

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:)
U.S. Patent No. 9,138,432 B2)
Issued: Sept. 22, 2015)
Application No.: 14/150,575)
Filing Date: Jan. 8, 2014)

For: **Methods for the Administration of Iloperidone**

FILED VIA PRPS

**DECLARATION OF DAVID L. FOGELSON, M.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,138,432**

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Declaration of David Fogelson, M.D., in Support of
Petition for *Inter Partes* Review of U.S. Patent No. 9,138,432

I, Dr. David Fogelson, resident of Santa Monica, California, hereby declare
as follows:

I. INTRODUCTION AND QUALIFICATIONS

1. I have been retained by Roxane Laboratories, Inc. (“Roxane”) to
provide my opinions concerning Claim 1 of U.S. Patent No. 9,138,432 (Ex. 1001,
“the ’432 Patent”) in support of Roxane’s Petition for *Inter Partes* Review of U.S.
Patent No. 9,138,432. I have not previously been employed or retained by Roxane
in any capacity.

2. Claim 1 of the ’432 Patent relates to a method of administering
iloperidone to a patient, where the dose of iloperidone is reduced if the patient is
concurrently being treated with fluoxetine.

3. I have extensive and ongoing expertise in treating psychotic disorders,
including prescribing iloperidone for the treatment of schizophrenia

4. I am a Clinical Professor of Psychiatry at the David Geffen School of
Medicine at the University of California, Los Angeles (UCLA) School of Medicine
and the UCLA Department of Psychiatry and Biobehavioral Sciences. In the past,
I have served as Assistant Director of the UCLA Outpatient Psychiatry
Department, Assistant Director of the UCLA Mood Disorders Outpatient Clinic,
Director of the UCLA Outpatient Psychopharmacology Clinic, Director of the
UCLA Anxiety Disorder Clinic at UCLA, and Director of the Westwood Hospital

Declaration of David Fogelson, M.D., in Support of
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Intensive Care Unit. I am a clinical supervisor for the psychiatry residents in the UCLA Outpatient Psychiatry Department, in which capacity I teach residents, interns, and medical students current community standard psychiatric practices, including how to account for potential drug-drug interactions while treating patients. I also regularly speak publicly at hospitals, universities, and clinics on various topics in psychopharmacology and schizophrenia.

5. I have treated patients as a licensed physician since 1977. I have been board certified in psychiatry and neurology since 1984. I currently see about 60 patients weekly and I supervise the care of dozens of others. Within the past 20 years, I have treated thousands of patients for schizophrenia. I have prescribed all major approved atypical antipsychotics, including iloperidone. I have also treated tens of thousands of patients for depression, and I estimate that I have administered fluoxetine over five thousand times. In my clinical practice, I have significant and ongoing experience adjusting the dosages of drugs administered to patients based on patients' medical histories and concurrent medications.

6. My primary areas of research have focused on the genetics, pathophysiology, and pharmacologic treatment of schizophrenia and related disorders. I was the Medical Director for the UCLA Family Study of Schizophrenia, a long-term clinical genetics study of schizophrenia. I previously served as President of the Pacific Psychopharmacology Research Institute, where I

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