

IPR2016-01370
U.S. Patent No. 8,664,231

Attorney Docket No.
110670-0009-651

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KOIOS PHARMACEUTICALS LLC,
Petitioner

v.

MEDAC GESELLSCHAFT FUER KLINISCHE
SPEZIALPRÄPARATE MBH,
Patent Owner

Case No. IPR2016-01370
Patent Number 8,664,231

Before JACQUELINE WRIGHT BONILLA, TONI R. SCHEINER,
and ERICA A. FRANKLIN, *Administrative Patent Judges*

EXPERT DECLARATION OF THOMAS ZIZIC, M.D.

June 9, 2017

Medac Exhibit 2092

I, Thomas Zizic, M.D., have been retained as an expert by counsel for medac Gesellschaft Für Klinische Spezialpräparate Mbh, Inc. (“Medac”) in the above-captioned *Inter Partes* Review (“IPR”).

I. QUALIFICATIONS

1. I am a rheumatology physician and Associate Professor of Medicine at The Johns Hopkins University (“Johns Hopkins”). I have treated arthritis since the 1970s and published extensively on the progression of treatment options. I routinely treat inflammatory autoimmune disease patients with methotrexate, including using oral, intramuscular, and subcutaneous administration, and have done so throughout my clinical experience. I have treated thousands of patients with rheumatoid arthritis since 1971.

2. I graduated from The Johns Hopkins University School of Medicine in 1965. I completed my internship and residency at Johns Hopkins between 1965 and 1967. I also completed a post-doctoral fellowship at Johns Hopkins from 1969 to 1971.

3. I am board qualified in Rheumatology. I am a founding fellow of the American College of Rheumatology. I am also a member of multiple professional societies related to inflammatory autoimmune diseases, including the American Rheumatism Association and the District of Columbia Rheumatism Association.

4. From 1971 to the present, I have held teaching and academic positions at Johns Hopkins. I was first an Instructor in Medicine from 1971 to 1975, and then became an Assistant Professor of Medicine from 1975 to 1981, when I became an Associate Professor of Medicine, a position I have held continuously since then.

5. Among my other publications, since 1980, I have authored multiple publications on the diagnosis and treatment of rheumatoid arthritis. These include three articles on methotrexate, nine articles and abstracts on rheumatoid arthritis, six book chapters on rheumatoid arthritis (including three that discuss methotrexate), and 13 clinical studies involving methotrexate.

6. My educational background, work experience, and a list of my publications are set forth in my *curriculum vitae*, which is attached as Tab A to this Declaration. A list of the cases in which I have testified as an expert at trial or by deposition over the previous 4 years is attached at Tab B.

II. SCOPE OF ASSIGNMENT AND SUMMARY OF MY OPINIONS

7. I am informed and understand that Koios Pharmaceuticals LLC (“Koios”) has petitioned for an IPR of Medac’s U.S. Patent No. 8,664,231 (Ex. 1001, “the ‘231 Patent”) and has requested the cancellation of claims 1-22 of the ‘231 Patent. I am informed and understand that in the IPR, Koios has relied on (among other documents) U.S. Patent No. 6,544,504 (Ex. 1003, “Grint”) and a

Wyeth product label “Methotrexate Sodium for Injection” (Ex. 1021, “Wyeth”). I also understand that the Patent Trial and Appeal Board (“Board”) has instituted trial on claims 1-22 in view of Grint and Wyeth, among other documents. *See* Feb. 8, 2017 Decision Granting Institution (“Decision”).

8. I am instructed that the challenged claims have a priority date of July 21, 2006. I have been asked to assess the knowledge of the skilled artisan at that date, how physicians used methotrexate to treat inflammatory autoimmune diseases at that date, and what the skilled artisan would have understood from Grint and Wyeth at that date.

9. In forming my opinions, I have relied upon my education, experience, and various written materials. A list of the written materials that I considered in rendering my opinions is attached to this declaration as Tab C. Each of these materials is a type of document that experts in my field would reasonably rely upon when forming their opinions.

10. I hereby declare 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 18 U.S.C. § 1001. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

III. LEVEL OF SKILL IN THE ART

11. I have been instructed, for the purposes of this Declaration, to opine on the knowledge and understanding of a person having ordinary skill in the art (“POSITA”) as of July 21, 2006.

12. I understand that the factors considered in determining the ordinary level of skill in the art include: (i) the levels of education and experience of persons working in the field; (ii) the types of problems encountered in the field; and (iii) the sophistication of the technology. I understand that a person having ordinary skill in the art is not a real person, but rather a hypothetical individual with the qualities based on the factors above.

13. I understand that Medac has previously stated that a POSITA with respect to the ‘231 Patent as of July 21, 2006 would have the understanding of: a) a person with an M.D. and experience using methotrexate to treat inflammatory autoimmune diseases; or b) a person with a Ph.D. or Pharm.D. in pharmacology, pharmaceuticals, or chemistry; or c) a person with a lesser degree but with at least several years of additional experience in methotrexate preparation (*e.g.*, a pharmacy technician or nurse) in either an academic or industrial setting.

14. Based on over 40 years of experience in treating inflammatory autoimmune diseases, using (among other things) oral, intramuscular, and

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