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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/002,171	09/10/2012	7666337	117744-00030	1084
23869	7590	03/27/2015	EXAMINER	
Hoffmann & Baron LLP 6900 Jericho Turnpike Syosset, NY 11791			DIAMOND, ALAN D	
			ART UNIT	PAPER NUMBER
			3991	
			MAIL DATE	DELIVERY MODE
			03/27/2015	PAPER

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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 2014-008893
Reexamination Control 95/002,171
Patent 7,666,337 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 7,666,337 B2 (hereinafter the "'337 patent").¹

¹ The '337 patent issued February 23, 2010, to Robert K. Yang, et al.

Appeal 2014-008893
Reexamination Control 95/002,171
Patent 7,666,337 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 April 18, 2014 (hereinafter "Req. App. Br."); Requester's Respondent Brief, dated May 22, 2014 (hereinafter "Req. Res. Br."); Requester's Rebuttal Brief, dated July 1, 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 31, 2014 (hereinafter "PO App. Br."); Patent Owner's Respondent Brief, dated May 19, 2014 (hereinafter "PO Res. Br."); Patent Owner's Rebuttal Brief, dated July 7, 2014 (hereinafter "PO Reb. Br.>").

The '337 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 is currently pending.

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

The '337 patent is directed to a method for forming a rapidly dissolving film containing an active ingredient evenly or uniformly distributed throughout the film. '337 patent, col. 1, ll. 35-40. According to the '337 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. 40-45.

The '337 patent originally contained claims 1-30, of which claims 1-24 were not subject to reexamination. During reexamination, Patent Owner cancelled claim 28 and added claims 31-404. Patent Owner cancelled claims 55-61, 76, and 78-404 in the Appeal Brief (*see* PO App. Br. 3 and 4) and in a separate Amendment filed April 22, 2014. The April 22, 2014 amendment was entered by the Examiner in a communication mailed April 24, 2014 and was noted in the Examiner's Answer. Thus, claims 25-27, 29-54, 62-75, and 77 currently are pending and are rejected by the Examiner.

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.

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

Claim 25 is the sole independent claims at issue in this appeal, is representative, and reads as follows (with underlining showing added language and brackets showing deleted language over the original patented claim):

25. A process for [making a]manufacturing a resulting pharmaceutical film suitable for commercialization and regulatory approval said film having a substantially uniform distribution of components comprising a pharmaceutical active, comprising the steps of:

(a) forming a flowable polymer matrix comprising a water-soluble polymer, a solvent and a[n] pharmaceutical active selected from the group consisting of [a list of pharmaceutical drug categories³] and combinations thereof, said matrix having a uniform distribution of said pharmaceutical active;

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

(c) conveying said polymer matrix through a drying apparatus and evaporating at least a portion of said solvent [from said flowable polymer matrix] to rapidly form a visco-elastic film having said pharmaceutical active uniformly distributed throughout by rapidly increasing the viscosity of said polymer matrix upon initiation of drying within about the first [10]4 minutes [or fewer]to maintain said uniform

³ In the interest of brevity, we do not repeat the entire list of over 100 recited pharmaceutical active categories, which are not particularly relevant to the issues on appeal. *See* PO App. Br. CA-1 to CA-2, Claim App'x; Req. App. Br. CA-1 to CA-2, Claim App'x.

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