HOW TO PROTECT BIOMARKERS AND COMPUTER ALGORITHMS IN BOTH THE US AND CHINA

Change in patent law for computer implemented inventions and life science inventions

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August 8, 2016

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35 USC 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."

Case Law and USPTO Guidelines

1. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 182 L. Ed. 2d 321 (U.S. 2012)
2. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (U.S. 2014)

2014-06 - Preliminary Examination Instructions in view of *Alice*

2014-12 - Interim Guidelines

2015-01 - Abstract Ideas Examples

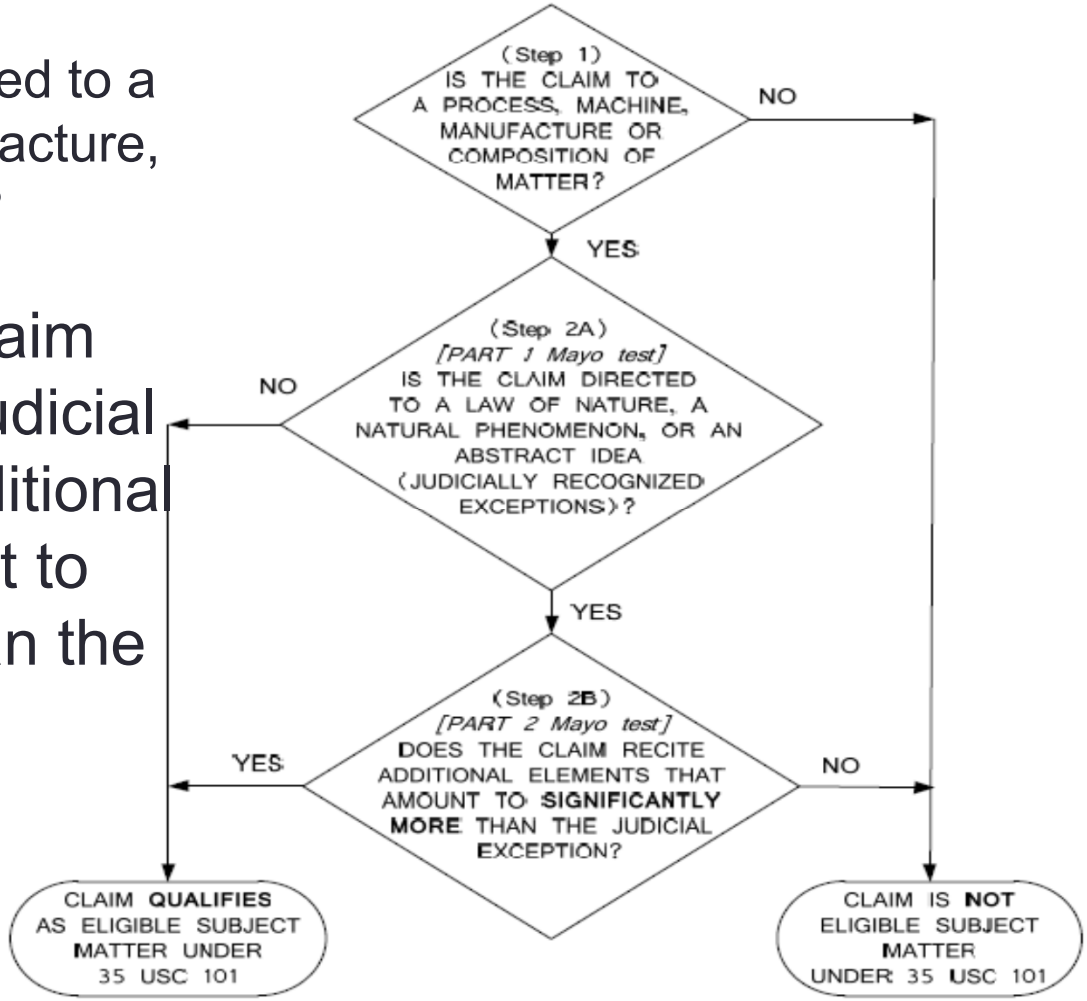
2015-07 – Subject Matter Eligibility Update

2016-05 – Subject Matter Eligibility Update

Post-*Alice vs. CLS Bank* – How to make software invention patent eligible?

