Paper No. ____
Filed: November 4, 2016

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN TECHNOLOGIES, INC.,
Petitioner,

v.

MONOSOL RX, LLC
Patent Owner.

Case No. IPR2017-00200
Patent No. 8,603,514

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,603,514

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I. INTRODUCTION

Mylan Technologies, Inc. ("Petitioner") requests review of U.S. Patent No. 8,603,514 to Yang *et al*. ("the '514 patent," EX1001), which issued on December 10, 2013. PTO records indicate that the '514 patent is assigned to MonoSol Rx, LLC ("Patent Owner"). This Petition demonstrates that there is a reasonable likelihood that claims 1-3, 9, 15, 62-65, 69-73, and 75 ("the challenged claims") are unpatentable for failure to distinguish over newly applied prior art.

The challenged claims are directed to a drug delivery film comprising a particulate active ingredient and a taste-masking agent. Each component of the claimed composition was described in the prior art, including the oral drug delivery film, the polymer used to form the film, the viscosity of the film-forming matrix, the particle size of the active ingredient, the uniform distribution of the active ingredient, and the type of taste-masking agents as well as the manner of taste-masking used in the film. EX1001, 67:34-56 & 73:48-74:9. The challenged claims represent nothing more than adding a well-known taste-masking agent to a drug delivery film intended for oral delivery.

This Petition applies a prior art reference to the claims of the '514 patent that has not been previously addressed in prosecution, district court litigation, or in a pending IPR involving a different petitioner (IPR2016-01111). In those other proceedings, the Patent Owner has primarily asserted patentability over the prior

art based on the claim element that "individual unit doses … do not vary by more than 10% of said at least one active." However, Ilango e*t al.*, *In-Vitro studies on Buccal strips of Glibenclamide using Chitosan,* 59 Indian J. Pharm. Sci. 232-235 (1997) ("Ilango," EX1005), which has not previously been considered by the Patent Office, expressly discloses uniform cast films with a variance of less than 5% in the amount of the active ingredient in uniformly sized individual unit doses. EX1005 (Ilango) at 234.

Thus, Ilango's films satisfy each of the elements recited in the challenged claims but for a taste-masking agent, such as a flavor, sweetener, flavor enhancer, or coating. Taste-masking strategies, however, were well-known in the art of oral delivery of drugs, as described in Chen, WO2000/42992 (EX1006) discussed below. This Petition shows that a person of ordinary skill in the art would have been motivated to employ a taste-masking strategy as disclosed in Chen with a film containing an active ingredient, as described in Ilango, and would have had a reasonable expectation of success. Other aspects taught in Chen and Ilango establish that the remaining claim limitations of independent and dependent claims were well-known in the prior art. Thus, based on the evidence provided in this Petition, the challenged claims of the '514 patent should be found unpatentable and canceled.

A. Brief Overview of the '514 Patent

The challenged claims are directed to drug delivery film compositions. Independent claim 62 is representative of the challenged claims and is reproduced below:

> 62. A drug delivery composition comprising:
> (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active; wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
> (ii) a particulate active substantially uniformly stationed in the matrix; and
> (iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;
> wherein the particulate active has a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is capable of being dried without loss of substantial uniformity in the stationing of said particulate active therein; and
> wherein the uniformity subsequent to casting and drying of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active.

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