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Paper 15
Date: January 15, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

IPR2020-01317
Patent 9,220,631 B2

Before ERICA A. FRANKLIN, ROBERT L. KINDER, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Regeneron Pharmaceuticals, Inc. ("Petitioner"),[1] on July 16, 2020, filed a Petition to institute *inter partes* review of claims 1–26 (all claims) of U.S. Patent No. 9,220,631 B2 (Ex. 1001, "the '631 patent"). Paper 3 ("Petition" or "Pet."). Novartis Pharma, AG, et al., ("Patent Owner")[2] filed a Preliminary Response to the Petition. Paper 10 ("Preliminary Response" or "Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply (Paper 13, "Reply") and Patent Owner filed a Sur-Reply (Paper 14, "Sur-Reply").

An *inter partes* review may not be instituted unless the information presented in the petition and the preliminary response shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2018). For the reasons set forth below, upon considering the Petition, Preliminary Response, Reply, Sur-Reply, and evidence of record, we exercise our discretion under 35 U.S.C. § 314(a) to deny institution.

II. BACKGROUND

A. Related Cases and Proceedings

In addition to IPR2020-01317, the '631 patent is involved in two district court cases and a proceeding pending before the International Trade

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[1] Petitioner identifies Regeneron Pharmaceuticals, Inc. as the real party in interest. Pet. 4.

[2] Patent Owner identifies the named parties (Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation) as the real parties in interest. Paper 6, 2.

Commission ("ITC"). Petitioner also filed a related petition requesting *inter partes* review in IPR2020-01318, challenging claims of the '631 patent. We address each below.

1. ITC Proceeding

The '631 patent is asserted in *Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof II*, Inv. No. 337-TA-1207, filed June 19, 2020 ("the ITC Investigation"). Pet. 4; Paper 6, 2. On July 21, 2020, the ITC issued a notice of institution of the investigation. Ex. 2042, 4–5.

The ITC Investigation alleges that Petitioner infringes claims 1–6 and 11–26 of the '631 patent. Pet. 4. The ITC Investigation has not been stayed and Petitioner did not request a stay. Reply 9. The "Procedural Schedule" sets a hearing for April 19–23, 2021, a final initial determination date of July 29, 2021, and a date of November 29, 2021, for completion of the investigation. Ex. 2002, 3–4. Petitioner notes that a "Presidential review period" will last until approximately January 29, 2022. Reply 13.

2. Northern District of New York Patent Infringement

The '631 patent is asserted in *Novartis Pharma AG v. Regeneron Pharm. Inc.*, 1:20-cv-00690 (N.D.N.Y.). Pet. 4; Paper 6, 2. On June 19, 2020, Patent Owner filed a complaint for patent infringement against Petitioner. Ex. 2043, 2. The complaint alleges that Petitioner infringes at least claim 1 of the '631 patent. *See* Pet. 4.

The case was stayed pursuant to 28 U.S.C. § 1659 in view of the parallel ITC Investigation. *See* Exs. 2042, 2043.

3. Southern District of New York Antitrust

The '631 patent also is involved in *Regeneron Pharmaceuticals Inc. v. Novartis Pharma AG*, 1:20-cv- 05502-AJN (S.D.N.Y.). Paper 6, 2; Ex. 2057. On July 17, 2020, Petitioner filed a complaint against Patent Owner alleging that the '631 patent was "fraudulently procured" and that "Novartis deliberately withheld" key prior art "from the USPTO during prosecution of the '631 Patent." Ex. 2057, 5, 6, 31.

Petitioner further alleges in this complaint that the '631 patent is unenforceable due to inequitable conduct because material prior art was withheld with an intent to deceive the USPTO. *Id.* at 32–33. Petitioner's 232-count complaint asserts various antitrust-based harms allegedly caused by Patent Owner, including attempted monopolization through *Walker Process* fraud in violation of Section 2 of the Sherman Act. *See id.* at 73 (asserting that "[t]he '631 Patent is unenforceable because Novartis committed fraud on the USPTO in order to obtain the '631 Patent.").

As of January 5, 2021, this case has not been stayed by the district court. *See* Ex. 3002.

