EQUIP Luncheon: Recent Patent Cases in the Supreme Court

Dr. Fangli Chen, Partner

S. James Boumil III, Associate

November 5, 2019

Proskauer

Topics

- *HP Inc. v. Berkheimer*
- *Hikma Pharms. et al. v. Vanda Pharm.*
- *Trading Techs. Int'l, Inc. v. IBG LLC*
- *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*

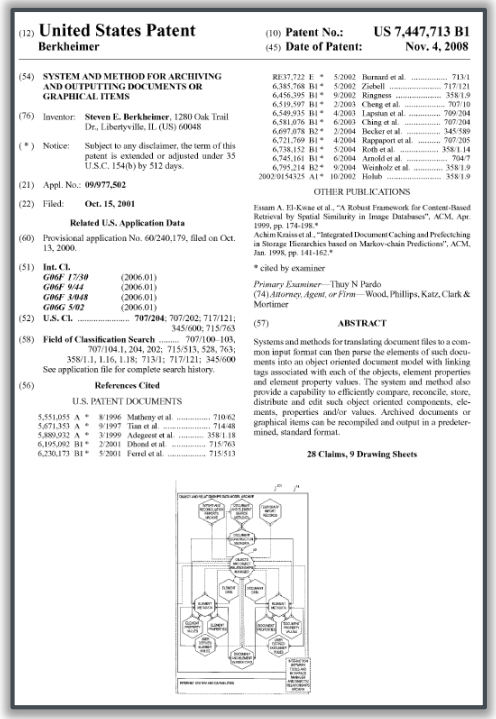
- Brief footnotes on:
  - *Peter v. NantKwest*
  - *Thryv, Inc. v. Click-To-Call Technologies, LP*

HP Inc. v. Berkheimer (Supreme Court, No. 18-415)

Whether patent eligibility is a question of law or fact (or both)

Berkheimer v. HP Inc. (Fed. Cir.) (No. 2017-1437)

- U.S. Pat. No. 7,447,713 claims directed to digitally processing and more efficiently archiving files in a digital asset management system
- District Court applied the two-step *Alice* analysis to determine whether patent claims are directed to patent-eligible subject matter:
  - Whether claims are directed to a patent-ineligible concept
  - Whether additional elements of each claim transform the nature of the claim into a patent eligible application (something more than well-understood, routine, and conventional activities)



(12) **United States Patent**
Berkheimer

(10) **Patent No.: US 7,447,713 B1**
(45) **Date of Patent: Nov. 4, 2008**

(54) **SYSTEM AND METHOD FOR ARCHIVING AND OUTPUTTING DOCUMENTS OR GRAPHICAL ITEMS**

(76) Inventor: **Steven E. Berkheimer**, 1280 Oak Trail Dr., Libertyville, IL (US) 60048

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 512 days.

(21) Appl. No.: **09/977,502**

(22) Filed: **Oct. 15, 2001**

Related U.S. Application Data

(60) Provisional application No. 60/240,179, filed on Oct. 13, 2000.

(51) **Int. Cl.**
G06F 17/30 (2006.01)
G06F 9/44 (2006.01)
G06F 3/048 (2006.01)
G06G 5/02 (2006.01)

(52) **U.S. Cl.** **707/204**; 707/202; 717/121; 345/600; 715/763

(58) **Field of Classification Search** 707/100–105, 707/104.1, 204, 202; 715/513, 528, 763; 358/1.1, 1.16, 1.18; 713/1; 717/121; 345/600
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,551,055	A *	8/1996	Matheny et al.	710/62
5,671,353	A *	9/1997	Tian et al.	714/48
5,889,932	A *	3/1999	Adegeest et al.	358/1.18
6,195,092	B1 *	2/2001	Dhond et al.	715/763
6,230,173	B1 *	5/2001	Ferrel et al.	715/513
RE37,722	E *	5/2002	Barnard et al.	713/1
6,385,768	B1 *	5/2002	Zisbell	717/121
6,456,395	B1 *	9/2002	Ringness	358/1.9
6,519,597	B1 *	2/2003	Cheng et al.	707/10
6,549,935	B1 *	4/2003	Lapstun et al.	709/204
6,581,076	B1 *	6/2003	Ching et al.	707/204
6,697,078	B2 *	2/2004	Becker et al.	345/589
6,721,769	B1 *	4/2004	Rappaport et al.	707/205
6,738,152	B1 *	5/2004	Roth et al.	358/1.14
6,745,161	B1 *	6/2004	Arnold et al.	704/7
6,795,214	B2 *	9/2004	Weinholz et al.	358/1.9
2002/0154325	A1 *	10/2002	Hohab	358/1.9

