UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DAIICHI SANKYO, INC. AND
ASTRAZENECA PHARMACEUTICALS, LP
Petitioner,

v.

SEAGEN INC.
Patent Owner.

Case No. PGR2021-00030
Patent 10,808,039

PATENT OWNER'S REHEARING REQUEST

Ex. No.	Description
Ex. 2001	*Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex. Feb. 8, 2021), Dkt. 48
Ex. 2002	Seagen Inc.'s Disclosure of Asserted Claims and Infringement Contentions, *Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex.), dated Jan. 6, 2021
Ex. 2003	Defendant's Invalidity Contentions, *Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex.), dated Mar. 3, 2021
Ex. 2004	*Daiichi Sankyo, Inc. v. Seagen Inc.*, No. 1:20-cv-01524-LPS (D. Del. Dec. 18, 2020), Dkt. 11
Ex. 2005	*Daiichi Sankyo, Inc. v. Seagen Inc.*, No. 1:20-cv-01524-LPS (D. Del. Jan. 18, 2021), Dkt. 19
Ex. 2006	*Daiichi Sankyo, Inc. v. Seagen Inc.*, No. 1:20-cv-01524-LPS (D. Del. Jan. 26, 2021), Dkt. 20 (public version)
Ex. 2007	Argument by Telephone Conference, *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. 1:20-cv-01524-LPS (D. Del. Apr. 23, 2021)
Ex. 2008	*Daiichi Sankyo Co., Ltd. v. Seattle Genetics, Inc.*, No. 1:19-cv-02087-CFC (D. Del. Nov. 22, 2019), Dkt. 13
Ex. 2009	*Daiichi Sankyo Co., Ltd. v. Seattle Genetics, Inc.*, No. 1:19-cv-02087-LPS (D. Del. Mar. 25, 2020), Dkt. 31
Ex. 2010	*Daiichi Sankyo Co., Ltd. v. Seattle Genetics, Inc.*, No. 1:19-cv-02087-LPS (D. Del. Nov. 13, 2020), Dkt. 44
Ex. 2011	Gene M. Dubowchik and Michael A. Walker, Receptor-mediated and enzyme-dependent targeting of cytotoxic anticancer drugs, 83 Pharm. & Therapeutics 67-123 (1999)
Ex. 2012	Franciscus M.H. de Groot et al., Anticancer Prodrugs for Application in Monotherapy: Targeting Hypoxia, Tumor-Associated Enzymes, and Receptors, 8 Current Med. Chem. 1093-1122 (2001)

Ex. No.	Description
Ex. 2013	Nitin K. Damle, Tumour-targeted chemotherapy with immunoconjugates of calicheamicin, Expert Op. 1445-1452 (2004)
Ex. 2014	Franciscus M.H. de Groot et al., Synthesis and Biological Evaluation of Novel Prodrugs of Anthracyclines for Selective Activation by the Tumor-Associated Protease Plasmin, 42(25) J. Med. Chem. 5277-5283 (Dec. 16, 1999)
Ex. 2015	Damon L. Meyer and Peter D. Senter, Chapter 23. Recent Advances in Antibody Drug Conjugates for Cancer Therapy, 38 Annual Rep. in Med. Chem. 229-237 (2003) ("Meyer & Senter 2003")
Ex. 2016	Raya Mandler et al., Synthesis and Evaluation of Antiproliferative Activity of a Geldanamycin-Herceptin™ Immunoconjugate, 10 Bioorganic & Med. Chem. Ltrs. 1025-1028 (2000)
Ex. 2017	Anna M. Wu and Peter D. Senter, Arming antibodies: prospects and challenges for immunoconjugates, 23(9) Nature Biotech. 1137-1146 (Sept. 2005)
Ex. 2018	Brian E. Toki et al., Protease-Mediated Fragmentation of p-Amidobenzyl Ethers: A New Strategy for the Activation of Anticancer Prodrugs, 67 J. Org. Chem. 1866-1872 (2002)
Ex. 2019	Yelena V. Kovtun and Victor S. Goldmacher, Cell killing by antibody–drug conjugates, 255 Cancer Ltrs 232-240 (2007)
Ex. 2020	Michael A. Walker et al., Synthesis of an Immunoconjugate of Camptothecin, 12 Bioorganic & Med. Chem. Ltrs. 217-219 (2002)
Ex. 2021	Requests for Correction of Inventorship in Provisional Patent Application for Application Nos. 60/557,116 and 60/598,899, filed on Nov. 29, 2004

