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95/001,753	09/12/2011	7,824,588	117744-00016	6620
23869	7590	04/17/2014	EXAMINER	
Hoffmann & Baron LLP 6900 Jericho Turnpike Syosset, NY 11791			DIAMOND, ALAN D	
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BEFORE PATENT TRIAL AND APPEAL BOARD

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BIODELIVERY SCIENCES INTERNATIONAL, INC.  
Requester

v.

MONOSOL RX, LLC  
Patent Owner and Appellant

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Appeal 2014-000547  
Reexamination Control 95/001,753  
Patent 7,824,588 B2  
Technology Center 3900

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Before CHUNG K. PAK, JEFFREY B. ROBERTSON, and  
RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

#### DECISION ON APPEAL

This is a decision on appeal by the Patent Owner from the Patent Examiner's decision to reject pending claims in an *inter partes* reexamination of U.S. Patent 7,824,588 B2 (herein after the "'588 patent").<sup>1</sup>

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<sup>1</sup> The '588 patent issued November 2, 2010, to Robert K. Yang, et al.

Appeal 2014-000547  
Reexamination Control 95/001,753  
Patent 7,824,588 B2

The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. We AFFIRM.

## I. BACKGROUND

A request for *inter partes* reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.902-1.997 for the '588 patent was filed on September 12, 2011, by a Third-Party Requester, BioDelivery Sciences International, Inc. (hereinafter "Requester"). See Request for *Inter Partes* Reexamination 1 (hereinafter "Request"); Requester's Respondent Brief, dated July 24, 2013 (hereinafter "Res. Br."). The Patent Owner and Appellant is MonoSol Rx, LLC (hereinafter "Patent Owner"). Patent Owner's Appeal Br. 1, dated June 24, 2013 (hereinafter "App. Br.>").

The '588 patent is the subject of a litigation proceeding in the United States District Court for the District of New Jersey styled *MonoSol Rx, LLC v. BioDelivery Sciences Int'l, Inc.*, 10-cv-5695. The litigation is currently stayed pending the outcome of this Reexamination proceeding. See App. Br. 2.

An oral hearing was held March 26, 2014. A transcript of the hearing will be entered into the record in due course.

The '588 patent is directed to a method for forming a rapidly dissolving film containing an active ingredient evenly or uniformly distributed throughout the film. '588 patent, col. 1, ll. 35-42. According to the '588 patent, "uniform distribution is achieved by controlling one or more parameters, and particularly the elimination of air pockets prior to and during film formation and the use of a drying process that reduces

aggregation or conglomeration of the components in the film as it forms into a solid structure.” *Id.* at col. 1, ll. 37-42.

The ’588 patent originally contained claims 1-191. During reexamination, Patent Owner amended claim 1 and added new independent claims 192 and 193. Claims 1-193 are currently rejected by the Examiner.

Although Patent Owner appeals the rejection of all of the claims so rejected, with respect to independent claims 25 and 50 and the claims that depend therefrom, Patent Owner does not address the Examiner's specific findings and conclusions articulated in the rejections or explain why these positions are deficient. PO App. Br. 4. Accordingly, we summarily affirm the Examiner’s rejections of claims 25 and 50 and the claims that depend therefrom.

Consistent with the arguments presented by Patent Owner, we address the rejections of claims 1-24, 75, 78, 81, 84, 87, 90, 93, 96, 99, 102, 105, 106, 111-132, 177, 178, 183, 186, 189, 192, and 193. *Id.*

Claims 1, 192 and 193 are at issue in this appeal and read as follows (with underlining showing additional language over the original patented claim):

1. A method of making a self-supporting therapeutic active-containing film comprising:
  - (a) Mixing at least one edible polymer component, a therapeutic active composition, and at least one polar solvent to form a matrix;
  - (b) Forming a wet film from said matrix, said wet film having a substantially uniform content of therapeutic active composition throughout said wet film;
  - (c) Removing said polar solvent from said matrix with heat and/or radiation energy by exposing said matrix to a

temperature greater than the degradation temperature of said therapeutic active composition to form a self-supporting film;  
wherein the temperature of the matrix is 100° C. or less during said step of removing said polar solvent from said matrix;

wherein the resulting self-supporting film maintains the substantially uniform content of therapeutic active composition per unit of film.

192. A method of making a self-supporting therapeutic active-containing film comprising:

(a) Mixing at least one edible polymer component, a therapeutic active composition and at least one polar solvent to form a matrix;

(b) Forming a wet film from said matrix, said wet film having a substantially uniform content of therapeutic active composition throughout said wet film;

(c) Removing said polar solvent from said matrix with heat and/or radiation energy by heating said matrix to a temperature that is less than the boiling point of said at least one polar solvent so as to form a viscoelastic film;

wherein the resulting viscoelastic film maintains the substantially uniform content of therapeutic active composition per unit of film.

193. A method of making a self-supporting therapeutic active-containing film comprising:

(a) Mixing at least one edible polymer component, a therapeutic active composition, and at least one polar solvent to form a matrix;

(b) Forming a wet film from said matrix, said wet film having a substantially uniform content of therapeutic active composition throughout said wet film;

(c) Using heat and/or radiation energy to remove said polar solvent from said matrix to form a self-supporting therapeutic active-containing film without forming bubbles;

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