OTHER PUBLICATIONS

Essam A. El-Kwae et al., "A Robust Framework for Content-Based Retrieval by Spatial Similarity in Image Databases", ACM, Apr. 1999, pp. 174-198.*
Achim Kraiss et al., "Integrated Document Caching and Prefetching in Storage Hierarchies based on Markov-chain Predictions", ACM, Jan. 1998, pp. 141-162.*

* cited by examiner

Primary Examiner—Thuy N Pardo
(74) *Attorney, Agent, or Firm*—Wood, Phillips, Katz, Clark & Mortimer

(57) **ABSTRACT**

Systems and methods for translating document files to a common input format can then parse the elements of such documents into an object oriented document model with linking tags associated with each of the objects, element properties and element property values. The system and method also provide a capability to efficiently compare, reconcile, store, distribute and edit such object oriented components, elements, properties and/or values. Archived documents or graphical items can be recompiled and output in a predetermined, standard format.

28 Claims, 9 Drawing Sheets

Proskauer

HP Inc. v. Berkheimer (Fed. Cir.) (No. 2017-1437)

- Fed. Cir. held that there existed a genuine issue of material fact as to eligibility, so summary judgment was inappropriate
  - "Claims 4-7, in contrast, contain limitations directed to the arguably unconventional inventive concept described in the specification." Op. at 16. See, e.g., claim 4: "storing a reconciled object structure in the archive without substantial redundancy"
- Petition for rehearing *en banc* by Fed. Cir. denied
- Petition for certiorari filed and pending with Supreme Court
  - Solicitor General invited to file comments on behalf of United States

HP Inc. v. Berkheimer (Supreme Court)

