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Via ECF

Honorable Allison D. Burroughs
United States District Court Judge
John Joseph Moakley U.S. Courthouse
1 Courthouse Way
Boston, Massachusetts 02210

Re: *Teva Pharmaceuticals International GmbH et al. v. Eli Lilly and Company*, Civil Action No. 1:18-cv-12029-ADB

Dear Judge Burroughs:

Lilly respectfully submits this letter in response to Teva's April 5, 2019, letter to the Court (Dkt. 40), which provided attorney argument that Lilly believes is inappropriate under Local Rule 7.1(b)(3). Specifically, Lilly seeks to correct Teva's mischaracterization of the Supreme Court's decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018) ("*SAS*"), which is irrelevant in this context, address Teva's misstatements concerning the Patent Trial and Appeal Board ("Board") decisions to institute *inter partes* review ("IPR") of the patents-in-suit, and explain why Teva's use of statistics to conclude that "the most likely outcome of Lilly's IPRs is that a substantial number of claims will remain in this litigation" is both misleading and wrong.

First, Teva's reliance on the *SAS* decision is misplaced.[1] While Teva contends otherwise (Dkt. 40 at 1), the Board continues to analyze the merits of ***every*** challenged claim before institution. *See e.g.*, *Apple, Inc. v. Uniloc Luxembourg S.A.*, No. IPR2018-00424 (P.T.A.B. Aug. 2, 2018) (analyzing the likelihood of Petitioner prevailing in showing each challenged claim is unpatentable). Consistent with this practice, and as Lilly stated in its April 4, 2019, letter (Dkt. 39), here the Board analyzed the merits of ***every*** challenged claim of each of the patents-in-suit before institution. Indeed, Teva points to nothing in any of the nine institution decisions that suggests the Board believes that any of the dependent claims for any of the nine patents-in-suit contained limitations that might impart patentability. Nor is Lilly aware of any such language.

[1] Teva also misstates the law under 35 U.S.C. § 314(a) in light of *SAS*: it does *not* require that the Board "institute review of all challenged claims, without regard to the merits of the other claims," if it finds that a single claim is reasonably likely to be unpatentable. In fact, on April 5, 2019, the PTAB designated as informative two decisions denying institution despite finding that the petitioner had demonstrated a reasonable likelihood of prevailing on more than one challenged claim. *Deeper, UAB v. Vexilar, Inc.*, No. IPR2018-01310 (P.T.A.B. Jan. 24, 2019); *Chevron Oronite Co. v. Infineum USA L.P.*, IPR2018-00923 (P.T.A.B. Nov. 7, 2018).

Compare Apple, Inc. v. Uniloc Luxembourg S.A., No. IPR2018-00424 at 39-40, 54 (P.T.A.B. Aug. 2, 2018) (Board instituting *inter partes review* of all challenged claims but making clear dependent claim 9 contained limitations that might impart patentability) *with* Dkt. 35-1 at 21; Dkt. 35-2 at 22–23; Dkt. 35-3 at 22; Dkt. 37-1 at 21; Dkt. 37-2 at 24; Dkt. 37-3 at 25; Dkt. 39-1 at 24; Dkt. 39-2 at 26; Dkt. 39-3 at 32. At bottom, Teva's discussion of the *SAS* decision should have no bearing on the pending motion to stay.

Second, Teva's account of the Board's institution decisions is misleading. For example, Teva relies, in isolation, on a single sentence of the Board's institution decision in which the Board "conclude[d] that [Lilly] has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim [of the '045 patent]" (Dkt. 40 at 1) and asserts that "[t]he other institution decisions contain similar language" (*id.* n.2). As an initial matter, this language does ***not*** appear in all of the institution decisions.[2] Moreover, contrary to Teva's representations, and as discussed above, the Board has articulated that ***all*** of the challenged claims warrant review and could be canceled by the Board in *inter partes* review. (*See e.g.*, Dkt. 39-3 at 32 ("[W]e determine that Petitioner has established a reasonable likelihood of prevailing on its contentions as to [the dependent claims], for similar reasons as for [the independent claim]."),)[3]

