

**UNITED STATES PATENT AND TRADEMARK OFFICE**

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

**COALITION FOR AFFORDABLE DRUGS VIII, LLC**

Petitioner,

v.

**THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA**

Patent Owner

---

**Case: IPR2015-01835**

**Patent No. 8,618,135**

---

**DECLARATION OF DANIEL J. RADER, M.D.**

PENN EX. 2026  
CFAD v. PENN

## **Introduction and Qualifications**

1. I, Daniel J. Rader, submit the following sworn declaration in PTAB IPR2015-01835 and IPR2015-01836 in support of the validity of U.S. Patent Nos. 7,932,268 (“the ’268 patent”) and 8,618,135 (“the ’135 patent”). I am the named inventor of the ’268 and ’135 patents. I have personal knowledge of the facts stated herein.

2. I am the Seymour Gray Professor of Molecular Medicine and Chair of the Department of Genetics at the University of Pennsylvania Perelman School of Medicine. I am a medical doctor with over 25 years of experience treating patients, with a focus on treating patients suffering from lipid disorders.

3. I received my B.A. from Lehigh University (summa cum laude) in 1981, and my M.D from Medical College Pennsylvania (summa cum laude) in 1984. I completed my internship and residency in internal medicine at Yale-New Haven Hospital. I also completed a fellowship at the NIH National Heart, Lung and Blood Institute.

4. I joined the University of Pennsylvania (“Penn”) in 1994 as Director, Preventive Cardiovascular Medicine and Lipid Clinic, a position I continue to hold today. As part of my work at the Preventive Cardiovascular Medicine and Lipid

Clinic, I see approximately 400 patients a year, primarily those with lipid disorders. I also lecture and train medical students in the field of lipid disorders.

5. My research focuses on lipid disorders and related metabolic disorders. I have been involved in a number of clinical trial programs testing new compounds or treatment regimens, including more than 20 clinical trials focusing on the treatment of lipid disorders, primarily Phase I and II trials. I have over 400 publications in peer-reviewed journals, treatises, and other scientific and medical publications. I have authored the chapter on Lipoprotein Disorders in the last several editions of Harrison's Textbook of Medicine, the premier medical textbook.

6. I have served as a reviewer of the draft report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel or ATP). ATP III constituted the National Cholesterol Education Program's (NCEP's) updated clinical guidelines for cholesterol testing and management, and became the standard of care for management and treatment of cholesterol levels after it was released in 2001.

7. I have received numerous grants, prizes, and awards over my career, including election to the National Academy of Medicine (formerly the Institute of Medicine), and the American Heart Association's Clinical Research Prize.

8. I serve as Deputy Editor of the journal Arteriosclerosis Thrombosis and Vascular Biology, on the editorial boards of several other journals, and as a reviewer on dozens of other peer-reviewed journals in the medical research field. Exhibit 2030 is a complete copy of my C.V.

9. I have been and currently am a consultant to Aegerion Pharmaceuticals, Inc.

### **Background on Lipid Diseases and Treatment**

10. Cholesterol is a type of lipid used by cells in the human body for a variety of purposes, including to produce cell membranes. Cholesterol is transported in the blood by lipoproteins. Lipoproteins transport cholesterol because it is not soluble in water.

11. There are a number of different types of lipoproteins. Low density lipoprotein (or LDL), very low density lipoprotein (VLDL), high density lipoprotein (or HDL), are a few examples. As is apparent in their nomenclature, lipoproteins are classified by their relative densities. Each type of lipoprotein carries cholesterol, but lipoproteins differ in their relationship to risk of heart disease. For example, a high level of LDL cholesterol (LDL-C) is associated with an increased risk of atherosclerosis, or the hardening of human arteries, and can lead to heart disease. In contrast, high HDL cholesterol (HDL-C) levels are

associated with reduced risk of heart disease. Hypercholesterolemia is a condition characterized by the presence of elevated levels of cholesterol in the blood.

Hypercholesterolemia can be inherited due to mutations in certain genes, and is associated with increased risk of heart disease.

12. Treatment for hypercholesterolemia has changed dramatically over the last few decades. The discovery of compounds effective in treating lipid disorders has allowed cardiovascular physicians like me to effectively treat patients with elevated levels of cholesterol. Among the most common treatment options for hypercholesterolemia are therapeutic drug classes known as statins (atorvastatin, simvastatin, etc.), fibrates (fenofibrate, gemfibrozil, etc.), or the cholesterol absorption inhibitor ezetimibe. In my practice, I regularly treat patients with hypercholesterolemia with these types of drugs, in addition to a suggested regimen of a low-fat diet and regular exercise.

### **Background on HoFH and Its Treatment**

13. Some forms of hypercholesterolemia, however, are more complex to treat and have required more significant intervention on the part of the physician. One such disease is homozygous familial hypercholesterolemia (“HoFH”). HoFH is a serious, rare and life-threatening genetic disease usually caused by mutations in the low density lipoprotein (LDL) receptor. Total plasma cholesterol levels are

# 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.