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. IPR2018-01670[1]
Patent No. 8,679,069

MYLAN REPLY TO PATENT OWNER PRELIMINARY RESPONSE

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[1] Mylan filed essentially the same reply in IPR2018-01670, -01682, 01696, and IPR2019-00122. Underlining indicates case-specific differences. Boxes indicate response to Sanofi's additional discretionary-denial argument.

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 present the "same arguments" and "same grounds" as the Petition, i.e., obviousness over Burroughs. POPR, 2, 8-10 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8, 19 (2018)). Sanofi asserts Mylan's contentions state that Burroughs, Steenfeldt-Jensen, and Møller with Steenfeldt-Jensen rendered claim 1 obvious. POPR, 9-10 (citing EX2007-10). Actually, Mylan contended Burroughs, Steenfeldt-Jensen, and Møller, each alone or in combination with *thirty-three* additional references rendered the claims obvious. EX2009, 348; *see also Intel Corp. v. Qualcomm, Inc.*, IPR2018-01152, Paper 9,

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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.

14-19 (2019)[4] (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 (*e.g.*, EX2010, 16-17), while Sanofi's evidence of *its* allegedly detailed validity positions is just an email demonstrating service (EX2011).[5] Thus, Sanofi's evidence does not support its allegation that the grounds and arguments are the same here and in district court. For this reason alone, the Board should decline to exercise discretion under §314(a).

In response to Mylan's earlier-filed replies, Sanofi argues that Mylan asserts obviousness over Burroughs alone in both this and the district court proceedings, and that Mylan has not "affirmed to the Board … that it will *not* continue to assert

[4] Should be IPR2018-01344, Paper 8.

[5] 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, 12.

the same ground against the challenged claims in the District Court case." POPR, 26-27.

The Board's claim construction standard differs from the district court's, as do the burdens of proof. Given these and other differences between district-court and Board proceedings, the records will be different. *Novartis AG v. Noven Pharm.*, 853 F.3d 1289, 1293-94 (Fed. Cir. 2017) (explaining why district-court and Board proceedings might not be redundant).

Notwithstanding, to simplify the issues for institution, Mylan agrees to not pursue in the district court action any specific ground that the Board institutes for this petition, or any of the proceedings in which Sanofi asserts that the Board should exercise it discretion to deny institution, including the IPRs in which Mylan has already filed a reply (IPR2018-01675, -01676, -01678, and -01680).

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, 6. The ten IPR petitions address *five* device patents that Sanofi chose to assert against Mylan (in addition to two formulation patents). 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.[6] 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.

As discussed above in Section 1, Mylan agrees that it will not proceed at the district court on any specific ground that the Board institutes in any of these proceedings, thereby mooting any allegations of a second bite. POPR, 28-29.

3. Litigation timeline

Sanofi's district-court timeline is speculative. Sanofi asserts that the litigation will "likely" (POPR, 12, 16-17) 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 would not be due until May 2020, eight months after the likely date of the District Court case trial." *Id.*, 12. Yet

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

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.

Sanofi continues to assert, without any empirical evidence, that the district court case will be tried by March 2020. POPR, 23-24. According to Sanofi, Mylan has continued to push for trial before that time period, in view of the 30-month stay and the Hatch-Waxman/BCIPA transition date that occurs at that time. POPR, 26 (citing EX2019, 1; EX2020, 19; EX2021, 1).

While Mylan advocated for a speedy trial, the schedule has already slipped (often from Sanofi action) and is certainly not guaranteed to be completed by March 2020. As noted above, currently no certain dates are set for expert discovery, much less trial. Even when the case is ready for trial, the court's busy docket might not be able to accommodate it. And Sanofi does not address the effect of the recently-filed appeals from IPR2017-01526 and IPR2017-01528 on

the timeline of the district court proceeding. In contrast, the Patent Owner in *NHK* provided a scheduling order that specifically set a trial date. *NHK*, 19.

According to Sanofi, the local patent rules require parties to address the 30-month stay in Hatch-Waxman cases to expedite matters. POPR, 11-12. Sanofi implies that, because Judge Chesler has presided over 50 Hatch-Waxman cases, the case will be done in 30 months. *Id*. Mylan was unable to substantiate Sanofi's argument using Lex Machina and DocketNavigator. The judge has been active in over 140 Hatch-Waxman cases, but only four reached trial. Of those four, two were assigned post-appeal, and the other two exceeded 30 months. The data is insufficient for any reliable prediction, but it nevertheless shows that Sanofi's argument is purely speculative and provides no basis for denial.

