

Patenting Natural Matters after Myriad & Mayo

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- *Bilski v. Kappos*
- *Mayo v. Prometheus*
- *AMP v. Myriad*
- *New USPTO Guideline*

Introduction

- Patentability criteria
 - Novelty
 - Unobviousness (inventiveness)
 - Enablement (sufficiency)
 - Written Description
- Patent-eligibility criteria
 - Statutory categories
 - Judicial exceptions
 - USPTO guidelines



Patent-Eligible

- Statutory Categories 35 U.S.C. § 101
 - Whoever invents or discovers any new and useful **process**, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
- Judicial Exceptions:
 - laws of nature, natural phenomena, and abstract ideas

Bilski v. Kappos - Litigation History

1. Rejection of Application (US08/833,892) by USPTO
2. Applicants appealed to the Board of Patent Appeals and Interferences (BPAI; now Patent Trial and Appeal Board)
3. Applicants appealed to the Court of Appeal of the Federal Circuit (CAFC)
4. Federal Circuit ordered arguments to be heard *en banc*
5. *en banc* court (CAFC) affirmed the rejection
6. Supreme Court issued an opinion on appeal that affirmed the judgment of the CAFC



Bilski v. Kappos - CAFC

- Patent Applicant appealed PTO's rejection of their claim for a method for handling hedge funds
 - Patent examiner held claims not patentable subject matter under § 101
 - Board of Patent Appeals and Interferences (BPAI) affirms
- In 2008, the Federal Circuit affirmed rejection of patent claims
 - Federal Circuit reiterated the machine-or-transformation (MOT) test as the test for patent eligible subject matter
 - "A claimed process is surely patent-eligible under § 101 if:
 - (1) it is tied to a particular machine or apparatus, or
 - (2) it transforms a particular article into a different state or thing."

Supreme Court Ruling 2010

- Bilski's claims not patentable
- "abstract ideas" not patentable
- "machine or transformation test" (MOT Test)
 - not the only test for determining whether a claim is patentable



Mayo v. Prometheus



- **Plaintiffs** -- Prometheus Laboratories, Inc.
 - sole and exclusive licensee of the '623 and '302 patents
 - sells diagnostic kits that embody the process the patents describe.
- **Defendants**-- Mayo Clinic Rochester and Mayo Collaborative Services
 - bought and used tests from Prometheus.
 - in 2004 Mayo announced it intended to begin using and selling its own tests.
 - the Mayo test measured the same metabolites, but used higher metabolite levels to determine toxicity.