Ex. No.	Description
Ex. 2022	Public Pair Application Data Tab for Provisional Application Nos. 60/598,899 and 60/557,116, retrieved from https://portal.uspto.gov/pair/PublicPair, on Mar. 8, 2021
Ex. 2023	*Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex. Jan. 7, 2021), Dkt. 33 (public version)
Ex. 2024	Lex Machina, Motion Metrics Report for District Judge James Rodney Gilstrap (JRG)
Ex. 2025	*Daiichi Sankyo, Inc. v. Seagen Inc.*, No. 1:20-cv-01524-UNA (D. Del. Nov. 13, 2020), Dkt. 4
Ex. 2026	U.S. Patent No. 9,808,537 (Masuda et al.)
Ex. 2027	Gene M. Dubowchik and Raymond A. Firestone, Cathepsin B-Sensitive Dipeptide Prodrugs. 1. A Model Study of Structural Requirements for Efficient Release of Doxorubicin, 8 Bioorganic & Med. Chem. Ltrs. 3341-3346 (1998)
Ex. 2028	Gene M. Dubowchik et al., Cathepsin B-Sensitive Dipeptide Prodrugs. 2. Models of Anticancer Drugs Paclitaxel (Taxol®), Mitomycin C and Doxorubicin, 8 Bioorganic & Med. Chem. Ltrs. 3347-3352 (1998)
Ex. 2029	Svetlana O Doronina et al., Development of potent monoclonal antibody auristatin conjugates for cancer therapy, 21(7) Nature Biotech. 778-784, 941 (2003)
Ex. 2030	Franciscus M.H. de Groot et al., Synthesis and Biological Evaluation of 2'-Carbamate-Linked and 2'-Carbonate-Linked Prodrugs of Paclitaxel: Selective Activation by the Tumor-Associated Protease Plasmin, 43(16) J. Med. Chem. 3093-3102 (Aug. 10, 2000)
Ex. 2031	Ravi V. J. Chari et al., Immunoconjugates Containing Novel Maytansinoids: Promising Anticancer Drugs, 52 Cancer Res. 127-131 (Jan. 1, 1992)

Ex. No.	Description
Ex. 2032	H. Dalton King et al., Monoclonal Antibody Conjugates of Doxorubicin Prepared with Branched Peptide Linkers: Inhibition of Aggregation by Methoxytriethyleneglycol Chains, 45 J. Med. Chem. 4336-4343 (2002)
Ex. 2033	Joseph A. Francisco et al., cAC10-vcMMAE, an anti-CD30-monomethyl auristatin E conjugate with potent and selective antitumor activity, 102(4) Blood 1458-1465 (Aug. 15, 2003)
Ex. 2034	Che-Leung Law et al., Efficient Elimination of B-Lineage Lymphomas by Anti-CD20-Auristatin Conjugates, 10 Clin. Cancer Res. 7842-7851 (Dec. 1, 2004)
Ex. 2035	157 CONG. REC. S1373 (daily ed. Mar 8, 2011)
Ex. 2036	157 CONG. REC. S1179 (daily ed. Mar. 3, 2011)
Ex. 2037	Collection of Judge J. Rodney Gilstrap's orders granting stipulated, unopposed, or patent owner-initiated motions to stay after institution of parallel PTAB proceedings.
Ex. 2038	Collection of Judge J. Rodney Gilstrap's orders granting opposed challenger-initiated motions to stay after institution of parallel PTAB proceedings.
Ex. 2039 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex. April 4, 2022), Dkt. 361 (Minutes for Jury Selection/Jury Trial Day No. 1 Held Before U.S. District Judge Rodney Gilstrap)
Ex. 2040 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex. April 4, 2022), Dkt. 369 (Verdict Form)
Ex. 2041 **[NEW]**	Attorney's Docket No.: 49223-0019011/1000-00369US, Disclaimer Under 35 U.S.C. § 253(A) and 37 C.F.R. § 1.321(A)

