Paper No. ___
Filed: October 22, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioners,

v.

BAYER INTELLECTUAL PROPERTY GMBH,
Patent Owner.

IPR2018-01143
Patent No. 9,539,218

PETITIONER'S PRE-INSTITUTION REPLY

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Bayer's Preliminary Response (Paper 6, "POPR") asserts a narrow and limiting claim construction that is undermined by Bayer's subsequent conduct. Further, the evidence and arguments against the '218 claims are properly set out in the Petition and Bayer's contrary complaints in the POPR should be disregarded.

I. BAYER'S CLAIM CONSTRUCTION IS ERRONEOUSLY NARROW

Bayer asks the Board to ignore evidence submitted with the Petition about the meaning of the term "rapid-release tablet" because the specification allegedly "explains and defines" the claim term rapid-release tablet "without ambiguity or incompleteness," such that "there is no need to search further for the meaning of the term." *Id.* POPR, 5, 14-15. But Bayer's recent actions in the district court show its proposed definition is neither unambiguous nor complete.

On September 18, 2018, after the district court adopted Bayer's proposed construction verbatim, Bayer asked the district court to further construe Bayer's construction of rapid-release tablet. EX1066. In response, Mylan asked the court to hold Bayer to its litigation argument that "there is no need for the Court to search further for the meaning of the phrase" other than adopting the "express definition" in the specification. EX1067. Bayer's reply asked the court to consider extrinsic evidence. EX1068. On September 28, 2018, the court expressly rejected Bayer's request to "further construe" the "lexicographic definition." EX1069. Bayer's request for further claim construction in district court contradicts the argument that

its "definition" construction in the POPR is unambiguous and complete, and confirms that evidence Mylan submitted with its Petition regarding the meaning of "rapid-release tablet" should be given substantial weight.

Bayer's district court briefing also resolves whether Bayer concedes Forsman satisfies the rapid-release limitation of claim 1. In its POPR, Bayer argued that Forsman's "disclosure of a rapid-release tablet according to the Board's prior construction" is merely something that "the Petition alleges." POPR at 2-3. In its district court briefing, Bayer discloses its interpretation of its rapid-release construction. EX1066; EX1068. Bayer can no longer equivocate its view on how its interpretation applies: Forsman satisfies the rapid-release element.

Bayer argues in its POPR (6-9) that the Board should adopt claim constructions from other proceedings. But the district court was not applying the broadest reasonable construction. And the ***fact finding*** in the *ex parte* appeal (FF4) was based on a limited record. The '218 patent specification does not say that rapid-release tablets are ***limited to only*** those tablets with a certain Q value. The POPR (13) argues the specification expressly identifies preferred embodiments as such immediately before and after the Q value description. But defined terms are expressly identified by quote marks and are each called a "term;" "rapid-release tablet" is not. If Bayer desires to limit the claims as it now proposes, Congress has provided a mechanism for this: a post-institution motion to amend.

Bayer concedes that the EPO Proceedings involved "the counterpart of the '218 patent," but argues that its embrace of a broader construction before the EPO is irrelevant. POPR, 14-16. But the EPO's adoption of that construction confirms Mylan's construction here is reasonable. Pet., 25-26.

II. BAYER'S § 325(D) ARGUMENTS ARE UNAVAILING

Bayer argues that Ground 1 should be denied if the Board adopts Bayer's narrowing claim construction. For the reasons discussed above in Section I, the Board should adopt Mylan's claim construction and institute Ground 1.

Regarding Ground 2, Bayer argues (POPR at 3, 24) that Forsman is cumulative to prior art considered during prosecution because the specification generically references a publication for measuring Q values. But disclosing a test is not the same as disclosing a tablet with the requisite Q value and teaching its use for thromboembolic disorders. Pet., 3, 10-11, 17-18, 46-48 (discussing EX1007).

Bayer concedes (POPR, 23) that, following its *ex parte* appeal, "the Examiner did not fill the evidentiary gap identified by the Board." That gap is precisely the one filled by the new evidence and argument submitted with Mylan's Petition. Bayer errs in describing that gap and in arguing that the Petition fails to address it with new evidence. The gap was not (*contra* POPR at 3, 23-24) whether "the pharmacokinetics of rivaroxaban" made it amenable to once-daily dosing in rapid-release dosage form. Indeed, the *ex parte* appeal found this would have been

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