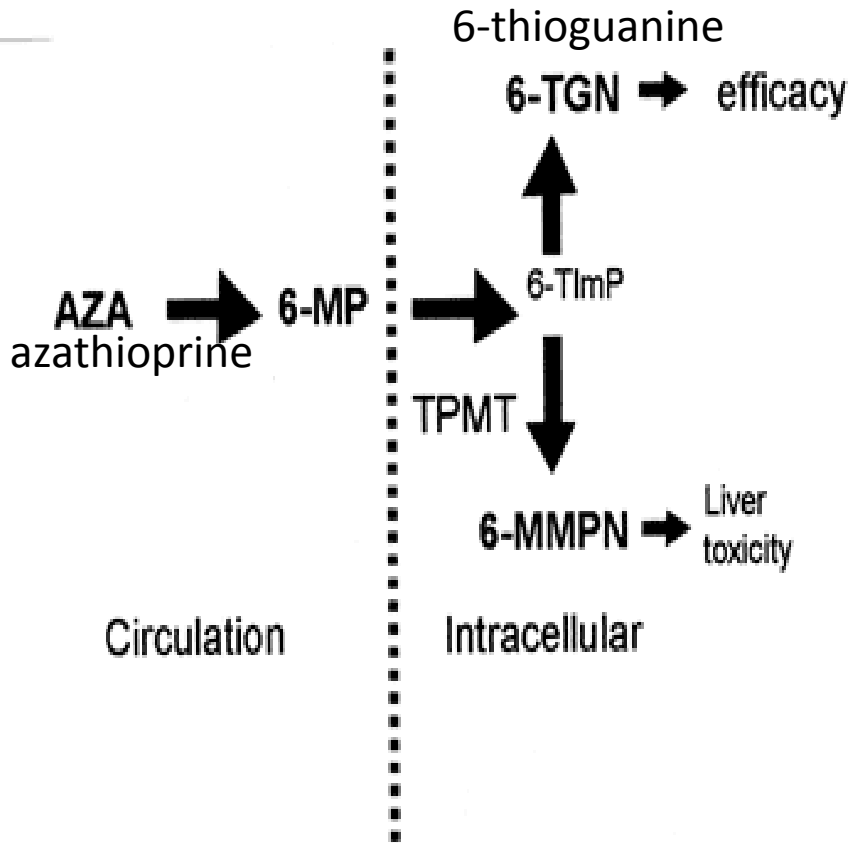
Claim 1 of US patent 6,355,623

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 8×10^8 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 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Summary of claim features



1. administering the drug to a subject,
2. determining metabolite levels, and
3. being warned that an adjustment in dosage may be required.

- (1) & (2) well known
- Dosage of metabolite was the invention



Litigation History

- District Court
- Federal Circuit I
- Supreme Court I
- Federal Circuit II
- Supreme Court II

Decision (District Court)

- Mayo's test would infringe the Prometheus '623 and '302 patents but....
- ...the '623 and '302 patents are invalid as the claimed subject matters are unpatentable laws of nature

Decision (Federal Circuit I)

- Reversed District Court's decision
- Claimed subject matters satisfy the MOT and section 101:
These steps involve the transformation of the human body or of blood taken from the body.

Decision (Supreme Court I)

- Accepted Mayo's filing of petition for certiorari in light of the decision of *Bilski v. Kappos* (Summer of 2010), which "clarified that the "machine or transformation test" is not a definitive test of patent eligibility, but only an important and useful clue."
- The Supreme Court has thus ordered the Federal Circuit to reconsider its *Prometheus* opinion in light of the decision of *Bilski v. Kappos*

Decision (Federal Circuit II)

- Upheld that '623 and '302 patents are valid as the claimed subject matters are statutory under 101:
“the . . . claims . . . do not encompass laws of nature or preempt natural correlations.”

Decision (Supreme Court II)

- Mayo again filed another petition for certiorari that was subsequently granted by supreme court
- Federal Circuit's judgment is reversed
- the three steps (as stated in the claims) simply tell "doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field"
- "...the relation [between the administered dose and toxicity] itself exists in principle apart from any human action"
- "The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes".
- They are "not sufficient to transform an unpatentable law of nature into patent-eligible applications"

AMP v. Myriad

- Plaintiff
 - Association for Molecular Pathology(AMP)
 - other plaintiffs : University of Pennsylvania, patient advocacy groups etc...
- Defendants
 - Myriad
 - University of Utah



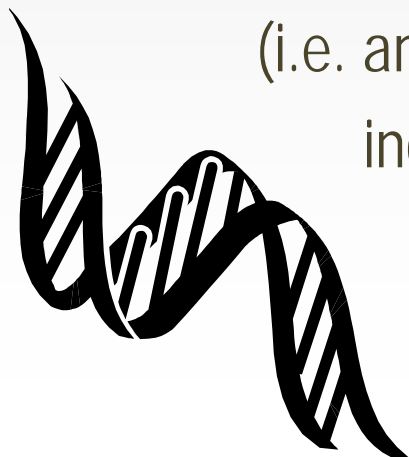
Background

- Patents of Myriad involved:
 1. US5,747,282 ('282 patent), filed 7 Jun 1995, granted 5 May 1998
 2. US5,693,473 ('473 patent), filed 7 Jun 1995, granted 2 Dec 1997
 3. US5,837,492 ('492 patent), filed 29 Apr 1996, granted 17 Nov 1998



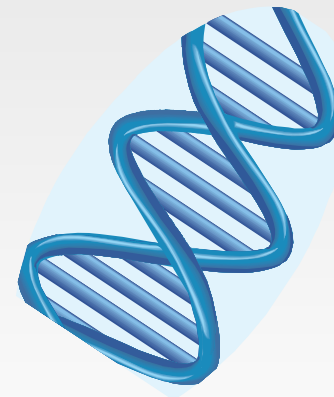
Representative claims ('282 patent):