Ex. No.	Description
Ex. 2042 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex. April 4-7, 2022), trial transcript excerpts addressing written description
Ex. 2043 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex. April 4-7, 2022), trial transcript excerpts addressing enablement
Ex. 2044 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex April 4-7, 2022), trial transcript excerpts addressing purported failure to particularly point out and distinctly claim that which the inventor or a joint inventor regards as his or her invention
Ex. 2045 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex April 4-7, 2022), trial transcript excerpts addressing purported anticipation by Ogitani
Ex. 2046 **[NEW]**	*Seagen Inc. v. Daiichi Sankyo, Co., Ltd.*, No. 2:20-cv-00337-JRG (E.D. Tex April 8, 2022), trial transcript excerpts addressing jury instructions

Pursuant to 37 C.F.R. § 42.71(d), Seagen requests rehearing of the Board's Decision Granting Petitioner's Request on Rehearing and Granting Institution of Post-Grant Review of U.S. Patent No. 10,808,039 ("Rehearing Decision") (Paper 17).

I. INTRODUCTION

The Board should reconsider its Rehearing Decision and use its discretion to deny institution in view of new important facts since its decision. The Rehearing Decision relies on the Board's decision to institute trial in a parallel PGR proceeding (PGR2021-00042) involving only claims 6-8 of the '039 patent, and grants Petitioner's rehearing request in view of its institution in that proceeding as well as the "merits" of Petitioner's lack of enablement argument for claims 1-5, 9, and 10. But the Board's bases for instituting this proceeding are no longer applicable: a jury has returned a verdict in favor of Seagen on invalidity of the remaining '039 patent claims 1-5, 9, and 10, including on the issue of enablement, and Seagen has disclaimed claims 6-8, the only claims which were not adjudicated at the district court proceeding.

Moreover, the Board's preliminary view on the merits of Petitioner's invalidity arguments cannot outweigh the numerous other *NHK Spring* and *Fintiv* factors that favor denial. Continuing with this proceeding would result in duplicative efforts and potentially conflicting results between the district court and

the Board. This is especially true given the advanced stage of the district court proceedings, where the jury returned a verdict finding claims 1-5, 9, and 10 not invalid after considering the very same arguments in the Petition here. In light of these new developments, the Board should order rehearing and exercise its discretion to deny institution in this proceeding.

II. BACKGROUND

Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP ("Petitioner") filed the present Petition on December 23, 2020, requesting post-grant review of claims 1–5, 9, and 10 of U.S. Patent No. 10,808,039 B2 (Ex. 1001, "the '039 patent"). (Paper 1.) Petitioner also filed a separate Petition on January 22, 2021, requesting post-grant review of claims 6-8 of the '039 patent. (PGR2021-00042 (the "042 Proceeding"), Paper 1). On June 24, 2021, the Board denied institution of both petitions under 35 U.S.C. § 324(a) in view of the *Fintiv* factors, including the consideration that trial on identical issues of invalidity was scheduled nearly four months before the estimated time for issuing a final written decision. (Paper 11 at 14, 17; PGR2021-00042, Paper 12 at 14-5.)

On July 26, 2021, Petitioner filed requests for rehearing and concurrently requested that the Board's Precedential Opinion Panel ("POP") reconsider its decisions denying institution. (Paper 13; Ex. 3001; PGR2021-00042 Paper 12 ("POP Requests").) Petitioner argued that because Seagen had dropped claims 6-8

of the ’039 patent from its infringement suit, *Fintiv* no longer applied in this proceeding. (*Id*.) On September 17, 2021, the POP declined to review the issues raised in Petitioner’s POP Requests, so the Board proceeded to Petitioner’s rehearing requests. (Paper 16; PGR2021-00042, Paper 17.)

