

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAYER INTELLECTUAL PROPERTY GmbH,
Patent Owner.

Patent No. 7,157,456

DECLARATION OF SALVATORE D. LEPORE, PH.D.

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I, Salvatore D. Lepore, declare as follows:

I. QUALIFICATIONS

1. I am currently a tenured full professor of Chemistry and Biochemistry at Florida Atlantic University (FAU) where I lead a team of researchers on projects related to the chemistry of drug discovery. I have over 20 years of experience in this area. I have been a member of the faculty at Florida Atlantic University since 2000.

2. I received a B.S. in chemical engineering from the University of South Florida in 1992 and a Ph.D. in organic chemistry from Purdue University in 1997. After completing my Ph.D., I was awarded a Postdoctoral Fellowship position at Eli Lilly and Company's World Headquarters (1997-2000). Under the direction of Dr. Michael R. Wiley, my research focus was on the synthesis of small-molecule and peptide-based direct thrombin inhibitors. One of my most notable contribution to Lilly's drug discovery program was the development of new solid-phase methods to prepare libraries of thrombin inhibitors containing a 2-hydroxybenzamidine moiety, leading to a significant improvement in oral bioavailability. My efforts while at Lilly resulted in four peer-reviewed publications, as well as three patent applications, including PCT Application No. WO 2006057845, entitled "Preparation of (hetero)aromatic ether amides as inhibitors of Factor Xa and/or thrombin," which resulted in several issued patents.

3. In August of 2000, I joined the faculty at Florida Atlantic University as an Assistant Professor in the Department of Chemistry and Biochemistry. I was promoted with tenure in 2006 to Associate Professor and in 2011 to Professor. My professional responsibilities include the scientific oversight of a team of doctoral students, technicians, and postdoctoral fellows. I teach doctoral level courses in the area of Medicinal Chemistry and Organic Synthesis with an emphasis on medicinally relevant organic small molecules. My research emphases over the course of my career at FAU fall into two main categories: the development of new reactions to expedite the incorporation of radiofluorine into small molecules for applications in positron emission tomography (PET); and, the development of synthesis methods involving allenes.

4. I have been funded by the National Institutes of Health (NIH) as a Principal Investigator for several multi-year projects to develop Organic Chemistry reactions and apply them to the synthesis of therapeutically valuable compounds. One of these funded projects was to utilize the unique reactivity of allenes for the partial total synthesis of vitisinol D, a natural product that has been briefly studied by others as an antiplatelet agent. I serve as a Scientific Advisory Board Member for CHS Pharma and also as a subcontractor in their drug discovery effort. I have also served as

a consultant to several biotech companies including Unison Pharmaceuticals and Xcovery.

5. I am an Associate Editor for the journal *Perspectives in Medicinal Chemistry* since 2006. This is an international, peer-reviewed journal that provides drug design experts with updates on recent advances in the field. In addition to serving as a long-time and consistent reviewer of manuscripts for many of the pinnacle journals in my field (including the *Journal of American Chemical Society* and *Organic Letters*), I am also a high frequency reviewer for the *European Journal of Medicinal Chemistry* earning a “top-tenth percentile reviewer” status. I am the author of nearly 30 peer-reviewed publications as an independent investigator for which I am the corresponding author in nearly all cases. In addition to numerous conference presentations, I have been invited to present my work throughout the US and internationally. I am the listed inventor or co-inventor on six patents or patent applications.

6. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately. EX1004.

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