- Claim 1: "An isolated DNA coding for a BRCA1 polypeptide...having the amino acid sequence set forth in SEQ ID NO:2..."
 - > SEQ ID NO:2 is a list of 1,863 amino acids that the typical BRCA1 gene encodes (i.e. any DNA sequence that encodes SEQ ID NO:2, including the genomic DNA of BRCA1)



Representative claims ('282 patent):

- Claim 2: "The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1."
 - > SEQ ID NO:1 = exons of BRCA1 only
= cDNA sequence
- The '473 and '492 patents: contain similar language



Litigation History

- District Court
- Federal Circuit
- Supreme Court

Decision (District Court)

- AMD filed suit in seeking a declaration that Myriad's patents are invalid under 35 U. S. C. §101.
- District court concluding that Myriad's claims were invalid because they covered products of nature.

Decision (Federal Circuit)

- Reversed District court's decision
- But found both isolated DNA and cDNA patent eligible on remand in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*
- "the claims cover molecules that are markedly different...from molecules that exist in nature."
- "...biologists may think of molecules in terms of their uses, but genes are...best described in patents by their structures rather than their functions."

Decision (Supreme Court)

- isolated DNA segment is a product of nature and not patent eligible: "separating that gene from its surrounding genetic material is not an act of invention."
- cDNA is patent eligible as it "retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived"
- Claim 1 but not claim 2 is invalid

