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Paper 13
Entered: July 09, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2018-00330
Patent 6,339,142 B1

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 1–3 of U.S. Patent No. 6,339,142 B1 (Ex. 1001, "the '142 patent"). Paper 1 ("Pet."). Petitioner also filed a Motion for Joinder to join this proceeding with *Pfizer, Inc. v. Genentech, Inc.*, Case No. IPR2017-02019 (the "2019 IPR") which was instituted on March 12, 2018. 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

The parties provide notice that the '142 patent is at issue in *Genentech, Inc. et al. v. Pfizer, Inc.* (D. Del) 1:17-cv-01672. Pet. 1; Paper 4, 4. Petitioner notes that the complaint in that litigation was served on November 20, 2017. Pet. 1.

On August 29, 2017, Petitioner filed a first petition for *inter partes* review of claims 1–3 of the '142 patent. 2019 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 '142 Patent

The '142 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, 1:12–15. The contaminant is a material that is different from the desired polypeptide product, and may be a variant of the desired polypeptide. *Id*. at 5:14–16. 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 3:35–38. 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 5:45–47. According to the Specification, an example of an acidic variant is a deamidated variant. 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 6:1–4.

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 13:58–65. When referring to the rhuMAb HER2 antibody in an example, the Specification identifies parenthetically "humAb4D5-8." *Id*. at 8:1–2; 20:48–49 (Example 1). Compositions comprising anti-HER2 antibody may optionally include a pharmaceutically acceptable carrier. *Id*. at 3:40–41;

19:35–62. 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 19:62–65.

C. Claims

Claims 1–3 are reproduced below:

> 1. 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%.
>
> 2. The composition of claim 1 further comprising a pharmaceutically acceptable carrier.
>
> 3. The composition of claim 1 wherein the anti-HER2 antibody is humMAb4D5-8.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–3 of the '142 patent on the following grounds:

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

[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).

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.

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

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