLARATION OF DR. ROBIN S. GOLAND IN SUPPORT OF PATENT  
OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 8,603,044**

Sanofi Exhibit 2111.001

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I, Robin S. Goland, M.D., have been retained by Sanofi-Aventis Deutschland GmbH (“Patent Owner” or “Sanofi”), as an independent expert witness in the above-captioned *inter partes* review (“IPR”) that has been instituted. I understand that Mylan Pharmaceuticals Inc. (“Mylan” or “Petitioner”) has requested that the U.S. Patent and Trademark Office cancel as unpatentable certain claims of this patent.

This declaration sets forth my analyses and opinions based on my experience and the materials I have considered. As I explain below, it is my opinion that Lantus® SoloStar® satisfied a long-felt but unmet need for a long-lasting insulin or insulin glargine drug in an easy-to-use disposable pen.

**I. Background and Experience**

1. Included as Exhibit 2112 to this declaration is my current curriculum vitae. I have summarized my educational and professional background below.

2. I received a Bachelor of Arts in History from Harvard University in 1976. After completing my undergraduate studies, I went on to obtain an M.D. degree from Columbia University in 1980.

3. After completing my internship in 1981, I undertook a residency in internal medicine at New York-Presbyterian/Columbia University from 1980-1984. I completed a fellowship in endocrinology at Columbia University College

of Physicians and Surgeons in 1987. I am board-certified in Internal Medicine and Endocrinology.

4. Since completing my residency and fellowship, I've held a number of academic positions at Columbia University College of Physicians and Surgeons, including Assistant Professor of Clinical Medicine (1987-1989), Assistant Professor of Medicine (1990-1996), Florence Irving Associate Professor of Medicine (1997-2008), Professor of Clinical Medicine (2008-present), Professor of Clinical Medicine and Clinical Pediatrics (2010-present), and J. Merrill Eastman Professor of Clinical Diabetes (2011-present).

5. Since 1987, I have been the Chief of the Diabetes Clinic at New York-Presbyterian Hospital/Columbia University. In 1997, I founded the Naomi Berrie Diabetes Center at Columbia University, and I have served the center as co-director ever since. The Naomi Berrie Diabetes Center serves 14,000 patients each year, approximately 40% of which have Type 1 diabetes. In addition, the Center conducts clinical research on diabetes.

6. During my career, I have authored or co-authored over 80 peer-reviewed articles. I am a member of the American Diabetes Association. I also served as a member of the Medical Advisory Board of the Juvenile Diabetes Foundation, New York Chapter, the Pharmacy and Therapeutics Committee of

Merck Health Solutions, and the Medical Advisory Board of the NY Stem Cell Foundation.

7. I am an experienced clinical investigator and principal investigator in diabetes trials. In 1996-1999, I received the Irving Scholar Award for Clinical Investigation from Columbia University.

8. My other qualifications are set forth in my curriculum vitae.

## **II. Fees and Prior Testimony**

9. In the past five years, I have testified as an expert in deposition and at trial in the *Sanofi v. Merck* litigation, Case No. 16-812-RGA, in the District of Delaware.

10. I am being compensated for my time at my standard rate of \$750 for each hour of service that I provide in connection with these proceedings. This compensation is not contingent upon my opinions or testimony, the outcome of these proceedings, or any issues involved in or related to this IPR.

## **III. Materials Reviewed and Information Considered**

11. The declaration and opinions set forth herein are based on references and other documents cited in this declaration and/or identified in the list of materials at the end of this Declaration, and my personal education, professional experience, and other relevant knowledge.

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