

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

Patent No. 8,664,231

Title: Concentrated Methotrexate Solutions

Declaration of Dr. Michael H. Schiff

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I, DR. MICHAEL H. SCHIFF, DECLARE THE FOLLOWING:

I. INTRODUCTION

1. I have been retained by Koios Pharmaceuticals 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, filed July 21, 2006. Ex. 1001 at Front Cover.

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.

4. In forming my opinions, I have reviewed the previous declaration submitted by Dr. Michael Weinblatt in support of another challenge to the ’231 patent, as well as the relevant materials cited therein, and have relied on and incorporated those opinions into this declaration where appropriate. I know Dr. Weinblatt personally and have co-authored a number of publications with him. I have nonetheless applied my personal judgment, knowledge, and experience in

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