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How Courts Treat USPTO Subject Matter Eligibility Guidelines

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Law360, New York (August 29, 2017, 12:59 PM EDT) -- It's no secret that the U.S. Supreme Court's foray into 35 U.S.C. § 101 has left life sciences and software companies searching for renewed certainty of what is and what is not patent eligible. While the court has seemingly returned to a slumber on issues of § 101, these companies continue to press lower courts, the U.S. Patent and Trademark Office and Congress for solutions. The chances of a legislative solution remain far off, thus these companies must seek guidance through the USPTO and courts.

In Mayo, the court outlined a two-step test to determine whether a patent claim is eligible.[1] Step one requires analyzing whether the claims are directed to a patent-ineligible concept (i.e., law of nature, abstract idea, or natural phenomenon). If the claim is directed to one of these categories, then the analysis proceeds to step two: Determine "whether the claims do significantly more than simply describe these [laws of nature, abstract ideas, or natural phenomena]."[2] Application of the Mayo two-step test continues to evolve.[3]

To help its examiners apply the Mayo two-step test, the USPTO released subject matter eligibility guidelines in 2014. The USPTO continues to update its guidelines by applying the growing body of § 101 case law to sample claims pursued in the life sciences and software industries.[4] While the guidelines can provide a useful tool to overcome § 101 rejections during prosecution, patent owners have relied on the guidelines in court with mixed success. And, until a recent decision in Cleveland Clinic v. True Health Diagnostics LLC, No. 1:17-cv-198 (E.D. Va., Aug. 4, 2017) ("CC3"), a court has not analyzed a patent under § 101 where the USPTO issued the patent based on application of its guidelines.

Below we discuss the CC3 court's application of the guidelines, as well as a brief review of other decisions where district courts have considered the guidelines when deciding subject matter eligibility. We conclude with some tips and takeaways for patent owners and challengers to consider when considering the eligibility of a patent claim.

Cleveland Clinic v. True Health Diagnostics

CC3 marks the first time a district court analyzed a patent under § 101 where the USPTO applied its own guidelines during prosecution of the asserted patent. In CC3, the Cleveland Clinic alleged that True Health Diagnostics ("THD") infringed three patents. THD moved to dismiss, alleging that two of the patents,[5] including US Pat. No. 9,575,065 ("the '065 patent"), were invalid as directed to natural laws.[6] The '065 patent recites a method of detecting elevated myeloperoxidase ("MPO") mass in a patient sample. Following the Federal Circuit's affirmance of invalidity of the '065 parent patent in Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017), the CC3 court granted THD's motion to reconsider the motion to dismiss.[7]

USPTO's Patent Eligibility Analysis

The USPTO's guidelines appeared to play a significant role in the allowance of the '065 patent.[8] In response to the patent examiner's § 101 rejection, the clinic analogized its pending claim to claim 1 of Example 29 of the guidelines, which recites: "[a] method of detecting JUL-1 in a patient, said method comprising: a. obtaining a plasma sample from a human patient; and b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody." The guidelines reason that this claim is patentable because its focus is on detection, not a natural correlation.

While the clinic also included a Mayo two-step analysis during prosecution, the patent examiner cited Example 29 of the guidelines approvingly in the notice of allowance.[9] Without more, the USPTO issued the '065 patent with its sole claim:

A method of detecting elevated MPO mass in a patient sample comprising: a) obtaining a plasma sample from a human patient having atherosclerotic cardiovascular disease (CVD); and b) detecting elevated MPO mass in said plasma sample, as compared to a control MPO mass level from the general population or apparently healthy subjects, by contacting said plasma sample with anti-MPO antibodies and detecting binding between MPO in said plasma sample and said anti-MPO antibodies.

District Court's Patent Eligibility Analysis

Unlike the patent examiner, the court dismissed the guidelines. In its briefing, the Clinic asserted that the claims are not directed to a law of nature, and "relie[d] on the reasoning of the patent examiner[], who found the analogy to USPTO Guidelines Example 29, claim 1 persuasive."[10] The court disagreed, both with the analogy and with the persuasiveness of the guidelines.

