IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: SITAGLIPTIN PHOSPHATE ('708 & '921) PATENT LITIGATION	MDL No. 19-2902-RGA C.A. Nos. 19-310-RGA, 19-311-RGA, 19-312-RGA, 19-313-RGA, 19-314-RGA, 19-317-RGA, 19-318-RGA, 19-319-RGA, 19-321-RGA, 19-347-RGA, 19-1489-RGA

DECLARATION OF GRAHAM BUCKTON, Ph.D., D.Sc.

I, Graham Buckton, declare and state as follows:

I. INTRODUCTION

1. I have been retained as an expert witness by Teva Pharmaceuticals USA and Watson Laboratories, Inc.; Sandoz Inc.; Lupin Limited and Lupin Pharmaceuticals, Inc.; Anchen Pharmaceuticals, Inc. and Par Pharmaceutical, Inc.; and Wockhardt Bio AG and Wockhardt USA LLC; Sun Pharmaceutical Industries Ltd; Apotex Inc. and Apotex Corp.; and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, "Defendants"). I have been asked by counsel for Defendants to provide my opinion about the meaning, to a person of ordinary skill in the art, of the following terms in the claims of U.S. Patent No. 7,326,708 ("the '708 patent"):

- "crystalline monohydrate [of the dihydrogen phosphate salt of sitagliptin]" (claims 4 and 24)

- "characteristic absorption bands obtained from the X-ray powder diffraction pattern at spectral d-spacings of" (claims 5-7)

- "crystallizing the dihydrogenphosphate salt of [sitagliptin] at 25 °C" (claim 24)

2. I have personal knowledge of the facts stated herein and am competent to testify to the same.

II. SUMMARY OF OPINIONS

3. In my opinion, a person of ordinary skill in the art:

- would understand the phrase "crystalline monohydrate [of the dihydrogen phosphate salt of sitagliptin]" to mean "a repeating unit cell incorporating a fixed 1:1 ratio of water to a dihydrogenphosphate salt of sitagliptin"

- would not understand the literal meaning of the term "characteristic absorption bands obtained from the X-ray powder diffraction pattern at spectral d-spacings of" as written; and

- would understand the phrase "crystallizing the dihydrogenphosphate salt of [sitagliptin] at 25 °C" to mean "performing the crystallization of the monohydrate of sitagliptin dihydrogenphosphate wherein the formation of crystalline solids begin at 25 °C."

III. QUALIFICATIONS AND CREDENTIALS

4. I am currently working as a pharmaceutical consultant and am an Emeritus Professor of Pharmaceutics at UCL School of Pharmacy, University of London.

5. I received my Bachelor of Pharmacy from Chelsea College, University of London in 1981, a Ph.D. from King's College, University of London in 1985, and a Doctor of Science from University of London in 1997 for my research work in pharmaceutical materials science.

6. From 1988 to 2015, I was on the faculty of the School of Pharmacy at University of London. I became a Professor of Pharmaceutics in 1998, and served as the Head of the Department of Pharmaceutics from 2001 to 2007. My research interests during my academic career related to investigating the behaviour of pharmaceutical materials, in relation to

pharmaceutical processing and formulation. This work included modifying the physical properties of powders by crystallisation and physical manipulation as well as preparation and analytical characterisation of powders for pharmaceuticals.

7. Prior to joining the faculty at the School of Pharmacy at University of London, I was a Lecturer in Pharmacy at Chelsea Department of Pharmacy at King's College at the University of London from 1984 to 1988. I also worked as a pre-registration pharmacist at the Charing Cross Hospital from 1981 to 1982, as well as a *locum tenens* pharmacist from 1982 to 1988. In 1987, I was seconded at Ciba-Geigy Pharmaceuticals in their Advanced Drug Delivery Research unit for about 6 months.

