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Paper 17
Date: September 16, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LTD.
Petitioner,

v.

JANSSEN PHARMACEUTICA NV,
Patent Owner.

IPR2020-00440
Patent 9,439,906 B2

Before JOHN G. NEW, KRISTINA M. KALAN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge.*

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

I. INTRODUCTION

Petitioner Mylan Laboratories Ltd. ("Petitioner") has filed a Petition (Paper 3, "Petition" or "Pet.") requesting *inter partes* review of claims 1–21 of US Patent 9,439,906 B2 (Ex. 1001, "the '906 patent"). Patent Owner Janssen Pharmaceutica NV ("Patent Owner") has filed a Preliminary Response (Paper 8, "Preliminary Response" or "Prelim. Resp."). On July 2, 2020, the panel issued an order authorizing Petitioner to file a Reply to the Preliminary Response and further authorizing Patent Owner to file a Sure-Reply (Papers 12 and 14, "Reply" and "Sur-Reply," respectively.

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition." Upon consideration of the Petition, and of the supporting evidence, we exercise our discretion under § 314(a) to deny institution.

II. BACKGROUND

A. Real Parties-in-Interest

The real parties-in-interest for Petitioner are Mylan Laboratories Ltd., Mylan Institutional LLC, Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. Pet. 4. Patent Owner's Mandatory Notices identify Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc., which are wholly-owned subsidiaries of Johnson & Johnson ("J&J"), as the real parties-in-interest for Patent Owner. Paper 6, 1.

B. Related Matters

Petitioner identifies the following district court actions involving the '906 patent: (1) *Janssen Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, 2-18-cv-00734 (D.N.J.); (2) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 2-19-cv-16484 (D.N.J.); (3) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 1-19-cv-00153 (N.D. W. Va.); (4) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 1-19-cv-01488 (D. Del.); (5) *Janssen Pharmaceuticals, Inc. et al. v. Pharmascience Inc. et al.*, Case No. 2-19-cv-21590 (D.N.J.); (6) *Janssen Pharmaceuticals, Inc. et al. v. Pharmascience Inc*. et al., 1-19- cv-02313 (D. Del.). Pet. 5. The Patent Owner similarly identifies these actions as involving the '906 patent. Paper 6, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that the '906 patent is unpatentable based on the following grounds:

Claim Challenged	35 U.S.C. §	Reference(s)/Basis
1–7, 15, 17–21	103[1]	Citrome[2], Cleton[3], '544 patent[4]
8–14, 16	103	Citrone, Cleton, Palperidone Formulary[5], '544 patent
1–7, 15, 17–21	103	Citrome, '544 patent
8–14, 16	103	Citrone, Palperidone Formulary, '544 patent

[1] Because the patent at issue has an effective filing date before March 16, 2013, the effective date of the applicable provisions of the Leahy Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA"), we apply the pre-AIA version of 35 U.S.C. §103(a) in this decision.

[2] L. Citrome, *Paliperidone: Quo Vadis*? 61(4) INT. J. CLIN. PRACT. 653–62 (2007) ("Citrome") (Ex. 1004).

[3] The Cleton reference is collectively constituted of: (1) A. Cleton et al., *Assessment of the Dose Proportionality of Palperidone Palmitate 25, 50, 100 And 150 mg eq., A New Long-Acting Injectable Antipsychotic Following Administration in the Deltoid or Gluteal Muscles* (Abstract PI-74); and (2) A. Cleton et al., *Evaluation of the Pharmacokinetic Profile of Gluteal Versus Deltoid Intramuscular Injections of Palperidone Palmitate 100 Mg Equivalent in Patients with Schizophrenia* (Abstract PI-75), in 83(Supp. 1) CLIN. PHARMACOL. & THERAPS. S31 (2008) ("Cleton") (Ex. 1003). The Patent Owner routinely refers to these references as "PI-74" and "PI-75."

[4] US 6,555,544 B2, April 29, 2003 (the "'544 patent") (Ex. 1005).