4. IPR2020-01318

Petitioner filed a petition in IPR2020-01318 also challenging all claims of the '631 patent. *See Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, IPR2020-01318, Paper 3 ("the IPR1318 proceeding"). On December 7, 2020, we granted Petitioner's Unopposed Motion to Terminate the IPR1318 proceeding. *Id.*, Paper 17.

B. The '631 Patent

The '631 patent is titled "SYRINGE." Ex. 1001, code (54). The '631 patent "relates to a syringe, particularly to a small volume syringe such as a syringe suitable for ophthalmic injections." *Id*. at code (57). The U.S. application resulting in the '631 patent was filed on January 25, 2013, and identifies multiple foreign priority applications, the earliest of which was purportedly filed on July 3, 2012. Ex. 1002, 226; Pet. 13–14.

The Specification notes that for small volume syringes intended for eye injections, sterilization can present issues that are not necessarily associated with larger syringes. Ex. 1001, 1:22–30. Further, certain therapeutics are particularly sensitive to sterilization techniques, thus it is important for the syringe to remain robustly sealed but also easy to use in that the force required to depress the plunger to administer the medicament must not be too high. *Id.* at 1:31–40.

Figure 2 of the '631 patent, reproduced below, illustrates a cross section through the syringe. *Id.* at 10:60–67.

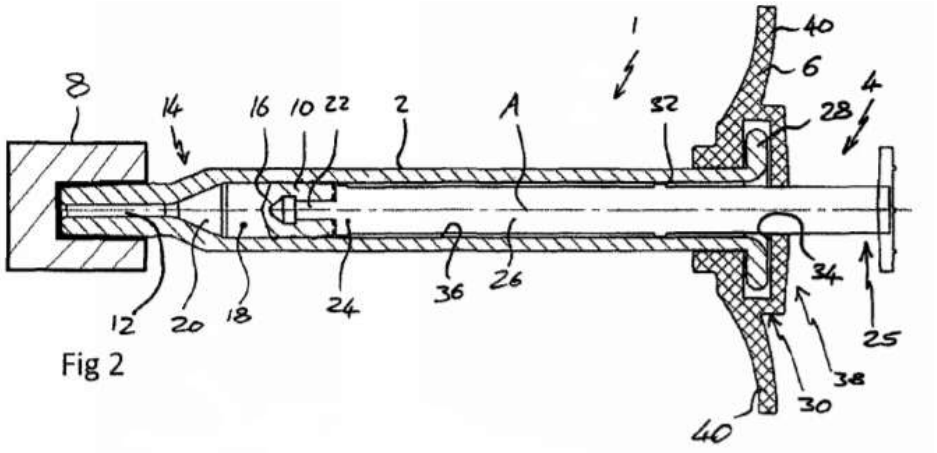

Figure 2 (above) depicts a cross section of a top down view of a syringe. *Id.* at 10:48–49.

Syringe 1 comprises body 2, stopper 10 and plunger 4. *Id.* at 10:61–67. Syringe 1 extends along first axis A, and body 2 comprises outlet 12 at outlet end 14. *Id.* Stopper 10 is arranged within body 2 such that front surface 16 of stopper 10 and body 2 define variable volume chamber 18. *Id.* Variable volume chamber 18 contains injectable medicament 20 comprising an ophthalmic solution comprising a VEGF antagonist. *Id.* at 10:67–11:2. Injectable fluid 20 can be expelled though outlet 12 by movement of stopper 10 towards outlet end 14 thereby reducing the volume of variable volume chamber 18. *Id.* at 11:3–5.

C. *Challenged Claims*

The '631 patent includes twenty-six claims, and Petitioner challenges each claim. Claim 1 is illustrative and reads as follows:

> 1. A pre-filled, terminally sterilized syringe for intravitreal injection, the syringe comprising a glass body forming a barrel, a stopper and a plunger and containing an ophthalmic solution which comprises a VEGF-antagonist, wherein:
>
> a) the syringe has a nominal maximum fill volume of between about 0.5 ml and about 1 ml,
>
> (b) the syringe barrel comprises from about 1 µg to 100 µg silicone oil,
>
> (c) the VEGF-antagonist solution comprises no more than 2 particles >50 µm in diameter per ml and wherein the syringe has a stopper break loose force of less than about 11N.

Ex. 1001, 19:2–13.

