CLAIMING PATENT ELIGIBLE SUBJECT MATTER

Compliance with Section 101 in View of *Myriad*, *Prometheus*, and *Classen*

Cases & Claims

DIAMOND v. CHAKRABARTY, 447 U.S. 303 (1980).

The claims-at-issue, directed to engineered *Pseudomonas*, were initially rejected on two grounds: (1) that micro-organisms are "products of nature," and (2) that, as living things, they are not patentable subject matter under § 101. Chakrabarty appealed and the Board affirmed the rejection. Chakrabarty then took the case to the CCPA, which reversed the Board's decision. The CCPA took a second look at the case after the Supreme Court GVR'd *In re Bergy* in light of *Parker v. Flook*, and the CCPA again came to the same conclusion. The Supreme Court agreed in its subsequent decision.

From the Supreme Court decision (*Chakrabarty*, 447 U.S. at 308-310, internal citations omitted):

In cases of statutory construction we begin, of course, with the language of the statute. And "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning." We have also cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed.

Guided by these canons of construction, this Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery." Similarly, "composition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.

The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man."

This is not to suggest that § 101 has no limits, or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity "having a distinctive name, character [and] use."

***STATE STREET BANK TRUST CO. v. SIGNATURE FINANCIAL GROUP, INC.*, 149 F.3d 1368 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).**

Federal Circuit decision on the appeal from the decision of the District Court for the District of Massachusetts granting a motion for summary judgment in favor of State Street Bank & Trust Co., finding U.S. Patent No. 5,193,056 invalid on the ground that the claimed subject matter is not encompassed by 35 U.S.C. § 101. The District Court decision was reversed.

Claim 1, the only independent claim, of 5,193,056:

1. A data processing system for managing a financial services configuration of a portfolio established as a partnership, each partner being one of a plurality of funds, comprising:

(a) computer processor means for processing data;

(b) storage means for storing data on a storage medium;

(c) first means for initializing the storage medium;

(d) second means for processing data regarding assets in the portfolio and each of the funds from a previous day and data regarding increases or decreases in each of the funds[’] assets and for allocating the percentage share that each fund holds in the portfolio;

(e) third means for processing data regarding daily incremental income, expenses, and net realized gain or loss for the portfolio and for allocating such data among each fund;

(f) fourth means for processing data regarding daily net unrealized gain or loss for the portfolio and for allocating such data among each fund; and

(g) fifth for processing data regarding aggregate year-end income, expenses, and capital gain or loss for the portfolio and each of the funds.

From the Federal Circuit decision (*State Street*, 149 F.3d at 1373-1375):

Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces “a useful, concrete and tangible result”-a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

* * *

As an alternative ground for invalidating the '056 patent under § 101, the court relied on the judicially-created, so-called “business method” exception to statutory subject matter. We take this opportunity to lay this ill-conceived exception to rest. Since its inception, the “business method” exception has merely represented the application of some general, but no longer applicable legal principle, perhaps arising out of the “requirement for invention” - which was eliminated by § 103. Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.

LABORATORY CORP. v. METABOLITE LABS., INC., 126 S. Ct. 2921 (2006).

Claim 13 of U.S. Patent No. 4,970,658, held by Metabolite, was found valid and willfully infringed by LabCorp. The Supreme Court initially granted Cert as to the following question:

"Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."

Cert was subsequently dismissed as improvedently granted - the question presented, and particularly how it was tied to patent-eligibility under Section 101, had not been raised during the course of the District Court case or the Federal Circuit's review.

Claim 13 of the '658 patent:

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

assaying a body fluid for an elevated level of total homocysteine; and

correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

From Justice Breyer's Dissent, joined by Justices Stevens and Souter (*Labcorp*, 126 S. Ct. at 2924-2928):

Claim 13, [the patent holder] argued, created a protected monopoly over the process of "correlating" test results and potential vitamin deficiencies. The parties agreed that the words "assaying a body fluid" refer to the use of any test at all, whether patented or not patented, that determines whether a body fluid has an "elevated level of total homocysteine." And at trial, the inventors testified that claim 13's "correlating" step consists simply of a physician's recognizing that a test that shows an elevated homocysteine level "by that very fact" shows the patient likely has a cobalamin or folate deficiency. App. 108-111 (testimony of Dr. Sally Stabler); id., at 131-148 (testimony of Robert Allen). They added that, because the natural relationship between homocysteine and vitamin defic-iency was now well known, such "corre-lating" would occur automatically in the mind of any competent physician. Id., at 137-138.

* * *

Even were I to assume (purely for argument's sake) that claim 13 meets certain general definitions of process patentability, however, it still fails the one at issue here: the requirement that it not amount to a simple natural correlation, i.e., a "natural phenomenon". . . At most, respondents have simply described the natural law at issue in the abstract patent language of a "process." But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge . . . One might, of course, reduce the "process" to a series of steps, e.g., Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce any process to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable "natural phenomenon," and I can find nothing in claim 13 that adds anything more of significance.

