

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LOWER DRUG PRICES FOR CONSUMERS, LLC

PETITIONER

v.

FOREST LABORATORIES HOLDINGS LIMITED

PATENT OWNER

Case No.: Unassigned

Patent No. 6,545,040

Filed: January 24, 1992

Issued: April 8, 2003

Inventors: Xhonneux and Van Lommen

Title: METHOD OF LOWERING THE BLOOD PRESSURE

DECLARATION UNDER 37 CFR § 42.53(a)

BY RONALD W. MILLARD, Ph.D.

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	QUALIFICATIONS AND EXPERIENCE	2
III.	EXPERIENCE WITH PATENTS	11
IV.	PRIORITY DATE AND POSITA.....	13
V.	BACKGROUND SCIENCE.....	17
	A. Hypertension.....	17
	B. Adrenergic Receptors	23
	C. Adrenergic receptor blockers as treatment for hypertension.....	26
	D. Stereoselectivity and β -Blocker Research.....	31
VI.	CLAIM CONSTRUCTION.....	41
VII.	THE '040 PATENT	42
	A. Claims of the '040 Patent	42
	B. Background of the invention—the '362 Patent (Van Lommen) and Compound 84 as prior art.....	42
	C. The disclosures of the '040 Patent.....	47
VIII.	MOTIVATION TO COMBINE PRIOR ART REFERENCES	48
IX.	SPECIFIC GROUNDS OF INVALIDITY.....	55
X.	CONCLUSION.....	59

I, Dr. Ronald W. Millard, provide the following sworn testimony by way of this declaration, and would testify to the same if asked to testify live in a court of law or other similar proceeding:

I. Introduction

1. My name is Dr. Ronald Millard. I am over the age of eighteen (18) and I am otherwise competent to make this declaration and provide the following testimony.

2. The Petitioner has retained me as an expert in this *Inter Partes* Review to provide scientific and technical testimony related to the patentability of the claims of U.S. Patent No. 6,545,040 (“the ’040 Patent”) (Ex. 1001). I have not been asked to provide an opinion on the ultimate legal issue of whether the claims of the ’040 Patent are patentable. Instead, I have been asked to provide testimony on the discreet scientific and technical topics discussed below.

3. In connection with my analysis, I have reviewed each of the Exhibits referred to throughout this declaration. If asked, I will review additional relevant materials (such as, for example, exhibits submitted by the Patent Owner in this IPR) and supplement my testimony as necessary.

4. I have been compensated at my standard hourly rate of \$250 per hour for the time I have worked to draft this declaration.

5. Despite the fact that the Petitioner is compensating me appropriately for my time in this matter, I do not consider myself an advocate for the Petitioner. I view my role in this case as being an objective expert offering testimony to the Patent Trial and Appeal Board within my fields of expertise. Maintaining objectivity is a role I take very seriously, in the same way it has been and remains a core value in my career as an academic researcher and educator. The testimony I offer is based on the best of my knowledge and understanding as established by generally accepted facts and evidence in available published literature, textbooks, and similar highly authoritative sources, in addition to my own personal knowledge and experience. I would not under any circumstances offer testimony that I did not believe to be true and well founded in the facts and evidence from reliable sources and from my own professional experience. I understand fully that my declaration and any deposition I might give in this matter will become part of the public record of these proceedings and will be publicly accessible to my professional colleagues and peers in the scientific community.

II. Qualifications and Experience

6. My current curriculum vita is provided as an Exhibit in this IPR. It will be sequentially numbered as the exhibit following this declaration. A summary of my qualifications for providing expert testimony in this matter follows.

7. My testimony in this declaration includes expert testimony and opinions based on my professional career in the fields of new cardiovascular drug research, and certain aspects of the application of these principles and drugs to cardiovascular fields of clinical medicine. At the time of the priority date for the '040 Patent (*i.e.*, March 23, 1988), I was a full-time tenured professor of pharmacology and cell biophysics and head of the cardiovascular pharmacology section at the University of Cincinnati College of Medicine in Cincinnati, OH, a public university within the State of Ohio university system. In March of 1988, I also held appointments as research professor in the Division of Cardiology, Department of Internal Medicine, and in the Division of Nuclear Medicine, Department of Radiology, at the same institution. My scope of responsibilities at the time included: (a) designing and directing original discovery research on the physiology, pathology, and pharmacology of the cardiovascular system in laboratory animals (pigs and dogs), in particular as illustrated in my curriculum vitae; (b) collaborating and publishing with physiologists, biochemists, pharmacologists, chemists, biomedical engineers, mechanical engineers, aerospace engineers, cardiologists, nuclear medicine specialist, medical physicists, and cardiovascular surgeons in discovery research and in clinical studies; (c) mentoring and advising PhD candidates in their thesis research projects in cardiac effects of both protective and toxic agents, and in the study of calcium channel blocking

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