D. Asserted Grounds of Unpatentability

Petitioner asserts several grounds of unpatentability (Pet. 22–23), which are provided in the table below:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1–3, 5–9, 14–22, 24	103(a)[3]	Sigg,[4] Boulange,[5] "and if necessary USP789"[6]
4, 10, 23	103(a)	Sigg, Boulange, Fries,[7] "and if necessary USP789"
11–13	103(a)	Sigg, Boulange, Furfine,[8] "and if necessary USP789"
25	103(a)	Sigg, Boulange, Macugen Label,[9] "and if necessary USP789"
26	103(a)	Sigg, Boulange, Dixon,[10] "and if necessary USP789"

[3] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. § 103. Because the challenged claims of the '631 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103 in this Decision.
[4] PCT Patent Publication No. WO 2011/006877 (Ex. 1007).
[5] PCT Patent Publication No. WO 2009/030976 (Ex. 1008).
[6] U.S. Pharmacopeia, USP 789, Particulate Matter in Ophthalmic Solutions, USP 34 NF 29 (2011) ("USP789") (Ex. 1019).
[7] Arno Fries, *Drug Delivery of Sensitive Biopharmaceuticals With Prefilled Syringes*, 9(5) DRUG DELIVERY TECH. 22 (2009) (Ex. 1012).
[8] PCT Patent Publication No. WO 2007/149334 (Ex. 1021).
[9] Internet Archive WayBack Machine, March 7, 2011 Record of Drugs.com, *Macugen Prescribing Information*, *available at* https://web.archive.org/web/20110307065238/http://www.drugs.com:80/pro/macugen.html (Ex. 1009).
[10] James A. Dixon, et al. "VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration." *Expert opinion on investigational drugs* 18.10 (2009): 1573–1580 (Ex. 1030).

Petitioner also relies on the declarations of Horst Koller (Ex. 1003) and James Agalloco (Ex. 1005). Patent Owner relies on the declaration of Karl R. Leinsing (Ex. 2001). The parties rely on numerous other exhibits relevant to our determination as we examine below.

III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)

Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review. *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."); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("*SAS*") ("[Section] 314(a) invests the Director with discretion on the question whether to institute review." (emphasis omitted)); *Harmonic v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

Patent Owner argues that we should exercise discretion under 35 U.S.C. § 314 and deny institution, because the '631 patent is the subject of a pending ITC proceeding involving the same parties with a trial scheduled to begin on "April 19, 2021," and "the ITC is set to issue a decision on the validity of the '631 patent by July 29, 2021." Prelim. Resp. 1, 8–9 (citing Ex. 2002); *see generally* PO Sur-Reply 1–7.

In the Petition, Petitioner elected not to address discretionary denial or the Board's precedential *Fintiv*[11] decision, which issued about two months

[11] *Apple Inc. v. Fintiv, Inc.*, IPR2020–00019, Paper 11 (Mar. 20, 2020) (designated precedential May 5, 2020) ("*Fintiv*").

prior to the filing of the Petition. For reasons stated in Paper 12, we allowed Petitioner to file a Reply to the Preliminary Response.

In its Reply, Petitioner disagrees, and argues that the Board should not exercise discretion to deny institution because Petitioner filed its Petition less than a month after Patent Owner filed its ITC complaint. Reply 1. Petitioner also notes that "the NDNY district court litigation was stayed." *Id.* Further, Petitioner "has stipulated that if the Board institutes trial, it will not pursue at the ITC the invalidity grounds set forth in both petitions." *Id.* (citing Ex. 1067).

A. Parallel Proceedings

As previously described, Patent Owner has asserted the '631 patent against Petitioner in the ITC Investigation as well as in the Northern District of New York ("NDNY Patent Litigation"). Paper 5, 2; Paper 6, 2. Petitioner challenges the enforceability of the '631 patent in the Southern District of New York antitrust litigation ("SDNY Antitrust Litigation").[12]

In the ITC Investigation, the evidentiary hearing is scheduled to be completed by April 23, 2021, and the initial determination is scheduled for

[12] Patent Owner asserts that the SDNY Antitrust Litigation provides additional support for denying institution because "[t]he complaint relies on the same basic argument advanced in its Petition—i.e., that Novartis's '631 patent would not have issued had the examiner known about the Sigg reference" and because this additional litigation also calls for analyzing Sigg in the context of the '631 patent's enforceability. Sur-reply 3 n.1. We do not reach that additional argument because we conclude that discretionary denial is warranted based upon our analysis of the ITC Investigation and the NDNY Patent Litigation.