[5] D.J. Cada et al., *Formulary Drug Review: Palperidone*, 42(7) HOSP. PHARM. 637–47 (2007).

Petitioner also relies upon the Declaration of its expert, Dr. Mansoor M. Amiji (the "Amiji Declaration") (Ex. 1002).

D. The '906 Patent

The '906 patent is directed to a method of treating patients in need of treatment with long acting injectable paliperidone palmitate formulations.

E. Illustrative Claims

Independent claim 1 is representative of the claims of the '906 patent and recites:

> 1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
>
> (1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
>
> (2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and
>
> (3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (± 7 days) after the second loading dose.

Ex. 1001 col. 32, ll. 11–30. Independent claim 8 is similar to claim 1, and is directed to the treatment of renally-impaired patients:

> 8. A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
>
> (a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
>
> (b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and
>
> (c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.

Id. at cols. 32–33, ll. 66–20.

III. ANALYSIS

A. Claim Construction

In an *inter partes* review for a petition filed on or after November 13, 2018, the "[claims] of a patent … shall be construed using the same claim construction standard that would be used to construe the [claims] in a civil

action under 35 U.S.C. § 282(b), including construing the [claims] in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *See* 37 C.F.R. § 42.100(b) (2019); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (*en banc*). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner asserts that it is unaware of prior claim construction determination concerning the '906 patent in any of the related proceedings listed in II.B. *supra*. Pet. 9. Petitioner therefore argues that no claim construction is necessary and the challenged claims should be afforded a meaning "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* (quoting 37 C.F.R. § 42.100(b)). Patent Owner does not dispute the Petitioner's assertions.

We consequently conclude that resolving whether we should institute *inter partes* review does not require any express claim construction.

B. A Person of Ordinary Skill in the Art

The Petitioner asserts that, with respect to the '906 patent, a person of ordinary skill in the art would have had: (1) several years' experience in designing and formulating drug delivery systems including parenteral systems based on analyzing pharmacokinetic data such as blood serum or

drug plasma levels and clearance rates and familiarity with depot formulations; (2) an advanced degree (M.S. and/or Ph.D.) in pharmaceutical sciences, and/or pharmaceutics or a related degree; and (3) experience with the formulation of therapeutic agents, their dosing, and the literature concerning drug developmental study and design. Pet. 13–14. The Petitioner also asserts that a skilled artisan might consult with individuals having specialized expertise, for example, a physician with experience in the administration, dosing, and efficacy of drugs, and/or a regulatory affairs specialist. *Id.* at 14 (citing Ex. 1002 ¶¶ 33–37).

Absent any objection by Patent Owner, we adopt Petitioner's proposed definition of a person of ordinary skill in the art as of the date of invention because it is consistent with the level of skill in the art at the time of the invention as reflected by the prior art and the Specification of the '906 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. The Board's Discretion to Deny Institution under 35 U.S.C. § 314(a)

The Patent Owner urges the Board to exercise its discretion under 35 U.S.C. § 314(a) and deny institution of the proposed *inter partes* review. Prelim. Resp. 6. The Patent Owner argues that, under § 314(a), the Board must consider whether the nature of co-pending district court litigation on the same patent is such that instituting trial "would be an efficient use of the Board's resources." *Id.* at 6–7 (quoting *NHK Spring Co. v. Intri-Plex*

Techs., Inc., IPR2018-00752, Paper 8 at 19–20 (PTAB Sept. 12, 2018) (precedential)).

Patent Owner contends that, under our precedential decision in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12–17 (PTAB May 13, 2020), in deciding "whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding," the Board should consider a variety of factors, and, in evaluating these factors, "takes a holistic view of whether efficiency and integrity of the system are best served." Prelim Resp. 11 (quoting *Fintiv*, Paper 11 at 5–6; also citing *Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2020-00117, Paper 11 at 7–11 (PTAB May 28, 2020) (same). According to Patent Owner, granting the Petition for *inter partes* review would be an inefficient use of Board resources. *Id.*

Specifically, Patent Owner points to two of the related litigations cited in Section II.B. *supra*: (1) *Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al.*, 2-18-cv-00734 (D.N.J.) (the "*Teva* litigation"); and (2) *Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd.*, 2-19-cv-16484 (D.N.J.) (the "*Mylan* litigation"). Patent Owner contends that the procedural postures of each of these cases is such that institution by the Board of an inter partes review would be an inefficient use of Board resources.