8. Additionally, in 2000, I founded, and was Chief Executive Officer of, Pharmaterials Ltd, a company that provided salt selection, polymorph screening, pre-formulation, formulation development, analytical development, stability testing and GMP clinical trial manufacturing. I sold my final stake in the company in 2012.

9. I am currently a member of the Chemistry, Pharmacy and Standards Subcommittee of the Commission on Human Medicines[1], and I am on the steering committee of The Handbook of Pharmaceutical Excipients. I was Editor of the International Journal of Pharmaceutics for a 10-year period and served on the editorial boards of several journals, including Pharmaceutical Research, the American Association of Pharmaceutical Scientists (AAPS) Journal and AAPS Pharm Sci Tech. I have received a number of awards and have been

[1] The Commission on Human Medicines (CHM) is the body which grants and revokes marketing authorisations for drug products in the UK, equivalent to the FDA in the US. Decisions are made through expert groups, following assessments by staff at the Medicines and Healthcare products Regulatory Agency (MHRA). Prior to CHM, UK medicines regulation was through the Committee on Safety of Medicines (CSM). I was a member of CSM and chaired its Chemistry, Pharmacy and Standards committee.

made a fellow of the Royal Pharmaceutical Society, the Royal Society of Chemistry, AAPS and the Academy of Pharmaceutical Sciences of Great Britain.

10. I have authored over 180 peer-reviewed journal publications as well as a book, and I have given over 130 invited and external lectures since 2001. I have also been named as an inventor on a number of patents and patent applications.

11. A copy of my curriculum vitae is attached as J.A. 26.

IV. MATERIALS CONSIDERED

12. In forming my opinions and preparing this declaration, I have relied upon my years of training, knowledge and experience in the relevant field, and have reviewed, among other things, the '708 patent, the Declaration of Professor Allan S. Myerson, Ph.D. Regarding Claim Construction (J.A. 3) and the materials cited therein, and the materials cited in this declaration.

V. LEGAL STANDARDS

13. In formulating my opinions, counsel in this case has informed me of certain principles of U.S. patent law that govern claim construction and indefiniteness of claim terms. The discussion of legal principles set forth below is not intended to be exhaustive and is merely intended to provide some context for the opinions that I provide.

14. I understand that terms in a patent claim are given the meaning they would have to a person of ordinary skill in the art at the time of the invention in view of the patent's claims, the specification, and prosecution history. I understand that when construing claim terms, the words of the claims provide the starting point for claim construction and must be given their ordinary and customary meaning in the field of the invention. I understand, however, that the inventors may assign their own meaning to the words of a claim by acting as their own lexicographers. I understand that any special definition given to words or terms must be clearly

defined in the specification or prosecution history to alter the plain and ordinary meaning of those terms. Furthermore, I understand that narrower definitions of claim terms may be appropriate if a patentee clearly and unambiguously surrendered subject matter during prosecution. I further understand that "extrinsic evidence," such as dictionaries or treatises, though not given as much weight as the claim language, may sometimes also demonstrate the ordinary and customary meaning of a term to a person of ordinary skill in the art.

15. I further understand that a claim is indefinite if it fails to inform those skilled in the art about the scope of the invention with reasonable certainty. I understand that if it would be apparent to one of skill in the art, based on the specification, that the invention set forth in a claim is not what the patentee regarded as his invention, then that claim is indefinite. I also understand that even when a POSA would understand that a disputed term may mean something other than what the words of a claim literally say, if the specification provides no alternative meaning for literal words of the claim, and the claim, as literally written, is nonsensical or incomprehensible, then that claim is indefinite. I understand that it is the role of neither a POSA nor the Court to redraft claims to make them operable or sustain their validity.

VI. THE PATENT-IN-SUIT AND THE DISPUTED CLAIM TERMS

16. The '708 patent is titled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor." I understand that the '708 patent was filed on June 23, 2004, and issued on February 5, 2008.

17. I understand that the following claims are representative of the claims implicated by the terms at issue for claim construction:

> 1. A dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I:

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