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Paper No. 11
Filed: October 30, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2018-01019
Patent 7,976,838 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review and Grant of Motion for Joinder
35 U.S.C. § 314(a); 37 C.F.R. § 42.122(b)

I. INTRODUCTION

Celltrion, Inc. (““Celltrion”) filed a Petition (Paper 1 (“Pet.”)), seeking an *inter partes* review of claims 1–14 of U.S. Patent No. 7,976,838 B2 (Ex. 1001; “the ’838 patent”). Along with the Petition, Celltrion also filed a Motion for Joinder seeking to join this proceeding to IPR2017-01923 (“Pfizer IPR”). Paper 3 (“Mot.”).

Genentech, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition (Paper 8 (“Prelim. Resp.”)) and an Opposition to the Motion for Joinder (Paper 7 (“Opp.”)).

As explained further below, we institute trial on all grounds raised in the Petition, which are the same grounds as instituted in IPR2017-01923, and grant Celltrion’s Motion for Joinder.

A. Related Proceedings

Patent Owner informs us of the following litigations involving the ’838 patent: *Genentech, Inc. v. Sandoz, Inc*., 2:17-cv-13507 (D.N.J.), filed December 21, 2017 in the District of New Jersey; *Genentech, Inc. et al. v. Celltrion, Inc. et al*., 1:18-cv-00574 (D.N.J.), filed January 12, 2018 in the District of New Jersey; and *Celltrion, Inc. et al. v. Genentech, Inc. et al*., 4:18-cv-00276 (N.D. Cal.), filed January 11, 2018 in the Northern District of California. Paper 6, 2.

Previously, the ’838 patent was challenged in IPR2015-00417 by petitioners Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, “Boehringer”). *Inter partes* review was instituted for claims 1–14. IPR2015-00417, Paper 11. Thereafter, the case was terminated upon a request by Boehringer. IPR2015-00417, Paper 18.

Prior to termination in IPR2015-00417, Celltrion filed a petition challenging the ’838 patent in IPR2015-01733 and a motion for joinder with IPR2015-00417. IPR2015-01733, Papers 2, 3. Subsequently, this petition was dismissed without prejudice upon a request by Celltrion. IPR2015-01733, Paper 12.

Celltrion later filed a petition challenging the ’838 patent in IPR2016-01667. That petition was subsequently denied. IPR2016-01667, Paper 15.

Pfizer, Inc. (“Pfizer”) later filed a petition challenging the ’838 patent in Pfizer IPR (IPR2017-01923). That petition was subsequently granted and the instituted *inter partes* review proceeding remains pending before the Board. IPR2017-01923, Paper 14.

The ’838 patent was challenged in IPR2017-02036 and IPR2017-02042 by another petitioner, Sandoz, Inc. Those petitions were subsequently denied. IPR2017-02036, Paper 13; IPR2017-02042, Paper 11.

B. The ’838 Patent

The ’838 patent discloses methods of treating rheumatoid arthritis (“RA”) in a human patient who experiences an inadequate response to a tumor necrosis factor α (TNFα) inhibitor. Ex. 1001, Abstract, 4:3–24. The methods of the claimed invention involve administration of an antagonist that binds to a B cell surface marker, such as CD20. *Id.* at 4:60–65.

The Specification describes treating patients who have experienced an inadequate response to a TNFα-inhibitor. *Id*. at 6:64−7:12. The Specification expressly defines the term “inadequate response to a TNFα-inhibitor” as follows:

> [A]n inadequate response to previous or current treatment with a TNFα-inhibitor because of toxicity and/or inadequate efficacy. The inadequate response can be assessed by a clinician skilled in treating the disease in question.

Id. at 5:25–29.

The '838 patent specifically discloses Etanercept (ENBREL®), Infliximab (REMICADE®) and Adalimumab (HUMIRA™) as examples of TNF inhibitors. *Id.* at 5:19–24.

