

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 10,888,601

Inter Partes Review No. IPR2023-00739

**PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

Pursuant to the Board's authorization, Ex.3001, Patent Owner submits this sur-reply to Petitioner's Reply to Patent Owner's Preliminary Response, Paper 7.

I. THE *FINTIV* FACTORS WEIGH AGAINST INSTITUTION DUE TO OVERLAPPING ISSUES IN THE DISTRICT COURT LITIGATION

Petitioner applies a non-existent legal standard whereby any difference between issues in the Petition and parallel litigation is sufficient to avoid discretionary denial. *Fintiv* is not so limited. Instead, *Fintiv* factor four considers any "overlap between issues raised in the petition and in the parallel proceeding," and whether the overlap creates "concerns of inefficiency and the possibility of conflicting decisions." *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, *5 (PTAB March 20, 2020). Such concerns arise where, as here, there is significant overlap between the Petition and the arguments in district court.

Overlapping claims—At trial, Defendant Mylan challenged dependent claims 11 and 19, a subset of the claims challenged in the Petition. The remaining claims in the Petition are 10 and 18 (from which 11 and 19 depend), 26–27 (which are identical to 18–19 except that they are directed to a method for "treating diabetic retinopathy in a patient with diabetic macular edema" rather than "treating diabetic retinopathy"), 12, 21, and 18 (which add the limitation "further comprising, after 20 weeks, administering, via intravitreal injection, 2 mg of aflibercept once every 4 weeks"), and 17, 25, and 33 (which add the exclusion criteria limitation). Petitioner incorrectly characterizes the exclusion criteria of

claims 17, 25, and 33 as an IPR-only issue, Reply 2—the exclusion criteria remain a live issue in the district court litigation because the district court construed the limitation, and the construction remains subject to appeal. *See* POPR 9–10, 43. Thus, only the two limitations “treating diabetic retinopathy in a patient with diabetic macular edema” and “further comprising, after 20 weeks, administering, via intravitreal injection, 2 mg of aflibercept once every 4 weeks” are at issue in the Petition but not the current phase of the parallel litigation.

“[T]he mere existence of non-overlapping claims does not support Petitioner’s position that this factor favors institution.” *Samsung Elecs. Co. v. Clear Imaging Rsch., LLC*, IPR2020-01399, Paper 13 at 21 (PTAB Feb. 3, 2021) (hereinafter, *Clear Imaging*). Where the overlap is incomplete, factor 4 weighs against institution if the claims challenged in each proceeding are “similar,” such that “the district court may resolve validity of enough overlapping claims to resolve key issues in the petition.” *Fintiv*, 2020 WL 2126495 at *6. Thus, discretionary denial is commonly warranted when the Petition includes challenged claims that are not at issue in the parallel proceeding. *Clear Imaging*, IPR2020-01399, Paper 13 at 19–24 (PTAB Feb. 3, 2021) (denying institution where 3 of the petition’s 29 claims were challenged in district court); *Supercell Oy v. Gree, Inc.*, IPR2020-00513, 2020 WL 3455515, at *6 (PTAB June 24, 2020) (denying institution where “claims 2-4 [were] challenged only in the Petition, not in district

court, but . . . ‘resolution of Petitioner’s challenges to . . . claim 1[] at the district court will necessarily resolve key issues . . . with respect to dependent claims 2-4.’”); *Next Caller Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 (PTAB Oct. 16, 2019) (denying institution where 7 of the petitions’ 52 claims were challenged in district court); *Kiss Nail Prod., Inc. v. Lashify, Inc.*, PGR2021-00046, 2021 WL 3504569 (PTAB Aug. 9, 2021) (denying institution where 6 of the petition’s 29 claims were challenged at the ITC). Petitioner fails to address any of this Board precedent in its Reply, even though Patent Owner expressly relied upon *Clear Imaging* in its Preliminary Response, POPR 42.

In *Clear Imaging*, the Board explained that all the petition’s challenged claims were similar because they were “directed to the same subject matter,” *i.e.*, “an imaging device for capturing and processing images” and its methods of use. *Clear Imaging*, IPR2020-01399, Paper 13 at 21–22. The Board further reasoned that “*some* of the non-overlapping claims (e.g., claims 1, 2, 21, and 22) recite *similar* limitations as those recited in claims 10, 12, and 20 that are asserted in the parallel litigation,” *id.* at 22 (emphasis added), although other claims added limitations not found in the claims challenged in district court.