July 29, 2021. Ex. 2002, 3–4. The ITC Investigation is slated to be completed by November 29, 2021. *Id.* According to Petitioner, the proceeding has not, and will not, be stayed. Pet. 4.

The NDNY Patent Litigation alleging infringement of the '631 patent was filed by Patent Owner on June 19, 2020, but the case was stayed on July 30, 2020, pending completion of the ITC Investigation. *See* Pet. 4; Exs. 2042, 2043.

B. Analysis

The Board's precedential decision in *NHK Spring Co. v. Intri-Plex Techs, Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential) guides us in determining whether to exercise discretion to deny institution on behalf of the Director. In *NHK*, the Board found that the "advanced state of [a] district court proceeding" was a "factor that weighs in favor of denying" the petition under § 314(a). *NHK*, Paper 8 at 20. The Board determined that "[i]nstitution of an *inter partes* review under these circumstances would not be consistent with 'an objective of the AIA . . . to provide an effective and efficient alternative to district court litigation.'" *Id.* (citing *Gen. Plastic Indus. Co., Ltd. v. Canon Kabushuki Kaisha*, IPR2016-01357, Paper 19, 16–17 (PTAB Sept. 6, 2017) (precedential in relevant part)).

The Board's precedential decision in *Fintiv* sets forth six factors that we consider when determining whether to use our discretion to deny institution due to the advanced state of a 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, Paper 11 at 6. *Fintiv* is a precedential decision establishing binding authority on all members of the Board.

"These factors relate 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." *Id.* In evaluating these factors, we take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* (citing Consolidated Trial Guide 58). We discuss the parties' arguments below in the context of considering the above factors.

1. Whether a Stay Exists or Is Likely to Be Granted if a Proceeding Is Instituted

A stay of a parallel proceeding pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts, and, as such, this fact has strongly weighed against exercising the authority to deny institution. *Fintiv*, Paper 11 at 6.

Petitioner recognizes that the ITC proceeding was not stayed but

Petitioner contends that "[a]sking for a stay of the ITC investigation would have been futile." Reply 9. Petitioner points out that the NDNY Patent Litigation has been stayed pending the outcome in the ITC investigation. *Id.*

Patent Owner argues that when parallel litigation has not been stayed, this factor favors denial of institution because institution of an IPR while parallel litigation on the same patent is ongoing leads to inefficiencies and duplication of efforts. Prelim. Resp. 8 (citing *Fintiv*, IPR2020-00019, Paper 11 at 6–8). Patent Owner contends that there is no possibility of a stay of the parallel ITC Investigation and the Board has recognized that *Fintiv* applies to parallel ITC Investigations the same as it does to district court cases. Sur-Reply 2 (citing in part *Google LLC v. EcoFactor, Inc.*, IPR2020-00968, Paper 10 at 10–11 (PTAB Nov. 18, 2020); *Fitbit, Inc. v. Koninklijke Philips N.V.*, IPR2020-00772, Paper 14 at 14–15 (PTAB Oct. 19, 2020) ("*Fitbit*")). Further, Patent Owner notes our precedential decision in *Fintiv* states, "as a practical matter, it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC." *Fintiv*, IPR2020-00019, Paper 11 at 8–9.

Patent Owner notes the NDNY Patent Litigation has been stayed, but will proceed after the ITC Investigation is complete. Prelim. Resp. 9.

At the outset, we note that Patent Owner is correct that *Fintiv* expressly addresses ITC investigations, and the Board has considered ITC investigations in weighing whether or not to exercise its discretion under 35 U.S.C. § 314. *Fintiv*, Paper 11 at 8 ("[E]ven though the Office and the district court would not be bound by the ITC's decision, an earlier ITC trial date may favor exercising authority to deny institution under *NHK* if the ITC

is going to decide the same *or substantially similar issues* to those presented in the petition.") (emphasis added); *Garmin International, Inc. v. Koninklijke Philips N.V*, IPR2020-00754, Paper 11 (PTAB Oct. 27, 2020). Further, the November 2019 Patent Trial and Appeal Board Consolidated Trial Practice Guide ("Consolidated Trial Guide") specifically identifies parallel ITC proceedings as an example of a proceeding that favors denying a petition because of their "'effect . . . on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings.'" *Id*. at 56.

