

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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COALITION FOR AFFORDABLE DRUGS X LLC,  
Petitioner,

v.

ANACOR PHARMACEUTICALS, INC.,  
Patent Owner.

Case No. IPR2015-01776  
Patent No. 7,582,621

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**DECLARATION OF HOWARD I. MAIBACH, M.D., PH.D., IN SUPPORT  
OF PATENT OWNER RESPONSE PURSUANT TO 37 C.F.R. § 42.120**

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I, Howard I. Maibach, hereby declare as follows:

1. I received B.A. and M.D. degrees at Tulane University, and honorary Ph.D. and M.D. degrees from L'Université de Paris-Sud in Paris, Université Claude Bernard in Lyon, Université de Franche-Comté in Besançon, and the University of Southern Denmark.

2. I completed my internship at the William Beaumont Army Hospital in El Paso and on-the-job training in neurology and psychiatry at the Walter Reed Army Hospital in Washington, DC. I then practiced neurology and psychiatry in the U.S. Army. My military service was followed by a residency in dermatology and a National Institutes of Health research fellowship at the University of Pennsylvania Hospital. I joined the faculty at the University of Pennsylvania following my residency and fellowship, and in 1961 moved to the University of California Medical School-San Francisco ("UCSF"), where I am currently a professor.

3. On arriving at UCSF, I initiated laboratory and clinical investigation into skin physiology, pharmacology, and toxicology. Our laboratory focuses on penetration of chemicals through skin and, more recently, through nails—in both humans, experimental animals, and in test-tube surrogates of the former (*in vitro* penetration).

4. I have been treating patients with dermatological conditions, including onychomycosis, since 1961. One of my first research endeavors involved the use of griseofulvin (the first oral antifungal indicated for treatment of onychomycosis). I have founded several clinics, including a psoriasis clinic in which some patients had fungal disease of the nail.

5. From approximately 1962 to 1995, I was the volunteer dermatologist for male prisoners in northern California state prisons. Once a week, I traveled to the California Medical Facility and examined inmate patients. Many of these patients had onychomycosis. During the course of my career, I have treated many hundreds of patients with onychomycosis. In addition to treating patients, I have led and participated in many clinical trials of onychomycosis therapies. I still see patients regularly at UCSF.

6. The psoriasis clinic I founded treats patients with psoriasis with and without nail involvement. The clinic offered outpatient treatment of skin diseases, and included a large in-patient service at UCSF. I also founded and acted as chief of the UCSF Patch Test Clinic and an occupational dermatology clinic. I encountered (and continue to encounter) patients with onychomycosis at these clinics.

7. Today, I work as a tertiary care consultant. I see onychomycosis patients in that work, too. I also direct laboratory work, including some of the work referred to in this Declaration.

8. I have authored and co-authored over one thousand published chapters and articles. I also have authored, co-authored, and edited approximately eighty-five published books, including *Topical Nail Products and Ungual Delivery* with Dr. Narasimha Murthy and the *Handbook of Systemic Drug Treatment in Dermatology* with Dr. Sarah Wakelin and Dr. Clive Archer.

9. I have consulted with and performed studies for many pharmaceutical companies in connection with potential treatments for onychomycosis, including the following.

10. I performed pre-clinical studies for Novartis—over several years—while that company attempted to develop a topical onychomycosis treatment using a formulation with terbinafine, an oral onychomycosis medication.

11. I performed pre-clinical studies for Power Paper Limited, and was a consultant in Power Paper's attempted development of an iontophoretic-based topical antifungal treatment.

12. I performed pre-clinical studies and acted as a consultant for Topica in their development of a topical onychomycosis therapy.

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