Rebutting 101 Rejections Asserting 'Idea Of Itself': Part 3

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This is the final part of a three-part article reviewing the decisions in which courts have found various concepts to be abstract ideas, specifically concepts that fall into the category of “an idea of itself.”


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By understanding the particular claims at issue in those cases as well as the courts’ reasoning, this article hopes to better equip practitioners and applicants to respond to rejections under § 101 where the USPTO asserts that the pending claims are similar to one of the broad concepts previously held to be abstract.

Part 1 reviewed the cases discussing “collecting and comparing known information,” “obtaining and comparing intangible data,” and “using categories to organize, store, and transmit information.” Part 2 reviewed the cases discussing “data recognition and storage,” “organizing information through mathematical correlations,” and “comparing new and stored information and using rules to identify options.”

A review of those cases reveals various considerations that appear to have guided the courts’ decisions:

- whether the claimed method could be performed entirely in the human mind or includes some additional physical step (Classen);[1]
- whether the claimed method steps are broad enough to encompass performance by a human using pen and paper (CyberSource);[2]
- whether a recited machine plays a significant part in permitting a claimed method to be performed (CyberFone);[3]
- whether recited machines are used solely in well-known and conventional ways (Content Extraction);[4]
- whether a claimed method only manipulates data without being sufficiently tied to a specific machine (Digitech);[5] and/or
- whether a clamed method recites using computing devices to perform a method that could otherwise be entirely performed in the mind of an individual (SmartGene).[6]

Part 3 reviews decisions addressing two final concepts falling within the category of “an idea ‘of itself’” that courts have held to be abstract: “comparing data to determine a risk level” and “comparing information regarding a sample or test subject to a control or target data.”

As noted in the first two parts of this article, practitioners and applicants may find it helpful when responding to subject matter rejections to distinguish their claims from those

associated with the concepts previously held to be abstract and explain why the courts' reasoning with respect to those claims does not apply to their own claims.

Comparing Data to Determine a Risk Level

The Federal Circuit addressed "comparing data to determine a risk level" in the post-Mayo, pre-Alice case of PerkinElmer Inc. v. Intema.[7]

In PerkinElmer, Intema's U.S. Pat. No. 6,573,103, titled "Antenatal Screening for Down's Syndrome," was at issue.

The claimed subject matter of the '103 patent was directed to methods for determining whether a pregnancy was at an increased risk for Down syndrome based on screening markers measured during various trimesters of a pregnancy. Accordingly, the data used to determine a risk level in PerkinElmer compared the measurements of the Down syndrome screening markers.

Claims 1 and 20 were selected as the representative claims.

Claim 1 recited a diagnostic method having three steps: (1) measuring a screening marker during a first trimester, (2) measuring a different screening marker during a second trimester, and (3) determining the risk of Down syndrome by comparing the measurements to observed frequency distributions of those markers in Down syndrome pregnancies. In addition, claim 1 recited that the measurements of the markers were performed by either assaying a sample for a biochemical screening marker or measuring an ultrasound screening marker during an ultrasound scan.

Claim 20 recited similar steps and differed in that the second measurement was only performed if the first measurement crossed a given threshold.

The district court found that the claims did recite patent-eligible subject matter because the claims satisfied the machine-or-transformation test. In particular, the district court concluded that assaying blood samples was sufficiently transformative and that measuring an ultrasound scan was sufficiently tied to the use of an ultrasound machine.

However, the Federal Circuit reversed the district court, holding that the claims of the '103 patent did not recite patent-eligible subject matter because they did not recite significantly more than the mental step of determining the risk of Down syndrome or the underlying natural law describing the relationship between that risk and various marker levels. In reaching its decision, the Federal Court asked whether the steps recited in the claims amounted to significantly more than that mental step or that law of nature. The court also concluded that the claims failed both prongs of the machine-or-transformation test.

With respect to the steps of measuring the screening markers, the Federal Circuit concluded that these measurement steps were routine and conventional steps that had been previously performed by scientists in the field. The court based this conclusion on statements in the '103 patent indicating that any effective marker may be measured using known methods.

