UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case No. IPR2018-01676[1]
Patent No. 8,603,044

MYLAN REPLY TO PATENT OWNER PRELIMINARY RESPONSE

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[1] Mylan filed essentially the same reply in IPR2018-01675, -01676, -01678 and -01680. Underlining indicates case-specific differences.

The Board authorized this Reply (Paper 14), allowing Mylan to respond to Sanofi's argument in its Patent Owner Preliminary Response ("POPR") that the Board should exercise discretion under §314(a)[2] and deny the Petition on the basis of co-pending district court litigation. Sanofi's arguments are legally and factually incorrect, and improperly invite shenanigans.

1. Failure of proof

Sanofi asserts without evidence[3] that Mylan's district-court invalidity contentions include the "exact same" art as the Petition, i.e., obviousness over Steenfeldt-Jensen and over the combination of Møller and Steenfeldt-Jensen. POPR, 7 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8, 19 (2018)); *see also* POPR, 11. Sanofi alleges that it faces the "same arguments" as in district court (*id.*, 2) based on the same art. *Id.*, 11 (citing EX2008, 202; EX2009, 268-269; EX2010). Actually, Mylan identified, *inter alia*, potential combinations of Steenfeldt-Jensen or Møller with *thirty-three* additional references. EX2009, 269; *see also Intel Corp. v. Qualcomm, Inc.*, IPR2018-01152,

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[2] Sanofi also cites §324(a) (POPR, 4), which is inapplicable to IPRs.

[3] New evidence with any sur-reply would be inappropriate. Sanofi had the opportunity to support its arguments in its POPR, but chose not to do so.

Paper 9, 14-19 (2019) (noting differences between IPR and district court proceedings). Similarly, Mylan's amended invalidity contentions are a claim chart listing the teachings of numerous references, with no additional argument (EX2010), while Sanofi's evidence of *its* allegedly detailed validity positions is merely an email demonstrating service (EX2011).[4] Thus, Sanofi's evidence does not support its allegation that it is facing the same arguments here and in district court. The Board should decline to exercise its discretion under §314(a) on this basis alone.

2. Multiple petitions

Sanofi's focus on the number of petitions filed, rather than the number of patents it asserted in district court, distorts the actual reason for the multiple filings. POPR, 11 n.4, 17. The ten IPR petitions address *five* device patents that Sanofi chose to assert against Mylan (in addition to two formulation patents). Mylan

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[4] Sanofi designated its contentions as confidential, leaving Sanofi in control of whether the Board could see them or not. In any case, Mylan denies Sanofi's assertion that its validity contentions were sufficiently detailed to offer "two bites at the apple." POPR, 13.

simultaneously filed two petitions for the '044 patent due to the word limits (37 CFR §42.24(a)(1)), which the Office expressly allows. 77 Fed. Reg. 48612, 48635 (2012) (Response to comment 91); *Intel*, IPR2018-01152, Paper 9, 15-16. Sanofi's suit created a time bar forcing Mylan to file petitions against all asserted patents within 1 year or forgo its remedies under the AIA.[5] 35 U.S.C. 315(b); *see also Click-to-Call Tech., LP, v. Ingenio, Inc.*, 899 F.3d 1321 (2018). Paradoxically, denying institution for timely filing multiple petitions within the AIA timeframe would penalize Mylan for Sanofi's litigation decision to assert multiple patents against Mylan in district court.

3. Litigation timeline

Sanofi's district-court timeline is speculative. Sanofi asserts that the litigation "should" (POPR, 8) "likely" (*id*., 12) be finished before the final written decision issues, since the parties requested a trial date in October 2019 and the 30-month stay of regulatory approval of Mylan's application expires March 18, 2020. According to Sanofi, the final written decision "on the same prior art and arguments would not issue until April 2020, six months after the likely date of the

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[5] Leahy-Smith America Invents Act Pub. L. No. 112-29, 125 Stat. 284 (2011).

District Court case trial." *Id.*, 12. Yet a Markman hearing is not scheduled to occur until March 21, 2019, and most deadlines are tied to the issuance of the Markman order, making Sanofi's predictions entirely speculative. Moreover, the Board has already held unpatentable all claims of two more Sanofi patents asserted in the same litigation. Sanofi has appealed those decisions to the Federal Circuit (IPR2017-01526, Paper 94; IPR2017-01528, Paper 92) but does not discuss how that appeal may alter the litigation timing. Sanofi's assertion about the litigation timing is too selective and speculative to support judgment on equitable grounds.

4. Petition timing

Sanofi's delay arguments are wrong, unsupported, and contrary to statute. Sanofi alleges that Mylan waited until "the eve of the one year statutory bar" and "intentionally staggered" its filings to gain an advantage. POPR, 1-2, 5-7, 14-16 (citing *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, 16-17 (2017) (precedential) ("*GP*")). Sanofi again offers no evidence for this incorrect assertion. With one exception, Mylan filed its petitions on the same day—

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