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Paper No. 7
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

Case IPR2018-01183
Patent 6,943,166 B1

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

INTRODUCTION

Aquestive Therapeutics, Inc., formerly MonoSol Rx, LLC ("Petitioner"), filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–12 of U.S. Patent No. 6,943,166 B1 (Ex. 1001, "the '166 patent"). ICOS Corporation ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

For the reasons provided below, we deny institution of an *inter partes* review. *See* 35 U.S.C. § 314(a).

Related Proceedings

According to the parties, Patent Owner asserted the '166 patent against numerous entities, but not Petitioner, in the district courts. Pet. 59; Paper 5, 1–2.

We previously denied a petition for *inter partes* review of the same challenged claims filed by IntelGenX Corporation. IPR2016-00678, Paper 13. Thereafter, IntelGenX filed a request for rehearing, and we authorized Patent Owner to file a responsive brief. IPR2016-00678, Papers 14, 15. Before Patent Owner filed any responsive briefing, Petitioner withdrew its request, and we terminated that proceeding. IPR2016-00678, Papers 16, 17.

The '166 patent is the subject of IPR2017-00323, filed by Mylan Pharmaceuticals Inc. We instituted an *inter partes* review in that case. IPR2017-00323, Paper 12. Because the parties later settled, we terminated that proceeding as well. IPR2017-00323, Paper 19.

The '166 patent is also the subject of IPR2017-01757 and IPR2017-01762, filed by Dr. Reddy's Laboratories, Inc. and Argentum Pharmaceuticals LLC, respectively. Each of those petitioners also sought to

join the Mylan case. Before we decided on either petition, however, the parties settled. We, thus, terminated those proceedings. IPR2017-01757, Paper 12; IPR2017-01762, Paper 11.

Petitioner here, under its former name MonoSol, filed IPR2017-00412, challenging claims 1–12 of the '166 patent. After substantive analysis, we denied that petition. IPR2017-00412, Paper 18.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds, each of which challenges the patentability of claims 1–12:

Basis	Reference(s)
§ 103	Daugan,[1] SNDA,[2] and the FDA Guideline[3]
§ 103	Daugan, SNDA, the FDA Guideline, and Cutler[4]
§ 103	Daugan, SNDA, the FDA Guideline, and Ruberg[5]

DISCUSSION

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), "the PTO is permitted, but never compelled, to institute an IPR proceeding"). When determining whether to

[1] Daugan, WO 97/03675, published Feb. 6, 1997 (Ex. 1005).
[2] Center for Drug Evaluation and Research, Approval Package for VIAGRA®, Approval Date March 27, 1998 (Ex. 1011, "SNDA").
[3] Dose-Response Information to Support Drug Registration, 59 Fed. Reg. 55972 (Nov. 9, 1994) (Ex. 1014, "the FDA Guideline").
[4] Cutler, et al., *Defining the Maximum Tolerated Dose: Investigator, Academic, Industry and Regulatory Perspectives*, 37 J. CLIN. PHARMACOL. 767–83 (1997) (Ex. 1016).
[5] Ruberg, *Dose Response Studies I. Some Design Considerations*, 5 J. BIOPHARM. STAT. 1–14 (1995) (Ex. 1018).

exercise our discretion under § 314(a), we consider the following non-exhaustive factors:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19, 15–16 (PTAB Sept. 6, 2017) (precedential).

After weighing these factors, we agree with Patent Owner that it is appropriate to deny institution of this second petition by Petitioner challenging the same claims of the '166 patent. *See* Prelim. Resp. 5–21.

The first two factors, for example, weigh heavily in favor of denying institution. Petitioner, under its former name MonoSol, previously unsuccessfully challenged the same claims of the '166 patent in IPR2017-00412. And at the time of filing IPR2017-00412, Petitioner knew

of at least four of the five references asserted here (Daugan, SNDA, the FDA Guideline, and Cutler). Regarding Ruberg, the only newly asserted prior art in this case, Petitioner states that it "was not previously known to Aquestive (or MonoSol) until a few weeks" before it filed this Petition. Pet. 5. But Ruberg was originally published in the Journal of Biopharmaceutical Statistics in 1995, and was published online in 2007. Petitioner should have known of Ruberg, and provides no explanation of why it was unaware of it.

Other factors also weigh in favor of denying institution. At the time of filing this Petition, Petitioner not only received Patent Owner's preliminary response but also our initial decision denying IPR2017-00412 and the decision denying its rehearing request. Patent Owner provides detailed accounts of how Petitioner used those decisions as a roadmap to reformulate its argument. Prelim. Resp. 9–13. We agree with Patent Owner's analysis.

In addition, Petitioner filed this Petition 18 months after filing IPR2017-00412 without reasonable justification. Petitioner argues that it "had considered a joinder with Mylan's granted Petition [i.e., IPR2017-00323], however, Mylan settled out of proceedings on July 7, 2017, making joinder legally impossible." Pet. 3. But in IPR2017-00323, we granted that petition on June 12, 2017, nearly a month before the parties filed their joint motion to terminate the proceeding. Petitioner had at least four weeks to join IPR2017-00323 after institution, but did not do so. *See* 37 C.F.R. § 122(b) (stating a party has up to one month after the institution date of the case it seeks to join to file a joinder motion).

Petitioner also analogizes this case with *Panduit Corp. v. CCS Technology Inc.*, IPR2017-01375, where a Board panel instituted review

based on a follow-on petition. Pet. 4. We are not persuaded by this argument that we should address the merits of this Petition. Putting aside other factual differences between the two cases, we reject Petitioner's argument that "Petitioner had relied on a proffered declaration supporting public accessibility [of two references asserted in its earlier Petition in IPR2017-00412], which is not unreasonable." *Id.* In Petitioner's previous case, we explained that those two references discussed events with dates after the priority date of the '166 patent. IPR2017-00412, Paper 11, 10–11. Petitioner's reliance on a declaration that was not supported by the references themselves, thus, was unreasonable. It certainly does not provide Petitioner with another opportunity to, using our previous decisions as a roadmap, challenge the same claims anew.

Under the totality of the circumstances in this case, we exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition.

ORDER

Accordingly, it is

ORDERED that Petitioner's request for an *inter partes* review of claims 1–12 of the '166 patent is *denied* and no *inter partes* review is instituted.

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