



[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO-P-2018-0033]

Request for Comments on Determining Whether a Claim Element is Well-Understood, Routine, Conventional for Purposes of Subject Matter Eligibility

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments.

SUMMARY: The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) recently issued a decision regarding the inquiry of whether a claim limitation represents well-understood, routine, conventional activities (or elements) to a skilled artisan in the relevant field. Specifically, the Federal Circuit found that whether a claim element, or combination of elements, represents well-understood, routine, conventional activities to a skilled artisan in the relevant field is a question of fact. The United States Patent and Trademark Office (USPTO) has implemented this decision in a memorandum recently issued to the Patent Examining Corps (the *Berkheimer* memorandum). The *Berkheimer* memorandum is available to the public on the USPTO's Internet Web site. Examiners

had been previously instructed to conclude that an element (or combination of elements) is well-understood, routine, conventional activity *only* when the examiner can readily conclude that the element(s) is widely prevalent or in common use in the relevant industry. The *Berkheimer* memorandum now clarifies that such a conclusion must be based upon a factual determination that is supported as discussed in the memorandum. Additionally the *Berkheimer* memorandum now also specifies that the analysis for determining whether an element (or combination of elements) is widely prevalent or in common use is the same as the analysis under 35 U.S.C. 112(a) as to whether an element is so well-known that it need not be described in detail in the patent specification. The USPTO is now seeking public comment on its subject matter eligibility guidance, and particularly its guidance in the *Berkheimer* memorandum to the Patent Examining Corps.

DATES: *Comment Deadline Date:* Written comments must be received on or before [Insert date 120 days after publication in the FEDERAL REGISTER].

ADDRESSES: Comments must be sent by electronic mail message over the Internet addressed to: Eligibility2018@uspto.gov.

Electronic comments submitted in plain text are preferred, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format. The comments will be available for viewing via the USPTO's Internet Web site

(<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Carolyn Kosowski, Senior Legal Advisor, at 571-272-7688 or Matthew Sked, Senior Legal Advisor, at 571-272-7627, both with the Office of Patent Legal Administration.

SUPPLEMENTARY INFORMATION:

I. Federal Circuit Decision in Berkheimer: The Federal Circuit recently issued a precedential decision holding that the question of whether certain claim limitations are well-understood, routine, conventional elements raised a disputed factual issue, which precluded summary judgment that all of the claims at issue were not patent eligible. *See Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018). Shortly thereafter, the Federal Circuit reaffirmed the *Berkheimer* standard in the context of a judgment on the pleadings and judgment as a matter of law.¹ While summary judgment, judgment on the pleadings, and judgment as a matter of law standards in civil litigation are generally inapplicable during the patent examination process, these decisions inform the inquiry into whether an additional element (or combination of additional elements) represents well-understood,

¹ *See Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (Fed. Cir. 2018) (reversing a judgment on the pleadings of ineligibility, finding that whether the claims in the challenged patent perform well-understood, routine, conventional activities is an issue of fact); *Exergen Corp. v. Kaz USA, Inc.*, Nos. 2016-2315, 2016-2341, 2018 WL 1193529, at *1 (Fed. Cir. Mar. 8, 2018) (non-precedential) (affirming a district court's denial of a motion for judgment as a matter of law of patent ineligibility, thus upholding the district court's conclusion that the claims were drawn to a patent eligible invention, concluding that the district court's fact finding that the claimed combination was not proven to be well-understood, routine, conventional was not clearly erroneous).

routine, conventional activity. The USPTO has implemented this decision in the *Berkheimer* memorandum, which was recently issued to the Patent Examining Corps and is available to the public on the USPTO's Internet Web site.

