Trials@uspto.gov
571-272-7822

Paper 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2018-00331
Patent 9,249,218 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review and
Dismissing Motion for Joinder
35 U.S.C. §§ 314 and 325(d), 37 C.F.R. § 42.122

I. INTRODUCTION

Pfizer, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1 and 5–7 of U.S. Patent No. 9,249,218 B2 (Ex. 1001, "the '218 patent"). Paper 1 ("Pet."). Petitioner also filed a Motion for Joinder to join this proceeding with *Pfizer, Inc. v. Genentech, Inc.*, Case No. IPR2017-02020 (the "2020 IPR") which was instituted on March 12, 2017. Paper 3 ("Mot."). Genentech, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 11 ("Prelim. Resp."). Patent Owner also filed an Opposition to the Motion for Joinder. Paper 7 ("Mot. Opp."). Petitioner filed a Reply to Patent Owner's Opposition. Paper 9.

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. *See also* 37 C.F.R. § 42.4(a). Upon considering the circumstances involved in this case, we exercise our discretion under 35 U.S.C. §§ 314(a) and 325(d) to deny instituting an *inter partes* review of the challenged claims.

A. Related Proceedings

Petitioner provides notice that the '218 patent is at issue in *Genentech, Inc. et al. v. Pfizer, Inc.* (D. Del) 1:17-cv-01672. Pet. 1. Petitioner notes that the complaint in that litigation was served on November 20, 2017. *Id*.

On August 29, 2017, Petitioner filed a first petition for *inter partes* review of claims 1 and 5–7 of the '218 patent. 2020 IPR, Paper 2. An *inter partes* review was instituted in that proceeding on March 12, 2018. *Id*. at Paper 16; *see also* Paper 25 (modifying institution to include all claims and all grounds). A Final Written Decision has not been entered in that proceeding.

B. The '218 Patent

The '218 patent relates to "a method for purifying a polypeptide (e.g. an antibody) from a composition comprising the polypeptide and at least one contaminant using the method of ion exchange chromatography." Ex. 1001, 1:23–27. The contaminant is a material that is different from the desired polypeptide product, and may be a variant of the desired polypeptide. *Id*. at 5:29–31. Further, the invention provides a composition comprising a mixture of anti-HER2 antibody and one or more acidic variants thereof, wherein the amount of the acidic variant(s) is less than about 25%. *Id*. at 3:49–53.

The Specification explains that an "acidic variant" is "a variant of a polypeptide of interest which is more acidic (e.g. as determined by cation exchange chromatography) than the polypeptide of interest." *Id*. at 5:60–62. According to the Specification, an example of an acidic variant is a deamidated variant. *Id*. at 5:62–63. The Specification states that "[i]t has been found, for example, that in preparations of anti-HER2 antibody obtained from recombinant expression, as much as about 25% of the anti-HER2 antibody is deamidated." *Id*. at 6:15–18.

The Specification explains that the term "humMAb4D5-8" refers to humanized anti-HER2 antibody comprising the light chain amino acid sequence of SEQ ID NO:1 and the heavy chain amino acid sequence of SEQ ID NO:2, or amino acid sequence variants thereof which retain the ability to bind HER2 and inhibit growth of tumor cells which overexpress HER2. *Id*. at 13:65–14:5. When referring to the rhuMAb HER2 antibody in an example, the Specification identifies parenthetically "humAb4D5-8." *Id*. at 8:14–15; 20:39–40 (Example 1). Deamidated humMAb4D5 antibody from

Example 1 in the Specification has Asn30 in CDR1 (complementarity determining region) of either or both of the V_L (light chain variable domain) regions thereof converted to aspartate. *Id*. at 6:1–3; 7:67–8:1.

Compositions comprising anti-HER2 antibody may optionally include a pharmaceutically acceptable carrier. *Id*. at 3:54–55; 19:30–53. According to the Specification, "[t]he humMAb4D5-8 antibody of particular interest herein may be prepared as a lyophilized formulation, e.g. as described in [Andya]; expressly incorporated herein by reference. *Id*. at 19:54–57. The Specification states that "[t]he polypeptide purified as disclosed herein or the composition comprising the polypeptide and a pharmaceutically acceptable carrier is then used for various diagnostic, therapeutic or other uses known for such polypeptides and compositions." *Id*. at 20:25–29.

