

Declaration of Metin Çelik, Ph.D.  
Patent No. 8,475,832

Attorney Docket No. 117744-00048

Paper No. \_\_\_\_\_

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
Petitioner

v.

RB PHARMACEUTICALS LIMITED  
Patent Owner

Patent 8,475,832

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Mailed: June 20, 2014

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**DECLARATION OF METIN ÇELİK, PH.D.  
UNDER 37 CFR § 1.132**

I, Metin Çelik, Ph.D., do hereby make the following declaration:

## **I. QUALIFICATIONS**

1. I am currently the President of Pharmaceutical Technologies International, Inc. (“PTI”), a company that I founded in 1997. PTI develops management tools, databases and expert systems for the pharmaceutical industry worldwide and provides expert consultant services to various international pharmaceutical, food, excipient and equipment companies and to law firms throughout North America.

2. Since 2008, I am also a Research Professor of Pharmaceutical Technology at the College of Pharmacy, Near East University in Cyprus where I have established a tableting research center.

3. Over the past thirty years, working in industry, academia, and as a consultant, I have been continuously involved in the development and formulation of pharmaceutical products. I have also provided expert consultant services to the Food and Drug Administration (“FDA”).

4. My involvement in the formulation and process of pharmaceutical products has given me specialized expertise in the areas of solid dosage forms, integrated compaction research systems, the theory and practice of pharmaceutical compaction, excipient functionality testing, multiunit dosage form development,

artificial neural networks, design and development of pharmaceutical formulation and processing expert systems, preformulation and compaction databases and the development of Management Information Systems for FDA inspection preparations and general project management purposes.

5. With respect to formulation and process of oral dosage forms, my practical experience began at Novartis (formerly known as Sandoz) – Switzerland in 1984. My knowledge in this area continued to develop during my time at Novartis, in Switzerland and Turkey, and then as a professor in the College of Pharmacy at Rutgers University in Piscataway, New Jersey. As a member of the faculty at the latter institution, I lectured in this field (within and outside the University) and conducted research both as an advisor to a Ph.D. project and as a consultant to the pharmaceutical industry.

**A. Education and Work Experience**

6. I earned my B.Sc. (Hons.) degree in Pharmacy from Hacettepe University in Turkey in 1979.

7. I was awarded a Ph.D. degree in Pharmaceutical Technology by the Department of Pharmaceutical Technology, School of Pharmacy, De Montfort University (formerly known as Leicester Polytechnic), the United Kingdom, in 1984.

8. After completing my Ph.D. in 1984, I took a position in the Galenical R&D Department at Novartis in Switzerland, where I was involved in pharmaceutical technology research and development. I was then promoted to Development Co-ordinator, Galenical R&D at Novartis in Turkey, where I was responsible for establishing a pharmaceutical research department.

9. In 1986, I joined Smith Kline & French Laboratories (presently known as GlaxoSmithKline) in Swedeland, Pennsylvania, where I developed and established the first state-of-the-art Compaction Simulator System in the Western hemisphere.

10. In 1988, I joined the faculty at the College of Pharmacy, Rutgers University, where I stayed until 1997. During my tenure at Rutgers, I taught various courses to both undergraduate and graduate students that focused on the theory and practice of pharmaceutical formulation and process development. Such courses included Drug Delivery, Problems in Pharmaceutics, and Pharmaceutical Processes and Equipment.

11. At Rutgers, in my position as Director of Pharmaceutical Compaction Research Laboratory & Information Center, I developed a second Compaction Simulator System. The Compaction Simulator System at Rutgers was the first to be developed in academia in the U.S.A., and consequently established Rutgers as an internationally recognized pharmaceutical research centre.

12. Between 2004 and 2008, I was a Pharmaceutical Processing Research Professor at the Department of Industrial Engineering (2004-2008) at Rutgers where I was involved in the development of a Process Analytical Technology (PAT) program at Rutgers.

**B. Professional Affiliations, Activities and Awards**

13. I am or have been a member of the following professional organizations: the American Association of Pharmaceutical Scientists (AAPS), the New Jersey Pharmaceutical Association of Science and Technology (NJPhAST), the American Association of Colleges of Pharmacy (AACP), and the Ankara Chamber of Pharmacists (ACP).

14. I have been extensively involved with several groups in the AAPS. For example, from 1995 to 1998, I held the position of chair of the AAPS Process Development Focus Group. I am also a founder and the former chair of the AAPS Excipients Focus Group and a founder and the former chair of the AAPS Expert Systems Focus Group. I have also served as a member of the Pharmaceutical Technology Section Programming Committee.

15. In 1991, 1993, and 1994, I received the Faculty Academic Service Increment Program Award in recognition of my service at Rutgers.

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