With regard to this factor, we agree with Patent Owner that a stay of the ITC Investigation is unlikely given that the hearing in the ITC Investigation is scheduled to occur in April 2021. Ex. 2001, 4.

For the reasons set forth above, we determine that this factor weighs in favor of exercising authority to deny institution.

2. Proximity of the Court's Trial Date to the Board's Projected Statutory Deadline

According to *Fintiv*, we must consider the "trial date" of the parallel proceeding compared to our projected statutory deadline for our final decision. *Fintiv*, Paper 11 at 9 ("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*."). "This factor looks at the *proximity* of the district court's trial date to the expected statutory deadline for the Board's final decision." *Philip Morris Prods., S.A. v. RAI Strategic Holdings, Inc.*, IPR2020-00921, Paper 9 at 16 (PTAB Nov. 16, 2020).

Patent Owner contends this factor strongly weighs in favor of denial because the parallel ITC hearing is set to begin on April 19, 2021, and the ITC is set to issue an initial determination on the validity of the '631 patent by July 29, 2021. Prelim. Resp. 9 (citing Ex. 2002). Patent Owner further notes that, because the final determination from the Commission will be made no later than November 29, 2021, the ITC will issue its final decision months before our January 2022 statutory deadline. Sur-Reply 3 (citing Ex. 2047). Patent Owner argues that the "trial date" is the key date of consideration for this factor and, for ITC proceedings, the Board examines primarily the initial determination and final commission determination dates:

> Unsurprisingly then, the Board has considered *both* the ALJ's determination date and the ITC's final determination date. *See Fitbit* at 16, 23 ("We weigh *heavily* the fact that in the ITC proceeding, *both* the Initial Determination *and* the final commission determination will pre-date a final written decision" (emphasis added)).

Id. at 4 (quoting *Fitbit, Inc. v. Koninklijke Philips N.V.*, IPR2020-00772, Paper 14 (PTAB Oct. 19, 2020)).

Petitioner contends "[t]he Board and ITC schedules are as close in proximity as practicably possible because Regeneron filed its petition less than a month after Novartis filed its ITC complaint and before institution of the ITC proceedings." Reply 13. Petitioner makes several policy arguments as to why we should consider the expedience of its IPR filing date. *See id.* at 14. Petitioner argues that if its expediency does not favor institution "then this factor could never weigh in favor of a petitioner unless the petition were filed preemptively and well before any ITC complaint." *Id.* Petitioner,

however, does not point us to any Board decision considering this *Fintiv* factor to take into account diligence in filing for this factor. Instead, as noted above, this *Fintiv* factor compares the "trial date" to our statutory date for issuing a final written decision.

We agree with Patent Owner that the advanced stage of the ITC investigation weighs in its favor for this factor. The evidentiary hearing in the ITC Investigation is set for April 19, 2021, and the proceeding will reach a final determination on or before November 29, 2021. Our final written decision is due about two months later in January 2022. These facts weigh against institution.

As noted above, the NDNY Patent Litigation is stayed, and, thus, has no trial date.

For the reasons set forth above, we determine that this factor weighs in favor of our exercise of discretion to deny against institution.

3. Investment in the Parallel Proceeding by the Court and Parties

We consider the amount and type of work already completed in the parallel litigation or proceeding by the court and the parties at the time of the institution decision. *Fintiv*, Paper 11 at 9.

Patent Owner contends this factor favors denial. Prelim. Resp. 11–12; Sur-Reply 1–3. Patent Owner argues that, "[b]y the time an institution decision is due on January 22, 2021, the ITC and the parties will have already invested significant resources in the investigation." *Id.* at 11. According to Patent Owner:

Fact discovery is set to close on December 18, 2020. As of the

> date of this Preliminary Response, the parties have already served responses to 365 requests for production and 43 interrogatories; collected, reviewed, and produced more than 59,606 documents; served 3,710 pages of initial invalidity and infringement contentions; served subpoenas on seven third parties; and have received 2,121 pages of production from those third parties. By the time the institution decision is due, the parties will likely have produced thousands more documents and will likely have taken more than a dozen fact depositions.