Teva misleadingly asserts that it is "incredibly unlikely" that Lilly will succeed in persuading the Board to cancel all of its claims. Teva's misuse of IPR statistics (Dkt. 40 at 2) improperly treats each claim as entirely independent, ignoring that the likelihood of survival of similar claims in the same patent are interrelated. Teva similarly ignores the interrelatedness of the patents-in-suit. The fallacy of Teva's analysis is underscored by the fact that in only about 17% of IPR proceedings are some claims canceled while other claims survive.[4]

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[2] In case nos. IPR2018-01424, IPR2018-01427, and IPR2018-01712, the Board concluded that Lilly "has demonstrated a reasonable likelihood of prevailing on its assertion that [the challenged claims] of the [challenged patent] are unpatentable." (Dkt. 35-3 at 2, 29; Dkt. 37-3 at 2, 31; Dkt. 39-3 at 38.)

[3] The Board made the same finding in its decisions for the other eight patents-in-suit. (*See* Dkt. 35-3 at 22 (same); Dkt. 37-3 at 25 (same); Dkt. 35-1 at 20–21, 34 ("Having considered the arguments and evidence, and at this stage of the proceeding, we are persuaded that Petitioner has sufficiently shown that the combination of [prior art references] teaches or suggests each limitation of [the independent claim(s)]. We are also persuaded that Petitioner has sufficiently shown as to [the independent claim(s)] that a person of ordinary skill in the art would have had a reason to combine the teachings of [the prior art references] with a reasonable expectation of success. . . Petitioner provides further evidence and arguments regarding [the challenged dependent claims]. . . Patent Owner does not advance any substantive arguments regarding [the challenged dependent claims]. . . For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that one or more of [the challenged claims] of the [challenged] patent are unpatentable."); Dkt. 35-2 at 22–23, 35 (same); Dkt. 37-1 at 21, 33 (same); Dkt. 37-2 at 23–24, 38 (same); Dkt. 39-1 at 23–24, 40 (same); Dkt. 39-2 at 25–26, 40 (same).)

[4] *See* Elliot C. Cook et al., Claim and Case Disposition, AIA Blog, https://www.finnegan.com/en/america-invents-act/claim-and-case-disposition.html.

Teva also argues that "Lilly has yet to articulate how the fact discovery that will take place over the next 12 months will be simplified in any meaningful way if the Board potentially cancels some—but not all—challenged claims." (Dkt. 40 at 2.) At the outset, Teva ignores that the most likely outcome is that all of its claims will be canceled, thereby disposing of the case altogether. But, even if the Board were to cancel some but not all of the claims, fact discovery would be simplified in many ways. As one such example, pursuant to Local Rule 16.6(d), during fact discovery the parties must exchange Automatic Patent-Related Disclosures including infringement claim charts, non-infringement claim charts, invalidity claim charts. Proceeding with fact discovery would not only result in the parties expending resources on voluminous disclosures for claims that could be canceled in less than 12-months-time, the Court could be faced with motions to resolve disputes arising out of these disclosure obligations for claims and/or entire patents that could be canceled in less than 12-months-time.

For the reasons set forth in Lilly's moving papers (Dkt. 18-20, 29-30) and by Lilly during the hearing held on March 5, 2019, Lilly respectfully requests that the Court grant its motion to stay this case until April 3, 2020, pending resolution of the IPR proceedings. Consistent with Lilly's request, Judge Bryson of the Federal Circuit Court of Appeals has expressed the view that "after the PTAB has instituted review proceedings, ***the parallel district court litigation ordinarily should be stayed***." *Parsons Xtreme Golf LLC v. Taylor Made Golf Co.*, No. CV-17-03125-PHX-DWL, 2018 WL 6242280, at *5 (D. Ariz. Nov. 29, 2018) (emphasis added) (quoting *NFC Tech. LLC v. HTC Am., Inc.*, No. 2:13-cv-1058-WCB, 2015 WL 1069111, at *4 (E.D. Tex. Mar. 11, 2015) (Bryson, J.). Should the Court's calendar permit, Lilly would appreciate the opportunity to respond more fully to Teva's newly crafted arguments in supplemental briefing or before the Court.

Respectfully submitted,

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cc: All counsel of record (*via ECF*)

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