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Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SEAGEN INC.,
Patent Owner.

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Case PGR2021-00030
Patent 10,808,039 B2

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Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and CHRISTOPHER M. KAISER, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
*35 U.S.C. § 324*

# I. INTRODUCTION

Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP (collectively "Petitioner") filed a Petition requesting a post-grant review of claims 1–5, 9, and 10 of U.S. Patent No. 10,808,039 ("the '039 patent," Ex. 1001). Paper 1 ("Pet."). Seagen Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). Petitioner filed a Reply to Patent Owner's Preliminary Response. Paper 8 ("Reply"). Patent Owner filed a sur-reply to Petitioner's Reply. Paper 9 ("Sur-reply").

We have authority to determine whether to institute a post-grant review. 35 U.S.C. § 324(c); 37 C.F.R. § 42.4(a). The standard is set forth in § 324(a), which provides that a post-grant review shall not be instituted unless "the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."

After considering the Petition and the Preliminary Response, and the evidence cited therein, we exercise our discretion under 35 U.S.C. § 324(a) to deny institution.

## *A. Real Parties in Interest and Related Proceedings*

Petitioner identifies Daiichi Sankyo Company, Limited and AstraZeneca UK Limited and Petitioners Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP as real parties in interest. Pet. 88.

Patent Owner identifies Seagen Inc. as a real party in interest. Paper 5, 1.

*B. Related Matters*

Petitioner filed a separate Petition for post-grant review of Claims 6–8 of the '039 patent as IPR2021-00042.

The parties list the following co-pending matters:

*Daiichi Sankyo Co., Ltd. v. Seattle Genetics, Inc.*, No. 1:19-cv-02087-LPS (D. Del.) (closed Nov. 13, 2020);

*Seattle Genetics, Inc. v. Daiichi Sankyo Co., Ltd.*, American Arbitration Association Case No. 01-19-0004-0115 (Brown, Arb.);

*Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 2:20-cv-00337 (E.D. Tex.) ("the Texas Litigation");

*Daiichi Sankyo, Inc. et al. v. Seattle Genetics, Inc*., No. 1:20-cv-01524-LPS (D. Del.) ("the Delaware Litigation"). Pet. 83; Paper 5, 1.

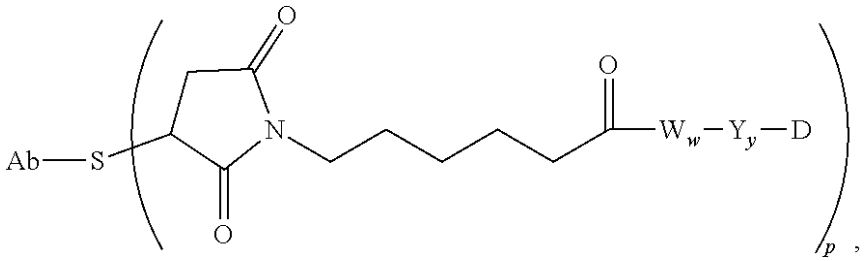
Patent Owner identifies the following US patents and pending published applications that claim the benefit of priority of the filing date of the '039 patent: US 7,498,298; US 7,994,135; US 7,964,566; US 7,964,567; US 7,745,394; US 8,703,714; US 8,557,780; US 10,414,826; US 10,808,039; US 2020/0347149. Paper 5, 1–2.

*C. The '039 Patent*

The '039 patent discloses antibody-drug conjugates ("ADCs"). Ex. 1001, 1:58–63. "The drug moiety (D) of the [ADCs] are of the dolastatin/auristatin type[,] which have been shown to interfere with

microtubule dynamics, GTP hydrolysis, and nuclear and cellular division." *Id.* at 71:21–25 (citations omitted).

Embodiments of this invention can take many forms, including having the formula:




*Id* at 70:18–30.