Regarding the step of determining the risk of Down syndrome, the Federal Circuit concluded that this step only recited the mental step of comparing the marker measurements to well-known and conventional information (i.e., the observed statistical frequencies) using well-known and conventional statistical calculations. Again, the court pointed to statements in

the ‘103 patent indicating that the statistical techniques employed were already known.

As a result, the Federal Circuit held that the measuring steps and the determining step could not transform the claims into patent-eligible subject matter.

Turning to the transformation prong of the machine-or-transformation test, the Federal Circuit concluded that the claim feature of “assaying a sample” was not sufficiently transformative since it was broad enough to encompass assays that do not involve transformations to measure screening markers.

For the machine prong of the test, the court noted that the claims did not require taking an ultrasound (only measuring data from previous ultrasounds), and, even if they had, the step of taking an ultrasound would be a conventional, extra-solution data gathering step and thus insufficient to impart subject matter eligibility.

The Federal Circuit also rejected Intema’s reliance on In re Abele[8] for the proposition that measurements of an ultrasound scan involve a sufficient transformation of data into a visual depiction. The court distinguished the claims of the ‘103 patent from those at issue in Abele, noting that Abele’s claims recited a patent-eligible application of an algorithm to improve the CAT scan process. The court also noted that the claims of the ‘103 patent did not actually require any tangible output or visual depiction of the determined risk for Down syndrome.

The court also distinguished the claims of the ‘103 patent from those reciting patent-eligible subject matter in Myriad[9] and Classen.[10] With respect to Myriad, the court noted that claim 20 of U.S. Pat. No. 5,747,282 recited patent-eligible subject matter because the claimed method utilized non-naturally occurring cells that were themselves patent-eligible subject matter. Regarding Classen (also discussed in part 1 of this article), the court noted that the claims reciting patent-eligible subject matter required the additional physical step of performing an immunization based on the knowledge obtained by comparing immunization schedules. For the claims of the ‘103 patent, however, the court noted that the claims did not recite any features that were themselves patent-eligible subject matter and did not recite any physical steps that applied the knowledge acquired from comparing the measured screening markers to the observed statistical frequencies.

Practitioners and applicants may find additional useful commentary in PerkinElmer regarding claim features that are and are not sufficient to impart subject matter eligibility on claims involving diagnostic methods.

Comparing Information Regarding a Sample or Rest Subject to a Control or Target Data

The Federal Circuit discussed “comparing information regarding a sample or test subject to a control or target data” in the post-Mayo and post-Alice case of In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patient Litigation (BRCA).[11]

In BRCA, three of Myriad’s patents were at issue: U.S. Pat. Nos. 5,753,441, 5,747,282 — each titled “17Q-Linked Breast and Ovarian Cancer Susceptibility Gene” — and U.S. Pat. No. 5,837,492 — titled “Chromosome 13-Linked Breast Cancer Susceptibility Gene.”

Both the U.S. Supreme Court and the Federal Circuit had previously addressed the ‘441,‘282 and ‘492 patents,[12] and the Federal Circuit in BRCA addressed additional claims from

these patents that had not yet been considered by the courts.

In BRCA, the claims at issue included claims 7 and 8 of the ‘441 patent, claims 16 and 17 of the ‘282 patent, and claims 29 and 30 of the ‘492 patent. The claims of the ‘282 and ‘492 patents were directed to compositions of DNA primers that provided the starting material for synthesizing DNA with the BRCA1 gene. The claims of the ‘441 patent were directed to methods of screening a patient for alteration of the BRCA1 gene by comparing the patient’s gene sequence to the typical form (wild-type) of the gene sequence. Accordingly, the “sample or test subject” compared to “a control or target data” in BRCA related to the patient and wild-type gene sequences.

The method claims of the ‘441 patent depended from independent claim 1, which recited the step of comparing the gene sequences. Dependent claims 7 and 8 recited particular techniques for comparing those sequences.

