

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN TECHNOLOGIES INC.,
Petitioner,

v.

MONOSOL RX, LLC,
Patent Owner.

Patent No. 8,603,514

DECLARATION OF GRAHAM BUCKTON, PH.D.

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I, Graham Buckton, declare as follows:

I. QUALIFICATIONS

1. My name is Graham Buckton. I am an Emeritus Professor of Pharmaceutics in the UCL School of Pharmacy of the University of London. I was employed at the School of Pharmacy of the University of London from 1988 to 2015, initially as Lecturer, then Senior Lecturer, Reader and Professor, during which time I served as the Head of the Department of Pharmaceutics between January 2001 and April 2007. I served as Chair of the Master of Sciences in Pharmacy (MPharm) Exam Board between 2002 and 2012, and have been an MPharm (or Bachelors in Pharmacy, BPharm) Examiner at Queens University of Belfast, Cardiff University, University of Nottingham, Kings College, University of Colombo, Sri Lanka, Robert Gordon University and the University of East Anglia. I received my Ph.D. in Pharmaceutics from Kings College London in 1985.

2. In 2000 I founded a contract services company called Pharmaterials Ltd. I sold the majority stake to a U.S. company, Pharmaceutics International Inc. (PII), in 2008 and the remaining stake in 2012, at which time I exited. I was Chief Executive Officer from 2000-2012. Pharmaterials carries out materials characterization, salt selection, polymorph screening, pre-formulation, formulation development, assay development and clinical trial manufacture.

3. I have served on the Committee on Safety of Medicines (CSM), which is the body in the UK that grants (and revokes) marketing authorizations (the equivalent of the FDA in the US), and I chaired its Chemistry, Pharmacy and Standards (CPS) sub-committee. I remain a member of CPS of the Commission on Human Medicines (a renamed version of CSM). I have been a member of the British Pharmacopoeia Commission and have been a member of working parties for the European and the United States Pharmacopoeias.

4. I am the Managing Director of Buckton Consulting. I offer consulting services in the following areas: (1) physical form, formulation development, GMP manufacturing, and regulatory considerations, (2) company strategy review and management, (3) due diligence, and (4) expert witness. As a consultant to industrial companies, I advise on materials science, formulation (various products, including inhalation and oral delivery), and regulatory standards.

5. My research has focused on investigating the behavior of pharmaceutical materials, especially interfacial interactions between two or more material surfaces, and their use in processing and drug delivery. Applications of my research include studies of surface interactions, adaptation of physical properties of powders by crystallization and physical manipulation such as milling, and the preparation of drug dosage forms including solid oral dosage forms and

inhalation dosage forms, including film-coatings. I have published on my work in this field, presenting data on film coating solutions.

6. My research has been funded by such organizations as the Engineering and Physical Sciences Research Council (EPSRC), Pfizer, AstraZeneca, GSK, and Novartis, as well as other foundations and companies in industry.

7. I served a 10 year term as Editor of the International Journal of Pharmaceutics and have been a member of the editorial boards of a number of journals, including Pharmaceutical Research, the AAPS Journal and AAPS Pharm SciTec.

8. I have authored a book on Interfacial Phenomena in Drug Delivery and Targeting. I have also authored or co-authored over 180 peer-reviewed journal articles, of which numerous articles present original research related to solid dosage forms, including film-forming materials and film-coatings. In addition, I have authored or co-authored more than 100 abstracts and book reviews. I am listed as an inventor on 6 patents or patent applications. Additionally, I have lectured at over 130 conferences, seminars, and symposia around the world and have served as a testifying expert witness on 18 cases.

9. I have received numerous awards and honours, specifically, the appointment in 2003 as the Science Chairman for the British Pharmaceutical

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