A half a year passed, and trial began on April 4, 2022 in the district court litigation on issues of infringement and invalidity of the ’039 patent. (*See* Ex. 2039.) Three days later, on April 7, 2022 the Board issued its decision granting Petitioner’s rehearing request. The jury returned a verdict the day after, on April 8, 2022, finding that Defendants had failed to prove that asserted claims 1-5, 9, and 10 are invalid, and that Seagen had successfully proven that Defendants willfully infringed the asserted claims. (*Id.*; Ex. 2040.) On April 20, 2022, Seagen disclaimed claims 6-8 of the ’039 patent, which are the subject of the parallel 042 Proceeding. (*See* Ex. 2041.)

III. ARGUMENT

A. Claims 6-8 Are No Longer at Issue in the Parallel Proceeding

In ordering institution in the 042 Proceeding, the Board noted that claims 6-8 were dropped from the district court litigation between the parties, such that the validity of those claims would not be addressed in court. (Paper 17 at 6-7.) The Board then relied on its institution of the 042 Proceeding to institute review in this proceeding, reasoning that the two PGR proceedings had almost identical issues,

such that considerations of inefficiency, duplicative efforts, and conflicting results no longer applied. (*Id.* at 7.) [1]

Seagen disclaimed claims 6-8 of the '039 patent on April 20, 2022. (Ex. 2041.) In view of Seagen's disclaimer of claims 6-8, the 042 Proceeding should be terminated because there are no longer any remaining claims in that proceeding. *Advanced Micro Devices, Inc. v. Polaris Innovations Ltd.*, IPR2019-01514, 2020 WL 4458075, at *2 (P.T.A.B. Aug. 3, 2020). And with the termination of the 042 Proceeding, the Board's primary basis for instituting this proceeding—i.e., claims 6-8 being addressed in the 042 Proceeding but having been dropped from the district court litigation—no longer exists. (*See* Paper 17 at 6-7.) The Board should therefore terminate the 042 Proceeding and deny review of the present proceeding.

[1] Petitioner did not challenge claims 6-8 on grounds separate from the claims on which they depend, such that there was complete overlap between invalidity of claims 6-8 and that of the remaining claims in the district court litigation. (PGR2021-00042, Paper 8 at 18, 32-33.) Thus, under the *Fintiv* analysis, the grounds for invalidity were identical between the two PGRs and the district court litigation regardless of claims 6-8.

B. Petitioner's Arguments Have Been Rejected by a Fact Finder

In its Rehearing Decision, the Board also relied on its preliminary view on the merits of Petitioner's argument that the claims lack enablement. (Paper 17 at 3, 40-41.) But after a full trial on the merits of claim 1-5, 9, and 10, a jury rejected Petitioner's enablement defense, as well as Petitioner's other invalidity defenses. The jury heard testimony from fact and expert witnesses for both parties, including Seagen's expert witness (Dr. Carolyn Bertozzi), from whom the Board has not yet heard. The jury found that Defendants had failed to prove that the asserted claims are invalid, and that Seagen had successfully proven Defendants infringed the asserted claims. Defendants' defenses of written description, enablement, and anticipation were the *same* as the grounds in the Petition. Thus, a jury has already determined that Petitioner's invalidity arguments, including its lack of enablement argument, lack merit.

C. The *Fintiv* Factors Weigh Against Institution

Any "merits" of Petitioner's invalidity arguments cannot outweigh the numerous other *NHK Spring* and *Fintiv* factors that favor denial. The underlying rationales behind exercising discretionary review in *NHK Spring* and *Fintiv*—such as avoiding duplicative efforts and conserving resources—are squarely applicable here where a trial verdict *has already been reached* one year before the statutory deadline for the final written decision in this proceeding.

1. *Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted*

This factor strongly favors denial. The Texas district court did not grant a stay.[2] Indeed, the district court litigation involving claims 1-5, 9, and 10—the exact claims challenged in this proceeding—went to trial on April 4, 2022 and concluded in a jury verdict on April 8, 2022. (*See* Ex. 2040.)

