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**

---

[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,

---

[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

[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

[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—

not staggered—almost 2 months before the end of the 1-year grace period.[6] Sanofi also ignores the effect of unusual docketing delays ranging from 1 to 3 months. EX1038. Indeed, it is Mylan that has been prejudiced by these delays since they enable *Sanofi* to modify its responses serially according to what happens in the earlier-docketed IPR proceedings.

Sanofi's position is also contrary to the AIA framework. Although the Director has discretion under §314(a), that discretion is not unfettered. *SAS Institute, Inc., v. Iancu*, 138 S.Ct. 1348, 1356 (2018) ("*SAS*"). Congress addressed timing between the IPR and co-pending district court litigation in §315(b) and made a considered decision to give defendants a full year to file IPR petitions after service of a complaint. Sanofi invites shenanigans by urging an expansive use of discretion to countermand express congressional intent.

In *Click-to-Call*, the Federal Circuit explained that §315(b) is clear, unambiguous and binding. *Id.* at 1332 (quoting *Cuozzo Speed Tech., LLC v. Lee*, 136 S.Ct. 2131, 2142 (2016)) *SAS*, 138 S.Ct. at 1355. The court held "315(b)'s

---

[6] The only petition filed close to the §315(b) date, IPR2019-00122, was submitted to correct a filing error in the since-dismissed IPR2018-01677.

time bar concerns 'real-world facts that limit the agency's authority to act under the IPR scheme,' reflecting Congress's 'balancing [of] various public interests.'" *Click-to-Call*, 899 F.3d at 1331. The Federal Circuit also discussed §315(b)'s legislative history to support its construction, noting "the section 315(b) deadline afford defendants a *reasonable opportunity to identify and understand* the patent claims that are relevant to the litigation." *Id.* 1332 (quoting 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011)). Judge Taranto concurred, noting "[l]egislative history indications of congressional policy at most establish that §315(b) is generally based on an assessment of the period suitable for a formally accused infringer...to shape any IPR petition after formally receiving notice of a patentee's charges of infringement, with the patentee and district courts thereafter given repose against IPR petitions filed by that accused infringer...." *Id.* at 1347. Thus, Congress already balanced the competing interests, and §315(b) reflects the compromise Congress struck for the timing of district-court and IPR proceedings. Congress makes policy, *SAS*, 138 S.Ct. at 1358, and the Director must "follow its commands as written, not … supplant those commands with others [he] may prefer." *Click-to-Call*, 899 F.3d at 1332; *SAS*, 138 S. Ct. at 1355.

Sanofi further disregards Congress's role by effectively seeking a sector-specific nullification of §315(b) for ANDA suits. Adding §315(b)'s 1 year to the 18

month of an IPR equals 30 months, which approximates the 30-month stay in FDA approval in ANDA cases. *See*, *e.g.*, POPR, 8 n.2 (citing 21 U.S.C. 355(c)(3)(C)). Thus, Sanofi's proposal would essentially prevent *all* ANDA defendants from using the full grace period established by Congress. Moreover, Congress has considered but not adopted legislation addressing perceived redundancy between IPRs and Hatch-Waxman district court litigation, *e.g.*, H.R. 7251 (introduced 11 Dec. 2018), further highlighting that balancing AIA and district court proceedings is a policy decision for Congress, not an appropriate exercise of the Director's discretion. *SAS*, 138 S.Ct. at 1358.

Sanofi relies on *NHK* to propose a profound expansion of discretion under §314(a) that is contrary to statute and Federal Circuit precedent. POPR, 2. *NHK* notes an earlier Federal Circuit decision stating that "the PTO is permitted, but never compelled, to institute an IPR proceeding." *NHK*, 11 (quoting *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1345, 1367 (Fed. Cir. 2016)). *Harmonic*, however, issued before the Federal Circuit's *Click-to-Call* decision, as well as before the Supreme Court's *SAS* decision, and made this statement to uphold a partial institution. *Harmonic,* 815 F.3d at 1364. *Id. Harmonic* articulates an understanding of §314(a) that is no longer good law since *SAS*. Moreover, *Click-to-Call* specifically cautions against adding equitable or other non-textual restrictions to

§315(b) when instituting under §314(a). *Click-to-Call*, 899 F.3d at 1331. Thus, regardless of the timing of co-pending proceedings, the Director may not alter the statutory balance to attain a different policy goal.

