

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. & MYLAN LABORATORIES LIMITED,
Petitioners,

v.

BAXTER INTERNATIONAL INC.,
Patent Owner.

Patent No. 6,310,094

DECLARATION OF ROBERT J. LINHARDT, PH.D.

TABLE OF CONTENTS

I.	QUALIFICATIONS.....	1
II.	SCOPE OF WORK	3
III.	OVERVIEW OF THE '094 PATENT.....	3
IV.	FILE HISTORY OF THE '094 PATENT	6
V.	LEGAL STANDARDS	7
VI.	LEVEL OF ORDINARY SKILL AND RELEVANT TIME	9
VII.	CLAIM CONSTRUCTION	10
VIII.	THE STATE OF THE ART	12
IX.	CERTAIN REFERENCES DISCLOSE OR SUGGEST EACH OF THE CLAIMED FEATURES OF THE '094 PATENT.....	27
X.	CONCLUDING STATEMENTS	65
XI.	APPENDIX – LIST OF EXHIBITS.....	66

I, Robert J. Linhardt, declare as follows:

I. QUALIFICATIONS

1. My name is Robert J. Linhardt. I am currently the Ann and John H. Broadbent Senior Constellation Chair in Biocatalysis and Metabolic Engineering, and a Professor in the Departments of Chemistry and Chemical Biology, Biology, Chemical and Biological Engineering, and Biomedical Engineering at Rensselaer Polytechnic Institute (RPI). I have been a member of the faculty at RPI since 2003. I am also an Adjunct Professor in the Orthopaedics Department at Mount Sinai School of Medicine as well as an Adjunct Professor of Pharmaceutical Sciences at Albany College of Pharmacy. Prior to joining the faculty at RPI, I was a member of the faculty in the College of Pharmacy at the University of Iowa for 21 years, starting in 1982.

2. I received a B.S. in Chemistry from Marquette University in 1975, and an M.A. and a Ph.D. in Organic Chemistry from The Johns Hopkins University in 1977 and 1979, respectively. I received additional, post-doctoral training in Biochemical Engineering at Massachusetts Institute of Technology.

3. My current research program at RPI focuses on the study of bioactive carbohydrates, particularly the polysaccharide heparin, an anticoagulant which is administered parenterally, often continuously, due to its short half-life. I am currently using bioengineered Chinese hamster ovary cell lines to develop a biosynthetic pathway to produce a bioengineered heparin product. In addition to my studies on heparin, my research program also involves the determination of the therapeutic utility of proteoglycans and other glycoconjugates to determine new

pathways for drug development. I have extensive experience with pharmaceutical formulations, including the sterilization of parenteral formulations via autoclave.

4. My research has been funded by such organizations as the National Institute of Health and the National Science Foundation, as well as other government agencies and foundations, and I have also served as an Industrial Consultant in the areas of biocatalysis, biopolymers, carbohydrate chemistry, and drug delivery since 1981. I also serve, or have served, on the editorial board of 20 peer-reviewed journals such as the *Journal of Biological Chemistry*, *Applied Biochemistry and Biotechnology*, and the *Journal of Carbohydrate Chemistry*.

5. I have authored or co-authored more than 700 scientific publications, the vast majority of which are peer-reviewed journal articles. I have also authored 6 book chapters and been listed as an inventor on 65 issued patents. I have given over 130 invited seminars at scientific symposia and educational institutions.

6. I have received numerous honors and awards, including being named one of the Scientific American 10, an honor bestowed upon ten individuals who “demonstrated outstanding commitment to assuring that the benefits of new technologies and knowledge will accrue to humanity.” I also received the USP Award for an Innovative Response to a Public Health Challenge, numerous accolades from the American Chemical Society, as well as the Volweiler Research Achievement Award in Pharmaceutical Sciences.

7. 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. Ex. 1003.

II. SCOPE OF WORK

8. I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 6,310,094 (hereinafter “the ’094 patent,” Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the ’094 patent. I have reviewed the ’094 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004. I have also reviewed and considered various other documents in arriving at my opinions, and cite them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XI.

9. I am compensated at the rate of \$600/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE ’094 PATENT

10. The ’094 patent is entitled “Ready-To-Use Esmolol Solution.” The first page of the patent states that an application for the ’094 patent was filed on January 12, 2001.

11. The ’094 patent is generally directed to pharmaceutical compositions of the drug esmolol hydrochloride, and methods of making thereof. Claim 1 of the ’094 patent recites the following:

1. An injectable, aqueous pharmaceutical composition for the treatment of cardiac conditions, having a pH between 3.5 and 6.5 and comprising

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.