BILSKI v. KAPPOS, 130 S. Ct. 3218 (2010).

The claims were initially rejected during examination as directed to patent-ineligible abstract ideas. This finding was affirmed by the Board and during subsequent proceedings at the Federal Circuit. The Supreme Court ultimately affirmed the finding that the claims were directed to patent-ineligible subject matter.

Two Questions Presented:

Whether the Federal Circuit erred by holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing ("machine-or-transformation" test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court's precedent declining to limit the broad statutory grant of patent eligibility for "any" new and useful process beyond excluding patents for "laws of nature, physical phenomena, and abstract ideas."

Whether the Federal Circuit's "machine-or-transformation" test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear Congressional intent that patents protect "method[s] of doing or conducting business." 35 U.S.C. § 273.

Exemplary Claims (both found invalid)

1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

4. A method for managing weather-related energy price risk costs sold by an energy provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said energy provider and energy consumers wherein said energy consumers purchase energy at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers, wherein the fixed price for the consumer transaction is determined by the relationship: Fixed Bill Price = Fi + [(Ci + Ti + LDi) x (α + βE (Wi))] wherein, Fi = fixed costs in period i; Ci = variable costs in period i; Ti = variable long distance transportation costs in period i; LDi = variable local delivery costs in period i; E(Wi) = estimated location-specific weather indicator in period i; and α and ß are constants;

(b) identifying other energy market participants having a counter-risk position to said consumers; and

(c) initiating a series of transactions between said energy provider and said other energy market participants at a second fixed rate such that said series of transactions balances the risk position of said series of consumer transactions.

From the Supreme Court decision (*Bilski*, 130 S. Ct. at 3226-3231, internal citations omitted):

The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test. It is true that *Cochrane v. Deene*r, explained that a "process" is "an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." More recent cases, however, have rejected the broad implications of this dictum; and, in all events, later authority shows that it was not intended to be an exhaustive or exclusive test. *Gottschalk v. Benson*, noted that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." At the same time, it explicitly declined to "hold that no process patent could ever qualify if it did not meet [machine or transformation] requirements." *Flook* took a similar approach, "assum[ing] that a valid process patent may issue even if it does not meet [the machine-or-transformation test].

This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible "process."

* * *

Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk: "Hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class." The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.

Petitioners' remaining claims are broad examples of how hedging can be used in commodities and energy markets. *Flook* established that limiting an abstract idea to one field of use or adding token post-solution components did not make the concept patentable. That is exactly what the remaining claims in petitioners' application do. These claims attempt to patent the use of the abstract idea of hedging risk in the energy market and then instruct the use of well-known random analysis techniques to help establish some of the inputs into the equation. Indeed, these claims add even less to the underlying abstract principle than the invention in *Flook* did, for the *Flook* invention was at least directed to the narrower domain of signaling dangers in operating a catalytic converter.

***PROMETHEUS LABORATORIES, INC. v. MAYO COLLABORATIVE SERVICES*, 628 F.3d 1347 (Fed. Cir. 2010); Cert Granted.**

The Federal Circuit originally reversed a District Court decision that the claims of US Patents 6,335,623 and 6,680,302 were invalid as directed to patent ineligible subject matter under section 101. The Federal Circuit argued that the claims satisfied the machine or transformation test, through the inclusion of transformative steps. The Federal Circuit took a second look at the case after the Supreme Court GVR'd their initial decision (in light of *Bilski v Kappos*). The Federal Circuit came to the same conclusion the second time around. The Supreme Court has now granted Cert.

Question Presented (from the Supreme Court's Grant of Cert)**:**

Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve "transformations" of body chemistry.

Exemplary Claim with the admin step (Claim 1 of the '623 patent):

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Exemplary Claim without the admin step (Claim 46 of the '623 patent):

46. A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) determining the level of 6-thioguanine or 6-methylmercaptopurine in a subject administered a drug selected from the group consisting of 6-mercaptopurine, azathiop[u]rine, 6-thioguanine, and 6-methyl-mercaptoriboside, said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the[] amount of said drug subsequently administered to said subject, and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells or a level of 6-methylmercaptopurine greater than about 7000 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

From the Federal Circuit decision (*Prometheus*, 628 F.3d at 1356-1357, internal citations omitted):

The transformation here, however, is the result of the physical administration of a drug to a subject to transform - i.e., treat - the subject, which is itself not a natural process. It is virtually self-evident that a process for a chemical or physical transformation of physical objects or substances is patent-eligible subject matter. The administering step, therefore, is not merely data-gathering but a significant transformative element of Prometheus's claimed methods of treatment that is sufficiently definite to confine the patent monopoly within rather definite bounds.

