

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIOCON PHARMA LIMITED,  
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,  
Patent Owner.

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Case IPR2020-01263  
Patent 8,101,659

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**EXPERT DECLARATION OF DR. REZA TABRIZCHI**

NOVARTIS EXHIBIT 2004  
*Biocon v. Novartis*, IPR2020-01263  
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I, Reza Tabrizchi, declare as follows:

1. I have been asked by counsel for Novartis Pharmaceuticals Corporation to provide my opinion with respect to the state of the NEP inhibitor art as of January 17, 2002 on three issues: (1) the number and types of NEP inhibitors that were individually known, (2) whether Gomez-Monterrey (Ex. 1005) taught or suggested replacing a thiol NEP inhibitor with a carboxylate NEP inhibitor for optimal recognition of the zinc ligand of NEP, and (3) whether Gomez-Monterrey taught or suggested the NEP inhibitors SQ 28603 or sacubitril. I have considered these issues from the perspective of a person of ordinary skill in the art (“POSA”). For the purpose of this declaration, I have been asked to assume that the POSA is someone with experience in the fields of cardiology and pharmacology, including an understanding of drug-drug interactions, rationales for drug combinations, and development and availability of drugs for treatment of cardiovascular disorders. I have been asked to assume that a POSA would have had: (i) a doctoral degree in pharmacology, pharmacy, medicine, chemistry, biochemistry, medical chemistry or in a related field, with two years of the above described experience; (ii) a master’s degree in the same fields, with seven years of the above described experience; or (iii) a bachelor’s degree in the same fields, with ten years of the above described experience. I have also been asked to assume that the POSA may consult with individuals having specialized expertise, for example, a clinician or

practitioner with experience in the administration, dosing, and efficacy of drugs and/or a regulatory affairs specialist. I have been asked to assume that a POSA would have knowledge of the scientific literature concerning the same as of the priority date. I have been asked to assume a POSA may also work as part of a multidisciplinary team and draw upon not only his or her own skills, but also take advantage of certain specialized skills of others in the team to solve a given problem.

2. My opinions are based on the materials cited in this declaration and my education, knowledge, and experience as a pharmacologist, including in the field of cardiology, as of January 2002 to the present day.

#### **I. QUALIFICATIONS**

3. I am a Professor in the Division of BioMedical Sciences and Associate Dean of Research and Graduate Studies in the Faculty of Medicine at Memorial University of Newfoundland in Canada. I have been a tenured Professor of Pharmacology (Cardiovascular) there since September 1998. My research focuses on the influence of drugs that affect the function of the cardiovascular system. I have been in the fields of cardiology and pharmacology for more than 30 years.

4. I received my Bachelor of Science in Pharmacology with Honors from the University of Sunderland in the United Kingdom in 1983. I obtained a Master

of Science and Doctor of Philosophy in Pharmacology and Therapeutics in 1986 and 1988, respectively, from the University of British Columbia. Thereafter, I completed two post-doctoral fellowships and a research fellowship at Memorial University, the University of Calgary, and the University of British Columbia between 1988 and 1992. From 1992 to 1998, I was an Assistant Professor at the University of British Columbia and then Memorial University. I received tenure in 1998 at Memorial University, becoming an Associate Professor there, and have been a Professor at Memorial University since 2004.

5. I am a member of the American Society for Pharmacology and Experimental Therapeutics, the British Pharmacological Society, and the Canadian Hypertension Society.

6. I serve on the editorial boards of the Journal of Pharmacological & Toxicological Methods, Vascular Health and Risk Management, and the Journal of Cardiovascular Pharmacology. I have previously served on the boards of Expert Review of Cardiovascular Therapy and BioMed Central – Pharmacology and Toxicology.

7. I am also a peer reviewer for many prominent cardiology and pharmacology journals including the British Journal of Pharmacology, the Canadian Journal of Physiology and Pharmacology, Cardiovascular Research, Drug Development Research, the European Journal of Pharmacology, the Journal

of Cardiovascular Pharmacology, the Journal of Pharmacological & Toxicological Methods, the Journal of Pharmacy and Pharmacology, Pharmacological Research, Pharmacology & Therapeutics, The American Journal of Medicine, and The Canadian Journal of Cardiology.

8. I have received several fellowships for my work, including the Canadian Heart Foundation Fellowship, the Medical Research Council Fellowship, and the Heart and Stroke Foundation of Canada Scholarship. I have also received research funding as the principal investigator for over two decades from charitable organizations and national grant agencies in Canada.

9. I have been involved in teaching in the discipline of pharmacology, including at the undergraduate and graduate levels, since 1988. I have taught subjects including drug absorption, distribution, excretion, and metabolism, quantitative aspects of pharmacokinetics, drug interactions, antihypertensive drugs, and drugs for the treatment of heart failure.

10. I have been responsible for training and mentoring many graduate students, medical residents, undergraduate students and research assistants. I have also served on the academic supervisory committees of numerous graduate students.

11. I have served on many committees during my tenure, including the Pharmacological Society of Canada Nominating Committee, the Heart and Stroke

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