C. Challenged Claims

Claims 1, 2, 8, 10, and 11 are the independent claims among the challenged claims, and are reproduced below:

> **1.** A method of treating rheumatoid arthritis in a human patient who experiences an inadequate response to a TNFα-inhibitor, comprising administering to the patient an antibody that binds to CD20, wherein the antibody is administered as two intravenous doses of 1000 mg.
>
> **2.** A method of treating rheumatoid arthritis in a human patient who experiences an inadequate response to a TNFα-inhibitor, comprising administering to the patient an antibody which binds to CD20 in an amount that is effective to provide an ACR50 response at week 24, ACR70 response at week 24, or no erosive progression at weeks 24 and beyond, wherein the antibody is administered as two intravenous doses of 1000 mg.
>
> **8.** A method of treating rheumatoid arthritis in a human patient who experiences an inadequate response to a TNFα-inhibitor, comprising administering to the patient rituximab, wherein rituximab is administered as two intravenous doses of 1000 mg.
>
> **10.** A method of treating rheumatoid arthritis in a human patient who experiences an inadequate response to a TNFα-inhibitor, comprising administering to the patient rituximab, and methotrexate, wherein the patient has no erosive progression at

> weeks 24 and beyond, and wherein rituximab is administered as two intravenous doses of 1000 mg.
>
> **11.** A method of achieving a clinical response selected from the group consisting of ACR50 response at week 24, ACR70 response at week 24, and no erosive progression at weeks 24 and beyond, in a human rheumatoid arthritis patient who experiences an inadequate response to a TNFα-inhibitor, comprising administering to the patient rituximab, and methotrexate, wherein rituximab is administered as two intravenous doses of 1000 mg.

Claims 3–7 depend from claim 2, either directly or indirectly. Claim 9 depends directly from claim 8. Claims 12–14 depend directly from claim 11.

D. Evidence Relied Upon

Petitioner relies upon the following prior art references:

Ex. 1003, J. C. W. Edwards et al., *Efficacy and Safety of Rituximab, a B-Cell Targeted Chimeric Monoclonal Antibody: A Randomized, Placebo-Controlled Trial in Patients with Rheumatoid Arthritis*, Abstracts of the American College of Rheumatology 66th Annual Meeting, Oct. 24-29, 2002 (New Orleans, LA) ("Edwards 2002").

Ex. 1004, J.C.W. Edwards & G. Cambridge, *Sustained Improvement in Rheumatoid Arthritis Following a Protocol Designed to Deplete B Lymphocytes*, 40 RHEUMATOLOGY 205–11 (2001) ("Edwards 2001").

Ex. 1005, Seisuke Takemura et al., *T Cell Activation in Rheumatoid Synovium Is B Cell Dependent*, 167 J. IMMUNOL. 4710–18 (2001) ("Takemura").

Ex. 1006, Piotr Klimiuk et al., *Tissue Cytokine Patterns Distinguish Variants of Rheumatoid Synovitis*, 151(5) AM. J. PATHOLOGY 1311–19 (1997) ("Klimiuk").

Ex. 1007, Ann-Kristin Ulfgren et al., *Systemic Anti-Tumor Necrosis Factor A Therapy in Rheumatoid Arthritis Down-Regulates Synovial Tumor Necrosis Factor A Synthesis*, 43(11) ARTHRITIS & RHEUMATISM 2391–96 (2000) ("Ulfgren").

Ex. 1008, Patent Application Publication No. WO 00/67796 A1 by John G. Curd et al., published Nov. 16, 2000 ("Curd").

Ex. 1009, PHYSICIANS' DESK REFERENCE® (53rd ed. 1999) (excerpted), "Rituxan™ (Rituximab)" ("Rituxan Label").

Celltrion supports its challenge with the Declarations of Maarten Boers, M.D., Ph.D., M.Sc. (Ex. 1002); Elizabeth Greenfield, J.D., M.L.I.S. (Ex. 1034); and Jayesh Mehta, M.D. (Ex. 1041).

E. Asserted Grounds of Unpatentability

Celltrion challenges claims 1–14 of the '838 patent on the following grounds. Pet. 6–7.

Ground	References	Basis	Challenged Claim(s)
1	Edwards 2002, Takemura, Klimiuk, and Ulfgren	§ 103	1–5 and 7–14
2	Edwards 2002, Takemura, Klimiuk, Ulfgren, and Curd	§ 103	6
3	Edwards 2001, Rituxan Label, Takemura, Klimiuk, and Ulfgren	§ 103	1–3 and 7–8
4	Edwards 2001, Rituxan Label, Takemura, Klimiuk, Ulfgren, and Curd	§ 103	4–6 and 9–14

II. INSTITUTION OF *INTER PARTES* REVIEW

Celltrion can be joined as a petitioner in Pfizer IPR only if we determine the present Petition warrants institution on its merits. 35 U.S.C. § 315(c). We instituted trial in Pfizer IPR with respect to all challenged claims and on all the grounds set forth in Pfizer's Petition. IPR2017-01923, Papers 1, 14, 21.

