

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 RESPONSE TO  
PATENT OWNER'S IDENTIFICATION OF NEW ARGUMENTS**

## **I. Patent Owner's Request Fundamentally Ignores the Burden of Producing Evidence Associated with Alleging Unexpected Results.**

While the ultimate burden of persuasion on establishing invalidity lies with Petitioner, the initial burden of production on secondary considerations, and with that nexus, lies with Patent Owner. *J Squared, Inc. v. Sauder Mfg. Co.*, 2016 WL 3541199, \*16 (PTAB Jun. 27, 2016) (“The burden of showing that there is a nexus lies with the patent owner.”). Producing evidence of nexus *in this proceeding* is a prerequisite for Patent Owner to argue any secondary considerations outweighs the *prima facie* case, where the burden of persuasion lies with Petitioner. *Petroleum Geo-Services Inc. v. Westerngenco LLC*, 2015 WL 1276706, \*16 (PTAB Mar. 17, 2015) (“Patent Owner’s citations . . . and respective arguments for legal insufficiency of the Petition are premature, as the *evidence* of secondary indicia of non-obviousness *must be first developed in this proceeding by Patent Owner.*”) (emphasis added). The Federal Circuit’s *en banc* decision in *Aqua Products* confirms the shifting burden within obviousness is proper. *Aqua Prods., Inc. v. Matal*, 2015-1177 Slip. Op., p. 22-23 (Fed. Cir. Oct. 4, 2017). Only once Patent Owner’ evidence is presented can the shifting burdens in obviousness be followed. *In re Cyclobenzaprine Patent Lit.*, 676 F.3d 1063, 1078-80 (Fed. Cir. 2012).

Each of Patent Owner’s positions would require Petitioner to assert responsive argument and evidence concerning Patent Owner’s nexus case before Patent Owner ever makes its case. In these proceedings, Patent Owner claims nexus ought be

presumed. Paper 26 at 37. In organic prosecution, Patent Owner made no attempt at showing nexus, presumed or otherwise, despite the MPEP requiring it to do so. *See* MPEP Sec. 2145. All the Tanjoh declaration (the alleged showing of unexpected results) does is reproduce the experiment of Table 1 of the '180 patent. Ex. 1010, at 100-108. Petitioner demonstrated producing clear, precipitate free capsules was not an unexpected property of using HPMC. Paper 1, at 51-55. Patent Owner's Response, and subsequent deposition of its expert, confirmed Patent Owner possesses no evidence of solving a problem by difference in kind and not degree.

## **II. The Reply Was Responsive to Patent Owner's Nexus Presumption and Lack of Evidence that the Inventors Solved a Problem.**

Petitioner demonstrated that the art was motivated to make clear capsules and obtaining them was expected. Paper 1, at 55 (“a capsule with an HPMC base and the claimed percentages of [HPO] and [MO] groups result in the clarity and stability that is a purported object of the invention ...”). In its response, Patent Owner raised an argument that the inventors “discovered a surprising problem and invented an unexpected solution.” Paper 26, at 31. But in his deposition, Patent Owner's expert stated that whether the cloud spotting (what Patent Owner argues was the problem) and the precipitates of Table 1 and the Tanjoh Declaration (the data allegedly supporting the notion the problem was solved) were the same thing *was an assumption, but not his assumption*. Paper 38, at 19. Thus, the Reply was the first time Petitioner could rebut Patent Owner's argument by pointing to the *absence of*

*evidence* as to the nexus claim. Thus, the Reply was foundationally proper and directly responsive to Patent Owner’s arguments on its burden of showing nexus.

Patent Owner next argues that Petitioner admitted cloud spotting and potassium chloride (gelling aid) precipitation were the same thing. But as Patent Owner’s *doctored* “quote” on page 1 shows, Petitioner showed capsule shells free of *precipitation* were known and expected but Petitioner certainly never postulated the precipitates were the “gelling aid.” Only after Patent Owner argued its evidence supports nexus, and that evidence explored, could Petitioner satisfy its burden.

### **III. Patent Owner Had to Present Evidence of Criticality before Petitioner Could Rebut It.**

For its second and third complaints, Patent Owner again ignores *its* burden to produce *evidence* showing a problem was solved and that it was a difference of kind and not mere degree. Petitioner explained in Paper 1 at pages 52-53 the prior art taught clear, spot free capsules. It was first disclosed in Paper 26 at page 36-37 that Patent Owner contended 37.6% (the upper end of the claimed range) creates “a property lacking from [the prior art]....” But Table 1 confirms 37.6% still has precipitation, though measured subjectively. Thus, the Reply was the first time Petitioner could address Patent Owner’s *lack of evidence* that 37.6% demonstrated a “solution” or that whatever resulted from choosing 37.6% was anything more than an subjective improvement on appearance (Paper 1 at 52-53 showed clear capsules are a motivation) and thus merely a difference in degree. Paper 38, p. 20-21.

Dated: October 13, 2017

Respectfully submitted,

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