

Paper No. __
Filed: July 1, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners

v.

MEDAC GESELLSCHAFT FUER KLINISCHE SPEZIALPRÄPARATE MBH

Patent Owner

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

DECLARATION OF DR. MICHAEL E. WEINBLATT

Table of Contents

I. Introduction..... 1

II. Qualifications 1

III. Materials Reviewed 6

IV. Background of Methotrexate 8

V. Level of Skill In the Art 13

VI. The '231 Patent 14

VII. Claim Construction 16

 A. Claims of the '231 patent 17

 1. “subcutaneously” 17

VIII. Certain References Disclose or Suggest All Claims of the '231 Patent..... 18

 A. *Grint* discloses all elements of claims 1, 2, 4, 5, 6, 17, and 22 18

 1. *Grint* discloses “a method for treating inflammatory autoimmune diseases in a patient in need thereof” (Claim 1) 19

 2. *Grint* discloses “subcutaneously administering to said patient a medicament comprising methotrexate” (Claim 1) 19

 3. *Grint* discloses that the methotrexate is “in a pharmaceutically acceptable solvent at a concentration of more than 30 mg/ml” (Claim 1) 19

 4. *Grint* discloses that the methotrexate is “present at a concentration of more than 30 mg/ml to 100 mg/ml” (Claim 2) 20

 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

6.	<i>Grint</i> discloses “the inflammatory autoimmune disease is 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).....	22
7.	<i>Grint</i> discloses that “the sodium chloride solution is isotonic sodium chloride solution” (Claim 17).....	23
8.	<i>Grint</i> discloses methotrexate “present at a concentration of from 40 mg/ml to 80 mg/ml” (Claim 22)	23
B.	<i>Grint</i> In View Of <i>Alsufyani</i> Teaches Every Element of Claim 18.....	23
C.	<i>The PDR for Mexate®</i> (Ex. 1007) or <i>Hospira</i> (Ex. 1009) in view of <i>Brooks</i> (Ex. 1008) teach each element of Claims 1-5, 17, and 22 of the ’231 patent.....	25
1.	<i>The PDR for Mexate®</i> (Ex. 1007).....	25
2.	<i>Hospira</i> (Ex. 1009)	27
3.	<i>Brooks</i> (Ex. 1008)	28
D.	<i>Hoekstra</i> (Ex. 1004) and <i>Jørgensen</i> (Ex. 1005) Teach Every Element of Claims 1-6, 17, and 22.....	31
1.	<i>Hoekstra</i> (Ex. 1004)	31
2.	<i>Jørgensen</i> (Ex. 1005)	32
3.	<i>Hoekstra</i> (Ex. 1004) and <i>Jørgensen</i> (Ex. 1005), in view of secondary reference <i>Alsufyani</i> (Ex. 1006) Teach Every Element of Claim 18.....	34
IX.	Secondary Considerations	35
A.	Any toxicity associated with MTX after subcutaneous injection is dose, not concentration dependent.....	35
B.	The bioavailability of MTX after subcutaneous injection is dose, not concentration dependent.....	37

C.	Applicant's evidence of unexpected results is not based on a comparison of the claimed invention to the closest prior art.....	38
D.	<i>Zackheim</i> does not teach away from the claimed invention.....	42
X.	Conclusion	44

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.