C. Claims

Independent claim 1 is representative of the challenged claims and is reproduced below:

> 1. A therapeutic composition comprising a mixture of anti-HER2 antibody and one or more acidic variants thereof,
> wherein the amount of the acidic variant(s) is less than about 25%,
> and wherein the acidic variant(s) are predominantly deamidated variants wherein one or more asparagine residues of the anti-HER2 antibody have been deamidated,
> and wherein the anti-HER2 antibody is humMAb4D5-8,
> and wherein the deamidated variants have Asn30 in CDR1 of either or both VL regions of humMAb4D5-8 converted to aspartate,
> and a pharmaceutically acceptable carrier.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1 and 5–7 of the '218 patent on the following grounds:

Claim(s)	Basis	References
1 and 5–7	§ 102(b), § 103(a)	Andya[1]
1 and 5–7	§ 103(a)	Waterside[2]
1 and 5–7	§ 103(a)	Harris[3]

Petitioner also relies upon the Declarations of Drew N. Kelner, Ph.D. (Ex. 1002), Richard Buick, Ph.D. (Ex. 1015), and Keith L. Carson (Ex. 1020). Pet. 3.

II. ANALYSIS

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

Patent Owner requests that we deny institution of trial under 35 U.S.C. § 314(a), pursuant to the doctrine of *General Plastic Industries Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential), in view of the previously filed petition by the same petitioner, identified above in Section I.A. Prelim. Resp. 11.

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[1] International PCT Application No. WO 97/04801 published on Feb. 13, 1997 (Ex. 1004).
[2] Harris, *Chromatographic Techniques for the Characterization of Human MAbs (slides presented at the Waterside Monoclonal Conference held at the Omni Waterside Hotel in Harborside-Norfolk, Virginia on Apr. 22–25. 1996)*(Ex. 1005).
[3] Harris, *Processing of C-terminal Lysine and Arginine Residues of Proteins Isolated from Mammalian Cell Culture*, 705 J. CHROMATOGRAPHY A 129 (1995) (Ex. 1007).

In *General Plastic*, 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)). In applying these factors, we consider not only the congressional intent that *inter partes* review proceedings provide an effective and efficient alternative to district court litigation, but also the potential for abuse of the review process through repeated attacks by the same petitioner with respect to the same patent. *See Gen. Plastic*, slip. op. at 18 n.14 (citing H.R. Rep. No. 112-98, pt. 1, at 48 (2011) ("Allowing similar, serial challenges to the same

patent, by the same petitioner, risks harassment of patent owners and frustration of Congress's intent in enacting the Leahy-Smith America Invents Act").

Patent Owner contends the *General Plastic* factors support denial of the Petition. Prelim. Resp. 11–27. Regarding factors 1 and 2, Patent Owner argues that the Petition challenges the same claims with the same prior art as presented in the 2020 IPR. *Id.* at 12–13. Further, regarding factor 2, Patent Owner asserts also that the Petition additionally relies upon a new declaration from Dr. Buick describing a second set of experiments attempting to "recreate the product of the prior art" by expressing humMAb4D5-8 in HEK cells, wherein those experiments "were completed *before* Pfizer's first petition and thus could have been included in that petition as well." *Id*. at 13 (citing Paper 1, Ex. 1015). Patent Owner asserts also that Petitioner does not allege that it was unaware of the additional "background" references relied upon in the Petition, comprising books and journal articles published between 1987 and 2009, when it filed the petition in the 2020 IPR. *Id*. at 15.

Regarding factor 3, Patent Owner notes that Petitioner filed the Petition four days after Patent Owner filed its Preliminary Response in the 2020 IPR. *Id*. at 15. According to Patent Owner, the Petitioner uses that filing as a roadmap by attempting in its Petition to "remedy specific deficiencies that Genentech identified in its [2020 IPR] preliminary response." *Id*. at 15–16. Regarding factors 4 and 5, Patent Owner asserts that Petitioner has not provided any explanation for the time that elapsed between the filings of its petitions. *Id*. at 23. As for factor 6, Patent Owner asserts that the Board's finite resources should not be spent deciding the

Petition when Petitioner "could have included its evidence and argument in its first petition, yet chose to hold them back until after receiving Genentech's [2020 IPR] preliminary response." *Id*. at 25–26. Similarly, regarding factor 7, Patent Owner asserts that Petitioner has not provided any explanation for its follow-on petition and that such petition serves only to prolong its challenged to the same claims of the '218 patent over the same prior art, by relying on additional arguments and evidence. *Id*. at 27.