Here, the district court litigation involves a representative subset of the Petition’s challenged claims, which are all directed to the same general subject matter: “methods for treating diabetic macular edema” and “methods for treating

diabetic retinopathy” by administering aflibercept according to certain dosing regimens. The district court has addressed or will address all limitations of several of the Petition’s challenged claims (10–11, 17–19, 25), and all but two limitations that appear in the remaining claims (12, 21, 25–28, and 33), which do not alter the general subject matter of the claim. *See* POPR 42-43. Thus, the parallel litigation will resolve many key issues in the Petition.

Overlapping grounds—The prior art grounds also overlap enough to weigh against institution. Here, again, the Board looks to whether the overlap in issues “may result in duplication of work and create the potential for inconsistent decisions.” *Clear Imaging*, IPR2020-01399, Paper 13 at 24 (citing *Apple Inc. v. Maxell, Ltd.*, IPR2020-00203, Paper 12 at 14) (PTAB June 4, 2020). In *Clear Imaging*, the Board found a potential for duplication of work and inconsistent decisions even though the petitioner had stipulated that it would “not pursue district court invalidity challenges based on the petition’s asserted grounds or grounds sharing the same primary reference,” *Clear Imaging*, IPR2020-01399, Paper 13 at 20 (PTAB June 4, 2020), and the petitioner further raised in its petition two references, Manabe and Suh, that were not at issue in district court, *id.* 7, 23.

The issues in the present Petition overlap with the issues in the district court proceedings at least as much as in *Clear Imaging*. Both challengers argue the claims are invalid over the 2009 Press Release alone. Pet. 34; Ex.2018, 27. They

both rely on the 2q8 and PRN dosing regimens that the 2009 Press Release discloses to argue that five monthly loading doses would be anticipated or obvious. POPR 43–44; Ex.2018, 26–28; Pet. 34–35. Petitioner argues that its addition of Shams and Elman 2010, two references that discuss dosing regimens for Lucentis, makes its grounds distinct over the invalidity challenges raised at trial. Reply 3. But Mylan likewise argued at trial that the Lucentis art showed that monthly doses could be followed by less-frequent doses, Ex.2018, 29; Pet. 35–36, and that the Lucentis art taught five monthly doses, Ex.2018, 29; Pet. 42. Thus, the differences between the base invalidity arguments are insignificant.

Exclusion criteria—Institution of *inter partes* review is likely to lead to duplicative effort and potential conflicting decisions on the exclusion criteria as well. With respect to claim construction, Petitioner correctly notes that the Board tentatively construed the limitation to have no patentable weight in its decision instituting Mylan’s ’601 IPR. Ex.1053, 12–15. The district court’s construction also gave the exclusion criteria no patentable weight. Ex.2014, 29–37. If the Board maintained its construction in its final written decision in the Mylan ’601 IPR (due in January 2024), but the Federal Circuit reversed the district court’s construction, then the Board’s construction in this proceeding would necessarily conflict with either the Board’s own prior construction in the Mylan ’601 IPR or the Federal Circuit’s construction.

Petitioner’s alternative argument that the exclusion criteria would have been obvious creates further likelihood of duplicative effort and conflicting decisions. If it were to reverse the district court’s claim construction, the Federal Circuit would likely remand for the district court to consider validity of the claims that include this limitation. In that scenario, both the district court and the Board would consider the obviousness of this limitation in parallel and could reach different conclusions.

In sum, the substantial overlap in the claims and grounds between the district court litigation and Petition would lead to inefficient, duplicative effort and a possibility of conflicting decisions if the Board were to institute trial. Factor four thus weighs against institution. For the reasons discussed in Patent Owner’s Preliminary Response, the late stage of the district court litigation on these overlapping issues means that factors 1–3 also weigh against institution. POPR 40–42. As it regularly does when litigation is in an “advanced state,” the Board should deny institution here. *Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8, 20 (PTAB Sept. 12, 2018) (precedential).