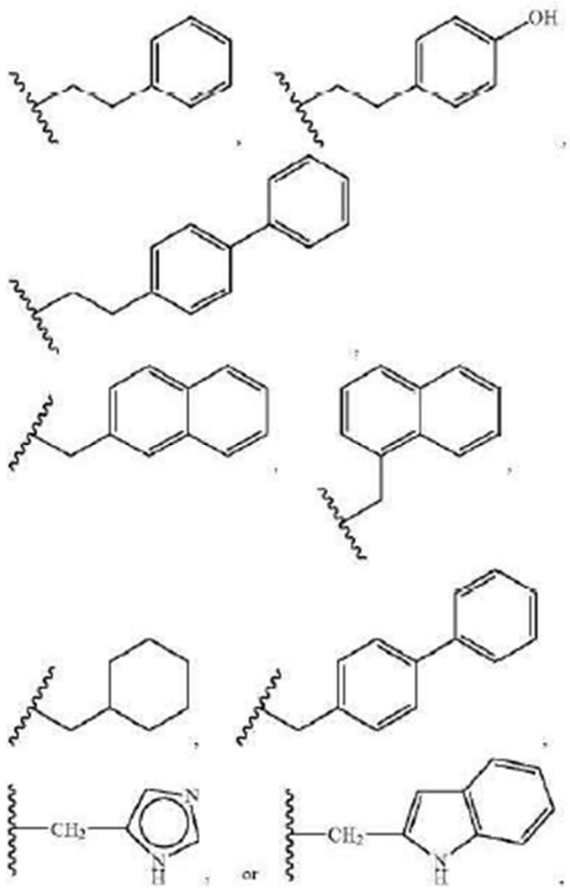
The formula's components can change, such as one embodiment where "an antibody drug conjugate (ADC), or a pharmaceutically acceptable salt or solvate thereof, wherein Ab is an antibody that binds one of the tumor-associated antigens." *Id.* at 111:33–37. Digestion of antibodies can produce two identical antigen-binding fragments, called "Fab" fragments. *Id.* at 27:14–15. Fab fragments can differ, such as some including a few cysteine residues at the carboxy terminus of the heavy chain $CH_3$ domain and at least one free thiol group. *Id.* at 27:36–43.

In some units, there is a Stretcher unit that, when present, is capable of linking a Ligand unit to an amino acid unit. For example, in one embodiment, "the Stretcher unit forms a bond with a sulfur atom of the Ligand unit. The sulfur atom can be derived from a sulfhydryl group of a Ligand." *Id.* at 63:54–56.

The peptide unit on the ADC can vary in size. The peptide unit can be a "dipeptide, tripeptide, tetrapeptide, pentapeptide, hexapeptide,

heptapeptide, octapeptide, nonapeptide, decapeptide, undecapeptide or dodecapeptide unit." *Id.* at 65:49–53.

The $R^{19}$ groups on the peptide chain can be selected from, but is not limited to, the groups of "hydrogen, methyl, isopropyl, isobutyl, sec-butyl, benzyl, p-hydroxybenzyl, —$CH_2OH$, —$CH(OH)CH_3$, —$CH_2CH_2SCH_3$, —$CH_2CONH_2$, —$CH_2COOH$, —$CH_2CH_2CONH_2$, —$CH_2CH_2COOH$, —$(CH_2)_3NHC(=NH)NH_2$, —$(CH_2)_3NH_2$, —$(CH_2)_3NHCOCH_3$, —$(CH_2)_3NHCHO$, —$(CH_2)_4NHC(=NH)NH_2$, —$(CH_2)_4NH_2$, —$(CH_2)_4NHCOCH_3$, —$(CH_2)_4NHCHO$, —$(CH_2)_3NHCONH_2$, —$(CH_2)_4NHCONH_2$, —$CH_2CH_2CH(OH)CH_2NH_2$, 2-pyridylmethyl-, 3-pyridylmethyl-, 4-pyridylmethyl-, phenyl, cyclohexyl,




*Id.* at 65:65–66:43.

The spacer unit, Y, "when present, links an Amino Acid unit to the Drug moiety when an Amino Acid unit is present." *Id.* at 68:14–16. In some embodiments, "y is 0, 1, or 2." *Id.* at 6:47. The average number of drugs per antibody in a molecule of a particular formula, p, can range from 1 to 20 (D) drugs per antibody. *Id.* at 61:44–46.