1. The *Teva* litigation

In the *Teva* litigation, the validity of claims 1–21 of the '906 patent is the only issue to be resolved at trial, and all claims are challenged as being obvious for reasons overlapping those of the instant Petition. Exs. 2006;

2007 at 40–41. In that litigation, Teva asserts that the '906 patent is invalid under 35 U.S.C. § 103(a) as being obvious over:

1. Cleton, the '548 Trial[6], and the '544 patent

2. Cleton, the '548 Trial, and the '544 patent, in view of Cleton 2007 and Paliperidone ER 2006

3. Cleton, the '548 Trial, the '544 patent and, optionally, in view of DOFA 2006 and Vieta 2001

4. Cleton, the '548 Trial, and/or the '544 patent, with the WO '312 application and the WO '384 application, in view of Cleton 2007 and paliperidone ER 2006

5. Cleton, the '548 trial, and the '544 patent, in view of Ereshefsky 1990, Ereshefsky 1993 and paliperidone ER 2006

6. Cleton, the '548 trial, and the '544 patent, in view of Gibaldi or Goodman & Gilman

7. Cleton, the '548 trial, and the '544 patent, in view of Ereshesky 1990, Ereshefsky 1993, paliperidone ER 2006 and Gibaldi or Goodman & Gilma

Ex. 2007 at 41.

Fact and expert discovery in the *Teva* litigation were completed in early 2020, and trial is set for September 28, 2020, ten days after the

[6] The "'548 Trial" refers to Clinicaltrials.gov, *NCT00210548 A Study to Evaluate the Effectiveness and Safety of 3 Doses of Paliperidone Palmitate in Treating Subjects With Schizophrenia*, *available at* https://clinicaltrials.gov/ct2/history/ NCT00210548?V_11 =View#StudyPageTop (last visited September 3, 2020) (Ex. 1032). The '548 Trial is summarized in Table 1 of Citrome, and, in the Petition, the Petitioner relies on Citrome as teaching these summarized aspects of the '548 Trial. *See, e.g.*, Pet. 36.

mandatory date for institution of this proposed *inter partes* review. Ex. 2005 ¶ 5.

2. The *Mylan* litigation

In the *Mylan* litigation, the validity of claims 1–21 of the '906 patent is also a central issue to be determined at trial. Exs. 2001; 2007. In that litigation, Mylan asserts that the '906 patent is invalid under 35 U.S.C. § 103(a) on the following grounds:

1. Claims 1-7, 15, and 17-21 as being obvious over the combination of NCT 548[7], Cleton [PI-]75[8], and/or the '544 patent

2. Claims 8-14, and 16 as being obvious over NCT 548, Cleton [PI-]75, the Paliperidone Formulary and/or the '544 patent

Ex. 2008 at 41, 53.

In this action, brought pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, all fact discovery is scheduled to be completed by November 13, 2020, and all expert discovery is due to be completed by February 19, 2021. Ex. 2003. A tentative trial date sometime in June 2021 has been proposed, but dates for the pretrial conference and the trial itself have yet to be determined. Exs. 2004, 2003. The statutory thirty-month stay imposed by 21 U.S.C. § 355(j)(5)(B)(iii) is due to expire on January 2, 2022. Ex. 2004 at 5.

[7] This reference appears to be the same as the '548 Trial, summarized in Citrome. *See* fn.6.

[8] *See* fn.3.

