UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CATALENT PHARMA SOLUTIONS, INC.,
Petitioner,

v.

PATHEON SOFTGELS INC.,
Patent Owner.

Case IPR2018-00422
Patent 9,693,979

DECLARATION OF PETER DRAPER REGARDING U.S. PATENT NO. 9,693,979

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U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I, Peter Draper, do hereby declare and state that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 12, 2018

Peter Draper

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I. INTRODUCTION

A. Background and Education

1. I am a scientist with extensive knowledge and experience in the field of pharmaceutical formulations and, in particular, with gelatin capsule formulations. I have been working in this field since 1991.

2. I became a Graduate of the Royal Society of Chemistry (UK) in 1972, and in 1994 received a Master of Science Degree in Pharmaceutical Sciences from the University of Strathclyde Glasgow (UK).

B. Professional Qualifications

3. Reckitt and Colman UK (Reckitt Benckiser): I held a number of positions at Reckitt and Colman Pharmaceuticals from 1964 to 1990. At the time of my employment, the company was engaged in the research, development and manufacture of new pharmaceutical active ingredients and pharmaceutical products based on drug delivery technologies. From 1964 to 1972, I was an Undergraduate Laboratory Technician and assisted in supporting the analyses of pharmaceutical materials and finished products. From 1974 to 1988, I was an Analytical Chemist working on the development of analytical methods associated with the development and stability evaluation of pharmaceutical active ingredients, a wide range of pharmaceutical dosage forms, and associated primary packaging. During that time, I also managed the analytical functions associated with the

development of new pharmaceutical products. From 1988 to 1990, I was a Technical Development Manager evaluating new products from within the company and external contract suppliers, and coordinating product developments between the Technical and Market Development functions.

4. RP Scherer North America: I worked for RP Scherer from 1991 to 2005. I originally was a Technical Director at RP Scherer (UK) and then transferred to RP Scherer North America. I was responsible for coordinating the development of new soft gelatin capsules and management of a number of major projects associated with the development and manufacture of soft gelatin capsule dosage forms and associated processes. I gained in-depth experience of soft gelatin capsule dosage form design, development and manufacture, particularly complex formulations for the optimum delivery of active pharmaceutical ingredients. I also provided relevant technical support to the Sales and Marketing functions in client meetings and presentations. Some of the major projects I worked on included establishing and managing a specialist suite for the development and manufacture of soft gelatin capsules containing cytotoxic pharmaceutical active ingredients, and closed vessel processing of capsule fill materials (such as the "liquid matrix" referred to in the claims of the '979 Patent). I also was a project leader for the identification and development of soft gelatin capsules based on non-gelatin

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