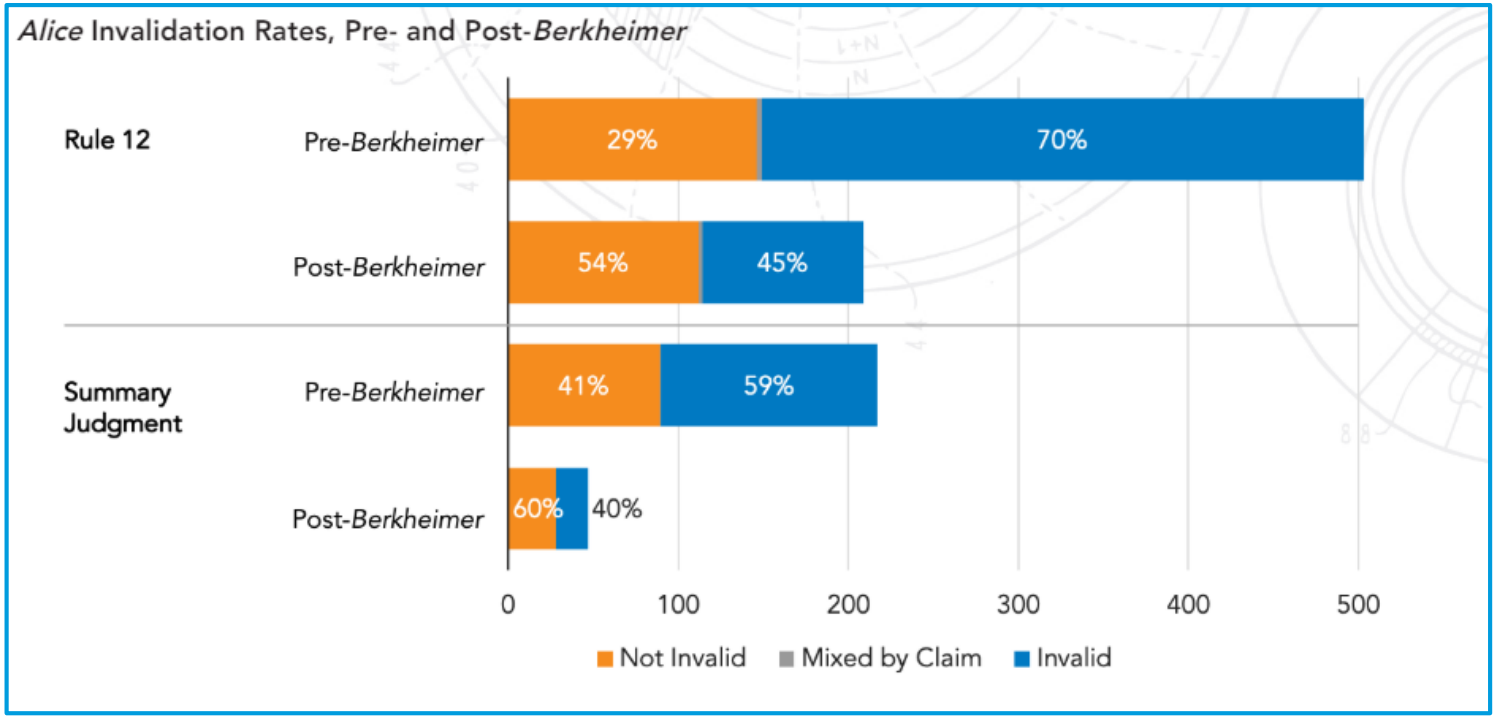
HP's Arguments

- Decision conflates eligibility with novelty and obviousness
- Step 2 of *Alice/Mayo* analysis has "always" been resolved as a matter of law, and should be decided as a matter of claim scope
- Will cause large, detrimental changes for both litigation and prosecution

Berkheimer's Arguments

- Whether something is "well-known in the art" is a classic factual dispute
  - In *Mayo*, the specification "explicitly acknowledged that those [additional] steps were already known in the art"
- HP does not specify any concrete legal analysis showing how such questions can always be resolved as a matter of law

Effect of *Berkheimer*



Source: RPX, *available at* https://www.rpxcorp.com/data-byte/patents-invalidated-under-alice-before-and-after-berkheimer-by-procedural-stage/

Proskauer

Hikma Pharms. et al. v. Vanda Pharm.

Whether treatment claims are patent eligible as applications of natural law

Hikma v. Vanda (Fed. Cir.) (Nos. 2016-2707, -2708)

- U.S. Pat. No. 8,586,610 claims are directed to a method of treating schizophrenia patients using dosage changes based on patient's genotype
- Fed. Cir. held that the claims are directed to patent-eligible subject matter; distinguished from *Mayo* as *Mayo* claim "was not directed to the application of a drug to treat a particular disease," overturning District Court
  - '610 patent claimed an ***application*** of relationship between genotype assay and administration of the drug
  - The "claims do not broadly 'tie up the doctor's subsequent treatment decision'" as did the claims in *Mayo*

Hikma v. Vanda

Hikma's Arguments

- Ruling below means that administering a known drug for a known purpose is automatically patent eligible
  - Will permit re-drafting "virtually any diagnosis claim" as a treatment claim to avoid Section 101
- Claims at issue require only treatment based on a well-understood natural law

Vanda's Arguments

- Fed. Cir. did not exempt method-of-treatment patents from § 101 analysis; it simply "faithfully applied" *Mayo* and held claims were properly directed to "application" of laws of nature rather than the laws themselves

Effect of *Hikma v. Vanda*

- Prosecution
- Review Vanda USPTO Memorandum
  - Claims should be directed not to the natural relationship, but to an application of that relationship, *i.e.* treatment
    - If the “application” is claimed, no need to go on to Step 2B of *Mayo* analysis
  - In PTO responses, remember that in Step 2A of *Mayo* analysis, claims must be considered “as a whole”
- Litigation
  - For plaintiffs: carefully construe claim language to ensure claim is construed as a method of treatment

Trading Techs. Int'l, Inc. v. IBG LLC

Whether GUI improvements qualify for CBM review and are patent eligible

Trading Techs. I

- Patents relate generally to GUIs for electronic trading
  - Specifications disclose various methods for displaying information regarding market conditions to facilitate trading
- PTAB found that patents were directed to Covered Business Methods and invalidated the claims under § 101
  - CBM does not include patents for technological inventions
- Fed. Cir. vacates PTAB's holding, finding that CBM was not applicable because the patents are for technological inventions