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, 4 (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. Mylan filed its petitions on the same day—not staggered—almost 2 months before the end of the 1-year grace period.[7] Sanofi also ignores the effect of unusual docketing delays ranging from 1 to 3 months. EX1038. Indeed, *Mylan* has been prejudiced by these delays since they enabled *Sanofi* to modify its responses serially according to what happens in the earlier-docketed IPR proceedings.[8]

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

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

[8] That is what in fact occurred. Specifically, because of staggered notices of filing dates entered in these proceeding, Sanofi has had the opportunity to respond to the arguments made in Mylan's replies in the IPR2018-01675, IPR2018-01676, IPR2018-01678, and IPR2018-01680 proceedings. EX1039, 20-21, 27-28.

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 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 one 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, 5-6 (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, 8-13. *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.

Sanofi asserts in response that "it is beyond dispute that 'the agency's decision to deny a petition is a matter committed to the Patent Office's discretion.'" POPR, 18 (quoting *Cuozzo*, 136 S. Ct. at 2140). The existence of discretion does not mean it is unfettered or open to abuse. *SAS*, 138 S. Ct. at 1356 (institution is guided by the petition, not discretion). "An abuse of discretion occurs where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed.Cir.2005). Like the patent owner in *SAS*, Sanofi asks the Board to abuse its discretion based on an erroneous statutory interpretation, in this case, of §315(b).

Sanofi's attempt to distinguish *Click-to-Call* also misses the mark. Sanofi argues that *Click-to-Call* is inapposite because it addressed whether filing outside the one-year grace period bars institution, rather than whether filing within the grace period "compel[s] institution." POPR, 18-19. However, Mylan does not argue that §315(b) *compels* institution of all timely-filed petitions; rather, Mylan notes that Sanofi's argument is contrary to the judicially-recognized legislative compromise of §315(b). Of course the Board may deny institution where a timely-filed petition fails to demonstrate a reasonable likelihood of success. The AIA also specifically enumerates other factors—for example, in §325(d)—that can support discretionary denial. But Congress *already* balanced the competiting interests invoked by Sanofi when it chose to give defendants one year to file IPR petitions after service of a complaint. Sanofi now asks the Board to reweigh those interests and discard the compromise that Congress struck. Sanofi's argument is thus an invitation to engage in policy-making on an issue where Congress has already spoken.[9] *See Click-to-Call*, 899 F.3d at 1331.

[9] To the extent Sanofi's statement that Mylan was aware of the patent before the one-year period began is meant to suggest additional shortening of the one-year

Numerous Board decisions have declined to extend the reasoning of *NHK* as urged by Sanofi. In *Intuitive Surgical, Inc. v. Ethicon LLC*, the Board rejected arguments similar to Sanofi's, explaining that:

> *NHK Spring* does not suggest, much less hold, that *inter partes* review should be denied under § 314(a) solely because a district court is scheduled to consider the same validity issues before the *inter partes* review would be complete.

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grace period, such argument even further disregards the balance struck by Congress in §315(b). Mylan's Paragraph IV notice certified that the claims of the '486 patent are not valid, are unenforceable, and will not be infringed, reflecting its understanding that Sanofi's suit is improper. *E.g.*, S. Rep. No. 11-259, 3-4 (2008) (noting that a reasonable defendant might not expect a patent to be enforced after reading its claims). If Mylan had filed an IPR without being served with a complaint, Sanofi presumably would have argued that Mylan lacked Article III standing to appeal any adverse decision of the Board to the Federal Circuit. *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1260-61 (Fed. Cir. 2014).

IPR2018-01703, Paper 7, 13 (2019); *see also Ericsson Inc. et al. v. Intellectual Ventures I LLC*, IPR2018-01256, Paper 6, 40-43 (2019); *Intel Corp. v. Qualcomm, Inc.*, IPR2018-01344, Paper 8, 14-17 (2019); *Samsung Electronics Co., Ltd. v.Immersion Corp.*, IPR2018-01499, Paper 11, 13-21 (2018); *Mylan Pharm. Inc. v. Biogen MA Inc.*, IPR2018-01403, Paper 12, 46 (2019). In fact, the Board has expressly recognized the contradiction between Sanofi's position and §315(b):

> Section 315(b) provides a one-year period after service of a complaint alleging infringement of a patent in which a party may file a petition seeking inter partes review of that patent. 35 U.S.C. § 315(b). The statute does not set forth any basis for treating petitions differently depending on which day within that year they are filed, nor does Patent Owner identify any authority supporting such an interpretation. Thus, the fact that the Petition was filed near (but before) the end of the § 315(b) period does not, by itself, support denial of institution.

Amazon.com, Inc. v. CustomPlay, Inc., IPR2018-01496, Paper 12, 7-8 (2019).

