UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner

v.

3M COMPANY et al.
Patent Owner

Case IPR2015-02002
Patent 6,743,413

DECLARATION OF RICHARD N. DALBY, PH. D.

I, Richard N. Dalby, declare as follows:

I. Qualifications

1) In 1983, I graduated with Honors with a B. Pharm. from Nottingham University School of Pharmacy.

2) In 1988, I earned a Ph. D. in Pharmaceutical Sciences from the University of Kentucky, College of Pharmacy. My research mentor was Dr. Peter Byron, a leading research scientist in respiratory drug delivery systems, including MDIs. My research involved aerosol formulations.

3) From October 1988 to August 1989, I worked as a Development Scientist for Fisons Pharmaceuticals (now Sanofi Aventis). In that role, I was responsible for development of new aerosol formulations based on using both chlorofluorocarbons (CFCs) and hydrofluoroalkanes (HFAs) as propellants.

4) From December 1989 to August 1992, I was a Research Assistant Professor at Medical College of Virginia /Virginia Commonwealth University in the Department of Pharmacy and Pharmaceutics. My research was directed to looking for alternatives to CFCs as propellants in aerosol formulations.

5) In 1992, I joined the Department of Pharmaceutical Sciences, University of Maryland as an Assistant Professor, becoming a full Professor in 2003.

6) Beginning in 1992, I have provided consulting services, workshops and seminars, primarily to pharmaceutical and biotechnology companies in the field of pharmaceutical aerosol formulations.

7) I have authored over 200 papers, abstracts, or book chapters related to pharmaceutical aerosol formulations. In 2002, I was appointed Deans Distinguished Educator by the University of Maryland, School of Pharmacy. In 2004, I was elected a Fellow of the American Association of Pharmaceutical Scientists.

8) I have served as a consultant and as a member of the FDA Advisory Committee on Orally Inhaled and Nasal Drug Products, and as a Special Reviewer for the NIH on the Development of Novel Drug and Gene Delivery Systems and Devices.

II. Person of Ordinary Skill

9) In my opinion, a person of ordinary skill in the pharmaceutical aerosol formulation field, in or about December 1991, would have been someone with either: (a) at least a bachelor's degree related to pharmaceutical sciences, or other related studies such as chemistry, chemical engineering, or colloidal science, along with corresponding 3-5 years of experience in the formulation and testing of pharmaceutical aerosol products and/or devices; or (b) an advanced degree (Masters or Ph.D.) in the same areas of academic study with about 1-2 years of

corresponding experience in the field of pharmaceutical aerosol products. The same level of skill would apply in May 1992. My opinions expressed herein would be the same if the relevant date were May 1992.

III. Background on Pharmaceutical Aerosol Formulations

10) Many drugs, especially those for treating respiratory and nasal disorders, are administered through the mouth or nose. Johnson '123 patent, Exhibit 2001, col. 1, lines 11-12. Inhalation is the most widely used route for delivering bronchodilating drugs and steroids to the airways of asthmatic patents. Purewal '183 patent, Exhibit 2004, col. 1, lines 15-17.

11) A metered-dose inhaler (MDI) is a handheld device designed to deliver a specific amount of medication in aerosol form. A MDI consists of a liquefied propellant-pressurized canister sealed with a metering valve that is attached to a plastic actuator incorporating a mouthpiece. During patient use the canister is oriented such that the value is pointed down. To use a MDI, the patient presses on the base of the canister to discharge a metered dose from the valve. This dose exits the mouthpiece and is inhaled into the lungs.

12) As of December 1991, there were basically two types of MDI formulations: those in which the drug is dissolved ("solution formulations") and those in which substantially all of the drug is suspended as fine particles

("suspension formulations"). Exhibit 2005 at 2. Suspension formulations were the predominant type of MDI formulation as of December 1991. Exhibit 2005 at 2.

13) Suspension formulations containing only drug and propellant are physically unstable. Exhibit 1015 at 339. Aggregated, flocculated, or discrete drug particles can float to the surface of the propellant or sink to the bottom of the canister (assuming the canister to be in the "valve-up" orientation). Whether a particle sinks or floats depends on its density relative to the liquefied propellant. Generally, the larger the aggregate, the floccule, or the discrete particle the more quickly it will either float to the top or sink to the bottom. Exhibit 2005 at 26. Sufficient suspension stability is necessary to achieve a viable therapeutic formulation.

14) As of December 1991, the most common propellants in MDIs were chlorofluorocarbons, known as CFCs. Exhibit 2003 at 1. At this time, CFCs were generally recognized to contribute to the depletion of the ozone layer, which led many countries to begin limiting, or even banning, their use. Exhibit 2003 at 1.

15) The Montreal Protocol, an international treaty signed in 1987, called for a series of decreasing limits on CFC use and production. Because of the impending phase-out of CFCs, pharmaceutical formulators were seeking alternative, non-CFC propellants suitable for use in MDIs. One class of propellants considered as a replacement for CFCs were hydrofluoroalkanes or

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