Prelim. Resp. 11. Patent Owner further notes that "[b]y the time of an institution decision, claim construction will be complete: the parties will have already fully briefed claim construction, taken depositions of claim construction declarants, and participated in the scheduled December 10, 2020 *Markman* hearing." *Id.* Similarly, "[o]pening expert reports are due on January 22, 2021, and summary determination motions on February 18, 2021." Sur-Reply 5. Patent Owner also notes that the parties "have exchanged detailed invalidity contentions on §§ 102–103, which overlap with the grounds in this petition." *Id.*

Addressing Petitioner's diligence in filing its IPR Petition, Patent Owner argues that Petitioner knew of the '631 patent as early as 2015, when it was approached with potential licensing offers. *Id.* at 6 (citing Ex. 2057 ¶¶ 137, 146). Patent Owner then argues that Petitioner "started to investigate an IPR challenge no later than July 2018." *Id.* (citing Ex. 1033, 43). Next, quoting the Board's *Fitbit* decision, Patent Owner argues "[i]n any event, even in cases where the petitioner *was* diligent, the Board has found that investments by '[t]he parties and the ALJ and staff of the ITC' still weigh 'somewhat against institution.'" *Id.* (quoting *Fitbit* at 17–18).

Petitioner contends this factor weighs in favor of institution.

Reply 11–12. Petitioner argues that it could not have brought its challenge faster than it did in this IPR proceeding and when it filed its petition, the ITC had not even instituted an investigation. *Id.* at 11. According to Petitioner, "ITC proceedings are statutorily required to be completed expeditiously . . . and it is thus inevitable that the parties will have invested resources in the ongoing ITC investigation." *Id.* at 12. Petitioner notes that it "also invested enormous time and resources in preparing and filing the two IPR petitions less than a month after learning of the complaints." *Id.*

We weigh this factor somewhat against institution. We acknowledge Petitioner's diligence in bringing this IPR proceeding, but the investment by the parties and the ITC in the parallel proceeding outweighs the effort expended so far in this proceeding.

More to the point, we agree with Patent Owner that the parties, the ALJ, and the staff of the ITC have expended considerable resources to date on the ITC investigation, in the form of addressing claim construction, completing substantial fact discovery, and preparing for expert reports and discovery. Ex. 2002, 2–3. In fact, under the current ITC schedule (*see* Ex. 2002), summary determination motions will be filed within a few weeks after this decision and the parties will complete substantially all pre-trial work within two months of this initial determination. *Id.*

Based on the record before us, we determine that the ITC has invested greater resources in evaluating the '631 patent's claims at issue than in the current proceeding. The amount and type of work already completed in the parallel ITC Investigation at the time of the institution decision weighs somewhat in favor of exercising our discretion to deny institution.

4. Overlap Between Issues Raised in the Petition and in the Parallel Proceeding

"[I]f 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*, Paper 11 at 12 (emphasis added).

To address this factor, Petitioner sent a "letter" to counsel for Patent Owner on November 25, 2020. *See* Ex. 1067. In this letter,[13] Petitioner writes:

> Respondent Regeneron Pharmaceuticals, Inc. hereby stipulates that, if the Patent Trial and Appeal Board ("Board") institutes one or both of the pending IPR petitions in IPR2020-01317 and IPR2020-[0]1318 challenging the patentability of the claims of U.S. Patent No. 9,220,631, then Regeneron will not pursue the instituted invalidity grounds in the ITC investigation 337-TA-1207.

Ex. 1067, 1. Petitioner notes the specific grounds challenged in each of IPR2020-01317 and IPR2020-01318. *Id.* at 1–2. Petitioner then states that "[i]f, however, the Board grants Regeneron's motion to terminate IPR2020-01318 and also institutes trial in IPR2020-01317, this stipulation applies and Regeneron will not pursue the above identified grounds in the ITC investigation." *Id.* at 2.

The stipulation does not address whether it would apply to any district

[13] There is no indication that this letter was filed with the ITC or any district court. For purposes of this decision, we presume Petitioner would be bound by this letter, and as such we refer to it as a "stipulation."

court proceeding. Based on the specific language quoted above, we determine it would only apply to the ITC Investigation.