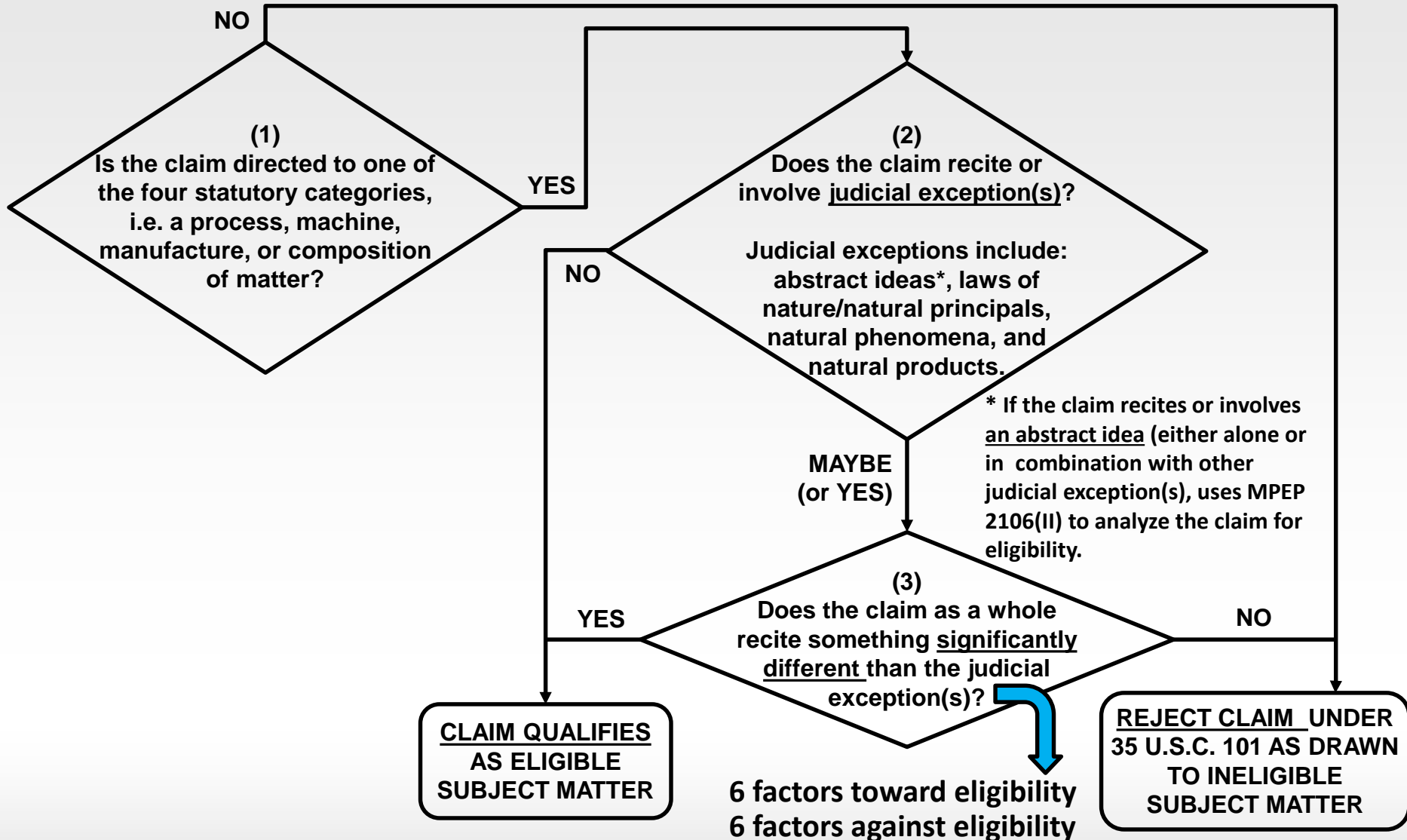
Myriad Mayo Guidance

USPTO Guidance for
Determining Subject Matter Eligibility of Claims
Reciting or Involving
Laws of Nature, Natural Phenomena, & Natural Products

What is “Significantly Different”?

- Addressing two pathways to eligibility:
 - 1. Product claim involving or reciting a natural product includes features or steps demonstrating a **marked difference from what exists in nature**; or
 - 2. Claim involving or reciting a judicial exception must also recite **meaningful limitations** that add something of significance to the judicial exceptions

USPTO Analysis Guideline : 3-Question Test



Weighing factors to Determine “Marked Different”

Factors that weigh toward eligibility (significantly different)

- a) Product claim recites something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.

Claim recites elements/steps in addition to the judicial exception(s) that:

- b) Impose meaningful limits on the claim scope.
- c) Relate to the judicial exception(s) in a significant way, e.g., they are more than insignificant extra-solution activity.
- d) Do more than describe the judicial exception(s) with general instructions to apply/use it.
- e) Include a particular machine or particular transformation, which implements or integrates the judicial exception(s).
- f) Add a feature that is more than well-understood, purely conventional or routine.

Factors that weigh against eligibility (not significantly different)

- g) Product claim recites something that appear to be a natural that is not markedly different in structure from naturally occurring products.

Claim recites elements/steps in addition to the judicial exception(s) that:

- h) Are recited at a high level of generality.
- i) Must be used/taken by others to apply the judicial exception(s).
- j) Are well-understood, purely conventional or routine.
- k) Are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- l) Amount to nothing more than a mere field of use.

Source: Slide #34, PTO Powerpoint Guidelines, 19 Mar 2014

EXAMPLES ON APPLYING THE THREE QUESTION TEST

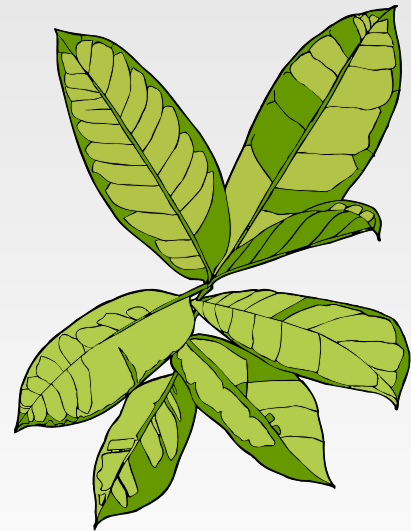
Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product

Claim 1: Purified amazonic acid.

Claim 2: Purified 5-methyl amazonic acid.

Claim 3: A method of treating colon cancer, comprising:

administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.



Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product

- Prior art knowledge:
 - Amazonian cherry tree is naturally occurring; its leaves contain chemical useful in treating breast cancer, while a patent must eat 30lbs of leaves per day for at least 4 weeks to be effective
 - Many have tried but failed to isolate the chemical
- What Applicant has discovered:
 - Purified cancer-fighting chemical from leaves - amazonic acid; the purified amazonic acid is structurally identical to the amazonic acid in the leaves, but a patient only needs to eat one teaspoon of the purified acid to get the same effects as 30lbs of leaves
 - Amazonic acid is useful to treat colon cancer as well as breast cancer
 - Made a derivative of amazonic acid (called 5-methyl amazonic acid), which is both structurally and functionally different from amazonic acid

Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product – Analysis on Claim 1



- Claim 1: Purified amazonic acid.
- Q1? YES (*composition of matter*)
- Q2? YES (amazonic acid is naturally occurring in leaves of Amazonian cherry trees - a *natural product*)
- Q3? NO - claim does not includes feature showing the recited product is markedly different from what exists in nature
 - Factors weighing towards eligibility: (a) **not satisfied** (no structural difference between the purified acid and acid in leaves); (b) to (f) **irrelevant** (claim doesn't include any elements in addition to the judicial exception of "natural product")
 - Factors weighing against eligibility: (g) **satisfied** (claimed acid is not markedly different from naturally occurring acid); (h) to (l) **irrelevant**
- So, Claim 1 **is not** an eligible subject matter

Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product – Analysis on Claim 2



- Claim 2: Purified 5-methyl amazonic acid.
- Q1? YES (*composition of matter*)
- Q2? YES (amazonic acid is naturally occurring in leaves of Amazonian cherry trees - a *natural product*)
- Q3? YES – claim includes feature showing the recited product is markedly different from what exists in nature
 - Factors weighing towards eligibility: (a) **satisfied** (5-methyl amazonic acid both structurally and functionally different from naturally occurring amazonic acid); (b) to (f) **irrelevant**
 - Factors weighing against eligibility: (g) **not satisfied** (claimed 5-methyl acid is markedly different); (h) to (l) **irrelevant**
- So, Claim 2 **is** an eligible subject matter

Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product – Analysis on Claim 3

- Claim 3: A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.
- Q1? YES (*process*)
- Q2? YES (amazonic acid is naturally occurring in leaves of Amazonian cherry trees - a *natural product*)



Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product – Analysis on Claim 3

- Q3? YES - claim includes feature showing the recited method is markedly different from what exists in nature
 - Factors weighing towards eligibility:
 - (a) irrelevant
 - (b) satisfied (particular dosage and particular length of time → limit to particular application of amazonic acid)
 - (c) satisfied (step involving manipulating amazonic acid in a particular and significant way)
 - (d) satisfied (particular administration – more than a general instruction to use)
 - (e) not satisfied (no machine or transformation recited)
 - (f) satisfied (prior usage – treat breast cancer; not well-known, routine or conventional to use amazonic acid for treating color cancer, or for treating any cancer at the recited dosage or for the recited period of time)

Ex. 1 - Composition vs Method Claims, Each Reciting A Natural Product – Analysis on Claim 3

- Q3? YES
 - Factors weighing against eligibility
 - (g) irrelevant
 - (h) not satisfied (administering step not at high level of generality)
 - (i) not satisfied (amazonic acid can be applied in other ways)
 - (j) not satisfied (not well-known to use amazonic acid for treating color cancer, or for treating any cancer at the recited dosage or for the recited period of time)
 - (k) not satisfied (administering step significantly related to amazonic acid)
 - (l) not satisfied (particular dosage and particular length of time is more than a mere field of use)
- So, Claim 3 is an eligible subject matter

Ex. 2 - Process Claim Involving a Natural Principle



- Claim 1: A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:
exposing the patient to sunlight, wherein the exposure to sunlight alters the neuronal activity in the patient's brain and mitigates the mood disorder.
- Claim 2: A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:
exposing the patient to a synthetic source of white light, wherein the exposure to white light alters the neuronal activity in the patient's brain and mitigates the mood disorder
- Claim 3: A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:
providing a light source that emits white light;
filtering the ultra-violet (UV) rays from the white light; and
positioning the patient adjacent to the light source ...