The court found persuasive THD's argument that the '065 patent claim and Example 29 claim 1 analogy was inapt. While Claim 1 of Example 29 refers to a 'method of detecting JUL-1," the '065 patent claim refers to a method of detecting elevated MPO concentrations. The court keyed in on the "elevated" requirement of the claim, which the method of detecting in Example 29 claim 1 did not have. The court reasoned that because the '065 patent claim was useful only for detecting elevated MPO levels, not all MPO levels, the patent examiner's reliance on Example 29 was "misplaced." The '065 patent claim did not avoid detecting the correlation.[11]

By footnote, the court dismissed the clinic's assertion regarding the persuasiveness of the guidelines. The clinic argued that the "[G]uidelines are entitled to Skidmore deference," but the court disagreed. The court

pointed out that the guidelines had not been through "formal adjudication or notice and comment rule making." The court also noted that the Federal Circuit had never held that the guidelines were entitled to Skidmore deference.[12]

The court did not end its analysis with its dismissal of the guidelines. Instead, the court applied the Mayo two-step: analyzing whether the claims are directed to a natural law (they are) and determining whether the additional steps in the claims add "significantly more" under the second step (they do not). Dismissing the Clinic's analogy to CellzDirect[13], where the Federal Circuit held the "end result of the . . . claims [was] not simply an observation or detection of' the natural law in question," the court stated that "the 'end result' of the claims in the '065 . . . patent[] is the 'observation or detection' of the natural law."[14]

Other District Courts Have Addressed the Guidelines

CC3 is the first district court decision to address a patent that issued, in part, based on a patentee's analogy of its claims to the guidelines. However, as just discussed, the district court did not find the guidelines persuasive. Patentees have argued patent eligibility based on analogy to the guidelines in other district court proceedings, with mixed success and only raising the argument in court — not during examination at the USPTO. A brief review of those proceedings provides additional insight into district courts' perceptions of the guidelines.

Xlear v. STS Health

Xlear Inc. v. STS Health LLC, No. 2:14-cv-00806-DN, 2015 WL 8967574 (D. Utah, Dec. 15, 2015), involves a patent that recites a method of nasal administration of xylitol. The patent issued prior to the release of the guidelines, but the patentee attempted to analogize its claims to the guidelines during a motion to dismiss. Specifically, the patentee analogized its claims to "[a] method of treating breast cancer or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer."[15] The guidelines explain that this claim is eligible because "the claim is focused on a process of practically applying the product to treat a particular disease [], and not on the product per se. Thus, it is not necessary to apply the markedly different characteristics analysis." Xlear argued that like the guidelines, there is no need to apply the markedly different characteristics test, but even if applied, the claims encompass a new method of using xylitol. The district court disagreed that the markedly different characteristics test should not apply, but dismissed the motion because the court must take Xlear's factual assertions (that the method is new) as true.[16] Thus, Xlear staved off the motion to dismiss by asserting that the method was new unlike other cases where the patentee admitted the parts of the claims were known in the art.[17]

Finjan v. Blue Coat

In Finjan Inc. v. Blue Coat Systems Inc., No. 13-cv-03999-BLF, 2015 WL 7351450 (N.D. Cal., Nov. 20, 2015), the patents-at-issue referred to a system and methods of network protection wherein an inspector reviews a piece of downloadable information for suspicious code or behavior. Blue Coat argued that the claim was an abstract idea that did not warrant patent protection. However, Finjan argued that "guidance from the Patent Office has held a similar claim towards isolating and removing malicious code from electronic messages through receiving data, storing data, scanning data, and creating a new data file is not abstract." After a bench trial, the court found Finjan's analogy to the guidelines persuasive, stating that the asserted claim is "inextricably tied to computer technology and distinct from the types of concepts found by the courts to be abstract."[18]

Intellectual Ventures v. Symantec

Intellectual Ventures I LLC v. Symantec Corp., 100 F. Supp. 3d 371 (D. Del., April 22, 2015), involved methods for classifying the content of received files by creating a content identifier and then comparing that content identifier to a database of other identifiers. Symantec argued that the claims are directed to an abstract idea, and IV countered that the claims are "inextricably tied to computer technology," similar to claims deemed eligible by the guidelines. The guidelines-eligible claim recites a nonhuman executable method of "creating 'sanitized' versions of computer files by 'extracting, via file parsing, the malicious code, from computer files." During the motion for judgment on partial findings, the court disagreed with the guidelines analogy, finding that the claims recite "nothing more than a generic computer implementation of the human-executable abstract idea." While one claim survived district court scrutiny, as "inextricably tied to computer technology," the Federal Circuit reversed.[19]

Tips and Takeaways

CC3 highlights the potential pitfall of relying solely on the guidelines during prosecution of a patent application in the hopes of obtaining a patent that will withstand a court's (and challenger's) scrutiny. In its defense, the clinic did not rely solely on analogy to the guidelines; it also applied the Mayo two-step. But even patent applicants who make robust Mayo arguments can find themselves stymied by uncertainty in the law.