Celltrion represents that the current Petition is substantially identical to Pfizer's Petition. *See* Mot. 1 ("Celltrion's Petition relies on the references cited and follows the arguments raised in the Pfizer Petition, and is

essentially a copy of the Pfizer Petition."). Patent Owner does not dispute that the current Petition is substantively identical to the Pfizer's Petition. *See* Prelim. Resp. 1 (referring to Celltrion's Petition as a "copycat"). Moreover, we conducted our own review and determine that the Petition in this case is substantively identical to the one in Pfizer IPR. Accordingly, given that Celltrion's Petition is substantively the same or similar to Pfizer's Petition, we determine that Celltrion has demonstrated a reasonable likelihood that it would prevail in showing the challenged claims are unpatentable based upon the same grounds for the same reasons stated in our Institution Decision in the Pfizer IPR. *See* IPR2017-01923, Papers 14, 21.

We acknowledge Patent Owner's arguments and evidence supporting its position that the claims would not have been obvious. Prelim. Resp. 28–61. Certain of Patent Owner's arguments against the merits of the Petition have been previously addressed in our Institution Decision in the Pfizer IPR (IPR2017-01923, Paper 14), and we need not address them here again. Certain other arguments against the merits of the Petition closely mirror arguments made in the Patent Owner Response filed in the Pfizer IPR (*compare* Prelim. Resp. 28–61 and Pfizer IPR PO Resp. (IPR2017-01923, Paper 45, 16–62)). Those common arguments will be fully considered in the Pfizer IPR after Celltrion has replied and with the benefit of a complete record. In sum, based on the current record, Patent Owner's arguments made in its Preliminary Response in this case do not persuade us that Celltrion has not demonstrated a reasonable likelihood of success in prevailing on the same grounds as instituted in IPR2017–01923.

Patent Owner has also argued that we should deny the Petition under 35 U.S.C. § 314(a) and 35 U.S.C. § 325(d). Prelim. Resp. 6–22. We address those arguments next.

A. Discretionary Denial under 35 U.S.C. § 314(a)

In *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential), the Board identified seven nonexclusive factors that bear on the issue of whether the Board should invoke its discretion to deny institution of an *inter partes* review, based on a follow-on petition on the same patent, under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a):

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

General Plastic, slip op. at 15–16 (citing *NVIDIA Corp. v. Samsung Elec. Co.*, IPR2016-00134, slip op. 6–7 (PTAB May 4, 2016) (Paper 9)).

Patent Owner requests that we deny institution of trial under 35 U.S.C. § 314(a), pursuant to the doctrine of *General Plastic*, in view of Celltrion's previously filed petitions challenging the '838 patent, identified in Section I.A hereinabove. Prelim. Resp. 6–12.

In particular, Patent Owner contends that a) "[t]his Petition introduces more permutations of previously-considered art and arguments" (*id.* at 7); b) "Celltrion relies on much of the same art in substantially the same manner" cited in its previously filed petitions (*id.* at 8); c) "Celltrion also seeks to benefit from the extensive (and repeated) attacks on other rituximab patents" (*id.* at 9); d) "Celltrion knew of its Edwards references plus Curd long before Pfizer's petition" (*id.*); and e) "Celltrion fails to even mention §314(a), and thus provides no explanation for not filing sooner" (*id.* at 10) (emphasis omitted).

We "recognize the potential for abuse of the review process by repeated attacks on patents." *General Plastic*, slip op. at 17. Nevertheless, "[t]here is no *per se* rule precluding the filing of follow-on petitions after the Board's denial of one or more first-filed petitions on the same patent." *Id.* at 15. Indeed, "there may be circumstances where multiple petitions by the same petitioner against the same claims of a patent should be permitted, and . . . such a determination is dependent on the facts at issue in the case." *Id.* at 18.

In this case, we do not find Patent Owner's analysis of the factors outlined in *General Plastic* to be particularly persuasive for establishing abuse of the review process for the situation where a different petitioner files a "me-too" or "copycat" petition in conjunction with a timely motion to join an *inter partes* review based upon the (essentially) copied petition filed by

different petitioner.[1] By its very nature, such a petition necessarily relies on substantially the same prior art and arguments previously considered by the Office, and is timely, even though such a petition is filed after our institution decision. *See* 37 C.F.R. § 42.122(b) ("Any request for joinder must be filed, as a motion under § 42.22, no later than one month after the institution date of any *inter partes* review for which joinder is requested.") In addition, although Celltrion has previously filed two petitions directed to the same claims of the same patent (*see* Section I.A), Patent Owner's arguments directed to these petitions lose force when we consider that we have already instituted trial in Pfizer IPR, Patent Owner has filed its Response in Pfizer IPR addressing the same patentability challenges, and the case is actively proceeding to a Final Written Decision. Celltrion's Petition does not present any ground or matter not already at issue in Pfizer IPR and Celltrion agrees that it will participate in the proceeding "[only] in a limited 'understudy' role." Mot. 1. Thus, under these circumstances, the concurrently filed motion to join the Pfizer IPR effectively obviates any concerns of serial harassment and unnecessary expenditure of resources.