3. The *Fintiv* Factors

In *NHK*, the Board held that, in the event there exists a parallel district court proceeding, in which the Petitioner asserted the same prior art and arguments, then instituting *inter partes* review "would not be consistent with 'an objective of the AIA . . . to provide an effective and efficient alternative to district court litigation.'" *NHK* at 20 (quoting *General Plastic Ind. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16–17 (PTAB Sept. 6, 2017). The parallel district court litigation in *NHK* was in its latter stages, with expert discovery ending two months after the mandatory date for the proposed institution of the *inter partes* review. *Id.* A jury trial was also set to begin six months afterward, concluding six months prior to the mandatory date for the Final Written Decision in the proposed *inter partes* review. *Id.* The Board therefore exercised its discretion under § 314(a) and declined to institute trial.

Our precedential decision in *Apple v. Fintiv* held that, as with other non-dispositive factors considered for institution under 35 U.S.C. § 314(a), an early trial date should be weighed as part of a "balanced assessment of all relevant circumstances of the case, including the merits." *Fintiv*, 5 (citing the Consolidated Trial Practice Guide, November 2019 ("TPG") at 58; *also citing Abbott Vascular, Inc. v. FlexStent, LLC*, IPR2019-00882, Paper 11 at 31 (PTAB Oct. 7, 2019) (declining to adopt a bright-line rule that an early trial date alone requires denial in every case)).

In *Fintiv*, the Board set forth six factors relating to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding:

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

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

3. investment in the parallel proceeding by the court and the 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 that impact the Board's exercise of discretion, including the merits.

Fintiv at 21. We consider these interrelated factors, as they apply to the facts of the Petition, as follows.

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

"A district court stay of the litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts. This fact has strongly weighed against exercising the authority to deny institution under *NHK*." *Fintiv* at 6 (citing *Precision Planting, LLC v. Deere & Co.*, IPR2019-01052, Paper 19 at 10 (PTAB Jan. 7, 2020)).

In neither the *Teva* litigation nor the *Mylan* litigation has a stay been entered. Furthermore, neither Petitioner nor Patent Owner has indicated that a motion for a stay has been filed, that there is an intention to file, or that filing has even been contemplated in either litigation. At this stage of the *Teva* litigation, with trial set to commence on September 28, 2020 (*see* Ex.

2005 ¶ 5), it seems highly unlikely that the district court, at this late stage of the proceeding, would enter a stay of the litigation pending the year-long duration of an *inter partes* review. Prelim. Resp. 12; Sur-Reply 1.

In the *Mylan* litigation, discovery is ongoing and all discovery is scheduled to be completed in February 2021. Although the court has not yet set a date for trial, a trial in June of 2021 has been proposed by both parties (*see* Ex. 2004), and with the 30-month limit provided for by 21 U.S.C. § 355(j)(5)(B)(iii) expiring on January 2, 2022, we think it unlikely that a stay will be granted in the *Mylan* litigation, either. *Id; see also* Prelim. Resp. 12; Sur-Reply 1.

We consequently conclude that the balance of facts in the two litigations indicate that no stay is likely to be entered in either, and therefore *Fintiv* factor 1 leans towards denial of institution.

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

If the trial dates in the parallel litigations are earlier than the projected statutory deadline, this weighs in favor of exercising authority to deny institution under *NHK*. *Fintiv* at 9. But if 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 the other *Fintiv* factors, such as the resources that have been invested in the parallel proceeding. *Id.*

The *Teva* litigation is scheduled to begin trial later this month, ten days after the mandatory decision date for institution of this *inter partes* review and almost a year prior to the deadline for a final written decision in

this *inter partes* review. Ex. 2005 ¶ 5. A trial date has not been set for the *Mylan* litigation, although both parties, in their Joint Proposed Discovery Plan, have proposed a trial date sometime in June 2021. Ex. 2004 at 5. The district court has, however, adopted the schedule set in the parties' Joint Proposed Discovery Plan for fact and expert discovery, with the former closing in November 2020 and the latter in February 2021. Ex. 2003 at 3. A trial date set in the summer of 2021, before the mandatory deadline for the Final Written Decision in this proposed *inter partes* review, therefore seems likely. We therefore find that this factor weighs strongly in favor of denying institution. *Fintiv*, 9.

c. *Fintiv* Factor #3: Investment in the parallel proceeding by the court and the parties.