Trading Techs. II

- *Trading Techs. II* dealt with similar claims to *TT I*—methods for "displaying market information on a screen"
  - Displaying information in different ways "focuses on improving the trader, not the functioning of the computer," so patent does not cover a technological invention and is eligible for CBM
  - Patent found ineligible under § 101 for claiming nothing more than the abstract idea of graphing or displaying bids to assist market traders to make orders
    - Improvements to the GUI improve only the ability of traders to trade; they do not improve the functionality of computers or technology

Trading Techs. III and Supreme Court Review

- *Trading Techs. III* – Trading Techs. made similar arguments in a third bid for Fed Cir. review, all of which were denied in a non-precedential opinion
- IBG petitioned for Supreme Court review of the first case (denied); TTI petitioned for review of the second and third
  - Filed in Sept. and Oct. 2019; the new question focuses not on the two prongs of the "technological invention" test but on (i) the eligibility of patents providing useful user functionality but not improving the computer itself, and (ii) the abstract idea exception generally

Acorda Therapeutics, Inc. v. Roxane Labs., Inc.

Whether blocking patents weaken evidence of secondary considerations

Acorda Therapeutics

- Acorda holds patents related to treatment of MS with a certain agent, and an exclusive license to another, broader patent related to the treatment of several conditions (including MS) with one of several agents
- In a District Court bench trial, the judge found certain facts supporting objective indicia of nonobviousness (secondary considerations), but discounted them due to the presence of the blocking patent, to which Acorda held an exclusive license
- Acorda's patents ultimately found invalid by District Court

Acorda Therapeutics

- Acorda argued that the District Court applied a “categorical rule” that the presence of a blocking patent diminishes any evidence of objective indicia
- The Federal Circuit disagreed:
  - “[I]t is clear that, if all other variables are held constant, a blocking patent diminishes possible rewards from a non-owner’s or non-licensee’s investment activity aimed at an invention whose commercial exploitation would be infringing, therefore reducing incentives for innovations in the blocked space by non-owners and nonlicensees of the blocking patent.”

Acorda Therapeutics

- In spite of considerable interest from *amici* in Fed. Cir. and Supreme Court, and a dissent from Fed. Cir. Judge Newman, the Supreme Court denied the *cert* petition
- Judge Newman in dissent:
  - A long history of failed studies and complete abandonment of research by owner of blocking patent should have supported nonobviousness
  - Minimal treatment of effect of blocking patent; but note that the statute provides safe harbor for certain activities even where they would otherwise be infringing

Two Final Footnotes

Two patent cases were granted c*ertiorari* this term (but they concern less interesting procedural issues)

Peter v. NantKwest

- The Supreme Court granted *cert* on the following question:

  Whether the phrase "[a]ll the expenses of the proceedings" in 35 U.S.C. § 145 encompasses the personnel expenses the United States Patent and Trademark Office incurs when its employees, including attorneys, defend the agency in Section 145 litigation.

- 35 U.S.C. § 145 (the provision authorizing the civil action) ends with the following sentence:

  All the expenses of the proceedings shall be paid by the applicant.

- The *en banc* Federal Circuit focused on the presumptive "American rule" on attorney fees, finding that the "all the expenses" phrase did not overcome the strong "American rule" presumption

Thryv, Inc. v. Click-To-Call Technologies, LP

- The Supreme Court granted *cert* on the following question:

  Whether 35 U.8.C. § 314(d) permits appeal of the PTAB's decision to institute an inter partes review upon finding that § 315(b)'s time bar did not apply.

