COALITION FOR AFFORDABLE DRUGS VIII, LLC
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
Patent Owner

Case: IPR2015-01836
Patent No. 7,932,268

DECLARATION OF DANIEL J. RADER, M.D.

PENN EX. 2026
CFAD v. PENN
IPR2015-01836

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

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.

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 arthrosclerosis, or the hardening of human arteries, and can lead to heart disease. In contrast, high HDL cholesterol (HDL-C) levels are

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

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