Under *Fintiv* factor #3, we consider 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. *Fintiv*, 9. Specifically, if, at the time of the institution decision, the district court has issued substantive orders related to the patent at issue in the petition, this fact favors denial. *Id.* at 9–10 (citing *E-One, Inc. v. Oshkosh Corp.*, IPR2019-00162, Paper 16 at 8, 13, 20 (PTAB June 5, 2019)). Similarly, district court claim construction orders may indicate that the court and parties have invested sufficient time in the parallel proceeding to favor denial. *Id.* at 10 (citing *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00963, Paper 8 at 13 (PTAB Oct. 28, 2019)).

However, if the district court has not issued orders related to the patent at issue in the petition, prior to the mandatory date for institution, this fact weighs against exercising discretion to deny institution under *NHK*. *Id.*

(citing *Facebook, Inc. v. Search and Social Media Partners*, LLC, IPR2018-01620, Paper 8 at 24 (PTAB Mar. 1, 2019) (district court proceeding in its early stages, with no claim constructions having been determined); *Amazon.com, Inc. v. CustomPlay, LLC*, IPR2018-01496, Paper 12 at 8–9 (PTAB Mar. 7, 2019).

Fintiv factor #3 is thus related to *Fintiv* factor #2, insofar as that more work completed by the parties and court in the parallel proceeding tends to support the arguments that the parallel proceeding is more advanced, a stay may be less likely, and instituting would lead to duplicative costs. *Id.*

Furthermore, under *Fintiv* factor #3, if 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* at 11 (citing, e.g., *Intel Corp. v. VLSI Technology LLC*, IPR2019-01192, Paper 15 at 12–13 (January 9, 2020)). If, however, the evidence shows that the petitioner did not file the petition expeditiously, such as at or around the same time that the patent owner responded to the petitioner's invalidity contentions, or even if the petitioner cannot explain the delay in filing its petition, these facts have favored denial. *Id.* at 12 (citing *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019)).

The *Teva* litigation is trial-ready, representing a very considerable investment by both parties. *See* Ex. 2005 ¶ 5. Furthermore, the Patent Owner contends, in the *Mylan* litigation, the parties have exchanged binding validity contentions, and fact discovery is presently ongoing. Prelim. Resp. 13. The Patent Owner also asserts that Petitioner did not file its Petition with the Board until the day it was scheduled to receive Janssen's response

to its invalidity contentions to file this Petition, which, the Petitioner asserts, weighs in favor of denial under *Fintiv* factor #3. *Id.* at 8, 13 (citing *Fintiv* at 12).

The Petitioner replies that the Petition was filed prior to receiving Janssen's responsive contentions. Reply at 2 (citing Prelim. Resp. 4–5). The Petitioner also argues that the Patent Owner admits that Mylan filed its Petition six months before the statutory deadline and without the benefit of Janssen's responsive validity contentions. Reply 3 (citing Prelim. Resp. 7, 8). The Petitioner points to *Oticon Medical AB et al. v. Cochlear Ltd*, IPR2019-00975, Paper 15 at 22–23 (October 16, 2019) (precedential) as demonstrating that this time of filing avoids any prejudice to Janssen. *Id.* (also citing *Apple Inc. v. Seven Networks LLC*, IPR2020-00156, Paper 10 at 11 (PTAB Jun. 15, 2020)).

Petitioner argues further that the Petition in this proceeding was filed six weeks after serving its invalidity contentions in the *Mylan* litigation. *Id.* at 4 (citing Ex. 2003 at 1). Petitioner points to *Seven Networks*, at 11, in which the Board declined to exercise §314(a) discretion when Petition filed "fourteen weeks after its initial invalidity contentions." *Id.* Petitioner asserts that it was reasonable for Mylan to avoid incurring any IPR expenses until litigation ensued and Janssen identified the asserted claims. *Id.* (citing *Fintiv* at 11) (holding that it was "reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it").

