UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.

Petitioner,

v.

BAYER INTELLECTUAL PROPERTY, GMBH,

Patent Owner.

Case No. IPR2018-01143
Patent No. 9,539,218

PATENT OWNER'S AUTHORIZED SUR-REPLY IN SUPPORT OF ITS PRELIMINARY RESPONSE

[PUBLICLY FILED VERSION]

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Nothing in Petitioner Mylan's Reply (Paper 8) warrants institution.

I. MYLAN'S CLAIM CONSTRUCTION IS UNSUPPORTED

Contrary to Mylan's assertion, the proceedings before the District Court do nothing to support the Petition. The District Court construed "rapid-release tablet" as the Board did, *i.e.*, a tablet "which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." Patent Owner Prelim. Resp. (Paper 6) ("POPR") at 8-9. Because that construction is based on the express lexicography in the '218 patent, it applies irrespective of which claim construction standard is used. *Id.* at 8 n.1.

As reflected in exhibits filed with the Reply, after *Markman* in the District Court, Mylan asserted—for the first time—[redacted]

[redacted]

Bayer therefore informed the District Court that the parties disputed what the District Court's construction meant. Ex. 1066 at 2. Any alleged ambiguity in the District Court's construction was a result of Mylan's belated and inconsistent positions, not any action by Bayer. *Cf.* Reply at 1-2.

In response, the District Court ultimately indicated that the parties' disagreement was not a *Markman* question, but rather appeared to be a "fact decision [for] trial" based on evidence as to what, "as a matter of fact, meets the lexicographic definition." Ex. 1069 at 1; *see also* Ex. 1067 at 3.

In short, nothing from the District Court supports Mylan's claim construction arguments in this proceeding. Indeed, Mylan's proposed interpretation of "rapid-release tablet" in the District Court is [redacted] than both the construction it proposes for Ground 1, and the construction it employs for Ground 2 as applied in the Petition. *See* Pet. at 47. Worse still, [redacted]

II. MYLAN'S § 325(d) ARGUMENTS DO NOT SAVE THE PETITION

The Reply's arguments under § 325(d) are misplaced. The issue on remand

from the Board was not the abstract question of "whether the prior art rendered obvious the use of a tablet having a Q value (30 minutes) of 75% in place of a rapid-release liquid that achieved maximum plasma concentrations within 30 minutes." Reply at 4. Rather, in the words of the Examiner, it was whether prior art rendered obvious "a method of treating the claimed thromboembolic disorders comprising ***administering rivaroxaban***" when "a rapid-release tablet is utilized." Ex. 1004 at 0055 (emphasis added).[1] However, Mylan's Reply (at 3) concedes that Forsman (Ex. 1007), at best, merely "disclos[es] a tablet with the requisite Q value and teaching its use for thromboembolic disorders"—*i.e.*, totally divorced from rivaroxaban. That rapid release tablets were known in other contexts does not explain why such a tablet should be used with rivaroxaban.

Moreover, while Bayer disagrees that the Petition provides "new art and evidence" that fills the "gap" identified by the Board, Reply at 3-4, Mylan's reliance on that allegedly "new art and evidence"—in particular, the declarations of Drs. Benet and Doherty and the Forsman reference—warrants denial given the

[1] Bayer did not "concede[] Forsman satisfies the rapid-release limitation of claim 1" in the District Court. *Cf.* Reply at 2. Bayer merely explained that the Petition's reading of Forsman supports Bayer's view as to what qualifies as "a Q value (30 minutes) of 75%," [redacted] Ex. 1066.

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