Not all of the asserted claims, however, contain the administering step. That omission, which occurs in claims 46 and 53 of the '623 patent, does not diminish the patentability of the claimed methods because we also hold that the determining step, which is present in each of the asserted claims, is transformative and central to the claimed methods. Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or some other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. As stated by Prometheus's expert, "at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue." That is clearly a transformation. In fact, Mayo does not dispute that determining metabolite levels in the clinical samples taken from patients is transformative, but argues that this transformation is merely a necessary data-gathering step for use of the correlations. On the contrary, this transformation is central to the purpose of the claims, since the determining step is, like the administering step, a significant part of the claimed method. Measuring the levels of 6-TG and 6-MMP is what enables possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment. The determining step, by working a chemical and physical transformation on physical substances, likewise sufficiently confines the patent monopoly, as required by the machine-or-transformation test.

* * *

The crucial error the district court made in reaching the opposite conclusion was failing to recognize that the first two steps of the asserted claims are not merely data-gathering steps. While it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not "merely" for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol, and they are transformative. As explained above, the administering step provides thiopurine drugs for the purpose of treating disease, and the determining step measures the drugs' metabolite levels for the purpose of assessing the drugs' dosage during the course of treatment.

***AMP v. USPTO and MYRIAD*, ** F3d **, 2011 WL 3211513 (Fed. Cir. 2011).**

A variety of individuals and associations jointly brought suit in the Southern District of New York arguing that the claims-in-suit (see below) were invalid under a variety of theories, including that the claims were directed to patent-ineligible subject matter under section 101. The District Court found that all of the claims-in-suit were invalid as directed to patent-ineligible subject matter. The Federal Circuit reversed in part, finding that the challenged composition of matter claims and one of the challenged method claims were directed to patent eligible subject matter, and affirmed in part, finding that the challenged method claims-in-suit were directed to patent-ineligible subject matter.

Claims-in-suit:

- 1, 2, 5, 6, 7, & 20 of 5,747,282;
- 1, 6, & 7 of 5,837,492;
- 1 of 5,693,473;
- 1 of 5,709,999;
- 1 of 5,710,001;
- 1 of 5,753,441; and
- 1 and 2 of 6,033,857.

Exemplary Composition of Matter claims
- From the '282 Patent
1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

- From the '492 Patent
6. An isolated DNA molecule coding for a mutated form of the BRCA2 polypeptide set forth in SEQ ID NO:2, wherein said mutated form of the BRCA2 polypeptide is associated with susceptibility to cancer.

- From the '473 Patent
1. An isolated DNA comprising an altered BRCA1 DNA having at least one of the alterations set forth in Tables 12A, 14, 18 or 19 with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.

Exemplary Method claim deemed valid
- From the '282 Patent
20. A method for screening potential cancer therapeutics which comprises:

growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic,

growing said transformed eukaryotic host cell in the absence of said compound,

determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells,

wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

Exemplary Method claims deemed invalid
- From the '999 Patent
1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

Exemplary Method claims deemed invalid (Cont.)

- From the '001 Patent

1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises gene [sic] comparing a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.

- From the '441 Patent

1. A method for screening a germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.

- From the '857 Patent

1. A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.

2. A method for diagnosing a predisposition for breast cancer in a human subject which comprises comparing the germline sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type BRCA2 gene or the sequence of its mRNA, wherein an alteration in the germline sequence of the BRCA2 gene or the sequence of its mRNA of the subject indicates a predisposition to said cancer.

From the Federal Circuit decision

(*Myriad*, 2011 WL 3211513 at 19-24, internal citations omitted):

The distinction, therefore, between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature. Specifically, the Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given "markedly different," or "distinctive," characteristics. Applying this test to the isolated DNAs in this case, we conclude that the challenged claims are drawn to patentable subject matter because the claims cover molecules that are mark-edly different - have a distinctive chemical identity and nature - from molecules that exist in nature.

* * *

As the above description indicates, isolated DNA is not purified DNA. Purification makes pure what was the same material, but was previously impure. Although isolated DNA must be removed from its native

cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body …in this case, the claimed isolated DNA molecules do not exist as in nature within a physical mixture to be purified. They have to be chemically cleaved from their chemical combination with other genetic materials. In other words, in nature, isolated DNAs are covalently bonded to such other materials. Thus, when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity. In fact, some forms of isolated DNA require no purification at all, because DNAs can be chemically synthesized directly as isolated molecules.