We find that the balance of facts in evidence weigh in favor of denial. As we have explained, the *Teva* litigation is poised to go to trial within the next few weeks. *See* Ex. 2005 ¶ 5. In the *Mylan* litigation, Mylan has served Janssen with its initial invalidity contentions, and Janssen has served

Mylan with its responses to the invalidity contentions. *See* Exs. 2008, 2002. The court in the *Mylan* litigation has entered its scheduling order, with fact discovery to be completed in November, 2020 and expert discovery in February, 2021. Neither party has acknowledged any potential issues of claim construction that need to be resolved. *See, e.g.*, Pet. 9. It is therefore reasonably likely that the *Mylan* litigation will go to trial sometime in June 2021, or shortly thereafter, as proposed by the parties in their Joint Proposed Discovery Plan. Ex. 2004 at 5. Consequently, in both the *Teva* and *Mylan* litigations, we find that the district court has issued substantive orders related to the patent at issue in the petition regarding scheduling of discovery and trial (the latter in the case of the *Teva* litigation), and claim construction is not likely to be at issue. *See Fintiv* at 9–10. These facts favor denial. *Id.*

Furthermore, *Fintiv* states, with respect to factor #3, that "notwithstanding that a defendant has one year to file a petition, it may impose unfair costs to a patent owner if the petitioner, faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition at the Office." *Fintiv* at 11. *Fintiv* continues in this vein:

> If, however, the evidence shows that the petitioner did not file the petition expeditiously, *such as at or around the same time that the patent owner responds to the petitioner's invalidity contentions*, or even if the petitioner cannot explain the delay in filing its petition, these facts have favored denial.

Fintiv at 11–12 (emphasis added) (citing *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019) (finding that "Had [the Petitioner] filed this Petition … around the same time as the service of the initial invalidity contentions, the proceeding in this case may have

resolved the issues prior to the Parallel District Court Proceeding" and concluding that this delay favored denial). In this instance, Petitioner did not file the Petition at or about the time (December 20, 2019) Mylan served its initial invalidity contentions in the *Mylan* litigation. *See* Prelim. Resp. 8 (indicating that the Petition was filed when Janssen served Mylan with its response to Mylan's initial invalidity contentions on February 7, 2020).

Because we therefore find that: (1) there is a near certainty that trial will be completed in the *Teva* litigation imminently, so that the district court will have invested significant resources in assessing the validity of the challenged patent well before the Board would issue a Final Written Decision should we institute *inter partes* review; (2) there is a reasonable likelihood that, given the current investment of time and resources by the parties and the court in the *Mylan* litigation and the fact that a stay is unlikely, the district court and the parties will have invested significant resources in assessing the validity of the challenged patent well before the Board would issue a Final Written Decision; and (3) the timing of the Petitioner's filing its Petition for *inter partes* review, we conclude that *Fintiv* factor #3 favors denial.

d. *Fintiv* Factor #4: overlap between issues raised in the petition and in the parallel proceeding.

With respect to factor #4, *Fintiv* informs us that:

> 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. Conversely, if the petition includes materially different grounds, arguments and/or evidence than those presented in the district court, this fact has

> tended to weigh against exercising discretion to deny institution under *NHK*.

Fintiv at 12–13 (internal references omitted). In this instance, the validity of claims 1–21 of the '906 patent is a principal (and in the *Teva* litigation, the *only*) issue to be determined at trial. In the Petition, claims 1–7, 15, 17–21 are alleged to be invalid over the combined teachings of Cleton, Citrome, and the '544 patent, and claims 8–14 and 16 are alleged to be invalid over Citrone, Cleton, the '544 patent, and the Palperidone Formulary. Pet. 14–15. In the *Teva* litigation, claims 1–21 are alleged to be invalid over the combination principally of Cleton, the '548 Trial, and the '544 patent, and optionally with, or in view of, certain other references. Ex. 2007 at 41. In the *Mylan* litigation, claims 1–7, 15, 17–21 are alleged to be invalid over the combination of NCT 548, Cleton [PI-]75, and/or the '544 patent, and claims 8–14 and 16 are alleged to be invalid over NCT 548, Cleton [PI-]75, and/or the '544 patent, and the Palperidone Formulary. Ex. 2008 at 41, 53.