II. PETITIONER’S OBJECTIONS TO THE TERM “FIXED” ARE INCORRECT AND INCONSEQUENTIAL

Petitioner does not dispute that the claims require a specific, invariable schedule of doses, yet Petitioner objects to describing that schedule as “fixed.” Petitioner’s semantic quibble appears motivated by the fact that none of the prior

art describes even one instance of aflibercept being dosed on the specific claimed schedule of five monthly loading doses followed by doses every eight weeks.

Thus, Petitioner's validity challenges are premised on its rote speculation that as-needed (PRN) dosing might coincidentally result in the claimed regimen.

Petitioner's new arguments on reply are contradicted by its own evidence and by the '601 patent itself. Indeed, Petitioner's expert describes non-PRN dosing required by the labels of the major VEGF antagonists (including, in the case of Eylea, the claimed schedule) as "fixed dosing schedules," contrasting them with administering the drugs "at frequencies that vary based on physician preference and individual patient response." Ex.1002 ¶ 61. Petitioner's preferred nomenclature is inconsistent with the patent itself, which refers to dosing on a particular schedule as "fixed interval" dosing, Ex.1001, 8:39–44, and reserves the terms "as needed" or "PRN" for dosing according to retreatment criteria, *id.* 14:60–65, 15:29–34. Petitioner's references also describe dosing on a particular schedule as "fixed." Ex.1008, 4 (describing Phase II trial's "fixed dosing period"); Ex.1005 (same).

The exemplary claim Petitioner discusses proves the point: Claim 10 requires dosing "approximately every 4 weeks for the first 5 injections followed by 2 mg approximately once every 8 weeks or once every 2 months." Reply 7. That claim language stands in stark contrast to other claims in the same family, which

require dosing “on an as-needed/pro re nata (PRN) basis, based on visual and/or anatomical outcomes as assessed by a physician or other qualified medical professional.” U.S. Patent No. 9,669,069 at 21:50–54. Thus, Petitioner, not Patent Owner, is engaging in backdoor (and belated) claim construction, in an attempt to shoehorn PRN dosing into the scope of the claims. In contrast, Patent Owner is giving the claim language its plain and ordinary meaning. No formal claim construction is needed to see that claim 10 would not be met by a physician who *varied* the label regime for Eylea to administer three initial monthly doses instead of five. An appropriate term for a dosing regimen that does not permit variations is “fixed.”¹

Petitioner’s quotes from the specification do not refute this. Petitioner cites a portion of the specification that, after discussing various fixed regimens, differentiates them from assessment-based dosing by stating that “[t]he frequency of administration may *also* be adjusted during the course of treatment . . .” Ex.1001, 4:32–46 (emphasis added). The specification describes some

¹ It is also appropriate to describe such a dosing regimen as “predetermined.” A blueprint for a house includes predetermined measurements, even if it is theoretically possible that someone constructing a house by trial-and-error may chance upon those measurements.

embodiments where dosing is fixed (like the claims) and others where dosing is not fixed, but the claims of the '601 patent are drawn to the former. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015) (“every claim does not need to cover every embodiment”).

Nor are the exclusion criteria limitations that Petitioner references, Reply 8, indicative of PRN dosing; rather, they identify the screening physicians must perform in connection with administering the fixed dosing schedules of the claimed methods. And notwithstanding Petitioner’s view that claims 12, 21, and 28 “make[] no sense,” they likewise recite dosing on a particular schedule and are not satisfied by variations on it.

Semantics aside, the final two pages of the Reply make clear that Petitioner recognizes the distinction the POPR draws between assessment-based regimens like those disclosed in Shams or Elman 2010, and the fixed dosing of the 2009 Press Release’s 2q8 regimen. Reply 9–10. No matter whether “fixed” or some other term is used to describe it, Petitioner implicitly recognizes that the dosing regimen disclosed in the 2009 Press Release is not the same as the regimen described in the Challenged Claims. Petitioner is forced to argue either that the disclosure of three loading doses would make *any* number of loading doses obvious (despite the absence of any results in the 2009 Press Release or elsewhere that would motivate injecting additional drug into a patient’s eye) or, alternatively,

that it would be obvious to combine the 2009 Press Release with the very different class of references disclosing assessment-based dosing. POPR 11–37. Petitioner’s failure—even on Reply—to articulate any motivation to combine these two different types of references, further demonstrates that institution should be denied.

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE was served on the below date on the Petitioner via e-mail (by consent) to the following counsel of record:

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