

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

QUALICAPS CO., LTD,
Patent Owner

Case IPR2017-00203
Patent 6,649,180

**PATENT OWNER'S IDENTIFICATION OF NEW
ARGUMENTS IN PETITIONER'S REPLY**

As authorized by the Board (Ex. 2075), Patent Owner identifies Section III(B) of the Reply (p. 17, l. 1–p. 21, l. 14) as exceeding the scope permitted under 37 C.F.R. § 42.23(b), and provides a brief explanation for each contention.

I. New Argument: Whether the '180 patent record shows that the cloud spotting defects in capsules were composed of gelling aid precipitates.

Petitioner argues that the inventors improperly inferred gelling aid precipitation to be the problem solved by the claimed invention, when the real problem was instead residual salts in the HPMC or water. Reply, p. 18, l. 3–p. 19, l. 13 (p. 18, l. 6: “Precipitation of residual salts may cause spotting”; p. 18, ll. 12-14 (arguing that the inventors admit inferring that gelling aid precipitation was the problem); p. 19, ll. 4-9 (arguing that an unsupported inference is “insufficient” and that “any reduction in spotting is due to a prior art feature – commercially available HPMC or water with low residual salt content.”)).

This argument is new for at least the reason that it contradicts the Petition, where Petitioner argued that the prior art inherently prevented the cloud spotting problem. Petition, Section C., p. 51, l. 11–p. 55, l. 6; Petition, p. 52, ll. 5-8 (“Accordingly, the properties of the capsule shell that prevent [gelling aid] precipitation are . . . inherent and foreseeable by one of ordinary skill in the art in creating and selecting a desirable medicinal capsule shell.”). Petitioner’s new causation argument was raised for the first time in the Reply, and is an improper new issue not argued or explained in the Petition. *See Arista Networks, Inc. v. Cisco Sys.,*

Inc., IPR2016-00308, Paper 42 at 13–14 (May 25, 2017) (new theory in reply was a non-responsive attempt to fill petition gaps identified in patent owner response).

Not only is this argument presented for the first time in the Reply, it is not responsive to the Patent Owner Response, being premised on evidence available at the time the Petition was filed: the '180 patent and Tanjoh prosecution declaration. Reply, p. 18, ll. 3-5 (discussing data in the '180 patent and Tanjoh prosecution declaration); *id.* at p. 20, l. 17–p. 21, l. 2 (same). The Reply cites nothing from the Tanjoh deposition exhibits produced by Patent Owner in support of this argument (production only “confirms” what inventor reported in the '180 patent). Reply, p. 18, l. 15–p. 19, l. 3 (citing Ex. 1029 (Ex. 2064–2072)).

II. New Argument: Whether, even if the cloud spotting defects were gelling aid precipitates, the claimed invention prevented these defects.

Petitioner argues for the first time in the Reply that the claimed invention lacks nexus with the unexpected solution. Reply, p. 15, l. 11–p. 18, l. 2; p. 19, l. 14–p. 21, l. 14 (p. 17, ll. 13-16: “Patent Owner possesses no evidence linking the optimization of a single variable (substitution ranges) to the alleged benefit, which merely reduces, but does not eliminate, the alleged cloud spotting”; p. 19, ll. 18-20: “[T]he alleged unexpected benefit was to remove spots, but that is not what the claim encompasses.”; p. 20, l. 17–p. 21, l. 5: “[A]ll that [the Table 1] data shows is between 38.1% and 36.4/36.7 there is some level of aesthetically acceptable spotting.”).

Like New Argument I, this argument also contradicts the Petition, where Petitioner instead assumed that the claimed invention, like the prior art, led to the solution. Petition, Section C., p. 51, l. 11–p. 55, l. 6; Petition, pp. 55, ll. 3–6 (“[A POSA] at the time of the invention would have recognized that a capsule with an HPMC base and the claimed percentages of hydroxypropyl and methoxyl groups result in the clarity and stability that is a purported object of the invention of the ’180 Patent.”).

This argument is not responsive to the Patent Owner Response. Petitioner had all the data used in the Reply at the time the Petition was filed, and knew that unexpected results had been at issue during prosecution. Patent Owner Response (Paper 26), pp. 37–40. *See Arista*, IPR2016-00308, Paper 42 at 13–14.

III. New Argument: Whether an “acceptable amount” of spotting can be determined by a “subjective” assessment.

Petitioner newly argues that Patent Owner’s evidence of unexpected results is entitled to little or no weight because it is based on a “subjective distinction between acceptable spotting and unacceptable spotting.” Reply, p. 19, l. 14–p. 21, l. 14 (quotation at p. 21, ll. 11-12). This argument is new as it contradicts the position Petitioner took at pages 54-55 of the Petition, where Petitioner relied on subjective assessments of film quality (such as “Poor – very hazy, quite rough”) to support its obviousness case.

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Respectfully submitted,

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