Part 1: Is the claim directed to a process, machine, manufacture, or composition of matter?

Part 2: Whether a claim that is directed to a judicial exception recites additional elements that amount to significantly more than the exception.



Examples for Step 2A

1. Fundamental economic practices
2. Certain methods of organizing human activities
3. An idea ‘of itself’
4. Mathematical relationships/formulas

Examples for Step 2B

1. Improvements to another technology or technical field;
2. Improvements to the functioning of the computer itself;
3. Applying the judicial exception with, or by use of, a particular machine;
4. Effecting a transformation or reduction of a particular article to a different state or thing;
5. Adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application;
6. Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.

DDR Holdings, LLC v. Hotels.com et al

A system useful in an outsource provider serving web pages offering commercial opportunities, the system comprising:

(a) a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually perceptible elements correspond to the plurality of first web pages;

(i) wherein each of the first web pages belongs to one of a plurality of web page owners;

(ii) wherein each of the first web pages displays at least one active link associated with a commerce object associated with a buying opportunity of a selected one of a plurality of merchants; and

(iii) wherein the selected merchant, the outsource provider, and the owner of the first web page displaying the associated link are each third parties with respect to one other;

(b) a computer server at the outsource provider, which computer server is coupled to the computer store and programmed to:

(i) receive from the web browser of a computer user a signal indicating activation of one of the links displayed by one of the first web pages;

(ii) automatically identify as the source page the one of the first web pages on which the link has been activated;

(iii) in response to identification of the source page, automatically retrieve the stored data corresponding to the source page; and

(iv) using the data retrieved, automatically generate and transmit to the web browser a second web page that displays: (A) information associated with the commerce object associated with the link that has been activated, and (B) the plurality of visually perceptible elements visually corresponding to the source page.

DDR Holdings, LLC v. Hotels.com et al.

Claims	Step 2A
A system useful in an outsource provider serving web pages offering commercial opportunities, the system comprising: a)a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually perceptible elements correspond to the plurality of first web pages wherein[…]; b)a computer server at the outsource provider […] programmed to […] using the data retrieved, automatically generate and transmit to the web browser a second web page that displays: (A) information associated with the commerce object associated with the link that has been activated, and (B) the plurality of visually perceptible elements visually corresponding to the source page;	"The claim addresses a business challenge (retaining website visitors) that is particular to the Internet. […] it does not "merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet. Instead, the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks."

DDR Holdings, LLC v. Hotels.com et al.

Claims	Step 2B
A system useful in an outsource provider serving web pages offering commercial opportunities, the system comprising: a) a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually perceptible elements correspond to the plurality of first web pages wherein[…]; b)a computer server at the outsource provider […] programmed to […] using the data retrieved, automatically generate and transmit to the web browser a second web page that displays: (A) information associated with the commerce object associated with the link that has been activated, and (B) the plurality of visually perceptible elements visually corresponding to the source page;	The claims here specify how interactions with the Internet are manipulated to yield a result that is not routine or conventional, contrary to events ordinarily triggered by the click of a hyperlink.

Observations – 2A

Computer-rooted technologies/improvements are not abstract ideas:

- Isolating and Removing Malicious Code from Electronic Messages (internet-centric challenge/computer-related technology)
- E-Commerce Outsourcing System/Generating a Composite Web Page (internet-centric challenge)
- Constructing a “self-referential” database (computer-related technology)
- GUI for relocating obscured textual information (computer-related technology)

Claims directed to such improvements should be patent eligible under Step 2A.

