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Paper No. 21
Entered: August 29, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Petitioner,

v.

RB PHARMACEUTICALS LIMITED,
Patent Owner.

Case IPR2014-00325
Patent 8,475,832

Before TONI R. SCHEINER, JACQUELINE WRIGHT BONILLA, and ZHENYU YANG, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
37 C.F.R. § 42.5

1. Introduction

On August 26, 2014, an initial conference call was conducted between respective counsel for the parties and Judges Scheiner, Bonilla, and Yang. BioDelivery Sciences International, Inc. ("Petitioner") was represented by counsel, Danielle Herritt. RB Pharmaceuticals Limited ("Patent Owner") was represented by counsel, James Bollinger and Daniel Ladow. The purpose of the call was to determine if the parties have any issues concerning the Scheduling Order (Paper 18) and to discuss any motions contemplated by the parties.

Prior to the call, both parties filed a list of proposed motions. Papers 19, 20. Both lists indicated that the parties may file a motion to exclude and a motion for observation on cross-examination. *Id*. Consistent with Patent Owner's List of Proposed Motions (Paper 20), Patent Owner confirmed during the conference call that it would not file a motion to amend.

In its list, Petitioner indicated that it may file a motion for additional discovery regarding "Facts Relevant to Determination" of whether MonoSol Rx, LLC ("MonoSol") is a real party-in-interest in relation to Patent Owner, and a "Motion for Determination" that MonoSol is a real party-in-interest. Paper 19. Petitioner also indicated that it may file a motion for additional discovery regarding secondary considerations, a motion to request oral argument, and a motion for supplemental information and evidence. *Id*.

2. Scheduling Order

The parties stated during the call that they may wish to modify one or more of DUE DATES 1-5 in the Scheduling Order (Paper 18). We reminded the parties that, without obtaining prior authorization from the Board, they may stipulate to different dates for DUE DATES 1-5 by filing an appropriate notice with the Board.

3. Motions to Exclude, Observations on Cross-Examination, and Requests for Oral Hearing

Both parties are authorized to file a motion to exclude evidence, a motion for observation on cross-examination, as well as a request for oral argument, as indicated in the Scheduling Order (Paper 18).

4. Discovery

The parties are reminded of the discovery provisions of 37 C.F.R. §§ 42.51-52 and Office Patent Trial Practice Guide. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761-62 (Aug. 14, 2012). Discovery requests and objections are not to be filed with the Board without prior authorization. If the parties are unable to resolve discovery issues between them, the parties may request a conference with the Board. A motion to exclude, which does not require Board authorization, must be filed to preserve any objection. *See* 37 C.F.R. § 37.64; Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,767.

Each party may depose experts and affiants supporting the opposing party. The parties are reminded of the provisions for taking testimony found at 37 C.F.R. § 42.53 and the Office Patent Trial Practice Guide at 77 Fed. Reg. at 48,772, App. D. The parties shall file entire transcripts of any depositions, rather than portions or sections, when relying on such testimony in a paper.

In its motions list, Petitioner indicated that it may file two different motions for additional discovery. Paper 19 at 2-3. During the conference call, counsel for Petitioner requested that the Board authorize, at this time, the filing of Petitioner's proposed motion for additional discovery regarding "Facts Relevant to Determination" of whether MonoSol is a real party-in-interest, particularly as it relates to three agreement documents outlined in Petitioner's motion list. Paper 19 at 2. We asked Petitioner to explain why obtaining such information would be

useful, i.e., how it would uncover information of substantive value to a contention of Petitioner in this proceeding. *See Garmin Int'l Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 at 6-7.

Petitioner responded that a different pending patent application, allegedly assigned to Monosol, addresses claims that Petitioner contends are not patentably distinct from claims challenged in this proceeding. Petitioner referred to the estoppel provision of 37 C.F.R. § 42.73(d)(3)(i), which states that a "patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent: (i) A claim that is not patentably distinct from a finally refused or canceled claim." Petitioner also cited 37 C.F.R. § 42.8(b)(1), which states that Patent Owner's mandatory notice must "[i]dentify each real party-in-interest for the party."

As an initial matter, we note Patent Owner's Second Amended Mandatory (Paper 16) states that MonoSol was the original assignee of the '832 patent and that "named inventors were, and in some cases remain, MonoSol employees," but that MonoSol now has exclusive manufacturing rights under the patent and "therefore is an implied, exclusive licensee." *Id*. at 2. In that Notice, Patent Owner also states "[t]o the extent these facts are sufficient to render MonoSol a real party-in-interest, Patent Owner also identifies MonoSol under 37 CFR § 42.8(b)(1)." *Id*. We are satisfied that Patent Owner adequately meets the notice requirement of § 42.8(b)(1).

In relation to Petitioner's assertions regarding a pending patent application assigned to Monosol, we note that the estoppel provision of § 42.73(d)(3)(ii) will apply to Patent Owner only in the event that we enter an adverse judgment against Patent Owner, i.e., an event that has yet to occur, if it ever will. 37 C.F.R.

§ 42.73(b), (d)(3). Moreover, Petitioner's assertions assume that Monosol, as a "patent applicant or patent owner" under § 42.73(d)(3), in the future, in a different patent application, will pursue or obtain claims that are not patentably distinct from claims disclaimed or cancelled in this proceeding. Such assertions are entirely speculative, not only in view of where we stand in this proceeding, but also in view of the fact that any pending application is still pending, i.e., an applicant can still amend claims.

Moreover, Petitioner stated in its motions list, and during the call, that it requests additional discovery in relation to whether Monosol is a real party-in-interest (Paper 19 at 2), but then indicated on the call that it actually seeks information as to whether Monosol is a "patent applicant or patent owner" for the purposes of § 42.73(d)(3). A motion for additional discovery regarding a real party-in-interest is not the proper avenue to seek information as to whether Monosol, as a "patent applicant or patent owner," is estopped from taking action in an entirely different matter. Even assuming Patent Owner is subject to an adverse judgment at a later date in this case, the time and place to address whether an applicant or patent owner is subject to § 42.73(d)(3) is after an adverse judgment is entered, and in a proceeding relevant to the pending application or patent potentially impacted by the estoppel, i.e., not in this proceeding relating to claims of the '832 patent.

Thus, we do not authorize Petitioner to file its proposed motion for additional discovery regarding "Facts Relevant to Determination" of whether MonoSol is a real party-in-interest, or its proposed "Motion for Determination" that MonoSol is a real party-in-interest. Paper 19 at 2.

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