

Patent No. 8,603,506
Petition for *Inter Partes* Review
Attorney Docket No. REDDY 7.1R-015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.
Requestors

v.

GALDERMA LABORATORIES, INC.
Patent Owner

Patent No. 8,603,506
Issue Date: December 10, 2013
Title: METHOD OF TREATING ACNE

Inter Partes Review No. Unassigned

(Exhibit 1004)
DECLARATION OF MICHAEL PAYETTE, M.D., M.B.A.

Dr. Reddy's Laboratories, Ltd., et al. v. Galderma Laboratories, Inc. IPR2015-_____
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I, MICHAEL PAYETTE, hereby declare as follows:

1. I am a U.S. citizen and a resident of the state of Connecticut.

2. I am a board-certified dermatologist and an assistant professor for the Department of Dermatology at the University of Connecticut School of Medicine. I hold a B.A. from Dartmouth College in Biochemistry in 2002, an MBA from the University of Connecticut focusing on healthcare management in 2008, and my medical degree is also from the University of Connecticut in 2008. My current *curriculum vitae* is provided. (Exh. 1005.)

3. I am primarily a clinical dermatologist and 70% of my time is dedicated to direct patient care in an academic university setting. My clinical areas of interest are complex medical dermatology and skin cancer, but I treat the entire spectrum of dermatologic diseases and all age groups, from newborns to geriatricians. I almost always have dermatology residents, residents in primary care specialties, and/or medical students working with me in clinic. The nonclinical 30% of my time is dedicated to resident and medical student education as well as to administrative duties inherent in running an ACGME (Accreditation Council for Graduate Medical Education)-certified dermatology residency program.

4. Outside of my clinical and administrative roles, I am an active publisher in the field of dermatology. I have an interest in cost efficacy and medical ethics. I serve as a peer-reviewer for submitted manuscripts for leading

dermatology journals. I am a consultant to several pharmaceutical companies as well (Amgen, Lilly, and Abbvie). Finally, I am a very active educator. I lecture to medical students, medicine residents, dermatology residents, and other physicians on all topics in dermatology, including the topics of acne and rosacea. I am constantly educating medical students, medicine residents, and most importantly dermatology residents in the clinical setting, with emphasis on the pathophysiology, diagnosis, and medical management of dermatologic conditions.

5. I have been retained by Lerner, David, Littenberg, Krumholz & Mentlik, LLP (“counsel”) to provide my opinions in the field of dermatology, the treatment of acne and rosacea as well as the treatment of certain symptoms common to acne and rosacea. I have read and understood U.S. Patent No. 8,603,506 (“the ‘506 Patent”) (Exh. 1001), its predecessors (Exhs. 1016, 1020, 1026, 1036), and all other references discussed in this declaration. I am being compensated for my time in an amount consistent with my customary consulting fee and my compensation is not contingent on my opinion or the outcome of this proceeding.

A Person of Ordinary Skill In The Art

6. I understand from counsel that patents such as the ‘506 Patent are neither addressed to experts nor to laymen; rather they are addressed to persons of ordinary skill in the relevant art at the time that the invention was made, which I

have been told by counsel to assume is April 5, 2001. I also understand from counsel that factors relevant to the level of skill in the art include, without limitation: the educational level of the inventor, the types of problems encountered in the relevant area, prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. In my opinion, considering these factors, a person of ordinary skill in the art would be a licensed, board-certified, and practicing dermatologist. And when I give my opinions herein, unless stated otherwise, it is my opinion of what such a person of ordinary skill in the art would know or do at the time.

7. I note first that the claims in question, which I understand to be claims 1, 7, 8, 14, 15, and 20 of the '506 Patent (Exh. 1001 col.31 1.60 to col.32 1.65) are directed to methods of treating an extremely common symptom of rosacea, a condition treated virtually every day by practicing dermatologists at even the most entry level. Treating skin conditions is the province of medical doctors in the U.S. As such, I would not consider those without formal medical training to be persons of ordinary skill. That said, as discussed below, treatment here involves administering a well-known active agent (doxycycline), in a well-established way (orally), for treating conditions and symptoms that were well-known by April 5, 2001 to be treated in that fashion (papules and pustules of

rosacea). Furthermore, the relevant doses of the active agent were all already FDA approved and commercially available. Accordingly, while the claims in question are clearly directed to dermatologists, I would not consider this technology to be sophisticated, particularly relative to other forms of dermatological medical treatments or research.

8. In reaching my conclusion, I have also considered the type of problems addressed by the '506 Patent, and prior art solutions to these types of problems. In my opinion they all involve balancing the need for treatment with a pharmaceutically active agent and the need to avoid exposing the patient to possible side effects and/or unintended consequences from the proposed treatment. This is a problem that is faced by every treating physician, every time they prescribe any medication, or decide not to do so. And the solutions, that of deciding to prescribe anything, deciding what to prescribe, how much to prescribe, and for how long, are well established and within the sound discretion of treating dermatologists.

9. While some general practitioners (such as pediatricians, internal medicine physicians, and family medicine physicians) do treat acne and rosacea, they typically do so in a limited fashion, using select common therapies (often advertised ones), and with adherence to the standard of care. They generally do not have expertise in the pathophysiology of acne or rosacea, the variety of clinical

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