### 5. Procedural shenanigans

Even if such policy preferences could override congressional intent—and they cannot—Sanofi's proposal would violate the Administrative Procedure Act ("APA"), which requires *actual* notice. 35 U.S.C. 552(a)(1) ("[A] a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published."). The August 2018 Update to the Office Trial Practice Guide ("Update") states that the considerations under §316(b) may apply in situations other than follow-on petitions, such as "events in other proceedings related to the same patent ... [such as] in district courts." Update, 10. The Update, however, does not elaborate on what those other considerations may be, imposes no actual requirement, and does not account for *Click-to-Call*. Moreover, the Federal Circuit has noted the Trial Practice Guide is only a guide, and not binding. *Applications in Internet Time*, *LLC, v. RPX Corp.*, 897 F.3d 1336, 1344 n.2 (Fed. Cir. 2018). *NHK* is also not binding and issued after Mylan filed the instant petition. *American Silicon Technologies v. United States*, 261 F.3d 1371, 1381 (Fed. Cir. 2001). Mylan thus complied with all then-applicable statutes and

rules. Imposing additional post hoc requirements would violate process due under the APA.

Sanofi's own discussion of the Update demonstrates the lack of notice. Sanofi justifies its position by arguing that, per the Update, the Director's discretion under §314(a) is "informed by" the requirement of §316(b) to consider, *inter alia*, efficiency and timeliness. POPR, 8-9 (quoting Update, 9). Yet §316(b) is explicitly a *rulemaking* authority. Sanofi's invocation of rulemaking considerations to justify a policy imposed outside of the rulemaking process is internally inconsistent. Imposing additional requirements on petitioners by applying the rulemaking considerations of §316(b) via §314(a) discretion would be an end run around notice-and-comment rulemaking requirements. *See* 5 U.S.C. 552(a), 553; 35 U.S.C. 2(b)(2)(B); *Aqua Products, Inc. v. Matal*, 872 F.3d 1290, 1318-20 (Fed. Cir. 2017); *Supernus Pharm., Inc. v. Iancu*, No. 2017-1357, slip. op. 17-18 (Fed. Cir. Jan. 23, 2019).

In any event, *Click-to-Call*'s construction of §315(b) bars Sanofi's argument. *Click-to-Call* issued after the Update, and *NHK* does not address its impact; neither can overrule it. Nor does Sanofi address *Click-to-Call* and its impact on the cited portions of the Update. Sanofi would hold Mylan to non-binding authority, while ignoring clearly binding authority—*Click-to-Call*. Mylan filed after *Click-to*-Call and complied with §315(b). Sanofi's assertion that Mylan had notice is thus wrong.

Sanofi also argues that *GP* factors favor non-institution. POPR, 14-18. *GP* addresses follow-on petitions, and Sanofi cannot shoehorn litigation into the *GP* factors. *Wirtgen America, Inc. v. Caterpillar Paving Products Inc.*, IPR2018-01201, Paper 13, 11 (2019).

### 6. Workload and resource shenanigans

Sanofi asserts that allowing an AIA challenge based on the "same invalidity grounds" as in district court is not a quick and efficient alternative to litigation, but a waste of the Board's and the parties' resources. POPR, 2 (citing H.R. Rep. No. 112–98, pt. 1, at 48 (2011); *NHK*, 19-20). Sanofi is factually wrong about the "same" grounds and arguments, and Congress has already struck the balance it wanted. Substituting workload and resources considerations on a case-by-case basis is contrary to clear statutory text, inviting further shenanigans. *SAS*, 138 S.Ct. at 1359; *Cuozzo*, 136 S.Ct. at 2141-42. As discussed above, both the Supreme Court and the Federal Circuit have explained that discretion under §314(a) is not unfettered. *SAS*, 138 S.Ct. at 1356; *Click-to-Call*, 899 F.3d at 1329. This is especially true for workload and resources.

Sanofi's broad view of §314(a) is also "at odds with one of the most basic interpretive canons" because it renders superfluous other specific grants of authority to limit IPR institutions based on workload and efficiency considerations. *Corley v.*

*United States*, 556 U.S. 303, 314 (2009). In the AIA, Congress authorized the Director to limit the number of IPRs instituted during the first four years to prevent the Office from being "overwhelmed". Pub. L. 112-29, sec. 6(c)(2)(B)) 125 Stat. 304 (2011); 157 Cong. Rec. S1376-77 (Mar. 8, 2011). Congress thus believed it needed to give the Director separate, express authority to limit the institution of IPRs for workload, and Congress set that authority to expire in 2016. If capping for workload and resources were inherent in §314(a) discretion, Congress would not have needed to grant such authority. Similarly, Sanofi's broad reading of §314(a) discretion would render authority to deny institution under §325(d) superfluous.