As we have explained *supra*, both the '548 Trial in the *Teva* litigation, and NCT 548 in the *Mylan* litigation, refer to NCT00210548, a Phase III clinical palperidone palmitate trial in patients diagnosed with schizophrenia. *See* fn.6 *supra*. The pertinent details of the '548 Trial (i.e., dosage, dosage intervals, and duration of the study) are included in Table 1 of Citrone, upon which Petitioner relies in arguing the invalidity of the '906 patent in the present Petition. *See, e.g.*, Pet. 36; *see also* fn.6 *supra*.

We consequently find that both the *Teva* and *Mylan* litigations assert that claims 1–21 of the '906 patent are invalid over a combination of the '544 patent, Cleton (which includes PI-75[9]), and the '548 Trial/NCT 548,

[9] *See* fn.3, *supra*.

which is summarized in pertinent part in Citrome. These references are also all relied upon in the Petition's allegation that claims 1–21 of the '906 patent are invalid. The only reference that the Petition relies upon that is not cited in the *Teva* litigation (though cited in the *Mylan* litigation) is the Palperidone Formulary with respect to claims 8–14 and 16 of the '906 patent. The Petitioner relies upon the Palperidone Formulary as teaching that "[t]he dose of paliperidone should be reduced in patients with moderate or severe renal function impairment." Pet. 46 (citing Ex. 1006 at 638). We cannot discern whether the remaining references relied upon in the *Teva* litigation address the issue of reducing the dosage of palperidone palmitate in renally-impaired patients, although we think it likely, given the express limitations of claims 8–14 and 16. *See, e.g.*, claim 8 of the '906 patent: "A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising…."

Because we find that the validity of claims 1–21 of the '906 patent are central to both the *Teva* and *Mylan* litigations, and is, in fact, the *only* issue in at least the former case, and because we find that both litigations and the proposed *inter partes* review rely primarily upon the same references in their invalidity contentions, *viz.*, Cleton, the '544 patent, and the '548 trial/NCT 548, which is summarized, with respect to the relevant elements of the study, in Citrome, we conclude that the balance of facts with respect to *Fintiv* factor #4 favors denial.

e. *Fintiv* Factor #5: whether the petitioner and the defendant in the parallel proceeding are the same party.

Petitioner in the proposed *inter partes* review and the defendant in the *Mylan* litigation is the same party, *viz.*, Mylan. *See* Pet. 4; Ex. 2001 at 1. The defendant in the *Teva* litigation is, self-evidently, an unrelated party, i.e., Teva Pharmaceuticals USA, Inc. *See, e.g.*, Ex. 2006 at 1. This would appear to balance the facts with respect to Factor #5. However, *Fintiv* informs us that:

> Even when a petitioner is unrelated to a defendant [ ], if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nonetheless, exercise the authority to deny institution. An unrelated petitioner should, therefore, address any other district court or Federal Circuit proceedings involving the challenged patent to discuss why addressing the same or substantially the same issues would not be duplicative of the prior case even if the petition is brought by a different party.

Fintiv 14 (internal references omitted).

The Petitioner responds that at least one other panel has questioned the relevance of *Fintiv* factor #5. Reply 5 (citing *Seven Networks* at 20, fn.12 (not disagreeing that Factor #5 could appear "contrary to the goal of providing district court litigants an alternative venue to resolve questions of patentability") and *Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.*, IPR2020-00122, Paper 15 at 10 (PTAB May 15, 2020) (APJ Crumbley, dissenting)).

According to the Petitioner, 35 U.S.C. § 315(b) states that the defendant who was "served with a complaint alleging infringement of the patent" has one year to file its Petition. And, the Petitioner asserts, Congress

has mandated that the defendant file the IPR, or be subject to the one year bar. *Chevron v. Natural Resources Defense Council Inc.*, 467 US 837, 842–843 (1984) ("First, always, is the question whether Congress has directly spoken to the precise question at issue."). Therefore, the Petitioner concludes, *Fintiv* factor #5 is neutral.