- 35 U.S.C. § 314(d) states that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable"
- The en banc Federal Circuit held that the IPR should not have been instituted because prior litigation triggered the 1-year time-bar, and the "nonappealable" language does not bar appeals where the decision to institute exceeds the statutory authority

EQUIP Luncheon: Recent Patent Cases in the Supreme Court

Dr. Fangli Chen, Partner

S. James Boumil III, Associate

November 5, 2019

Proskauer

The information provided in this slide presentation is not intended to be, and shall not be construed to be, either the provision of legal advice or an offer to provide legal services, nor does it necessarily reflect the opinions of the firm, our lawyers or our clients. No client-lawyer relationship between you and the firm is or may be created by your access to or use of this presentation or any information contained on them. Rather, the content is intended as a general overview of the subject matter covered. Proskauer Rose LLP (Proskauer) is not obligated to provide updates on the information presented herein. Those viewing this presentation are encouraged to seek direct counsel on legal questions. © Proskauer Rose LLP. All Rights Reserved.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

DATE: April 19, 2018

TO: Patent Examining Corps

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

SUBJECT: Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)

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, 132 S. Ct. 1289, 1293-1294 (2012)). This memorandum provides additional USPTO guidance that will further clarify how the USPTO is determining subject matter eligibility in accordance with prevailing jurisprudence. Specifically, this 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.

The U. S. Court of Appeals for the Federal Circuit (Federal Circuit) recently issued a precedential decision holding that the question of whether certain claim limitations represent well-understood, routine, conventional activity 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

[1] In *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (Fed. Cir. 2018), the Federal Circuit reversed a judgment on the pleadings of ineligibility, similarly finding that whether the claims in the challenged patent perform well-understood, routine, conventional activities is an issue of fact. In *Exergen Corp. v. Kaz USA, Inc.*, Nos. 2016-2315, 2016-2341, 2018 WL 1193529, at *1 (Fed. Cir. Mar. 8, 2018) (non-precedential), the Federal Circuit affirmed a district court's denial of a motion for judgment as a matter of law of patent ineligibility (thus

standards in civil litigation are generally inapplicable during the patent examination process, *Berkheimer* informs the inquiry into whether an additional element (or combination of additional elements) represents well-understood, routine, conventional activity.

I. Federal Circuit Decision in Berkheimer: In *Berkheimer*, the invention relates to digitally processing and archiving files in a digital asset management system. The patent specification explains that the system eliminates redundant storage of common text and graphical elements, which improves system operation efficiency and reduces storage costs. With respect to *Mayo/Alice* step 1 (step 2A in the USPTO's guidance), the Federal Circuit held that the claims are directed to the abstract ideas of parsing and comparing data (claims 1-3 and 9), parsing, comparing, and storing data (claim 4), and parsing, comparing, storing, and editing data (claims 5-7) based upon a comparison of these claims to claims held to be abstract in prior Federal Circuit decisions. *Berkheimer*, 881 F.3d at 1366-67. With respect to *Mayo/Alice* step 2 (step 2B in the USPTO's guidance), the Federal Circuit considered the elements of each claim both individually and as an ordered combination, recognizing that "whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Id.* at 1367-68. While observing that the specification discussed purported improvements (*e.g.*, reducing redundancy and enabling one-to-many editing as the purported improvements), the Federal Circuit held claims 1-3 and 9 ineligible because they do not include limitations that realize these purported improvements. *Id.* at 1369-70.

In contrast, the Federal Circuit held that claims 4-7 do contain limitations directed to purported improvements described in the specification (*e.g.*, claim 4 recites "storing a reconciled object structure in the archive without substantial redundancy," which the specification explains improves system operating efficiency and reduces storage costs), raising a genuine issue of material fact as to whether the purported improvements were more than well-understood, routine, conventional activity previously known in the industry. *Id.* at 1370. The Federal Circuit therefore reversed the district court's decision on summary judgment that claims 4-7 are patent ineligible, and remanded for further fact finding as to the eligibility of those claims. *Id.* at 1370-71.

Finally, the Federal Circuit drew a distinction between what is well-understood, routine, conventional, and what is simply known in the prior art, cautioning that the mere fact that something is disclosed in a piece of prior art does not mean it was a well-understood, routine, conventional activity or element. *Id.* at 1369.

II. Well-Understood, Routine, Conventional Activity: 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." *Id.* at 1369.

---

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.

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. This memorandum clarifies that such a conclusion must be based upon a factual determination that is supported as discussed in section III below. This 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]

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: This 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

---

[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").

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 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-

---

[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).

