

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.  
Petitioner

v.

QUALICAPS CO. LTD.  
Patent Owner

Case IPR2017-00203  
Patent No. 6,649,180

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**PETITIONER MYLAN PHARMACEUTICALS INC.'S MOTION FOR  
ADDITIONAL DISCOVERY UNDER 37 C.F.R. § 42.51(b)(2)**

Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) submits this Motion for Additional Discovery under 37 C.F.R. 42.51(b)(2), requesting the deposition of Mr. Masaru Tanjoh, whose Declaration Patent Owner relied on in its Response. Petitioner also seeks production of all documents in Patent Owner and/or Mr. Tanjoh’s possession, custody, or control, supporting or refuting Patent Owner’s assertion that the invention of the U.S. Patent 6,649,180 (“the ‘180 patent’”) yielded unexpected results. Because Mr. Tanjoh has been deposed, and Patent Owner has offered some, but not all of his deposition for use here in lieu of the Board ordering his deposition, Petitioner would alternatively request the Board simply order Patent Owner produce the entirety of the deposition with exhibits including any portion or document marked confidential. An extremely unburdensome request.

## **I. BACKGROUND**

In Patent Owner’s Response (Paper 26), Patent Owner argues that Petitioner has not rebutted Patent Owner’s evidence of secondary considerations of non-obviousness—namely, unexpected results. (*Id.* at pp. 28-37.) Patent Owner alleges the challenged claims of the ‘180 patent “reflect the inventors’ surprising discovery that controlling the degree of HPO/MO substitution in HPMC more stringently than that required by the pharmacopeia results in capsules whose appearance does not deteriorate after prolonged storage.” (Paper 26 at 28-29 (citing Declaration of Jason T. McConville, Ex. 2028, at ¶ 94; Ex. 1001 at 6:15-

28.) In support of this argument, Patent Owner and its expert, Dr. McConville, point to a declaration submitted by Mr. Tanjoh during prosecution of the '180 patent. (*See* Paper 26 at pp. 31-37; Ex. 2028 at ¶ 99-100 (citing Tanjoh Declaration (Ex. 1010 at 105-108)).) In this declaration, Mr. Tanjoh asserts, in relevant part, that “controlling the total content of methoxyl and hydroxypropoxyl groups in the hydroxypropoxyl methyl cellulose to 23-37.6 is effective for preventing the gelling aid from precipitating on the capsule surface.” Ex. 1010 at 107. Dr. McConville asserts that the importance of the claimed ranges is confirmed by Mr. Tanjoh’s prosecution history declaration. (Ex. 2028 at ¶ 99-100 (citing '180 patent at 5:26 to 6:20; Tanjoh Declaration at 106–7).) He concludes that “the POSA would have found this result surprising an unexpected . . . .” (*Id.*)

Given Patent Owner and Dr. McConville’s reliance on Mr. Tanjoh’s declaration to support their critical secondary considerations case, Petitioner requested Patent Owner present Mr. Tanjoh for cross-examination. (*See* July 25, 2017 Email from Jonathan Olinger, attached hereto as Ex. 1021). Patent Owner has refused to produce Mr. Tanjoh for deposition and has not provided the basis for its refusal. (*See* August 4, 2017 Email from Jessica Parezo, attached hereto as Ex. 1022.) Patent Owner, however, has offered to consent to using the Mr. Tanjoh’s March 2017 deposition testimony from the related litigation (Civil Action Nos. 2:15-cv-1471; 2:15-cv-1740 (E.D. Tex.)) in this proceeding, *but* has refused to

permit the filing of those deposition exhibits marked “Restricted-Attorney’s Eyes Only.” (See August 10, 2017 Email from Jessica Parezo, attached hereto as Ex. 1023.) Petitioner requested a conference with the Board on August 3, 2017, and received authority to file the instant motion that same day.

## II. LEGAL STANDARD

37 C.F.R. § 42.51 provides that “[w]here the parties fail to agree [to additional discovery], a party may move for additional discovery. The moving party must show that such additional discovery is in the interests of justice.” The Board has provided the following five factors for such analysis: (Factor 1) whether there is more than a possibility and mere allegation that something useful will be uncovered; (Factor 2) whether the requested discovery seeks litigation positions and underlying basis; (Factor 3); whether the requesting party has the ability to generate equivalent information by other means; (Factor 4) whether the requested discovery is easily understandable; (Factor 5) and, whether the requested discovery is not overly burdensome. See *Garmin Int’l Inc. et al. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, Paper 26 (PTAB March 5, 2013).

Petitioner submits that all five *Garmin* factors support granting the relief.

## III. ARGUMENT

### A. **There is more than a Mere Possibility that Something Useful will be Uncovered from Mr. Tanjoh’s Deposition and Related Documents Will Result in Useful Information**

As discussed, Patent Owner and Dr. McConville rely on Mr. Tanjoh's declaration as evidence of the surprising and "unexpected results" of the claimed invention in an effort to outweigh the *prima facie* case of obviousness from overlapping ranges. (See Paper 26 at pp. 31-37; Ex. 2028 at ¶¶ 99-100 (citing Tanjoh Declaration (Ex. 1010 at 105-108)).) Because the patent claims an upper bound of 37.6%, which is within the prior art's range of substitution, the surprising or unexpected result of the narrowed range must be supported by evidence of the criticality of the bound and not simply that the bound represents a matter of mere degree. Thus, the inventor's self-serving testimony that the claim possesses surprising or unexpected import would properly be tested with cross-examination testimony concerning if and to what extent testing existed to show the critical nature of the range boundaries, including evidence that no such evidence exists. This is the type of examination needed to weigh, much less credit, *ex parte*, self-serving assertions of "objective" indicia of non-obviousness.

Further, secondary considerations were at issue in the district court litigation. There, pursuant to Federal Rule of Civil Procedure 30(b)(6), Petitioner served a notice on Patent Owner for a witness to testify regarding "[s]econdary considerations or objective indicia of non-obviousness, if any, relating to the patent-in-suit, including, but not limited to . . . unexpected results." (See Amended 30(b)(6) Notice to Qualicaps, attached as Ex. 1024). Patent Owner designated Mr.

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