As to the interplay with Hatch-Waxman litigation, Sanofi argues that the math—the 30-month stay in FDA approval matching the one-year statutory time period plus the approximate 18 months for completing an IPR—is irrelevant because Mylan initially sought an expedited schedule in district court and noted the upcoming transition to the BCPIA. POPR, 25-26 (citing EX2020, 19). Sanofi offers no evidence, however, that the *actual* timeline—including delays that have

already occured—is an outlier for Hatch-Waxman cases. As explained above in Section 3, Sanofi's discussion of the litigation timeline is speculative and incomplete, which provides no basis for distinguishing Mylan's case schedule from that of a typical Hatch-Waxman case.

Sanofi also asserts that it is not seeking sector-specific treatment for Hatch-Waxman cases because the policy it urges would also impact non-ANDA defendants. *Id.* While the even-broader impact of a policy that is contrary to the AIA and APA hardly supports Sanofi's position, Sanofi cannot deny that its logic particularly disadvantages ANDA defendants—an outcome Congress did not contemplate in the AIA, and has subsequently contemplated but not adopted. H.R. 7251; *see In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985) (judicial anticipation of legislation is not appropriate). For example, as Sanofi itself acknowledges (POPR, 11), New Jersey Local Patent Rule 2.1 requires parties to address the 30-month stay in the initial case-planning conferences and joint discovery plan to expedite matters, which would apply to all Hatch-Waxman cases, regardless of whether the Hatch-Waxman to BPCIA transition date is implicated. EX2018, 1.

5. Procedural shenanigans

Even if Sanofi's 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, 7 (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 argues discretionary denial under §314(a) would not violate the APA because Mylan does not state what more elaboration would be required beyond the

guidance provided by the Update. POPR, 20-22. Sanofi asserts that the Office complied with 5 U.S.C. §552(a)(1), because it published a Federal Register notice announcing the Update and because its decisions, such as *NHK*, are available online. *Id.* However, as Mylan pointed out in its earlier replies, notice-and-comment rulemaking is required for compliance with the APA. 35 U.S.C. §316(a)(2); *see also* Update, 8 ("Under 35 U.S.C. § 316(a)(2), the Director *shall prescribe regulations* 'setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a).'") (emphasis added), 9 ("The Director's discretion is informed by 35 U.S.C. §§ 316(b) and 326(b), which require the Director to '*consider the effect of any such regulation* ....'") (emphasis added).

Additionally, as Sanofi acknowledges (POPR, 21), the Update itself was not published in the Federal Register. Rather, the Federal Register only provided notice that the Update had issued. 83 Fed. Reg. 39989 (Aug. 13, 2018). The Update itself was not incorporated into the notice to comply with APA requirements. 1 C.F.R. §51.9 (incorporation requirements). Moreover, although the Update provides guidance, it is not binding and does not constitute substantive rule-making. *Applications in Internet Time*, 897 F.3d at 1344 n.2. Additionally, even if were appropriate to provide guidance on an ad hoc basis about factors for

discretionary denial under §314(a), *NHK* itself is not binding on the panel or Mylan.

Sanofi notes that the Update cites the Board decision *NetApp, Inc. v. Realtime Data LLC*, IPR2017-01195, Paper 9, 12-13 (2017) as an example of an institution denial because the final written decision would not be issued until after the district-court trial date. POPR, 21-22. The non-binding *NetApp* decision, however, does not support Sanofi's position, because this pre-*SAS* decision relies on the same rule (37 C.F.R. §42.108(a)) that *SAS* held did not provide discretion to ignore a statute. *NetApp*, 9; *SAS*, 138 S. Ct. at 1354-55. *NetApp* is also readily distinguishable and thus provides no actionable notice. Indeed, multiple Board decisions have explained why *NetApp* and *NHK* do not apply to situations such as this where no earlier petition was filed before the Board. *E.g., Intel Corp. v. Qualcomm, Inc.*, IPR2018-01344, Paper 8, 15 ("[I]n *NetApp*..., the exercise of discretion to deny institution was based primarily on the filing of an earlier petition before the Board...."); *Samsung Electronics Co., Ltd. v. Immersion Corp.*, IPR2018-01499, Paper 11, 13 (similarly distinguishing *NHK*, *NetApp*, and other cases).

Sanofi also asserts that *Click-to-Call* is not relevant, so there was no reason for the Update to account for that decision. POPR, 22. According to Sanofi, Mylan

is confusing "a necessary condition with a sufficient one," as compliance with the applicable statutes and rules is necessary, but not automatically sufficient to secure institution, as otherwise, the Board would not have discretion not to institute. *Id*. Sanofi again misapprehends Mylan's arguments. As noted above, Mylan does not contend that the Board lacks discretion; instead, Mylan notes the well-established principle that this discretion is not unlimited. For example, §316(a)(2) requires the Director to set standards for exercising discretion under §314(a) by notice-and-comment rule-making, not by ad hoc guidance and nonbinding opinions. In addition, as discussed in *Click-to-Call*, §315(b) already reflects Congress' balance between the interests between patentees and patent challengers involved in concurrent district-court litigation. *Click-to-Call*, 899 F.3d at 1331. This leaves no room for the Director to elaborate contrary requirements, let alone to set such requirements outside the rule-making process.

