

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. Donald Miller, Pharm.D

Table of Contents

I. INTRODUCTION.....	1
II. QUALIFICATIONS .....	2
III. MATERIALS REVIEWED.....	5
IV. THE '231 PATENT .....	7
V. LEVEL OF SKILL IN THE ART .....	8
VI. CLAIM CONSTRUCTION.....	9
A. Claims of the '231 patent.....	9
1. “pharmaceutically acceptable solvent” .....	10
2. “Injection device” .....	11
3. “Ready-made syringe” .....	12
4. “Pen injector” .....	13
VII. BACKGROUND REGARDING MTX SOLUTIONS AND DEVICES FOR THEIR INJECTION .....	14
VIII. CERTAIN REFERENCES DISCLOSE OR SUGGEST THE FEATURES RECITED IN THE '231 PATENT CLAIMS.....	18
A. <i>Grint</i> .....	18
B. <i>Arthur</i> .....	22
C. <i>Moitra</i> .....	24
D. <i>Insulin Admin.</i> .....	25
E. <i>Wyeth</i> .....	28
F. <i>Hoekstra and Jørgensen</i> .....	31
1. <i>Hoekstra</i> .....	31
2. <i>Jørgensen</i> .....	32

3. *Hoekstra* in combination with *Jørgensen* teaches the use of highly concentrated MTX solutions for subcutaneous administration ..... 32

IX. CONCLUSION ..... 34

I, Dr. Donald Miller, 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. I further understand that the ’231 patent is assigned to medac GmbH.

3. I have been asked to provide information concerning the formulation of pharmaceutical solutions containing methotrexate (“MTX”) for injection by various routes of administration prior to July 2006. I have also been asked to consider whether certain references disclose or suggest features recited in the claims of the ’231 patent. My opinions are set forth below.

4. In forming my opinions, I have reviewed the previous declaration submitted by Dr. David Gammon in support of another challenge to the ’231 patent, as well as the materials cited therein, and have relied on and incorporated those opinions into this declaration where appropriate. I

have applied my personal judgment, knowledge, and experience in reviewing and incorporating those opinions, and all opinions set forth in this declaration are my own. I have also reviewed and considered Medac's Preliminary Response to a challenge brought by Frontier Therapeutics, LLC, and Dr. Elena Massarotti's declaration in support of that document. I address certain of the views expressed in those documents, and reserve the right to address the arguments and opinions presented by Medac's lawyers and experts (and any other relevant information) further should the Board institute this *inter partes* review.

## II. QUALIFICATIONS

5. My curriculum vitae, which includes a detailed summary of my background and experience and a list of my publications is attached as Exhibit A to this Declaration.

6. I am Professor of Pharmacy Practice at the North Dakota State University School of Pharmacy, within the College of Health Professions. Until 2015, I was Chairman of the Department of Pharmacy Practice at NDSU. I am also Associate Faculty for the Master of Public Health program at NDSU.

7. I received my Pharm.D. from the University of Michigan and my Certificate of Residency from University Hospital in Saskatoon,

# 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.