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 by this memorandum.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

DATE: June 7, 2018

TO: Patent Examining Corps

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

SUBJECT: Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*

On April 13, 2018, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") held the claims at issue in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018), **patent eligible** under 35 U.S.C. § 101 because they are not "directed to" a judicial exception. The claims recite a method of treating a patient having schizophrenia with iloperidone, a drug known to cause QTc prolongation (a disruption of the heart's normal rhythm that can lead to serious health problems) in patients having a particular genotype associated with poor drug metabolism. In particular, a representative claim is below:

> A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
>
> **determining** whether the patient is a CYP2D6 poor metabolizer by:
>
> **obtaining** or having obtained a biological sample from the patient;
>
> and
>
> **performing** or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
>
> if the patient has a CYP2D6 poor metabolizer genotype, then internally **administering** iloperidone to the patient in an amount of 12 mg/day or less, and
>
> if the patient does not have a CYP2D6 poor metabolizer genotype, then internally **administering** iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
>
> wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day

> or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

The primary steps include "determining" with a genotyping assay, and then "administering" a certain quantity of drug based on that determination, in order to "treat a particular disease." *Id.* at 1134. The Federal Circuit distinguished *Mayo*,[1] stating: "The inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an **application** of that relationship. Unlike the claim at issue in *Mayo*, the claims here require a treating doctor to administer iloperidone." *Id.* at 1135 (emphasis added). As a result, the Federal Circuit held the claims in *Vanda* patent eligible under the first step of the *Alice/Mayo* framework (Step 2A in the USPTO's subject matter eligibility guidance), because the claims "are directed to a method of using iloperidone to treat schizophrenia," rather than being "directed to" a judicial exception.

The Federal Circuit's decision in *Vanda* illustrates several important points regarding the subject matter eligibility analysis. First, the Federal Circuit evaluated the claims as a whole, including the arguably conventional genotyping and treatment steps, when determining that the claim was not "directed to" the recited natural relationship between the patient's genotype and the risk of QTc prolongation. The importance of evaluating the claims as a whole in Step 2A was also emphasized by the Federal Circuit in previous cases, such as *Finjan Inc. v. Blue Coat Systems, Inc.*, 879 F.3d 1299 (Fed. Cir. 2018), and *Core Wireless Licensing S.A.R.L., v. LG Electronics, Inc.*, 880 F.3d 1356 (Fed. Cir. 2018). The two prior cases are discussed in a memorandum dated April 2, 2018 to examiners titled "Recent Subject Matter Eligibility Decisions."

Second, the Federal Circuit cited the Supreme Court "[t]o further underscore the distinction between method of treatment claims and those in *Mayo*." *Id.* at 1135. Method of treatment claims (which ***apply*** natural relationships as opposed to being "directed to" them) were identified by the Supreme Court as *not* being implicated by its decisions in *Mayo* and *Myriad* because they "confine their reach to particular applications." *Id.* The Federal Circuit noted that while the "claim in Mayo recited administering a thiopurine drug to a patient, the claim as a whole was not directed to the application of a drug to treat a particular disease." *Id.* at 1134. That is, while the *Mayo* claims recited a step of administering a drug to a patient, that step was performed in order to gather data about the natural relationships, and thus was ancillary to the overall diagnostic focus of the claims. The *Mayo* claims were not "method of treatment" claims that practically apply a natural relationship.

Lastly, the Federal Circuit did **not** consider whether or not the treatment steps were routine or conventional when making its "directed to" determination. Since the claim was determined eligible in the step 2A "directed to" part of the test, there was no need to conduct a step 2B analysis.

The USPTO's current subject matter eligibility guidance and training examples are consistent with the Federal Circuit's decision in *Vanda*, with the understanding that: (1) "method of treatment" claims that practically apply natural relationships should be considered **patent**

---

[1] *Mayo Collaborative Servs.* v. *Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

eligible under Step 2A of the USPTO's subject matter eligibility guidance; and (2) it is not necessary for "method of treatment" claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered **patent eligible** under 35 U.S.C. § 101. For example, claims 5 and 6 of USPTO Example 29 (Diagnosing and Treating Julitis) should be considered patent eligible under Step 2A of the USPTO's subject matter eligibility guidance in light of the Federal Circuit decision in *Vanda*.

This memorandum addresses the limited question of how to evaluate the patent eligibility of "method of treatment claims" in light of the Federal Circuit decision in *Vanda*. 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 area of subject matter eligibility in the future.