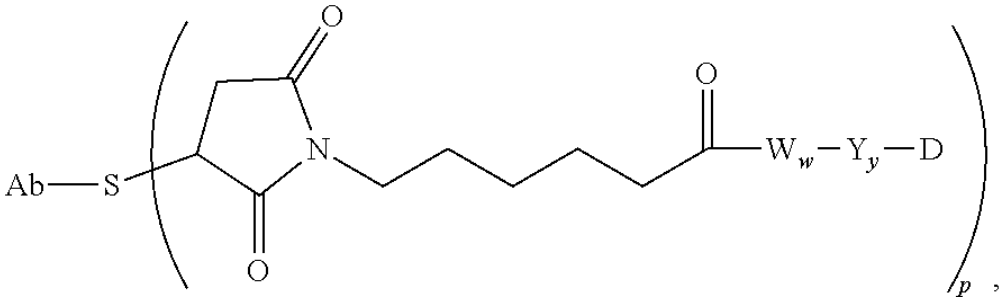
In some embodiments of the invention, "a substantial amount of the drug moiety is not cleaved from the antibody until the antibody-drug conjugate compound enters a cell with a cell-surface receptor specific for the

antibody of the antibody-drug conjugate, and the drug moiety is cleaved from the antibody when the antibody-drug conjugate does enter the cell." *Id.* at 18:56–61. In other aspects of the invention, "the bioavailability of the [ADC] or an intracellular metabolite . . . is improved when compared to a drug compound comprising the drug moiety of the [ADC], or when compared to an analog of the compound not having the drug moiety." *Id.* at 18:62–67.

*D. Illustrative Claim*

Claim 1, the only independent claim, is illustrative and reproduced below.

1. An antibody-drug conjugate having the formula:

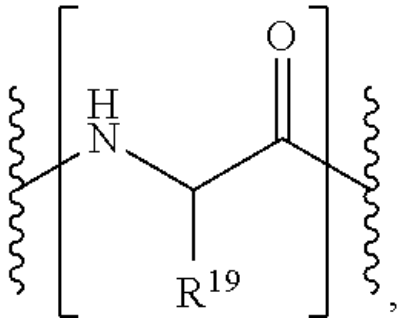



or a pharmaceutically acceptable salt thereof, wherein:

Ab is an antibody,

S is sulfur,

each —$W_w$— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein $R^{19}$ is hydrogen or benzyl,

Y is a Spacer unit,

y is 0, 1 or 2,

D is a drug moiety, and

p ranges from 1 to about 20,

wherein the S is a sulfur atom on a cysteine residue of the antibody, and

wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate.

Ex. 1001, 331:36–332:40.

*E. The Asserted Grounds of Unpatentability*

Petitioner asserts the challenged claims are unpatentable on the following grounds:

| Basis/Reference | Statutory Basis | Challenged Claims |
|---|---|---|
| Written Description | § 112(a) | 1–5, 9, 10 |
| Enablement | § 112(a) | 1–5, 9, 10 |
| Failing to particularly point out and distinctly claim that which the inventor or a joint inventor regards as his or her invention | § 112(b) | 1–5, 9, 10 |
| Ogitani[1] | § 102 | 1–5, 9, 10 |

Pet. 5.

Petitioner relies on the Declaration of Dr. John M. Lambert, Ph.D. (Ex. 1002) in support of the Petition.

## II. ANALYSIS

*A. Discretion under 35 U.S.C. § 324*

35 U.S.C. § 324(a) states that

> [t]he Director may not authorize a post-grant review to be instituted unless the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more

[1] Ex. 1009, Ogitani, Yusuke et al., *Bystander Killing Effect of DS-8201a, a Novel Anti-Human Epidermal Growth Factor Receptor 2 Antibody-Drug Conjugate, in Tumors with Human Epidermal Growth Factor Receptor 2 Heterogeneity*, 107 CANCER SCI. 1039 (June 22, 2016) ("Ogitani").

> likely than not that at least 1 of the claims challenged in the petition is unpatentable.

The portion of the statute reading "[t]he Director may not authorize . . . unless" mirrors the language of 35 U.S.C. § 314(a), which concerns *inter partes* review. This language of sections 314(a) and 324(a) provides the Director with discretion to deny institution of a petition. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); Consolidated Trial Practice Guide November 2019 ("TPG")[2] at 55.

In exercising the Director's discretion under 35 U.S.C. §§ 314(a) and 324(a), the Board may consider "events in other proceedings related to the same patent, either at the Office, in district courts, or the ITC." TPG at 58. The Board's precedential *NHK Spring* decision explains that the Board may consider the advanced state of a related district court proceeding, among other considerations, as a "factor that weighs in favor of denying the Petition under § 314(a)." *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential).