Sanofi also argues that *GP* factors favor non-institution. POPR, 13-17. *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).

Sanofi asserts that Mylan's replies failed to address the *GP* factors. POPR, 17. Sanofi is incorrect, as *Wirtgen*, cited in the earlier replies, explains that the *GP*

factors do not translate to co-pending non-PTO proceedings, as the petitions at issue in *GP* were *follow-on* IPR petitions. *Wirtgen,* 10. Although the co-pending proceeding in *Wirtgen,* was an ITC proceeding, the analysis applies equally to a co-pending district-court proceeding. *See also Samsung Elec. Co., LTD. V. Bitmicro, LLC*, IPR208-01411, Paper 14, 17-18 (2019).

In any event, even if the *GP* factors did apply here, they still would not favor denial. Factors 1-5 expressly address follow-on petitions, which the current petitions indisputably are not. *See Samsung Electronics Co., Ltd. v.Immersion Corp.*, IPR2018-01499, Paper 11, 14-16. Even if these factors could be twisted to apply to district court proceedings, Sanofi offers no evidence that Mylan unfairly waited to obtain a "road map" for its petitions. *See id.*, 15-16. Mylan filed its petitions within the one-year grace period of §315(b), and Sanofi again offers nothing beyond an email demonstrating service (EX2011) to substantiate its baseless claim that Mylan obtained a strategic advantage by filing its petitions after receiving Sanofi's supposedly "detailed" validity contentions. POPR, 6, 12. Factor 6 is intended to conserve Board resources "from repeat or multiple staggered petitions...*before the Board*", which again is not the case here. *Samsung Electronics Co., Ltd. v. Immersion Corp.*, IPR2018-01499, Paper 11, 16-18 (emphasis added). Sanofi does not even attempt to explain how institution would

impact the Board's ability to issue a decision within a year of institution per Factor 7. POPR, 16-17. The *GP* factors do not apply to the present petition, do not require denial of this petition, and—if applied as Sanofi suggests—would violate both statute and binding precedent.

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, 1-2 (citing H.R. Rep. No. 112–98, pt. 1, at 48 (2011); *NHK*, 19-20). Sanofi is factually wrong about the "same" grounds, and 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 does not refute that the Board should address resource concerns by rulemaking, and not on an ad hoc basis. Rather, Sanofi asserts that it has not asked the Board to deny institution on the basis of workload. POPR 19-20. While Sanofi is free to abandon the workload argument, its assertion is inconsistent with other statements in its POPR. For example, Sanofi asserts that institution would be "highly inefficient" and "would waste the Board's finite resources". *Id.*, 2-3. In addition, Sanofi specifically argued that *GP* factor 6 favors denial, asserting "the

Board's finite resources should not be spent on proceedings that will ultimately be moot." *Id.*, 16-17. Sanofi cites *NHK*, which also relied on resources and workload in concluding that institution could have been denied under §314(a). *NHK*, 20 ("Patent Owner argues persuasively that instituting a trial under the facts and circumstances here would be an inefficient use of Board resources."). Additionally, Congress was not just concerned with the finite resources of the Board, but was also concerned with the finite resources of the district courts, further favoring institution. *See* 157 Cong. Rec. S1363 (Mar. 8, 2011); *see also Intuitive Surgical, Inc. v. Ethicon, LLC*, IPR2018-01703, Paper 7, 11-12 (2019) (noting that district court may stay, satisfying "the AIA's objective of providing 'an effective and efficient alternative to district court litigation.'").

Sanofi proposes to repurpose §314(a) in a way that disproportionately 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: 11 March 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	Reserved
1037	Reserved
1038	Graph showing PTAB Days to Docketing for Review Proceedings filed between 2016-2018
1039	Transcript, Conference Call (February 13, 2019)

Exhibit No.	**Description**
1040	Declaration of Elham F. Steiner in Support of *Petitioner's Motion for Pro HacVice Admission*
1041	Elham F. Steiner – Attorney Biography

CERTIFICATE OF SERVICE

I certify that on 11 March 2019 this Reply and EX1038 was served 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
Sundip K. Kundu	sundip.kundu@weil.com
Kathryn M. Kantha	kathryn.kantha@weil.com
William S. Ansley	sutton.ansley@weil.com
Matthew D. Sieger	matthew.sieger@weil.com
Adrian C. Percer	adrian.percer@weil.com
Brian C. Chang	brian.chang@weil.com
WEIL, GOTSHAL & MANGES LLP	Sanofi.IPR.Service@weil.com

Respectfully submitted,

Date: 11 March 2019

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