UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A. AND

DR. REDDY'S LABORATORIES, INC.

Petitioners

v.

INDIVIOR UK LIMITED.

Patent Owner

U.S. PATENT NO. 9,687,454

TITLE: SUBLINGUAL AND BUCCAL FILM COMPOSITIONS

Case No. IPR2019-00329

Petitioners' Reply to Patent Owner's Response

Table of Contents

Table of Authorities

Page(s)

Cases

Patent Owner does not dispute that Myers (the publication of the '571 application) substantively destroys the novelty of the subject claims of the '454 patent. Patent Owner simply contests the issue of priority, leaving as the only disputed issue before the Board whether the disclosure of the '571 application provides written description support for the challenged claims such that Patent Owner can claim priority thereto. As set forth in the Petition, and as the Board found in its decision on institution, the '571 application fails to provide such support, and Patent Owner fails to show otherwise. To the contrary, Patent Owner and its declarant, Dr. Cremer, who is a European patent attorney and IP consultant, concede that there is no express disclosure of ***either*** the claimed polymer weight percentage ranges or the claimed range of buprenorphine:polymer ratios in the '571 application. Lacking any "blaze marks" that would enable a POSA to understand the applicants to be in possession of these limitations, Patent Owner is left to try and backfill using calculated values derived by Dr. Cremer from cherry-picked portions of the application, notwithstanding any direction in the application to do so, and unsupported speculation concerning possible variations on the example formulations that are disclosed in the application. That Patent Owner must resort to these machinations shows that there is no basis in the specification for a POSA to have understood the inventors to be in possession of the claimed polymer weight percentages or buprenorphine:polymer ratios. And regardless, Dr.

Cremer's calculated values—which are wholly divorced from any direction in the application—do not provide written description support for these limitations. The Board should therefore conclude, as it did at the Institution stage, that the challenged claims are not entitled to a priority date of August 7, 2009, that Myers is prior art to the '454 patent and, as Patent Owner does not dispute, Myers anticipates the challenged claims. The challenged claims should therefore be canceled.

I. THE CHALLENGED CLAIMS ARE NOT ENTITLED TO CLAIM PRIORITY TO THE '571 APPLICATION, AND PATENT OWNER HAS NOT SHOWN OTHERWISE

A. The Claimed Polymer Weight Percentages Lack Written Description Support in the '571 Application

The challenged claims of the '454 patent recite three different polymer weight percentages: "about 40 wt % to about 60 wt %" (claim 1), "about 48.2 wt % to about 58.6 wt %" (claims 7 and 12), and "about 48.2 wt %" (claim 8). Patent Owner points to only four portions of the '571 application as support for these claimed ranges: paragraph [0065], claim 5, and Tables 1 and 5 (Test Formulation 2 only).[1] (Paper 33 at 12, 15–16, 29–30; Ex. 2008 at 15–18, 25.)

[1] During prosecution, the applicants identified paragraph [0032] as providing written description support for the claim amendment that added the "about 40 wt % to about 60 wt %" limitation. (*See* Paper 1 at 23–24, n.6.) Paragraph [0032] states

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.