We disagree. The Petitioner is indisputably the defendant in the *Mylan* litigation, which, as we have explained, is reasonably likely to go to trial prior to what would be the mandatory date of the Final Written Decision if we instituted *inter partes* review on this Petition. Mylan will have the opportunity to fully litigate the invalidity of the '906 patent in that case, which is already well underway. Furthermore, although the defendant in the *Teva* litigation is unrelated to the Petitioner, we have found that "the issues [in both the *Mylan* and *Teva* litigations] are the same as, or substantially similar to, those already or about to be litigated." *Fintiv* at 14; *see* Section III.C.3.d (*re Fintiv* factor #4) *supra*. We therefore conclude that, because the Petitioner is the same as the defendant in the *Mylan* litigation, and because the issues in both the *Teva* and *Mylan* litigations are substantially the same as those raised in the Petition, *Fintiv* factor #5 favors denial.

f. *Fintiv* Factor #6: other circumstances that impact the Board's exercise of discretion, including the merits.

In *Fintiv* factor #6, we consider any other relevant circumstances in the case, including whether the merits favor institution or denial of inter partes review. *See Fintiv* at 14. If, for example, the merits of a ground raised in the petition seem particularly strong on the preliminary record, this fact has favored institution. *Id.* at 14–15 (citing, e.g., *Illumina, Inc. v.*

Natera, Inc., IPR2019-01201, Paper 11 at 6 (PTAB August 27, 2019)). However, if the merits of the grounds raised in the petition are a closer call, then that fact has favored denying institution when other factors favoring denial are present. *Id.* at 15 (citing *E-One, Inc. v. Oshkosh Corp.*, IPR2019-00162, Paper 16 at 8, 13, 20 (PTAB June 5, 2019)). A full analysis of the merits is not required, however. *Id.* at 15–16.

The Patent Owner contends that the Petition suffers from numerous alleged deficiencies warranting denial on the merits. Prelim. Resp. 16. Briefly, the Patent Owner contends that Grounds 1 and 2 of Mylan's petition rely on references (*viz.*, Cleton PI–74 and PI–75[10]) that are not prior art. Prelim. Resp. 20. The Patent Owner further alleges that the Petitioner's arguments and its accompanying expert testimony are conclusory, hindsight-driven, and unsupported or contradicted by the record. *Id.* at 25. Finally, the Patent Owner contends that the Petitioner fails to provide evidentiary foundations for its obviousness grounds. *Id.* at 61.

The Petitioner responds that Citrome is the primary reference employed in all four grounds, thus reducing the draw on Board resources. Reply 6 (citing Pet. 27). The Petitioner further alleges that, with an unopposed expert and only attorney argument in response, Petitioner's arguments are "particularly strong on the preliminary record." *Id.* (citing *Fintiv* at 14, 15 fn.29). The Petitioner further replies that it is likely to prevail upon the merits, which favors institution.

Balancing the factors, we conclude that *Fintiv* factor #6 is neutral. Although we do not provide a complete analysis of the merits, we find the question of whether Cleton qualifies as prior art to be a close call, and does

[10] *See* fn.3 *supra*.

not tip the balance in either direction. We conclude that Factor #6 is neutral in our analysis of the *Fintiv* factors.

4. Summary

For the reasons we have explained, we find that *Fintiv* factors #1–#5 favor denial, and that *Fintiv* factor #6 is neutral. No factors in our analysis weigh towards institution. We consequently exercise our discretion under 35 U.S.C. § 314(a) and decline to grant Petitioner's Petition seeking *inter partes* review.

IV. CONCLUSION

For the reasons we have explained, we conclude that, pursuant to an analysis of the factors set forth in our precedential opinion in *Fintiv* with respect to the specific facts of this case, we find that the balance of the factors favor the exercise of our discretion to deny the Petition for institution of *inter partes* review in this case.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), that the Petition for *inter partes* review of claim 1–21 of the '428 patent is DENIED with respect to all grounds in the Petition; and

FURTHER ORDERED that no *inter partes* review is instituted.

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