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MEMORANDUM

DATE: February 22, 2018

TO: Patent Examining Corps

FROM: Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy

SUBJECT: **Clarification of Written Description Guidance For Claims Drawn to Antibodies and Status of 2008 Training Materials**

The purpose of this memorandum is to clarify the applicability of USPTO guidance regarding the written description requirement of 35 U.S.C. § 112(a), specifically concerning the written description requirement for claims drawn to antibodies.

I. Federal Circuit Clarification of the Law of Written Description As It Applies to Antibodies

Recently, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) decided *Amgen v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), which concerned adequate written description for claims drawn to antibodies. These claims are usually handled in Technology Center 1600. The Federal Circuit explained in *Amgen* that when an antibody is claimed, 35 U.S.C. § 112(a) requires adequate written description of the antibody itself. *Amgen,* 872 F.3d at 1378-79. The *Amgen* court expressly stated that the so-called "newly characterized antigen" test, which had been based on an example in USPTO-issued training materials and was noted in dicta in several earlier Federal Circuit decisions, should not be used in determining whether there is adequate written description under 35 U.S.C. § 112(a) for a claim drawn to an antibody. Citing its decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the court also stressed that the "newly characterized antigen" test could not stand because it contradicted the *quid pro quo* of the patent system whereby one must describe an invention in order to obtain a patent. *Amgen*, 872 F.3d at 1378-79, quoting *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1345 (Fed. Cir. 2010). In view of the *Amgen* decision, adequate written description of a newly characterized antigen alone should not be considered adequate written description of a claimed antibody to that

newly characterized antigen, even when preparation of such an antibody is routine and conventional. *Id.* The *Amgen* decision will be added to the MPEP in due course.

II. Examples in the 2008 Written Description Training Materials Are Outdated

On March 25, 2008, the USPTO issued revision 1 of the Written Description Training Materials. As indicated on the USPTO web site at https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials, these training materials have been archived. Written description training materials containing examples that reflect developments in the law regarding 35 U.S.C. §§ 101 and 112 are being prepared. The archived training materials are outdated and should **not** be relied upon as reflecting the current state of the law regarding 35 U.S.C. §§ 101 and 112.

III. Available Current Guidance On Written Description

USPTO personnel should continue to follow the guidance in the MPEP regarding written description (see, e.g., MPEP 2161.01 and 2163), except insofar as MPEP 2163 indicates that disclosure of a fully characterized antigen may provide written descriptive support of an antibody to that antigen. The MPEP will be updated in due course to reflect these changes.

Other guidance and training materials that remain applicable and should be followed by USPTO personnel (see https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials) include:

- The 2015 training module entitled "Examining Claims for Compliance with 35 USC 112(a): Overview & Part I - Written Description"
- The 2015 Written Description Workshop materials
- The 2015-16 training slide set entitled "Antibody Decisions and Their Compliance with the Written Description Requirement," which discusses the *Centocor v. Abbott, 636 F.3d 1341 (Fed. Cir. 2011)* and *AbbVie v. Janssen*, 759 F.3d 1285 (Fed. Cir. 2014) decisions, with the exception of bullet 2 on slide 17 which references the dicta in *Centocor* that cites to the 2008 USPTO Written Description Training Materials

Accordingly, patent examiners who handle applications containing claims drawn to antibodies should continue to follow the "Antibody Decisions" training slide set as well as the MPEP, except as noted previously.