

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONTIER THERAPEUTICS, LLC

Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE
SPEZIALPRÄPARATE MBH

Patent Owner

Inter Partes Review Case No. Unassigned

Patent No. 8,664,231

Title: Concentrated Methotrexate Solutions

DECLARATION OF M. ERIC GERSHWIN, M.D.

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 3. Grint discloses that the methotrexate is “in a pharmaceutically acceptable solvent at a concentration of more than 30 mg/ml” (Claim 1)21

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 5. Grint discloses the “[p]harmaceutically acceptable solvent [] selected from water, water for injection purposes, water comprising isotonic additives and sodium chloride solution” (Claim 4)22

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selected from rheumatoid arthritis, juvenile arthritides, vasculitides, collagenoses, Crohn’s disease, colitis ulcerosa, bronchial asthma, Alzheimer’s disease, multiple sclerosis, Bechterew’s disease, joint arthroses, or psoriasis” (Claim 5) and “wherein the inflammatory autoimmune disease is rheumatoid arthritis” (Claim 6).....23

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I. INTRODUCTION

1. I, Dr. M. Eric Gershwin, M.D., have been retained by Frontier Therapeutics, LLC (“Petitioner”) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office.

2. I understand that this proceeding involves U.S. Patent No. 8,664,231 (“the ’231 patent”) (Ex. 1001). I further understand that the ’231 patent claims priority to German Application No. DE 10 2006 033 837.5, filed July 21, 2006. Ex.1001 at Front Cover. I further understand that the ’231 patent is assigned to medac GmbH.

3. I have been asked to provide information regarding the use of methotrexate (“MTX”) to treat inflammatory autoimmune diseases, particularly rheumatoid arthritis, and the various routes of administration used for MTX prior to July 2006. I have also been asked to consider whether certain references disclose or suggest the features recited in the claims of the ’231 patent. My opinions are set forth below.

II. MY EXPERIENCE AND QUALIFICATIONS

4. My curriculum vitae, which includes a detailed summary of my background and experience and a list of my publications and patents is attached as Exhibit 1031.

5. I am a Distinguished Professor of Medicine, and Chief of

Rheumatology, Allergy and Clinical Immunology in the School of Medicine at the University Of California, Davis. My official title is Distinguished Professor of Medicine.

6. I received my A.B. degree (summa cum laude) in Zoology from Syracuse University in 1966. In 1975, I graduated with an M.D. from Stanford University School of Medicine in Palo Alto, California. I was an intern and medical resident from 1971-1973 at Tufts-New England Medical Center, Boston, MA. From 1973 to 1977, I was a Clinical Associate, Immunology, National Institute of Health, Bethesda, MD.

7. From 1975-1977, I was an Assistant Professor of Medicine (Rheumatology and Clinical Immunol.), University of California, Davis.

8. From 1976-1979, I was the Director of the Tissue Typing Laboratory at the University of California, Davis.

9. From 1977-1981, I was an Associate Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California, Davis.

10. From 1981 to the present time, I have been a Professor of Medicine, Division of Rheumatology/Allergy and Clinical Immunology, University of California, Davis.

11. From 1982 to the present time, I have been the Chief of the Division

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