UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

Case No. IPR2022-01102 - Patent No. 9,610,321
Case No. IPR2022-01103 - Patent No. 9,616,097
Case No. IPR2022-01104 - Patent No. 9,919,024
Case No. IPR2022-01105 - Patent No. 9,925,231

DECLARATION OF GRAHAM BUCKTON, PH.D.

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I, Graham Buckton, declare as follows:

I. QUALIFICATIONS

1. I am an Emeritus Professor of Pharmaceutics of 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. 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. I 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 in 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 addition to my academic experience, I have extensive practical experience in formulation development. 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 carried out materials characterisation, salt selection, polymorph screening, pre-

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formulation, formulation development, assay development, clinical trials, and manufacturing.

3. I served on the Committee on Safety of Medicines (CSM), which is the body in the United Kingdom 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 have consulted in the fields of physical form and formulation development for companies in Europe, USA, and India.

5. My research has focused on investigating the behaviour of pharmaceutical materials. Applications of my research include studies of surface interactions, adaptation of physical properties of powders by crystallisation and physical manipulation such as milling, and the preparation of drug dosage forms including solid oral-dosage forms and inhalation dosage forms. I also organised the Royal Pharmaceutical Society of Great Britain (RPSGB) course on Tabletting Technology every year between 1989-2004, and invited industrial colleagues to assist with the teaching. I gave many lectures during the period as organiser and

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