The legislative history cited in *GP* confirms that §314(a) discretion does not extend to ad hoc consideration of workload issues beyond the merits of the petition. *GP* notes that the "legislative history reflects recognition of a desire for a 'safety valve' to alleviate backlog," stating further that the "exercise of discretion under 35 U.S.C. § 314(a) [is not limited] to only circumstances in which there is a high volume of pending proceedings." *GP*, 19 (citing 157 Cong. Rec. S1377 (Mar. 8, 2011)). The cited Congressional Record text, however, requires the Director to address workload by notice-and-comment rulemaking. The cited text invokes *rulemaking* authority under §316, explaining that "[i]t is expected that the Office will include in the *threshold regulations* a safety valve that allows the Office to

decline to institute further proceedings" when overwhelmed. 157 Cong. Rec. S1377 (Mar. 8, 2011) (emphasis added); 35 U.S.C. 2(b)(2)(B).

The Director has only addressed workload and resources by rule in setting petitioner fees, which must account for "the aggregate costs of the review." 35 U.S.C. 311(a). No one contends that Mylan has failed to pay the fees for this petition. Thus, even if Office did not have sufficient resources, the Director must address that issue through rules, not on an ad hoc basis. Additionally, the Board is at a high-point in staffing, while appeal and trial dockets are falling. *See, e.g.*, Appeal and Interference Statistics, Patent Trial and Appeal Board, 2018, 3; Organizational Structure and Administration of the Patent Trial and Appeal Board, 1. Sanofi provides no credible basis for using workload or resources to contravene clear statutory requirements.

Sanofi proposes to repurpose §314(a) in a way that unfairly targets ANDA defendants while violating the AIA, the APA, and Federal Circuit precedent. For the reasons set forth above, the Board should not exercise discretion under §314(a) to deny the petition. Mylan respectfully requests institution of *inter partes* review.

Date: 30 January 2019

/ Richard Torczon /
Richard Torczon, Lead Counsel
Reg. No. 34,448

## UPDATED EXHIBIT LIST

| Exhibit No. | Description |
|---|---|
| 1001 | U.S. Patent 8,679,069, *Pen-Type Injector* (issued Mar. 25, 2014) |
| 1002 | U.S. Patent 8,603,044, *Pen-Type Injector* (issued Dec. 10, 2013) |
| 1003 | U.S. Patent 8,992,486, *Pen-Type Injector* (issued Mar. 31, 2015) |
| 1004 | U.S. Patent 9,526,844, *Pen-Type Injector* (issued Dec. 27, 2016) |
| 1005 | U.S. Patent 9,604,008, *Drive Mechanisms Suitable for Use in Drug Delivery Devices* (issued Mar. 28, 2017) |
| 1006 | File History for U.S. Patent 8,679,069 |
| 1007 | File History for U.S. Patent 8,603,044 |
| 1008 | File History for U.S. Patent 8,992,486 |
| 1009 | File History for U.S. Patent 9,526,844 |
| 1010 | File History for U.S. Patent. 9,604,008 |
| 1011 | Expert Declaration of Karl Leinsing MSME, PE in Support of Petition for *Inter Partes* Review of U.S. Patent Nos. 8,679,069; 8,603,044; 8,992,486; 9,526,844 and 9,604,008 |

| **Exhibit No.** | **Description** |
|---|---|
| 1012 | *Curriculum Vitae* of Karl Leinsing MSME,PE |
| 1013 | U.S. Patent 6,221,046 - A. Burroughs et al., "Recyclable Medication Dispensing Device" (issued Apr. 24, 2001) |
| 1014 | U.S. Patent 6,235,004 – S. Steenfeldt-Jensen & S. Hansen, "Injection Syringe" (issued May 22, 2001) |
| 1015 | U.S. Patent Application US 2002/0053578 A1 – C.S. Møller, "Injection Device" (pub'd May 2, 2002) |
| 1016 | U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek, "Medication Delivery Pen" (issued Aug. 23, 2005) |
| 1017 | U.S. Patent 6,582,404 B1 – P.C. Klitgaard et al., "Dose Setting Limiter" (issued June 24, 2003) |
| 1018 | File History for U.S. Patent 6,582,404 |
| 1019 | Plaintiffs' Preliminary Claim Constructions and Preliminary Identification of Supporting Intrinsic and Extrinsic Evidence, *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105 (D.N.J.) (filed Sep. 5 2018) |
| 1020 | U.S. Patent 4,865,591 – B. Sams, "Measured Dose Dispensing Device" (issued Sep. 12, 1989) |
| 1021 | U.S. Patent 6,248,095 B1 – L. Giambattista et al., "Low-cost Medication Delivery Pen" (issued June 19, 2001) |