Additionally, the Board's precedential *Fintiv* Order identifies several factors to be considered when analyzing issues related to the Director's discretion to deny institution, with the goal of balancing efficiency, fairness, and patent quality. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) ("the *Fintiv* Order"). These factors include: 1) whether a stay exists or is likely to be granted if a

[2] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

proceeding is instituted; 2) proximity of the court's trial date to the Board's projected statutory deadline; 3) investment in the parallel proceeding by the court and parties; 4) overlap between issues raised in the petition and in the parallel proceeding; 5) whether the petitioner and the defendant in the parallel proceeding are the same party; and 6) other circumstances and considerations that impact the Board's exercise of discretion, including the merits. *Id*.

We recognize that *NHK Spring* and the *Fintiv* Order apply the Director's discretion pursuant to 35 U.S.C. § 314(a), and do not specifically extend their application to 35 U.S.C. § 324(a), which is the relevant statute that applies to this PGR proceeding. As noted above, however, the pertinent statutory language is the same in both section 314(a) and section 324(a). Moreover, the overall policy justifications associated with the exercise of discretion—inefficiency, duplication of effort, and the risk of inconsistent results—apply to post-grant review proceedings under 35 U.S.C. § 324(a). Accordingly, we apply the factors set forth in the *Fintiv* Order to the facts here. *See, e.g.*, *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, PGR2019-00048, Paper 19 at 11 (PTAB Nov. 20, 2019) (analyzing *NHK Spring* and instituting trial); *Stripe, Inc. v. Boom! Payments, Inc.*, CBM2020-00002, Paper 22 (PTAB May 19, 2020) (analyzing the *Fintiv* Order and instituting trial).

We, however, recognize that there are differences between *inter partes* review and post-grant review that, when relevant to specific *Fintiv* factors, may be considered. Those differences include the fact that the

window for filing a petition for post-grant review is open only for nine months from the date of issuance. *See* 35 U.S.C. § 321(c). Furthermore, "[t]he intent of the post-grant review process is to enable early challenges to patents, while still protecting the rights of inventors and patent owners against new patent challenges unbounded in time and scope." H.R. Rep. No. 112-98, pt. 1, 47–48 (2011).

Patent Owner argues that we should exercise our discretion under 35 U.S.C. § 324(a) to deny institution due to the common issues being litigated in parallel district court cases. Prelim. Resp. 18–32. We have considered the circumstances and facts before us in view of the *Fintiv* factors and determine that the circumstances presented here weigh in favor of exercising discretion under § 324(a) to deny institution of post-grant review.

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

Patent Owner is concurrently engaged in two parallel district court proceedings involving the '039 patent with Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc.—the Texas Litigation and the Delaware Litigation. *See Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 2:20-cv-00337 (E.D. Tex.); *see*

*Daiichi Sankyo, Inc. v. Seattle Genetics, Inc.*, No. 1:20-cv-01524-LPS (D. Del.)[3,4]; Reply 1; Prelim. Resp. 20.

The Delaware Litigation has been stayed "pending a determination by the Eastern District of Texas as to whether Seagen's action in that court is going to remain there." Prelim. Resp. 5. The district court in the Texas Litigation has not granted a stay, and Daiichi Sankyo Co., Ltd. has not requested a stay. Reply 1. However, Petitioner claims Daiichi Sankyo Co., Ltd. will seek a stay upon institution. *Id.* Although the Delaware Litigation has been stayed, it has been stayed pending the Texas Litigation, which may resolve many of the issues of the Delaware Litigation. Accordingly, our focus is on the Texas Litigation.

Petitioner argues that a post-institution stay in the Texas Litigation is likely. Pet. 75–76. Petitioner states that the district court judge views institution as "highly significant" and has granted a stay in fifteen of the seventeen cases that the Board has instituted in parallel. Reply 1. Patent Owner counters this by arguing that only 22 out of 30, or 73%, of post-institution stay requests were granted and, of these 22 granted post-institution stay requests, 16 were based off stipulated, unopposed, or patent owner initiated motions. Sur-reply 1.

[3] Seagen Inc. was formerly known as "Seattle Genetics, Inc." Pet. 1.

[4] Daiichi Sankyo, Inc. is a subsidiary of Daiichi Sankyo Co., Ltd., the defendant in the Texas Litigation. Prelim. Resp. 27.