Observations – 2B

Improvement to another technology or technical field

- Half-toning gray scale image, digital image processing (*RCT*)
- Calculating absolute position for GPS (*SiRF*)
- Controlling synthetic rubber curing process by computer (*Diehr*)

Improvements to the functioning of the computer itself

- Half-toning gray scale image, digital Image processing (*RCT*)
- GUI for relocating obscured textual information (*SiRF*)

Applying the judicial exception with, or by use of, a particular machine

- Robotic Arm Assembly
- Internal combustion engine with a computerized control system

Observations – 2B (Continued)

Effecting a transformation or reduction of a particular article to a different state or thing

- Half-toning gray scale image, digital image processing (*RCT*)
- Controlling synthetic rubber curing process by computer (*Diehr*)

Other meaningful limitations beyond generally linking the use of an abstract idea to a particular technological environment

- Half-toning gray scale image, digital image processing (*RCT*)
- Calculating absolute position for GPS (*SiRF*)
- Controlling synthetic rubber curing process by computer (*Diehr*)

Tips

1. Machine-or-transformation test is still useful tool. A machine (robotic arm/internal combustion engine) with computer components (e.g., a control system) - eligible under streamline analysis.
2. Emphasize the improvement is rooted in computer technology (Step 2A).
3. Emphasize improvement to another technology or field (Step 2B).
4. Limit the application of the method to particular technological environment and emphasize transformation of the result (Step 2B).
5. Recite at least one inventive clause that provides a technical solution to a technical problem and the result of combining prior art structures/steps is not normal, expected, or predictable (Step 2B, hopefully).

Software Patenting in China

根据专利法第二条第二款的规定，专利法所称的发明是指对产品、方法或者其改进所提出的新的技术方案。涉及计算机程序的发明专利申请只有构成技术方案才是专利保护的客体。

如果涉及计算机程序的发明专利申请的解决方案执行计算机程序的目的是解决技术问题，在计算机上运行计算机程序从而对外部或内部对象进行控制或处理所反映的是遵循自然规律的技术手段，并且由此获得符合自然规律的技术效果，则这种解决方案属于专利法第二条第二款所说的技术方案，属于专利保护的客体.

What is eligible and what is not - Continued

Ineligible Subject Matter

1. A method that use software to calculate π
2. A method that use software to calculate dynamic friction coefficient
3. A method that uses software to convert languages
4. A method to code Chinese language
5. A computer-aided system with various modules for self-studying foreign languages

Eligible Subject Matter

1. A computer-aided method to cure rubber
2. A method to expand the data storage of mobile devices through the use of virtual drives
3. A method to eliminate image noise from digital imaging
4. A computer-implemented method to detect liquid viscosity
5. A method to code Chinese language for computer input

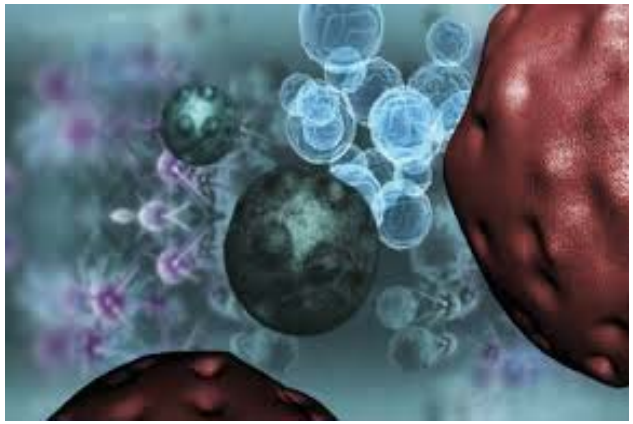
Takeaways

- A computer-implemented process claim directed to resolve a technical problem spell out specific steps performed by computer programs.
- A product claim shall spell out not only each specific component and the connections between them and describe how each function of the computer program is performed by a corresponding component.
- Business methods *per se*, or computer-aided business methods that fail to resolve a technical problem or produce a technical effect are not eligible for patent protection.

Biomarker

- **Definition:** A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacological responses to a therapeutic intervention.
- **Forms:** Specific cells, molecules, genes, gene products, enzymes, hormones, complex organ functions...
- **Applications**:

Disease risk prediction, cause, diagnosis, progression/regression



Overview - Biomarker Patent Protection

Claim Types:

1) **Product -** biomarkers itself, moieties or probes for detecting biomarkers, kits
2) **Process -** detection, diagnosis methods

Protect composition and the diagnostic/treatment method?

