UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,

Petitioner

v.

MONOSOL RX, LLC,

Patent Owner

U.S. Patent No. 8,603,514

Case IPR2016: Unassigned

EXPERT DECLARATION OF JAYANTH PANYAM, Ph.D.

1. My name is Jayanth Panyam. I have been retained by counsel for Teva Pharmaceuticals USA, Inc. ("Teva"). I understand that Teva is petitioning for *inter partes* review of U.S. Patent No. 8,603,514 (the "'514 patent"), which is assigned to Monosol RX, LLC ("Monosol"). I further understand that Teva is requesting that the United States Patent and Trademark Office cancel claims 1-3, 9, 15, 62-65, 69-73, and 75 of the '514 patent as unpatentable over Bess in view of Chen, and Chen in view of Cremer. This expert declaration supports Teva's petition.

I. Qualifications and Background

A. Education and Experience; Prior Testimony

1. My background, qualifications, and experience related to my opinions expressed in this report are given in my curriculum vitae attached as Ex. 1036.

2. I received my Bachelor's degree in Pharmacy in 1997 from the T.N. Dr. MGR Medical University. I continued my education at Banaras Hindu University and received my Masters degree in Pharmaceutics in 1999. In 2003, I received my Ph.D. in Pharmaceutical Science from the University of Nebraska Medical Center.

3. I have more than nine years of experience working in the pharmaceutical sciences. I am currently a professor with tenure at the University of Minnesota, in Minneapolis.

4. Throughout my career, I have published sixty peer-reviewed articles and five book chapters related to pharmaceutical sciences. I have also been invited to give presentations at more than thirty national meetings, including "Targeting circulating tumor cells and metastases in breast cancer," "Nanoparticles for Tumor-targeted Drug Delivery: Challenges and Opportunities," and "PLGA-induced inflammation is a double-edged sword."

5. I am a member of the American Association of Pharmaceutical Scientists, the Controlled Release Society, and the American Association of Colleges of Pharmacy.

6. I am named as an inventor on one issued patent entitled "Nanoparticles for imaging and treating chlamydial infection," as well as five pending patent applications and invention disclosures.

7. I have previously testified as an expert in a deposition.

B. Bases for Opinions and Materials Considered

8. Ex. 1037 includes a list of the materials I considered, in addition to my experience, education, and training, in providing the opinions contained herein.

C. Scope of Work

9. I have been retained by Teva as a technical expert in this matter to provide various opinions regarding the '514 patent. I receive $750 per hour for my services and $1,150 for time spent testifying at deposition, hearing, or trial. No

part of my compensation is dependent upon my opinions given or the outcome of this case. I do not have any other current or past affiliation as an expert witness or consultant with Teva. I do not have any current or past affiliation with Monosol, or any of the named inventors on the '514 patent.

II. Summary of Opinions

10. It is my opinion that the challenged claims – claims 1-3, 9, 15, 62-65, 69-73, and 75 – are obvious under 35 U.S.C. § 103 in view of the prior art, including the references cited below, which collectively teaches and motivates a person of ordinary skill in the art to make and use the same film formulation compositions that are claimed by the '514 patent.

11. I have reviewed the uniform thin film drug delivery prior art, and find that one of ordinary skill in the art would have understood that the Bess[1] and Chen[2] references, and the Cremer[3] reference, render obvious the challenged claims of the '514 patent.

12. The allegedly inventive concepts of the '514 patent were all well-known in the prior art. It was known at the time of the alleged invention of the '514 patent that uniform suspensions are important for use in drug delivery. Dispersion of pharmaceutical actives uniformly throughout a suspension was well

[1] Bess, Ex. 1004.
[2] Chen, Ex. 1005.
[3] Cremer, Ex. 1006.

known in the art. Uniformity was known to be challenging for those compounds that were not readily soluble, thereby forming suspensions. It would have thus been obvious by the priority date to use uniform dispersion of pharmaceutical actives throughout a suspension.

13. It was also known that uniform suspensions of particulate agents (before or after casting) were highly dependent on viscosity. One of skill in the art would have understood that uniformity in film formulations meant for human use was expected and readily achieved. (*See, e.g.*, Ex. 1013, *The Theory and Practice of Industrial Pharmacy*, at 56-57, 358-359, 368-369.)[4] The '233 patent[5] discloses that homogeneous suspensions of various polymers, including vinyl acetate and cellulose, were used for cast films. (Ex. 1022, '233 patent, at Abstract.) These films were also dried and considered to be homogenous. (*Id*. at 4:59-5:3.) Further, it was well known in the art that the uniformity of particulates in a suspension was directly related to the suspension's viscosity. (Ex. 1013, *The Theory and Practice of Industrial Pharmacy*, at 484.) The uniformity could also be affected by the mixing time and speed used for making a suspension. (*Id.* at 491-492.) Stoke's law, well known in the art by 2001, taught that settling of particulates in a suspension is directly related to, among other things, the density of the particles

[4] Ex. 1013, *The Theory and Practice of Industrial Pharmacy* (Lachman et al., eds., 3d ed. 1986).
[5] Ex. 1022, U.S. Pat. No. 5,166,233.

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.