We have considered the arguments and evidence presented by both parties. We recognize that many legitimate reasons may lead a party *not* to file a motion to stay a parallel proceeding prior to the Board's institution decision, including because such a motion may be viewed as premature. Be that as it may, our precedential guidance instructs us to consider whether the court has granted a stay of the parallel proceeding, or whether evidence exists that a stay may be granted upon institution. *Fintiv* Order at 5–6. As it stands, the record lacks sufficient evidence to suggest that a stay has been granted, or may be granted in the future. It is a judge who determines whether to grant a stay based on the facts of each specific case as presented in the briefs by the parties. We decline to infer, based on actions taken in different cases with different facts, how the district court judge would rule should a stay be requested in the Texas Litigation.

For these reasons, we determine that the facts underlying this factor are neutral.

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

Trial for the parallel Texas Litigation is scheduled to begin on April 4, 2022. *See* Prelim. Resp. 22. Given the statutory deadlines, our latest possible date for issuance of a final written decision in this proceeding is July 26, 2022. 35 U.S.C. §§ 324(c), 326(a)(11) (2018); *see* 37 C.F.R. § 42.100(c). Thus, our projected statutory deadline for a final written decision is about four months after the beginning of the Texas district court's trial.

Petitioner argues that the trial date predates the final written decision by a few months, and therefore, the decision whether to institute implicates other factors, which favor institution. Reply 2.

"If the court's trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*." *Fintiv* Order at 9. On the other hand, "[i]f the court's trial date is at or around the same time as the projected statutory deadline or even significantly after the projected statutory deadline, the decision whether to institute will likely implicate other factors discussed herein, such as the resources that have been invested in the parallel proceeding." *Id.* For these reasons, where trial in the parallel proceeding is scheduled to occur nearly four months prior to our Final Written Decision, we determine that the facts underlying this factor weigh toward denying institution.

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

Patent Owner argues that the parties have expended substantial resources on discovery and exchanged infringement and invalidity contentions in the Texas Litigation and that institution would only create duplicative costs. Prelim. Resp. 24 (citing Ex. 2002, 2003). For example, Patent Owner contends that the parties have exchanged a voluminous amount of discovery documents, that Patent Owner will file its opening claim construction brief on July 16, 2021, and that the parties have an upcoming claim construction hearing scheduled for August 2021. *Id.* at 24;

*see also Fintiv* Order at 9 (the Board considers "the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.").

Petitioner argues that only investment completed at the time of the institution decision is relevant to this factor. Reply 2. Petitioner contends that there has not been significant resource investment by the court or parties yet. Pet. 80. Petitioner also notes that it filed for post-grant review about two months after patent issuance with the second petition filed about two weeks after Patent Owner first alleged infringement of claims 6–8. Reply 3.

We have considered Patent Owner's position but note that, at this time, it appears considerable effort remains to be completed in the parallel litigation. In particular, it does not appear that the district court has issued any rulings as to claim construction and that important deadlines have not yet occurred. On balance, the level of investment by the parties and the court is not substantial.

Additionally, as part of our holistic analysis, we also consider the speed in which Petitioner acted. *See Apple Inc. v. Seven Networks, LLC*, IPR2020-00156, Paper 10 at 11–12 (PTAB June 15, 2020). Here, Petitioner represents it acted diligently by filing the Petition two months after the issuance of the '039 Patent. Reply 3; Sur-reply 2. Because Petitioner acted diligently and without much delay, this mitigates against the investment of the parties. *See Seven Networks*, Paper 10 at 11–12. As *Fintiv* Order states, "[i]f the evidence shows that the petitioner filed the petition expeditiously, such as promptly after becoming aware of the claims being asserted, this fact

has weighed against exercising the authority to deny institution under NHK." *Fintiv* Order at 11

Taken together, we find that this factor does not weigh for or against the exercise of our discretion to deny institution pursuant to § 324(a).

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

Based on the facts provided in the record, we are unable to determine if there is significant overlap in the issues addressed in the Texas Litigation and Petitioner's arguments. Petitioner does not argue lack of overlap between the two respective tribunals either. *See* Reply 3 ("And the overlap between the issues here and in court reinforces the likelihood of a stay . . . ."). Indeed, Petitioner appears to concede that there are overlapping issues in the Texas Litigation. *Id.* ("The litigation likely will be stayed before overlapping issues are resolved."). Patent Owner represents that the "Petition relies on *identical* grounds for unpatentability as those at issue in the [Texas Litigation]." Sur-reply 3; *see also* Ex. 2003 (the Texas Litigation invalidity contentions).