Ultimately, the Federal Circuit held that neither the composition claims nor the method claims recited patent-eligible subject matter. With respect to the composition claims, the Federal Circuit concluded that the DNA primers were naturally occurring products similar to the isolated DNA strands the Supreme Court held to be patent-ineligible subject matter in its Myriad decision. Regarding the method claims, the Federal Circuit concluded that the methods of comparing the gene sequences did not amount to significantly more than the abstract idea of comparing and analyzing two gene sequences.

The court addressed the methods recited in dependent claims 7 and 8 separately from the method recited in their base claim, independent claim 1. And rather than review the claims under that law of nature exception at the heart of Mayo, the court found that the claims instead implicated the abstract idea exception discussed in Alice.

The Federal Circuit noted that it had already determined that independent claim 1 of the ‘441 patent recited patent-ineligible subject matter, because the step of comparing two gene sequences and determining whether any alterations exist was determined to be an abstract mental process. Recalling its earlier decision, the court considered the breadth of claim 1 to be unduly preemptive. In particular, the court observed that claim 1 would encompass (1) an unlimited number of comparisons and yet-to-be discovered alterations, and (2) comparisons for purposes other than detecting a risk of breast or ovarian cancer. Any claims depending from independent claim 1 — e.g., claims 7 and 8 — thus inherited the exception.

The Federal Circuit then asked whether claims 7 and 8 recited subject matter that could transform the claims into a patent-eligible application of the abstract idea and concluded that they did not. In particular, the court found that claims 7 and 8 only recited well-known and conventional methods of comparing gene sequences, e.g., probe hybridization and gene amplification. The court determined that a skilled artisan tasked with comparing two gene sequences would recognize that either of the recited comparison techniques could be used to perform the comparison. As a result, the court concluded that the conventional gene comparison techniques recited in claims 7 and 8 did not add significantly more to the abstract idea of comparing and analyzing gene sequences.

The court likewise noted breadth of claims 7 and 8 as compared to claim 21 of the ‘441 patent. Without expressing any view of the subject matter eligibility of claim 21, the court observed that this claim was limited to the detection of specific predisposing alterations to the BRCA gene for the purpose of determining susceptibility to specific types of cancer. In contrast, the court deemed claims 7 and 8 to be more abstract since those claims would

encompass any comparison of a patient's BRCA gene sequence for any purpose.

For these reasons, the court held that dependent claims 7 and 8, like independent claim 1, did not amount to significantly more than comparing two gene sequences.

Practitioners and applicants may find additional useful commentary in BRCA regarding products derived from those that occur in nature and using such products for diagnostic purposes.

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[1] Classen Immunotherapies Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011).

[2] CyberSource Corp. v. Retail Decisions, Inc., 654 F.3d 1366 (Fed. Cir. 2011).

[3] CyberFone Sys. v. CNN Interactive Grp., 558 Fed. Appx. 988 (Fed Cir. 2014).

[4] Content Extraction & Transmission v. Wells Fargo Bank, N.A., 776 F.3d 1343 (Fed. Cir. 2014).

[5] Digitech Image Tech., LLC v. Electronics for Imaging, Inc., 758 F.3d 1344 (Fed. Cir. 2014).

[6] SmartGene, Inc. v. Advanced Biological Labs., SA., 555 Fed. Appx. 950 (Fed. Cir. 2014).

[7] 496 F. Appx. 65 (Fed. Cir. 2012).

[8] 684 F.2d 902 (CCPA 1982), abrogated by In re Bilski, 545 F.3d 943 (Fed. Cir. 2008)

[9] Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1336–37 (Fed. Cir. 2012).

[10] Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011).

[11] No. 2014-1361 and No. 2014-1366 (Fed. Cir. Dec. 17, 2014).

[12] See Ass'n for Molecular Pathology v. Myriad, 133 S. Ct. 2107 (2013); Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329 (Fed. Cir. 2011), vacated, 132 S. Ct. 1794 (2013); and Ass'n for Molecular Pathology v. Myriad, 689 F.3d 1303 (Fed. Cir. 2012), aff'd in part, rev'd in part, 133 S. Ct. 2107 (2013).