| **Exhibit No.** | **Description** |
|---|---|
| 1022 | U.S. Patent 6,921,995 B1 – A.A. Bendek et al., "Medication Delivery Pen Having An Improved Clutch Assembly" (issued July 13, 1999) |
| 1023 | U.S. Patent 5,226,895 – D.C. Harris, "Multiple Dose Injection Pen" (issued July 13, 1993) |
| 1024 | U.S. Patent 5,851,079 – R.L. Horstman et al., "Simplified Unidirectional Twist-Up Dispensing Device With Incremental Dosing" (issued Dec. 22, 1998) |
| 1025 | Application as filed: U.S. Patent App. 14/946,203 – R.F. Veasey, "Relating to a Pen-Type Injector" (filed Nov. 19, 2015) |
| 1026 | GB 0304822.0 – "Improvements in and relating to a pen-type injector" (filed Mar. 3, 2003) ('844 Priority Doc.) |
| 1027 | WO 99/38554 – S.Steenfeldt-Jensen & S.Hansen, "An Injection Syringe" (pub'd Aug. 5, 1999) (Steenfeldt-Jensen PCT) |
| 1028 | Mylan GmbH and Biocon's Preliminary Claim Constructions and Supporting Evidence Pursuant to L. Pat. R. 4.2*, Sanofi-Aventis U.S., LLC v. Mylan N.V.,* C.A. No. 17-cv-09105 (filed Sep. 5, 2018) |
| 1029 | Memorandum Opinion, *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 16-cv-812 (filed Jan. 12, 2018) |
| 1030 | Memorandum Opinion, *Sanofi -Aventis U.S. LLC v. Eli Lilly and Co*., No. 14-cv-113 (filed Jan. 20, 2015) |

| **Exhibit No.** | **Description** |
|---|---|
| 1031 | N. Sclater & N.P. Chironis, Mechanisms & Mechanical Devices Sourcebook 191-95, "Twenty Screw Devices" (3d ed., July 2, 2001) |
| 1032 | EP 0 608 343 B1 – L. Petersen & N.-A. Hansen, "Large Dose Pen" (pub'd Oct. 18, 1991) |
| 1033 | A.G. Erdman &G.N. Sandor, " Mechanical Advantage", §3.7 in 1 Mechanism Design: Analysis and Synthesis (1984) |
| 1034 | WO 01/83008 – S. Hansen & T.D. Miller., "*An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device*" (pub'd Nov. 8, 2001) |
| 1035 | K.J. Lipska et al., *Association of Initiation of Basal Insulin Analogs vs Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related Emergency Department Visits or Hospital Admissions and With Glycemic Control in Patients With Type 2 Diabetes*, 320 J. Am. Med. Ass'n 53-62 (2018) |
| 1036 | Transcript, Conference Call (January 15, 2019) |
| 1037 | RESERVED |
| 1038 | Graph showing PTAB Days to Docketing for Review Proceedings Filed between 2016-2018 |

## CERTIFICATE OF SERVICE

I certify that this Reply with Updated Exhibit List and EX1038 was served on 30 January 2019, on the Patent Owner at the email correspondence address of the Patent Owner as follows:

| | |
|---|---|
| Elizabeth Stotland Weiswasser | elizabeth.weiswasser@weil.com |
| Anish R. Desai | anish.desai@weil.com |
| Kathryn M. Kantha | kathryn.kantha@weil.com |
| William S. Ansley | sutton.ansley@weil.com |
| Matthew D. Sieger | matthew.sieger@weil.com |
| WEIL, GOTSHAL & MANGES LLP | Sanofi.IPR.Service@weil.com |

Respectfully submitted,

Date: 30 January 2019

/ Richard Torczon /
Richard Torczon, Lead Counsel
Reg. No. 34,448