We are mindful of the possibility that Pfizer and Patent Owner may settle their dispute and seek a termination of the Pfizer IPR. Even under that potential circumstance, however, instituting trial here would not result in undue prejudice against Patent Owner. First, the statute explicitly states that even "[i]f no petitioner remains in the inter partes review, the Office may . . .

[1] *Cf.* IPR2018-00330 (denying institution and joinder when petitioner essentially copies its own earlier petition and seeks to join a proceeding in which it is already a petitioner without providing a persuasive reason for doing so).

proceed to a final written decision." 35 U.S.C. § 317(a). The Federal Circuit also recognizes that the "Board may enter decision even after petitioner settles and drops out of the proceeding." *Progressive Cas. Ins. Co. v. Liberty Mut. Ins. Co.*, 625 Fed. Appx. 552, 556 (Fed. Cir. 2015). Second, once joined, this case will be on the same schedule as Pfizer IPR for all the filings and for the oral hearing. Celltrion cannot, therefore, "strategically stage their prior art and arguments in multiple petitions, using our decisions [in Pfizer IPR] as a roadmap." *See General Plastic*, Paper 19, 17.

Thus, based on these circumstances and our consideration of *General Plastic*, we determine that, even though this is the third petition filed by Celltrion challenging claims of the '838 patent, instituting *inter partes* review in this case would not result in undue prejudice to Patent Owner.

B. Discretionary Denial under 35 U.S.C. § 325(d)

We have discretion under 35 U.S.C. § 325(d) to reject a petition when the same or substantially the same prior art or arguments were presented previously to the Office. The relevant portions of that statute are reproduced below:

> In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

35 U.S.C. § 325(d). In exercising our discretion under § 325(d), we take into account numerous factors, including the facts of each case, and the burden on the parties and the Board. *See Conopco, Inc. v. Proctor & Gamble Co.*, Case IPR2014-00506, slip op. at 4, 6 (PTAB Dec. 10, 2014)

(Paper 25) (informative). We note that although we have the authority to decline to institute review on the basis that the same or substantially the same prior art or arguments were presented previously to the Office, the statute does not require that result.

Patent Owner asserts that we should exercise our discretion to deny the Petition under 35 U.S.C. § 325(d) because "[t]he Petition relies on substantially the same art and arguments previously presented in both prosecution and prior IPRs." Prelim. Resp. 13 (emphasis omitted). As noted by Patent Owner, however, we have "previously rejected Genentech's § 325(d) arguments in the context of Pfizer's Edwards 2002 grounds," namely Grounds 1 and 2 set forth in Celltrion's Petition. *Id.* at 15 (citing IPR2017-01923, Papers 14, 23). Similarly, we reject Patent Owner's § 325(d) arguments presented here with regard to Grounds 1 and 2 for the same reasons stated in our Institution Decision in the Pfizer IPR. IPR2017-01923, Paper 14.

We have also addressed Patent Owner's § 325(d) arguments in the context of Pfizer's Edwards 2001 grounds, namely Grounds 3 and 4 set forth in Celltrion's Petition. IPR2017-01923, Paper 33. For Grounds 3 and 4, we previously declined to exercise our discretion under § 325(d) in the Pfizer IPR because we determined that Grounds 1 and 2 in that proceeding had sufficient merit to institute trial.[2] *Id.* at 4. Similarly, we reject Patent

[2] That is, we previously determined that in Pfizer IPR, Pfizer demonstrated a reasonable likelihood that it will succeed on at least one of its challenges to patentability. Under the Office's Guidance implementing *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018): "[a]t this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." Guidance on the Impact of SAS on AIA Trial Proceedings ("Guidance"),

Owner's § 325(d) arguments presented here with regard to Grounds 3 and 4 for the same reasons stated in our decision denying Patent Owner's request for rehearing in the Pfizer IPR. IPR2017-01923, Paper 33. Moreover, as discussed above, Celltrion filed a concurrent motion to join the Pfizer IPR, effectively obviating any concerns of serial harassment and unnecessary expenditure of resources.