The USPTO recognizes that unless careful consideration is given to the particular contours of subject matter eligibility (35 U.S.C. 101), it could “swallow all of patent law.” *Alice Corp. v. CLS Bank International*, 573 U.S. ___, ___, 134 S. Ct. 2347, 2352 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012)). The *Berkheimer* memorandum provides additional USPTO guidance that will further clarify how the USPTO is determining subject matter eligibility in accordance with prevailing jurisprudence. Specifically, the *Berkheimer* memorandum addresses the limited question of whether an additional element (or combination of additional elements) represents well-understood, routine, conventional activity. The USPTO is determined to continue its mission to provide clear and predictable patent rights in accordance with this rapidly evolving area of the law and, to that end, may issue further guidance in the future.

II. Well-Understood, Routine, Conventional Activity: The USPTO's current understanding of the judicial framework distinguishing patents and applications that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts—the *Mayo-Alice* framework—is set forth in section 2106 of the Manual of Patent Examining Procedure (MPEP). While the *Berkheimer* decision does not change the basic subject matter eligibility framework as set

forth in MPEP § 2106, it does provide clarification as to the inquiry into whether an additional element (or combination of additional elements) represents well-understood, routine, conventional activity. Specifically, the Federal Circuit held that “[w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.” *Berkheimer*, 881 F.3d at 1369.

As set forth in MPEP § 2106.05(d)(I), an examiner should conclude that an element (or combination of elements) represents well-understood, routine, conventional activity **only** when the examiner can readily conclude that the element(s) is widely prevalent or in common use in the relevant industry. The *Berkheimer* memorandum clarifies that such a conclusion must be based upon a factual determination that is supported as discussed in section III below. The *Berkheimer* memorandum further clarifies that the analysis as to whether an element (or combination of elements) is widely prevalent or in common use is the same as the analysis under 35 U.S.C. 112(a) as to whether an element is so well-known that it need not be described in detail in the patent specification.²

² See *Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d 1369, 1377 (Fed. Cir. 2016) (supporting the position that amplification was well-understood, routine, conventional for purposes of subject matter eligibility by observing that the patentee expressly argued during prosecution of the application that amplification was a technique readily practiced by those skilled in the art to overcome the rejection of the claim under 35 U.S.C. 112, first paragraph); see also *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1463 (Fed. Cir. 1984) (“[T]he specification need not disclose what is well known in the art.”); *In re Myers*, 410 F.2d 420, 424 (CCPA 1969) (“A specification is directed to those skilled in the art and need not teach or point out in detail that which is well-known in the art.”); *Exergen Corp.*, 2018 WL 1193529, at *4 (holding that “[l]ike indefiniteness, enablement, or obviousness, whether a claim is directed to patent eligible subject matter is a question of law based on underlying facts,” and noting that the Supreme Court has recognized that “the inquiry ‘might sometimes overlap’ with other fact-intensive inquiries like novelty under 35 U.S.C. § 102”).

The question of whether additional elements represent well-understood, routine, conventional activity is distinct from patentability over the prior art under 35 U.S.C. 102 and 103. This is because a showing that additional elements are obvious under 35 U.S.C. 103, or even that they lack novelty under 35 U.S.C. 102, is not by itself sufficient to establish that the additional elements are well-understood, routine, conventional activities or elements to those in the relevant field. *See* MPEP § 2106.05. As the Federal Circuit explained: “[w]hether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.” *Berkheimer*, 881 F.3d at 1369.

III. Impact on Examination Procedure: The *Berkheimer* memorandum revises the procedures set forth in MPEP § 2106.07(a) (Formulating a Rejection For Lack of Subject Matter Eligibility) and MPEP § 2106.07(b) (Evaluating Applicant’s Response).

A. Formulating Rejections: In a step 2B analysis, an additional element (or combination of elements) is not well-understood, routine or conventional unless the examiner finds, and expressly supports a rejection in writing with, one or more of the following:

1. A citation to an express statement in the specification or to a statement made by an applicant during prosecution that demonstrates the well-understood, routine, conventional nature of the additional element(s). A specification demonstrates the well-understood, routine, conventional nature of additional elements when it describes the

additional elements as well-understood or routine or conventional (or an equivalent term), as a commercially available product, or in a manner that indicates that the additional elements are sufficiently well-known that the specification does not need to describe the particulars of such additional elements to satisfy 35 U.S.C. 112(a). A finding that an element is well-understood, routine, or conventional cannot be based only on the fact that the specification is silent with respect to describing such element.