Based upon its stipulation, Petitioner argues in its Reply that "the Board and the ITC thus will not address the same invalidity arguments." Reply 12. Further, Petitioner contends "[t]here is also no risk of inconsistent claim construction positions between the Board and the ITC, as there is no overlap between the terms identified in the Parties' ITC *Markman* briefing and the terms identified in the petition." *Id.*; *compare* Ex. 1071 *with* Pet. 27–28). Based on these two points, Petitioner concludes that "there are no 'concerns of inefficiency and the possibility of conflicting decisions' between the Board and ITC." *Id.* at 12–13 (quoting *Fintiv* at 12).

Patent Owner alleges that "[f]actor 4 weighs against institution because the petition asks the Board to review the same patent claims, based on the same prior art, that are at issue in the ITC investigation." Sur-Reply 7. Patent Owner contends that "the narrow stipulation that Regeneron touts . . . would not meaningfully reduce the overlap between its petition and its ITC invalidity contentions." *Id.* at 1. Patent Owner argues that such a narrow stipulation does not overcome the factors that favor denying institution. *Id.*

Patent Owner cites several of our recent proceedings for the proposition that a narrow stipulation like Petitioner's—*i.e.*, a promise not to pursue the identical grounds for invalidity in a parallel proceeding—at most weighs marginally against exercising discretion to deny institution. *Id.* at 7 (quotation and citations omitted). Patent Owner also contends that "Regeneron's narrow stipulation would not meaningfully limit the overlap

between an IPR and the ITC proceeding (and it does not apply to the district court litigation)." *Id.* Patent Owner notes that Petitioner's "theory is that a skilled artisan would have combined references that teach a method for terminal sterilization of PFS with a method for baked-on siliconization of PFS." *Id.* (citing Pet. 29). Patent Owner contends that Petitioner "has cited numerous, cumulative references that it asserts can be used for each half of that argument." *Id.* at 7–8 (citing Prelim. Resp. 18–22). Patent Owner argues that Petitioner's "stipulation would not preclude it from relying on different combinations of the asserted references." *Id.* at 8.

More specifically, Patent Owner points to the two IPR proceedings filed currently (IPR1317 and IPR1318) and notes that each has a lead reference that discloses terminal sterilization methods (Sigg and Lam) and two lead references that disclose siliconization methods (Boulange and Reuter). *Id.* at 7–8; Paper 2, 2. Patent Owner contends that "[t]he differences between the references in each category are modest and irrelevant to most of the claims," such that:

> It would thus be trivially easy for Regeneron to press the same arguments to the Board and the ITC without violating its stipulation—it need only change how it combines the reference types, *e.g.*, by changing its IPR pairing of Sigg/Boulange to Sigg/Reuter and Lam/Boulange in the ITC. The parties would thus be adjudicating the same basic invalidity issues in at least two different fora.

Sur-Reply 8.

We agree with Patent Owner that Petitioner's narrow stipulation, which only applies to the ITC Investigation, does not alleviate concerns of duplication given the Petitioner's ability to rely on substantially the same

prior art by slightly varying the combinations.

The scope of Petitioner's narrow stipulation is better understood by contrasting it with the broad stipulation from our recent precedential decision in *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (Dec. 1, 2020) (precedential as to § II.A). The stipulation in *Sotera:*

> states that if the PTAB institutes *inter partes* review, Petitioner "will not pursue in [the District Court] the specific grounds [asserted in the *inter partes* review], or on any other ground . . . that was raised or could have been reasonably raised in an IPR (i.e., any ground that could be raised under §§ 102 or 103 on the basis of prior art patent or printed publications)."

Id. at 13–14. This stipulation in *Sotera* leaves no doubt that the petitioner could no longer assert substantially the same grounds in the parallel proceeding. Such a stipulation ensures no overlap between issues raised in the petition and in the parallel proceeding, causing the fourth *Fintiv* factor to weigh strongly in favor of not exercising discretion to deny institution under 35 U.S.C. § 314(a). *See id.*

In the proceeding before us, it would be fairly easy for Petitioner to press the same arguments to the ITC without violating its stipulation. As noted above, this could be done by simply changing its IPR pairing of Sigg/Boulange to Sigg/Reuter and Lam/Boulange in the ITC. The ITC Investigation would thus have to decide substantially the same arguments and evidence as presented before us. *See Google LLC et al. v. Agis Software Development, LLC*, IPR2020-00873, Paper 16, 14 (PTAB Nov. 25, 2020) (finding that a stipulation to waive the specific grounds asserted in the IPR did not alleviate concerns of duplication given the petitioner's ability to rely

on the same prior art by slightly varying the combinations).