As highlighted by the recent report from the USPTO titled "Patent Eligible Subject Matter: Report on Views and Recommendations from the Public," "the public [has] argued that the [Mayo] two-part test provides an unworkable framework for the USPTO to make patent eligibility determinations with any reliability. ... [and] observed that the new standard yields unpredictable results in courts, leaving the public unsure whether something patented today, will be patent eligible tomorrow."[20]

The uncertainty provides defendants and patent challengers with an additional tool in their arsenal to avoid the threats of an injunction and/or damages that will disrupt their business. The success of THD in prevailing at the motion to dismiss stage reinforces the road map available to gain an early win in litigation, even as patents continue to issue that have gone through examination using the guidelines. Until the guidelines garner some level of deference, challengers can continue to undermine their persuasive value in front of a court.

But all is not lost for patent owners. Decisions such as CC3 and Finjan emphasize the importance of making sure that granted patent claims are supported during prosecution by both Mayo arguments, as well as substantive, not superficial, analogies to the guidelines. Moreover, patent applicants must carefully consider how their arguments may be interpreted by defendants in a future litigation. For example, looking to Xlear, Xlear's assertion that the claimed method was new, which would be a "markedly different characteristic" sufficient to survive § 101, helped Xlear avoid early dismissal of its suit. Thus, a patentee may bolster its chances of surviving a motion to dismiss by highlighting new and/or nonobvious aspects of its claims in its application, and potentially with a declaration supported by the literature during prosecution.

And patent applicants should at least carefully weigh making statements in their applications related to what techniques are and are not standard, routine, or conventional. Such an admission persuaded the court in Athena Diagnostics[21] to reconsider and grant a motion to dismiss when the court could not otherwise determine on the papers before it whether the claimed method applied routine and conventional techniques.

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[1] Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66, 77-80 (2012).

[2] Id. at 77.

[3] The two-step test in Mayo did not become clear until its decision in Alice Corp. v. CLS Bank, Int'l., 134 S. Ct. 2347, 2355-60 (2014).

[4] Subject Matter Eligibility, USPTO (last visited Aug. 23, 2017), https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.

[5] THD also asserted that the Clinic did not properly plead infringement of the third patent, US Pat. No. 9,612,242, which recited methods for detecting MPO activity and/or mass and F2-isoprostane levels.

[6] The other patent, US Pat. Nos. 9,581,597 ("the '597 patent") refers to methods of identifying the levels of the enzyme myeloperoxidase ("MPO") in patients suffering from atherosclerotic CVD.

[7] CC3, slip op. at 1 and 2.

[8] The Clinic did not analogize its pending claims in the '597 patent to the Guidelines during prosecution, most likely because the '597 patent claims do not recite methods of detecting, like Example 29, claim 1 of the Guidelines, but rather methods of identifying.

[9] CC3, slip op. at 4-7.

[10] CC3, slip op. at 13 and 14.

[11] CC3, slip op. at 15.

[12] CC3, slip op. at footnote 8.

[13] Rapid Litigation Management Ltd. v. CellzDirect. Inc., 827 F.3d 1042 (Fed. Cir. 2016).

[14] CC3, slip op. at 15-20 (internal citations omitted).

[15] Xlear, slip op. at *5; Example 3 of Nature-Based Products, USPTO (May 4, 2016), https://www.uspto.gov/sites/default/files/documents/mdc_examples_nature-based_products.pdf.

[16] Xlear, slip op. at *4-9.

[17] See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, No. 15-cv-40075-IT, 2017 WL 3336275, at *5 (D. Mass. Aug. 4, 2017) (patentee argued iodination methods involving proteins were not routine, but patentee's specification stated that "iodination of the label is a standard technique in the art.").

[18] Finjan, slip op. at *8-11; See also Finjan, Inc. v. Blue Coat Sys., LLC, No. 15-cv-03295-BLF, 2016 WL 7212322, *8-12 (N.D. Cal. Dec. 13, 2016) (holding the patent is not invalid under § 101 during a motion for judgment on the pleadings).

[19] Id. at 380-403; 838 F.3d 1307, 1322 (Fed. Cir. 2016) (holding that the eligible patent is ineligible because "it is directed to the use of conventional or generic technology in a nascent but well-known environment, without any claim that the invention reflects an inventive solution to any problem presented by combining the two"; see also Intellectual Ventures I LLC v. Erie Indemnity Co., 200 F. Supp. 3d 565, 574-77 (W.D. Pa. 2016), which involved a similar patent to the patent in Symantec and the court found the patent to be invalid using similar reasoning from Symantec.

[20] Report at 30.

[21] No. 15-cv-40075-IT, 2017 WL 3336275, at *5.
