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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ANTARES PHARMA, INC., LEO PHARMA A/S and LEO PHARMA INC.,

Petitioners

v.

MEDAC GESELLSCHAFT FUER KLINISCHE SPEZIALPRÄPARATE MBH

Patent Owner

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Case No.: Not yet assigned  
Patent No. 8,664,231  
Title: Concentrated Methotrexate Solutions

**DECLARATION OF DR. MICHAEL E. WEINBLATT**

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I, Dr. Michael E. Weinblatt, declare the following:

## **I. Introduction**

1. I have been retained by Antares Pharma, Inc., Leo Pharma A/S and Leo Pharma Inc. (“Petitioners”) 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. My opinions are set forth below.

## **II. 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.

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