Ex. 2 - Process Claim Involving a Natural Principle

- Prior art knowledge:
 - White light affecting a person's mood is a natural principle
 - Treating mood disorders to expose a person to white light in order to alter their neuronal activity and mitigate mood disorders



Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 1

- Claim 1: A method for treating a mood disorder in a human patient ... comprising exposing the patient in sunlight ...
- Q1? YES (*process*)
- Q2? YES (White light affecting a person's mood is a *natural principle*)



Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 1

- Q3 - Factors weighing towards eligibility:
 - (a) irrelevant
 - (b) not satisfied (step of exposing patient to sunlight cannot narrow the scope)
 - (c) satisfied (the step relate to the natural principle in a significant way)
 - (d) not satisfied (claimed step is no more than a general instruction to apply the natural principle)
 - (e) not satisfied (no machine or transformation recited)
 - (f) not satisfied (the step is well-understood, purely conventional or routine in the art)

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 1

- Q3 - Factors weighing against eligibility
 - (g) irrelevant
 - (h) satisfied (the step is at high level of generality)
 - (i) not satisfied (the step can be applied in other ways – e.g. exposing a patient to an artificial source of white light)
 - (j) satisfied (the step is well-understood, purely conventional or routine in the art)
 - (k) not satisfied (the step integrates natural principle into claim)
 - (l) satisfied (the step is a mere field of use with respect to the sunlight)
- Q3? NO - claim does not include step in addition to the judicial exceptions accounting for a practical application of the judicial exceptions
- So, Claim 1 **is not** an eligible subject matter

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 2

- Claim 2: A method for treating a mood disorder in a human patient ... comprising exposing the patient to synthetic source of white light ...
- Q1? YES (*process*)
- Q2? YES (white light affecting a person's mood is a *natural principle*)

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 2

- Q3 - Factors weighing towards eligibility:
 - (a) irrelevant
 - (b) satisfied (step of exposing patient to synthetic source of light narrow the scope)
 - (c) satisfied (the step relate to the natural principle in a significant way)
 - (d) not satisfied (claimed step is no more than a general instruction to apply the natural principle)
 - (e) not satisfied (no machine or transformation recited)
 - (f) not satisfied (the step is well-understood, purely conventional or routine in the art)

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 2

- Q3 - Factors weighing against eligibility
 - (g) irrelevant
 - (h) satisfied (the step is at high level of generality)
 - (i) not satisfied (the step can be applied in other ways – e.g. exposing a patient to sunlight)
 - (j) satisfied (the step is well-understood, purely conventional or routine in the art)
 - (k) not satisfied (the step integrates natural principle into claim)
 - (l) satisfied (the step is a mere field of use with respect to the sunlight)
- Q3? NO - claim does not include step in addition to the judicial exceptions accounting for a practical application of the judicial exceptions
- So, Claim 2 **is not** an eligible subject matter

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 3

- Claim 3: A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:
 - providing a light source that emits white light;
 - filtering the ultra-violet (UV) rays from the white light; and
 - positioning the patient adjacent to the light source ...
- Q1? YES (*process*)
- Q2? YES (white light affecting a person's mood is a *natural principle*)

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 3

- Q3 - Factors weighing towards eligibility:
 - (a) irrelevant
 - (b) satisfied (filtering and positioning steps narrow the scope)
 - (c) satisfied (the steps relate to the natural principle in significant way)
 - (d) satisfied (the steps are more than a general instruction to apply the natural principle)
 - (e) not satisfied (no machine or transformation recited)
 - (f) satisfied (step of positioning the patient is more than well-understood, purely conventional or routine in the art)

Ex. 2 - Process Claim Involving a Natural Principle – Analysis to Claim 3

- Q3 - Factors weighing against eligibility
 - (g) irrelevant
 - (h) **not satisfied** (the steps not at high level of generality but with specificity)
 - (i) **not satisfied** (the steps can be applied in other ways)
 - (j) **not satisfied** (step of positioning the patient is more than well-understood, purely conventional or routine in the art)
 - (k) **not satisfied** (the steps integrate natural principle into claim)
 - (l) **not satisfied** (the steps are more than a mere field of use with respect to the sunlight)
- Q3? YES - claim includes feature showing the recited method is markedly different from what exists in nature
- So, Claim 3 **is** an eligible subject matter

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