As Patent Owner correctly asserts, Petitioner does not address the *General Plastic* factors in the Petition. As such, we are left to wonder why Petitioner has filed a second petition challenging the same claims over the same grounds included in a first petition. Petitioner's Motion for Joinder with the 2020 IPR does not provide insight. Rather, in that motion, Petitioner confirms that "not only is there substantial overlap in the cited prior art, both [p]etitions rely on similar disclosures from each of the prior art to make substantially the same arguments for both anticipation and obviousness." Mot. 5.

Having considered the Petition and the Preliminary Response, we determine that Patent Owner's request for us to exercise our discretion to deny institution of an *inter partes* review in this proceeding under 35 U.S.C. § 314(a), in view of *General Plastic*, is well-reasoned and persuasive. For the reasons discussed by Patent Owner, we find that each *General Plastic* factor weighs in favor of denying the Petition. Significantly, we have already instituted an *inter partes* review of the challenged claims based upon a petition filed by Petitioner and including the same grounds set forth in the current Petition. Petitioner has not explained its reasons for filing the second petition or why the substance of the second petition was not, or could not

have been, included in the first petition. Indeed, Petitioner does not assert that the petitions materially differ.

Moreover, Petitioner has not explained, nor do we see, that other facts are at issue in this case such that the Petitioner should be permitted to challenge the same claims of the '218 patent in a second petition, apart from our consideration of the *General Plastic* factors. *See General Plastic*, slip op. at 18 (explaining that, apart from consideration of the *General Plastic* factors, "there may be circumstances where multiple petitions by the same petitioner against the same claims of a patent should be permitted, and that such a determination is dependent on the facts at issue in the case"). Accordingly, in view of Section 314(a) and *General Plastic*, we exercise our discretion to deny the Petition.

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

Patent Owner additionally asserts that we should exercise our discretion to deny the Petition under 35 U.S.C. § 325(d) because the asserted grounds rely upon the same prior art previously presented to the Office during the prosecution of the '218 patent and in the 2020 IPR. Prelim. Resp. 28.

Regarding consideration of the prior art during prosecution, Patent Owner asserts that Andya, Waterside, and Harris are "listed on the face of the ['218] patent (Paper 1, Ex. 1001, 1-3), and Andya is further described in the specification and incorporated by reference (*id*., 19:54-57)." Prelim. Resp. 28. Patent Owner does not provide further discussion or evidence from the prosecution history to substantiate its assertion. Thus, we decline to exercise our discretion under § 325(d) based upon that bare assertion as Patent Owner has not demonstrated adequately that the Examiner

substantively considered Andya, Waterside, or Harris in allowing the claims by merely directing us to portions of the issued patent.

Regarding Patent Owner's position that the asserted grounds rely upon the same prior art previously presented to the Office in the 2020 IPR, we agree. Indeed, as discussed above in Section II. A, Petitioner concedes that, "both [p]etitions rely on similar disclosures from each of the prior art to make substantially the same arguments for both anticipation and obviousness." Mot. 5. Petitioner has not asserted, however, any reason for us to not to exercise our discretion to deny the Petition under § 325(d) when such similarities exist between the two petitions, nor do we find one. Accordingly, because we are already considering the same prior art and substantially the same arguments in the 2020 IPR, we decline to do so again.

III. MOTION FOR JOINDER

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions 35 U.S.C. § 315(c), which governs joinder of *inter partes* review proceedings:

> (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.

Petitioner timely filed its Motion for Joinder within one month of the institution of the 2020 IPR, as required by 37 C.F.R. § 42.122(b). Mot. Patent Owner opposes the motion. Mot. Opp. In view of our determination to deny the Petition, we dismiss the Motion for Joinder as moot.

IV. CONCLUSION

For the foregoing reasons, we exercise our discretion under § 314(a) and § 325(d) to deny the Petition and dismiss the Motion for Joinder as moot.

ORDER

Accordingly, it is hereby:

ORDERED that Petitioner's request for an *inter partes* review of claims 1 and 5–7 of the '218 patent is *denied;* and

ORDERED that Petitioner's Motion for Joinder is *dismissed* as moot.

PETITIONER:

Thomas Meloro
Michael Johnson
WILLKIE FARR & GALLAGHER LLP
tmeloro@willkie.com
mjohnson1@willkie.com

PATENT OWNER:

David Cavanaugh
Lauren Blakely
Emily Whelan
Mark McBriar
WILMER CUTLER PICKERING HALE AND DORR LLP
david.cavanaugh@wilmerhale.com
lauren.blakely@wilmerhale.com
emily.whelan@wilmerhale.com
mark.mcbriar@wilmerhale.com

Adam Brausa
DURIE TANGRI LLP
abrausa@durietangri.com