* * *

Myriad claims that "comparing" and "analyzing" take on this meaning ["extracting" or "sequencing" DNA or otherwise "processing" a human sample] when read in light of the patent specifications. Specifically, Myriad argues that the specifications show that the claim term "sequence" refers not to information, but rather to a physical DNA molecule, whose sequence must be determined before it can be compared. We disagree. The patent specifications make clear that "sequence" does not exclusively specify a DNA molecule, but refers more broadly to the linear sequence of nucleotide bases of a DNA molecule. For example, Figure 10A-10H is described as showing the "genomic sequence of BRCA1." '473 patent col.5 l.66. Figure 10 does not show a physical DNA molecule; the figure lists a series of letters (Gs, As, Ts, and Cs) corresponding to the nucleotides guanine, adenine, thymine, and cytosine of a DNA molecule. Similarly, the patent specifications state that "[t]he nucleotide sequence for BRCA1 exon 4 is shown in SEQ ID NO: 11." Id. col.53 ll.50-53. SEQ ID NO: 11 again lists a series of Gs, As, Ts, and Cs corresponding to the nucleotide sequence of BRCA1 exon 4.

* * *

Myriad's claims, in contrast, do not include the step of "determining" the sequence of BRCA genes by, e.g., isolating the genes from a blood sample and sequencing them, or any other necessarily transformative step. Rather, the comparison between the two sequences can be accomplished by mere inspection alone. Accordingly, Myriad's claimed methods of comparing or analyzing nucleotide sequences fail to satisfy the machine-or-transformation test, and are instead directed to the abstract mental process of comparing two nucleotide sequences. The claims thus fail to claim a patent-eligible process under § 101.

* * *

Lastly, we turn to Myriad's method claim directed to a method for screening potential cancer therapeutics via changes in cell growth rates. '282 patent claim 20. Plaintiffs challenge this claim as directed to the abstract idea of comparing the growth rates of two cell populations and as preempting a basic scientific principle - that a slower growth rate in the presence of a potential therapeutic compound suggests that the compound is a cancer therapeutic. We disagree.

Starting with the machine-or-transformation test, we conclude that the claim includes transformative steps, an "important clue" that it is drawn to a patent-eligible process. Specifically, the claim recites a method that comprises the steps of (1) "growing" host cells transformed with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic, (2) "determining" the growth rate of the host cells with or without the potential therapeutic, and (3) "comparing" the growth rate of the host cells."

***CLASSEN IMMUNO v. BIOGEN IDEC*, ** F3d **, 2011 WL 3835409 (Fed. Cir. 2011).**

District Court found, on Summary Judgment, that all of the claims-in-suit were invalid as directed to patent-ineligible subject matter. In 2008, the Federal Circuit, in a non-precedential decision, affirmed the District Court's grant of Summary Judgment, arguing that the claims failed the machine or transformation test. The Federal Circuit took a second look at the case after the Supreme Court GVR'd their initial decision (in light of *Bilski v Kappos*). The Federal Circuit now finds the claims-in-suit stemming from two of the three asserted patents (6,638,739 and 6,420,139) are indeed directed to eligible subject matter, while the claims stemming from the third patent (5,723,283) are not.

Exemplary Method claim deemed valid
- From the '739 Patent

1. A method of immunizing a mammalian subject which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

Exemplary Method claim deemed invalid
- From the '283 Patent

1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

From the Federal Circuit decision (*Classen*, 2011 WL 3835409 at 9-10, internal citations omitted):

The claims of the ’139 and ’739 patents are directed to a method of lowering the risk of chronic immune-mediated disorder, including the physical step of immunization on the determined schedule. These claims are directed to a specific, tangible application, as in *Research Corporation*, and in accordance with the guidance of *Bilski v. Kappos* that “[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts,” exclusions from patent-eligibility should be applied “narrowly,” we conclude that the subject matter of these two patents traverses the coarse eligibility filter of §101.

* * *

Claim 1 of the ‘283 patent states the method of “determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder” by reviewing information on whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder. This stands in contrast to the ’139 and ’739 patent claims, which include the subsequent step of immunization on an optimum schedule. Claim 1 of the ’283 patent claims the idea of comparing known immunization results that are, according to the patent, found in the scientific literature, but does not require using this information for immunization purposes. Classen states, for example, that Merck induces direct infringement by parents when Merck provides and physicians distribute the book “What Every Parent Should Know About Vaccines,” because the book advises parents to understand vaccines and vaccination schedules.

* * *

The representative claim of the ’283 patent is directed to the single step of reviewing the effects of known immunization schedules, as shown in the relevant literature. Although recourse to existing knowledge is the first step of the scientific method, the method claimed in the ’283 patent simply invites the reader to determine the content of that knowledge. The ’283 claims do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases. In contrast, the claims of the ’139 and ’739 patents require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application. Determination of whether a proffered invention, as claimed, transcends an “abstract idea” is not subject to “categorical rules that might have wide-ranging and unforeseen impacts,” The invention as a whole, including the scope asserted by the patentee must be considered. We conclude that the immunization step moves the ’139 and ’739 claims through the coarse filter of §101, while the abstraction of the ’283 claim is unrelieved by any movement from principle to application.”