2. *Proximity of the court's trial date to the Board's statutory deadline for a final written decision*

This factor also strongly favors denial. As discussed above, trial in the district court litigation addressing all challenged claims in this proceeding began on April 4, 2022 and concluded on April 8, 2022. The statutory deadline for a Final Written Decision in this proceeding is in April 2023—one year *after* trial in the district court litigation. The Board previously found that this factor weighed towards denying institution when trial was scheduled to occur four months *prior* to the anticipated date for a final written decision. (Paper 11 at 14-15.) Now that trial has already been completed, this factor weighs even more strongly towards denying institution.

[2] Although *Daiichi Sankyo, Inc. et al. v. Seattle Genetics, Inc*., No. 1:20-cv-01524-LPS (D. Del.) has been stayed, it was stayed pending the Texas district court litigation, which resolved many of the issues of the Delaware litigation.

3. *Investment in the parallel proceeding by the court and the parties*

This is another factor that strongly favors denial. The district court and the parties have already expended all of the resources necessary to prepare for and bring the district court litigation to completion in the form of a trial—indisputably a significant undertaking and investment.

4. *Overlap between issues raised in the petition and in the parallel proceeding*

This factor, too, strongly favors denial. Under *Fintiv*, "if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial" because "concerns of inefficiency and the possibility of conflicting decisions [are] particularly strong." *Fintiv* at 12. Here, the district court litigation addressed the same claims and grounds as those presented in the Petition.

Petitioner presented four grounds for unpatentability in its Petition: (1) written description; (2) enablement; (3) failing to particularly point out and distinctly claim that which the inventor or a joint inventor regards as his or her invention; and (4) anticipation by Ogitani. The parties addressed each of these grounds during the district court trial. (*See* Ex. 2042 (trial transcript excerpts addressing written description); Ex. 2043 (trial transcript excerpts addressing enablement); Ex. 2044 (trial transcript excerpts addressing purported failure to

particularly point out and distinctly claim that which the inventor or a joint inventor regards as his or her invention); Ex. 2045 (trial transcript excerpts addressing purported anticipation by Ogitani); Ex. 2046 (final jury instructions on validity issues).) Accordingly, this factor weighs in favor of discretionary denial.[3]

5. *Whether the petitioner and the defendant in the parallel proceeding are the same party*

This factor strongly favors denial. As the Board previously found, the real parties in interest in this proceeding are the same parties in the district court litigation. (Paper 11 at 18-19.)

6. *Other circumstances that impact the Board's exercise of discretion, including the merits*

Finally, the merits of the Petition do not outweigh the other *Fintiv* factors that so strongly weigh in favor of discretionary denial of institution. This is especially true given that another forum has already addressed the merits of the Petition and found against them. *See, e.g.*, *Stryker Corp. v. KFx Med. LLC*, No. IPR2019-00817, 2019 WL 4419363, at *9 (P.T.A.B. Sept. 16, 2019) (fact that

[3] While the standard of proof is different between a district court action and a post-grant proceeding, that alone cannot be dispositive for this factor; a different standard of proof always exists when comparing district court and PTAB proceedings.

district court had already addressed validity of challenged claims weighed in favor of denying institution). As discussed above, a jury returned a verdict that Defendants had failed to prove claims 1-5, 9, and 10 are invalid on the basis of written description, enablement, indefiniteness, and anticipation—all the *same* grounds in the Petition. Like the other *Fintiv* factors, this factor thus also weighs strongly in favor of discretionary denial of institution.

IV. CONCLUSION

In view of Seagen's disclaimer of claims 6-8, the jury verdict in favor of Seagen on all invalidity grounds for claims 1-5, 9, and 10, and the *Fintiv* factors strongly favoring denial, Board should reconsider its Rehearing Decision (Paper 17) and deny institution. Continuing with this proceeding would result in duplicative efforts and potentially conflicting results between the district court and the Board. It would also unfairly give Petitioner a second bite at the apple on validity issues on which a jury has already made a determination.

Dated: April 21, 2022

Respectfully submitted,

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

I hereby certify that the attached PATENT OWNER'S REHEARING REQUEST was served as of the below date via email on the Petitioner at the following correspondence address:

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