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September 18, 2018

The Honorable Richard G. Andrews
United States District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

HIGHLY CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

FILED UNDER SEAL

Re: *Bayer Intellectual Property GmbH v. Taro Pharmaceutical Industries, Ltd.*
C.A. No. 17-462 (RGA)

Dear Judge Andrews:

Plaintiffs Bayer Intellectual Property GmbH, Bayer AG, and Janssen Pharmaceuticals, Inc., (collectively, "Plaintiffs") write to bring an additional claim construction dispute to the Court's attention, and to seek the Court's guidance on how to proceed. This dispute arises from [redacted][1]

On July 3, 2018, this Court issued a *Markman* Order construing the term "rapid-release tablet" in U.S. Patent Number 9,539,218 ("the '218 patent"). *See* D.I. 91. The Court adopted Plaintiffs' proposed construction, which was based on the express definition of the phrase provided in the '218 patent's specification: "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." *Id.* As described in further detail below, however, Plaintiffs and Mylan now dispute the meaning of the Court's construction.

[redacted] a petition for

[1] Plaintiffs seek to file this letter under seal because Plaintiffs do not have Mylan's permission to share information contained in this letter with the other defendants. *See* D.I. 27 at ¶ 7.2(a) (protective order).

[2] [redacted]

inter partes review of the '218 patent asserting that a tablet that releases more than 75% of its active ingredient in 30 minutes satisfies the claim limitation of "a tablet which, according to the USP release method using apparatus 2 (paddle), has a Q value (30 minutes) of 75%." *See* Exh. A (Mylan's IPR Petition) at 47-48 ("Forsman Example 1a released 94% of anticoagulant at pH 1 and at pH 6.8. As Dr. Benet [Mylan's expert] explains, such a tablet necessarily released 75% within 30 minutes as well. Forsman thus demonstrated that its Example 1A rapid-release tablet had a Q value (30 minutes) of 75% according to the USP release method using apparatus 2 (paddle) because it resulted in at least 75% dissolution within 30 minutes." (citations omitted)).

[redacted]

Mylan did not suggest [redacted] during the original claim construction proceedings, and Plaintiffs were unaware of it until well after the Court's *Markman* Order had issued. Indeed, Mylan did not make its position known until after it had served its First Supplemental Objections and Responses to Plaintiffs' Interrogatories on August 13, 2018. Plaintiffs then sought further clarity in a meet and confer call. Had Mylan timely raised this issue, the parties could have addressed it during the claim construction process.

Plaintiffs are prepared to brief this issue for the Court on an accelerated briefing schedule with short submissions by each side. Proceeding in this way would simplify expert discovery and the presentation of evidence at trial, including potentially eliminating the presentation of a doctrine of equivalents case in the alternative. Plaintiffs therefore proposed that the parties jointly seek supplemental claim construction; Mylan, however, rejected Plaintiffs proposal. Alternatively, the issue that Mylan has raised is straightforward and could also be addressed at trial rather than now, if that is the Court's preference.

Plaintiffs are available to discuss this issue further at the Court's convenience.

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

JBB/bac
Enclosure

cc: Clerk of the Court (via hand delivery; w/enclosure)
Counsel of Record Mylan Pharmaceuticals Inc. (via electronic mail; w/enclosure)

Exhibit A
Excerpt of Petition in IPR2018-01143

Filed on behalf of: Mylan Pharmaceuticals Inc.
By: Steven W. Parmelee
Michael T. Rosato
Jad A. Mills
Wilson Sonsini Goodrich & Rosati

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

PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT NO. 9,539,218

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