Under the *Fintiv* Order, "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* Order at 12. Based on the record before us and the representations made by Patent Owner, we determine that this factor on balance weighs in favor of discretionary denial.

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

Petitioner argues that neither Daiichi Sankyo, Inc. nor AstraZeneca Pharmaceuticals, LP are parties to the Texas Litigation. Pet. 80. Additionally, Petitioner argues that Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP could not have been named as Defendants in the Texas Litigation. *Id.*

Patent Owner does not dispute that Petitioner is not a defendant in the Texas Litigation. Prelim. Resp. 3. Rather, Patent Owner argues that the real parties in interest in this proceeding and the Texas Litigation are the same. Prelim. Resp. 27. Specifically, Patent Owner argues that "Daiichi Sankyo, Inc. is the wholly-owned subsidiary of Daiichi Sankyo," the Defendant in the Texas Litigation. *Id.* (citing Ex. 2025); *see also* Pet. 82 ("Real parties-in-interest include Petitioners Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, as well as Daiichi Sankyo Company, Limited and AstraZeneca UK Limited."). Patent Owner argues that "the parties to this petition and the parties in the litigation share a clear corporate relationship, and one that is specifically focused on the '039 Patent and the accused product" in the Texas Litigation. Prelim. Resp. 29. Patent Owner further argues that Petitioner AstraZeneca "has already participated in discovery in the Texas Action, and it is a party to the Delaware Action, where it opposed a stay and requested that discovery also commence." *Id.* at 30 (citing Ex. 2006).

Under the *Fintiv* Order, "[i]f a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion to deny institution under *NHK*." *Fintiv* Order at 13–14. Given that the real parties in interest in this proceeding are parties to the Texas Litigation, we determine that this factor on balance weighs in favor of discretionary denial.

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

When considering whether to exercise discretion to deny a petition, we undertake a balanced assessment of all relevant circumstances in the case, including the merits. *Fintiv* Order at 14. Although we need not undertake a full merits analysis when evaluating *Fintiv* Factor 6, we consider the strengths and weaknesses of the merits, where stronger merits may favor institution and weaker merits may favor exercising discretion to deny institution. *Id.* at 15–16. We also consider the other circumstances identified by the parties as pertinent to exercise of discretion.

We have reviewed Petitioner's unpatentability arguments and Patent Owner's Preliminary Response, and based on the record before us, we disagree with Patent Owner that the merits are substantively weak. Prelim. Resp. 31. In particular, we note that the present record shows that there may be merit to Petitioner's scope of enablement challenges. Pet. 44–63; *see also id.* at 46, 53–54 (Petitioner contending that disclosure offers relatively "scarce guidance," and the only examples provided include dolastatin/auristatin derivatives).

Patent Owner, on the other hand, contends that the prior art at the effective filing date would have allowed a person of ordinary skill in the art to determine whether an ADC is likely to be cleaved by intracellular enzymes through assays. Prelim. Resp. 59. These assays would have been able to demonstrate cleavage inside the cell. *Id.* at 59–60. Patent Owner also rebuts Petitioner's assertion that ADCs are not stable extracellularly, claiming there were assays available to a person of ordinary skill in the art to prove that a conjugate would be extracellularly stable. *Id.* at 61. Patent Owner further contends that a showing of enablement (1) does not require complete stability by the ADC and (2) that "the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled." *Id*. at 62 (citing *Concert Pharms., Inc. v. Incyte Corp*., PGR2017-00034, Paper 9 at 12–13 (PTAB Jan. 11, 2018)).

Having reviewed Petitioner's challenges and Patent Owner's preliminary responses, and based on the limited record before us, we do not find that the merits outweigh the other *Fintiv* factors favoring exercising our discretion to deny institution.

*7. Conclusion on Discretionary Denial under 35 U.S.C. § 324(a).*

Considering all the factors together as a whole, we determine under the particular circumstances of this case, the interests of efficiency and integrity of the patent system do favor exercising our discretionary authority under § 324(a) to deny institution of the Petition.

## III. CONCLUSION

Taking account of the information presented in the Petition, the Preliminary Response, additional authorized briefing, and the evidence of record, we exercise our discretion under 35 U.S.C. § 324(a) and deny institution of post-grant review. Accordingly, the Petition is denied, and no trial is instituted.

## IV. ORDER

Accordingly, it is

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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