In this proceeding, Petitioner challenges the same claims challenged in the ITC Investigation with substantially the same evidence and arguments. *See* Pet. 4; Prelim. Resp. 13–14; Ex. 2003, 9 ("A person of ordinary skill would have been motivated to combine these known elements to arrive at claims 1-26 of the 631 at least for the reasons set forth in Regeneron's Petitions for *inter partes* review in IPR2020-01317 and -01318, which are herein incorporated by reference."). Petitioner's letter to waive the specific grounds asserted in the two IPRs does not alleviate concerns of duplication given the Petitioner's ability to rely on the same prior art by slightly varying the combinations. Further, the stipulation does not apply to the NDNY Patent Litigation, where the same grounds before us could later be asserted by Petitioner.

Considering all the evidence above, including Petitioner's stipulation, we weigh this factor as somewhat favoring the exercise of our discretion to deny institution. We credit Petitioner's stipulation, but, as examined above, this stipulation only applies to the precise grounds and also does not apply to the NDNY Patent Litigation involving the '631 patent.

5. Whether the Petitioner and the Defendant in the Parallel Proceeding Are the Same Party

Patent Owner asserts that the same parties involved in the present proceeding are also involved in the ITC Investigation and NDNY Patent Litigation. Prelim. Resp. 14. Petitioner agrees. Reply 14.

Accordingly, this factor weighs in favor of exercising our discretion to deny institution. *Fintiv*, Paper 11 at 6.

6. Other Circumstances that Impact the Board's Exercise of Discretion, Including the Merits

Even assuming that the Petition has merit, instituting review in this proceeding will do little to resolve the disputes between the parties and achieve efficient resolution. The outcome of the ITC Investigation will be known months before we could reach a final determination. Petitioner also chose to pursue complex antitrust claims that implicate many of the same issues before us. Our final determination, however, would be only one small piece of that complex puzzle. Petitioner has other tribunals to press its claims, and giving it yet another does little to achieve the underlying purposes of the America Invents Act.

Despite Petitioner's contentions that the Board should be the "lead agency" because the "ITC[] defer[s] to the Board's expertise" and because "the ITC's validity determinations have no preclusive effect," *see* Reply 9–11 (citations omitted), *Fintiv* directs us to consider the state of a parallel ITC investigation to determine whether institution of an IPR proceeding would involve inefficient duplication of resources or the potential for inconsistent outcomes on the same or substantially the same issues. *Fintiv*, Paper 11 at 9 ("the parties should also indicate whether the patentability disputes before the ITC will resolve all or substantially all of the patentability disputes between the parties"). Notably, *Fintiv* states that "as a practical matter, it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC." *Fintiv*, Paper 11 at 9.

On balance, and even assuming the merits of the Petition are sufficient, we determine that the facts underlying the sixth factor weigh in favor of exercising discretion to deny institution under § 314.

7. Balancing the Fintiv Factors

We have considered the circumstances and facts before us in view of the *Fintiv* factors. Our analysis is fact driven and no single factor is determinative of whether we exercise our discretion to deny institution under § 314(a). Here, we determine that most of the *Fintiv* factors weigh in favor of exercising our discretion to deny institution under § 314(a). In our holistic review of all the *Fintiv* factors, the weight of the evidence sufficiently tips the balance in favor of exercising our discretion to deny institution under § 314(a).

Patent Owner argues persuasively that instituting a trial under the facts and circumstances here would be an inefficient use of Board resources. For these reasons, and the reasons discussed above with respect to each of the six *Fintiv* factors, we exercise our discretion to deny institution under § 314(a).

IV. CONCLUSION

After considering all the evidence and arguments presently before us, we determine that exercising our discretion under 35 U.S.C. § 314(a) to not institute trial is warranted. Accordingly, we do not institute an *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the Petition is denied.

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