UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,

Petitioner

v.

ANTECIP BIOVENTURES II LLC,

Patent Owner.

U.S. Patent No. 9,931,352 U.S. Patent No. 10,039,774 U.S. Patent No. 10,052,338

DECLARATION OF LAWRENCE POREE, M.D., PH.D.

TABLE OF CONTENTS

I. Introduction	1	
II. Qualifications	2	
III. Scope of Work and Opinions	4	
IV. Person of Ordinary Skill in the Art	4	
V. Claim Interpretation	6	
A. "A method of treating [a sign or symptom] associated with	[CRPS]"6	
VI. Grounds for Unpatentability	8	
A. Obviousness of the Independent Challenged Claims	8	
1. Obviousness Standard	8	
2. The Independent Challenged Claims	9	
3. The Prior Art Taught that Neridronate is Effective t CRPS and its Symptoms		
4. The Prior Art Taught that the Signs and Symptoms Independent Challenged Claims Are Defining Symp Signs, and Diagnostic Criteria of CRPS	ptoms,	
5. It Would Have Been Obvious to Administer Neridr Acid to Treat Patients Suffering from the Claimed S Symptoms Associated with CRPS	Signs and	
6. The Pain Intensity Limitations of the '774 Patent C	laims28	
B. Obviousness of the Dependent Challenged Claims		
 "wherein a total of about 200 mg to about 500 mg [400 mg] of the neridronic acid is administered parent to the human being" 	nterally	
2. "wherein a total of about 100 mg to about 200 mg on neridronic acid is administered parenterally to the h being within a period of about 1 month"	uman	
3. "wherein a total of about 250 mg of the neridronic a administered parenterally to the human being within period of about 1 month"	n a	
i		

4.	"wherein the neridronic acid is administered in divided parenteral doses" and "wherein each divided parenteral dose contains about 10 mg to about 150 mg of the neridronic acid"	34
5.	"wherein each divided parenteral dose contains about 62 mg to about 63 mg of the neridronic acid"	34
6.	"wherein the complex regional pain syndrome is associated with an inciting traumatic event"	35
7.	"wherein the human being has suffered from complex regional pain syndrome for at least 6 months" or "for about 6 months to about 12 months or "for about 1 year to about 2 years"	36
8.	"wherein the human being has an age of about 30 years to about 40 years"	38
9.	"wherein the human being has a pain intensity of at least 7 cm [or 8 cm or 9 cm] on the 10 cm visual analogue scale (VAS) or at least 7 [or 8 or 9] on the 0-10 numeric rating scale (NRS)	39
Indefini	teness of Claims 17-30 of the '338 Patent	40
Lack of	Written Description for All Challenged Claims	42

ii

C.

D.

I, Dr. Lawrence Poree, hereby declare as follows:

I. <u>Introduction</u>

1. I have been retained by Venable LLP on behalf of Grünenthal GmbH as an independent expert to provide my opinions on the subject matter recited in the claims of U.S. Patent No. 9,931,352 (Exhibit 1001, "the '352 patent"), U.S. Patent No. 10,039,774 (Exhibit 1002, "the '774 patent"), and U.S. Patent No. 10,052,338 (Exhibit 1003, "the '338 patent") in view of the state of the art at the time and various references that predate those patents, all of which I refer to in this declaration.

2. I understand that Grünenthal GmbH has petitioned the Patent Trial and Appeal Board (PTAB) to institute post-grant reviews (PGRs) of the '352 patent, the '774 patent, and the '338 patent, and has requested that the PTAB cancel the claims of those patents due to obviousness, lack of written description, and/or indefiniteness.

3. I understand that this declaration is being filed as Exhibit 1004 in each of the respective PGRs against the '352 patent, the '774 patent, and the '358 patent. In this declaration, I refer to these three patents collectively as the "Challenged Patents." I also refer to the totality of the claims of the Challenged Patents as the "Challenged Claims."

4. I make this declaration based upon personal knowledge. I am over the age of 21 and otherwise competent to make this declaration.

5. I am being compensated at the rate of \$800 per hour for work performed on this matter. My compensation does not depend on the nature of my findings, the presentation of my findings in testimony, or the outcome of this proceeding.

II. **Qualifications**

6. A copy of my CV, which fully describes my qualifications as an expert in the instant matters, is submitted as Exhibit 1005 in each of the respective PGRs against the '352 patent, the '774 patent, and the '358 patent. I have set forth particularly relevant qualifications to my testimony in these matters in the paragraphs that follow.

7. I am a Professor of Pain Medicine and the Director of Neuromodulation at the University of California at San Francisco.

8. I received my Ph.D. in Toxicology/Environmental Health Sciences from the University of California in 1988 and my M.D. from Stanford University School of Medicine in 1997. In 2002 I completed a Pain Fellowship at the University of California at San Francisco.

9. I have over 20 years of experience treating patients with chronic pain and studying treatments for pain disorders including complex regional pain

2

DOCKET A L A R M



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.