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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.
Requester and Cross Appellant

v.

MONOSOL RX, LLC
Patent Owner and Appellant

Appeal 2014-007671
Reexamination Control 95/002,170
Patent 7,897,080 B2
Technology Center 3900

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 7,897,080 B2 (hereinafter the "'080 patent").¹

¹ The '080 patent issued March 1, 2011, to Robert K. Yang, et al.

Appeal 2014-007671
Reexamination Control 95/002,170
Patent 7,897,080 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 '080 patent was filed on September 10, 2012, by a Third-Party Requester, BioDelivery Sciences International, Inc. (hereinafter "Requester"). See Request for *Inter Partes* Reexamination 1 (hereinafter "Request"); Requester's Cross-Appeal Brief, dated March 10, 2014 (hereinafter "Req. App. Br."); Requester's Respondent Brief, dated April 10, 2014 (hereinafter "Req. Res. Br."); Requester's Rebuttal Brief, dated May 27, 2014 (hereinafter "Req. Reb. Br."). The Patent Owner and Appellant is MonoSol Rx, LLC (hereinafter "Patent Owner"). Patent Owner's Appeal Brief 1, dated March 10, 2014 (hereinafter "PO App. Br."); Patent Owner's Respondent Brief, dated April 10, 2014 (hereinafter "PO Res. Br."); Patent Owner's Rebuttal Brief, dated May 27, 2014 (hereinafter "PO Reb. Br.>").

The '080 patent is the subject of a litigation proceeding in the United States District Court for the Eastern District of North Carolina styled *BioDelivery Sciences International, Inc. v. Reckitt Benckiser Pharmaceuticals, Inc. et al.*, 5-14-cv-00529 (NCED). The litigation was filed on September 20, 2014 and was stayed on December 23, 2014.

An oral hearing was held November 5, 2014. A transcript of the hearing will be entered into the record in due course.²

The '080 patent is directed to a method for forming a rapidly dissolving film containing an active ingredient evenly or uniformly distributed throughout the film. '080 patent, col. 1, ll. 35-42. According to the '080 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.*, col. 1, ll. 42-47.

The '080 patent originally contained claims 1-299. During reexamination, Patent Owner cancelled claims 12, 16, 91, 95, 173, 177, 254, 255, 257, 272, 273, 275, 290, 291, and 293 and added claims 300-318. Claims 1-11, 13-15, 17-90, 92-94, 96-172, 174-176, 178-253, 256, 258-271, 274, 276-289, 292 and 294-318 currently are pending and rejected by the Examiner. Patent Owner appeals the rejection of all of the claims. Requester appeals the Examiner's decision not to adopt rejections of all of the claims under 35 U.S.C. § 112, first and second paragraphs, for lack of clarity, lack

² Several new arguments were raised for the first time during the oral hearing. The oral hearing transcript identifies some of these new arguments, and we note others that were not necessarily identified during the hearing. The parties are reminded that such new arguments are not proper and will not be considered. 37 C.F.R. § 41.73(e)(1) ("At the oral hearing, each appellant and respondent may only rely on evidence that has been previously entered and considered by the primary examiner and present argument that has been relied upon in the briefs except as permitted by paragraph (e)(2) of this section."). We will only consider arguments and evidence addressed in the briefs of record in this appeal.

of enablement and/or lack of written descriptive support for several recitations within the claims.

Claims 1, 82, 161, and 315-318 are the independent claims at issue in this appeal. Claims 1 and 82 are representative and read as follows (with underlining showing added language and brackets showing deleted language over the original patented claim):

1. (Twice Amended) A process for manufacturing a resulting film suitable for commercialization and regulatory approval, said regulatory approval including analytical chemical testing which meets the standards of the U.S. Food and Drug Administration relating to variation of an active in individual dosage units, said [making a] film having a substantially uniform distribution of components comprising a substantially uniform distribution of said active in individual dosage units of said resulting film, comprising the steps of:

(a) forming a masterbatch pre-mix comprising a solvent and a polymer selected from the group consisting of water-soluble polymers, water-swallowable polymers and combinations thereof;

(b) adding [an] said active, said active selected from the group consisting of bioactive actives, pharmaceutical actives and combinations thereof, to a pre-determined amount of said masterbatch pre-mix to form a flowable polymer matrix, said matrix having a substantially uniform distribution of said active;

(c) casting said flowable polymer matrix, said flowable polymer matrix having a viscosity from about 400 to about 100,000 cps;

(d) controlling drying through a process comprising conveying said flowable polymer matrix through a drying apparatus and evaporating at least a portion of said solvent from said flowable polymer matrix to form a visco-elastic film, having said active substantially uniformly distributed throughout, within about the first [10]4 minutes [or fewer] by rapidly increasing the viscosity of said flowable polymer matrix

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