Accordingly, we decline to exercise our discretion to deny the Petition under § 325(d).

III. MOTION FOR JOINDER

As noted above, Celltrion requests that we join the present proceeding with IPR2017-01923. Mot. 1. Joinder is governed by 35 U.S.C. § 315(c), which recites:

> (c) JOINDER. —If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

When determining whether to grant a motion for joinder, we consider factors such as timing and impact of joinder on the trial schedule, cost, discovery, and potential simplification of briefing. *Kyocera Corp. v. SoftView, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15).

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available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (April 26, 2018). Accordingly, we instituted trial as to all claims and all grounds presented in Pfizer's petition based on the merits of Grounds 1 and 2.

As noted, the Petition in this case asserts the same unpatentability grounds on which we instituted review in the Pfizer IPR. Mot. 1; Prelim. Resp. 1. Celltrion also relies on the same prior art analysis and, although Celltrion relies on different experts than Pfizer, Celltrion asserts that its "copycat declarations" provide a discussion and analysis that "is substantially the same as the analysis of Pfizer's experts" and will not be relied upon unless Pfizer is terminated from the proceedings. Mot. 5. Thus, Celltrion's Petition does not present any ground or matter not already at issue in the Pfizer IPR. We are not persuaded by Patent Owner's arguments to the contrary. Opp.
12–15.

Furthermore, we are persuaded that the relevant factors weigh in favor of joinder. Celltrion timely filed its Motion for Joinder in the present proceeding. 37 C.F.R. § 42.122(b). Celltrion represents that the Petition in this case is "essentially a copy of the Pfizer Petition," including "the identical grounds presented in the Pfizer Petition." Mot. 1. Celltrion agrees that it will participate in the proceeding "[only] in a limited 'understudy' role," unless Pfizer is terminated as a party. *Id.*; *see also id.* at 7 (agreeing that, as long as Pfizer remains a party to the IPR, Celltrion will not produce its own testifying witnesses or file substantive papers). As a result, Celltrion avers that joinder will "create no additional burden for the Board, Pfizer or Genentech," "will not . . . add additional complexity to the case," "will not impact the trial schedule" of Pfizer IPR, and "will not add further complication to the proceedings or cause prejudice to the parties." *Id.* at 1, 4, 6.

In its Opposition, Patent Owner argues that we should deny the Petition under 35 U.S.C. § 314(a) and 35 U.S.C. § 325(d). Opp. 2–12. Patent Owner's arguments are unpersuasive for the reasons set forth in Section II.A. and II.B., above.

In view of the foregoing, we find that joinder based upon the conditions stated by Celltrion in its Motion for Joinder will have little or no impact on the timing, cost, or presentation of the trial on the instituted grounds in Pfizer IPR. Celltrion's Motion for Joinder is granted.

IV. CONCLUSION

For the reasons set forth above, we institute an *inter partes* review and grant Celltrion's Motion for Joinder.

V. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes review* of claims 1–14 of the '838 patent is instituted in IPR2018-01019 with respect to all grounds set forth in the Petition;

FURTHER ORDERED that the Motion for Joinder is *granted*, and Celltrion is joined as a petitioner in IPR2017-01923;

FURTHER ORDERED that, pursuant to 37 C.F.R. §§ 42.72 and 42.122, IPR2018-01019 is terminated and all further filings shall be made only in IPR2017-01923;

FURTHER ORDERED that the Scheduling Order in place for IPR2017-01923 shall govern the joined proceedings;

FURTHER ORDERED that, absent leave of the Board, Celltrion shall maintain an understudy role with respect to Pfizer, coordinate filings with Pfizer, not submit separate substantive filings, not participate substantively

in oral argument, and not actively participate in deposition questioning except with the assent of all parties;

FURTHER ORDERED that the case caption in IPR2017-01923 for all further submissions shall be changed to add Celltrion as a named Petitioner after Pfizer, and to indicate by footnote the joinder of IPR2018-01019 to that proceeding, as indicated in the attached form of caption;

FURTHER ORDERED that the parties shall file an updated Protective Order to reflect the addition of Celltrion as a named Petitioner; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2017-01923.

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Sample Case Caption

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC. and CELLTRION, INC.,
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v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01923[1]
Patent 7,976,838 B2

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[1] Case IPR2018-01019 has been joined with this proceeding.