2. A citation to one or more of the court decisions discussed in MPEP § 2106.05(d)(II) as noting the well-understood, routine, conventional nature of the additional element(s).

3. A citation to a publication that demonstrates the well-understood, routine, conventional nature of the additional element(s). An appropriate publication could include a book, manual, review article, or other source that describes the state of the art and discusses what is well-known and in common use in the relevant industry. It does not include all items that might otherwise qualify as a “printed publication” as used in 35 U.S.C. 102.³ Whether something is disclosed in a document that is considered a “printed publication” under 35 U.S.C. 102 is a distinct inquiry from whether something is well-known, routine, conventional activity. A document may be a printed publication but still fail to establish that something it describes is well-understood, routine, conventional activity. *See Exergen Corp.*, 2018 WL 1193529, at *4 (the single copy of a thesis written in German and located in a German university library considered to be a “printed

³ *See, e.g., In re Klopfenstein*, 380 F.3d 1345 (Fed. Cir. 2004) (publicly displayed slide presentation); *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986) (doctoral thesis shelved in a library); *Mass. Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1108-09 (Fed. Cir. 1985) (paper orally presented at a scientific meeting and distributed upon request); *In re Wyer*, 655 F.2d 221 (CCPA 1981) (patent application laid open to public inspection).

publication” in *Hall* “would not suffice to establish that something is ‘well-understood, routine, and conventional activity previously engaged in by scientists who work in the field’”). The nature of the publication and the description of the additional elements in the publication would need to demonstrate that the additional elements are widely prevalent or in common use in the relevant field, comparable to the types of activity or elements that are so well-known that they do not need to be described in detail in a patent application to satisfy 35 U.S.C. 112(a). For example, while U.S. patents and published applications are publications, merely finding the additional element in a single patent or published application would not be sufficient to demonstrate that the additional element is well-understood, routine, conventional, unless the patent or published application demonstrates that the additional element are widely prevalent or in common use in the relevant field.

4. A statement that the examiner is taking official notice of the well-understood, routine, conventional nature of the additional element(s). This option should be used *only* when the examiner is certain, based upon his or her personal knowledge, that the additional element(s) represents well-understood, routine, conventional activity engaged in by those in the relevant art, in that the additional elements are widely prevalent or in common use in the relevant field, comparable to the types of activity or elements that are so well-known that they do not need to be described in detail in a patent application to satisfy 35 U.S.C. 112(a). Procedures for taking official notice and addressing an applicant’s challenge to official notice are discussed in MPEP § 2144.03.

B. *Evaluating Applicant's Response:* If an applicant challenges the examiner's position that the additional element(s) is well-understood, routine, conventional activity, the examiner should reevaluate whether it is readily apparent that the additional elements are in actuality well-understood, routine, conventional activities to those who work in the relevant field. If the examiner has taken official notice per paragraph (4) of section (III)(A) above that an element(s) is well-understood, routine, conventional activity, and the applicant challenges the examiner's position, specifically stating that such element(s) is not well-understood, routine, conventional activity, the examiner must then provide one of the items discussed in paragraphs (1) through (3) of section (III)(A) above, or an affidavit or declaration under 37 CFR 1.104(d)(2) setting forth specific factual statements and explanation to support his or her position. As discussed previously, to represent well-understood, routine, conventional activity, the additional elements must be widely prevalent or in common use in the relevant field, comparable to the types of activity or elements that are so well-known that they do not need to be described in detail in a patent application to satisfy 35 U.S.C. 112(a).

The MPEP will be updated in due course to incorporate the changes put into effect the *Berkheimer* memorandum.

As discussed previously, the *Berkheimer* memorandum is available to the public on the USPTO's Internet Web site. The USPTO is seeking public comment on its subject matter eligibility guidance, and particularly its guidance in the *Berkheimer* memorandum.

Dated: April 18, 2018.

Andrei Iancu

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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