Trials@uspto.gov
Tel: 571-272-7822

Paper 12
Entered: February 16, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

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

v.

GALDERMA LABORATORIES, INC.,
Patent Owner.

---

Case IPR2015-01777
Patent 8,603,506 B2

---

Before ERICA A. FRANKLIN, ZHENYU YANG, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

## INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") filed a Petition (Paper 1; "Pet.") to institute an *inter partes* review of claims 1, 7, 8, 14, 15, and 20 of US 8,603,506 B2 (Ex. 1001; "the '506 patent"). Galderma Laboratories Inc. ("Patent Owner")[1] filed a Patent Owner Preliminary Response. Paper 9 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '506 patent. *See* 35 U.S.C. § 314(a). We, therefore, deny the Petition for an *inter partes* review.

a. *Related Proceedings*

Petitioner indicates that the '506 patent has been asserted in the United States District Court for the District of Delaware (Civil Action No. 15-670). Pet. 2; Paper 6, 2.

In addition to the case before us, Petitioner has requested *inter partes* review of claims 1, 7, 8, 14, 15, and 20 of US 8,603,506 B2 on other grounds in Case Nos. IPR2015-01778 and IPR2015-01782.

---

[1] Petitioner further indicates that the Complaint in Civil Action No. 15-670 states that Nestlé Skin Health S.A. is now the owner of the '506 patent. Pet. 2 n.1. Although Patent Owner does not directly address this assertion in the Preliminary Response, the USPTO Assignment Database indicates that patent is assigned to Galderma Laboratories, Inc. Absent additional information, we refer to Galderma Laboratories, Inc. as the Patent Owner.

b. *The '506 Patent*

The '506 patent is directed to the treatment of "all known types of acne," broadly defined as "a disorder of the skin characterized by papules, pustules, cysts, nodules, comedones, and other blemishes or skin lesions." Ex. 1001, 4:23–32. The genus "acne" is expressly defined as encompassing acne rosacea ("rosacea"),[2] a skin disorder "characterized by inflammatory lesions (erythema) and permanent dilation of blood vessels (telangectasia)." *Id*. at 4:31–43. The specification further states the "[t]he present invention is particularly effective in treating comedones." *Id.* at 4:23–43.[3]

By way of background, the '506 patent discloses that the efficacy of systemically-administered tetracycline compounds in the treatment of acne is commonly believed to be due, "in significant part, to the direct inhibitory effect of the antibiotics on the growth and metabolism of [] microorganisms" that "release microbial mediators of inflammation into the dermis or trigger the release of cytokines from ductal keratinocytes." Ex. 1001, 1:42–50. In addition to these antibiotic effects, the specification also notes that tetracyclines may have therapeutic anti-inflammatory effects due to, for example, the "inhibition of neutrophil chemotaxis induced by bacterial chemotactic factors," the "inhibition of [polymorphonuclear leukocyte] derived collagenase, and by scavenging reactive oxidative species produced by resident inflammatory cells." *Id.* at 2:21–32, 3:14–25.

---

[2] The parties agree that the term "acne rosacea" in the specification refers to rosacea. Pet. 30–31; Prelim. Resp. 15–16.

[3] Petitioner asserts, and Patent Owner does not contest, that comedones are not a feature of rosacea. Pet. 9, 25; *see* Prelim. Resp. 23–24; Ex. 1004 ¶ 13.

The ’506 patent teaches that although tetracyclines are administered in conventional antibiotic therapy, antibiotic doses of these compounds can result in undesirable side effects such as the reduction or elimination of healthy microbial flora and the production of antibiotic resistant microorganisms. *Id*. at 3:7–17, 3:31–36. To address the need for effective treatments that minimize these side effects, the ’506 patent discloses that “all known types of acne” may be treated by administering a tetracycline compound in an amount having “substantially no antibiotic activity (i.e. substantially no antimicrobial activity)” and, thus, “does not significantly prevent the growth of . . . bacteria.” *Id*. at 3:37–50; 4:31–32; 5:31–35. The ’506 patent defines “effective treatment” as “a reduction or inhibition of the blemishes and lesions associated with acne” (*id.* 5:31–33), which may be achieved by administering non-antibiotic tetracycline compounds (i.e., those lacking substantial antibiotic activity) or by using sub-antibiotic doses of tetracycline compounds having known antibiotic effects (*see, e.g., id*. at 3:26–29, 4:58–61, 5:1–9, 5:35–42). With respect to the latter, the specification indicates that a sub-antibiotic dose may comprise “10–80% of the antibiotic dose,” or “an amount that results in a serum tetracycline concentration which is 10–80% of the minimum antibiotic concentration.” *Id.* at 5:36–42; 6:7–12.

The specification teaches that, whereas exemplary *antibiotic* doses of tetracycline compounds include 50, 75, and 100 milligrams per day of doxycycline, in an especially preferred embodiment, doxycycline (as doxycycline hyclate) is administered as a 20 milligram dose, twice daily, i.e., 40 milligrams per day. *Id*. at 5:43–45; 5:59–63. The specification teaches that this 40 milligram daily dose provides the maximum non-

antibiotic (i.e., sub-antibiotic) of doxycycline based on steady-state pharmacokinetics. *Id*. at 5:49–52. In terms of serum concentration, doxycycline may also be administered in an amount that results in a serum concentration between about 0.1 and 0.8 μg/ml. *Id.* at 6:29–32.

Example 38 of the '506 patent discloses that in a six-month, placebo-controlled trial for the treatment of acne[4] using 20 mg doxycycline hyclate, twice daily, doxycycline-treated patients showed a statistically significant reduction in both comedones and inflammatory lesions (defined as "papules and pustules, less than or equal to 5 nodules") as compared to placebo. *Id.* at 19:54–55; 20:24–32. The six-month doxycycline treatment "resulted in no reduction in skin microflora . . . nor an increase in resistance counts when compared with placebo." *Id.* at 20:33–37; *see id.* at 5:64–6:4.

c. *Representative Claim*

Claim 1 of the '506 patent recites:

> 1. A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising
>
> administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof, in an amount that
>
> (i) is effective to treat the papules and pustules of rosacea;
>
> (ii) is 10–80% of a 50 mg dose of doxycycline per day; and

---

[4] Petitioner asserts that Example 38 is directed to treating common acne (acne vulgaris), presumably based on inclusion criteria requiring the presence of comedones, non-inflammatory lesions which are not a symptom of rosacea. *See* Pet. 9, 23, 25; Ex. 1001, 1:20, 19:54; Ex. 1004 ¶ 13. Patent Owner does not dispute this characterization. *See* Prelim. Resp. 21.

DOCKET ALARM

# 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.