It highly depends!

Natural-based Claims - U.S.

- Supreme Court: [*Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 12-398 (2013)
  - Naturally occurring gene is not eligible under 35 USC 101.
  - The breast and ovarian cancer-associated genes BRCA1/2 is existing before they were found by Myriad.
  - It is a discovery, not patentable under 35 USC 101.

Natural-based Claims - U.S.

***University of Utah Research Foundation vs Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014)**

Natural-based Claims - U.S.

Case Development

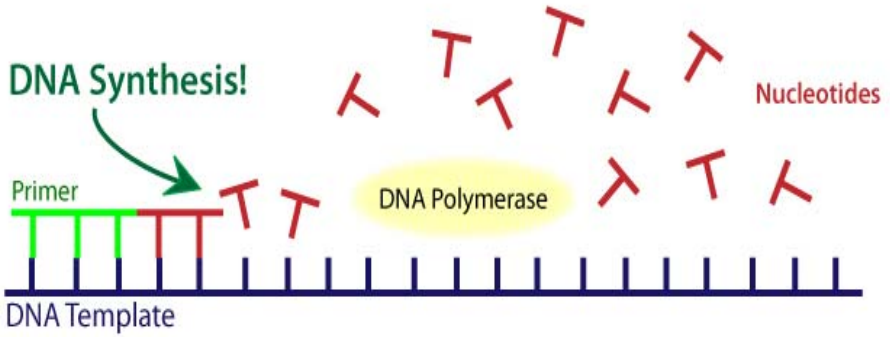
- Myriad owns U.S Patent No. 5,753,441 (“the ’441 patent”), U.S. Patent No. 5,747,282 (“the ’282 patent”), and U.S. Patent No. 5,837,492 (“the ’492 patent”), which cover compositions of matter and methods relating to the BRCA1 and BRCA2 genes.
- **July 2013**, Utah Univ alleged infringement and requested preliminary injunction.
- **March 2014**, district court denied preliminary injunction, finding ineligibility under 101
- **December 17, 2014,** CAFC affirmed the ineligibility of the subject matter

University of Utah Research Foundation vs Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)

Claim 16 of the ’282 patent

- A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.

↘ DNA primers derived from human chromosome



http://www.lookfordiagnosis.com/mesh_info.php?term=DNA+Primers&lang=1

Claim 7 of the ’441 patent

A method for screening 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,

wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.

→ Screening method that compares a patient’s BRCA1 sequence with the wild-type sequence for alteration.

Court's Ruling on Primer

"DNA primers derived from human chromosome"

1. Patentable because synthetically replicated? - Primers were structurally indistinguishable from the isolated DNA found to be patent ineligible in *Myriad*

2. Patentable because single-stranded DNA molecules are not found in nature? – Separating DNA from its surrounding genetic material "is not an act of invention.

3. Patentable for having "a fundamentally different function"? - primer's natural function is to bind to its complementary nucleotide sequence. It is the same function being exploited here.

"A DNA structure with a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature."

University of Utah Research Foundation vs Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)

Court's Ruling on Screening Method

"Screening method that compares sequences of BRCA1 genes for differences"

1) whether "the comparison of wild type genetic sequences with the subject's genetic sequence" corresponds to an abstract idea?

Here a step to compare two nucleotide sequences – with unchecked coverage:

> "[t]he covered comparisons are not restricted by the purpose of the comparison or the alteration being detected."

University of Utah Research Foundation vs Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)

Court's Ruling on Screening Method

"Screening method that compares sequences of BRCA1 genes for differences"

2) whether the claim elements in addition to the comparison step, either in isolation or combination with the comparison step, contained a "inventive concept"?

Here the additional features, such as the techniques used in comparing the genome sequences are routine and conventional.

University of Utah Research Foundation vs Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)

University of Utah Research Foundation vs Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)

Takeaway:

- 1) for biomarker-based product claims – highlight the difference;
- 2) process claims may be patent eligible if they are directed to diagnosing specific diseases.

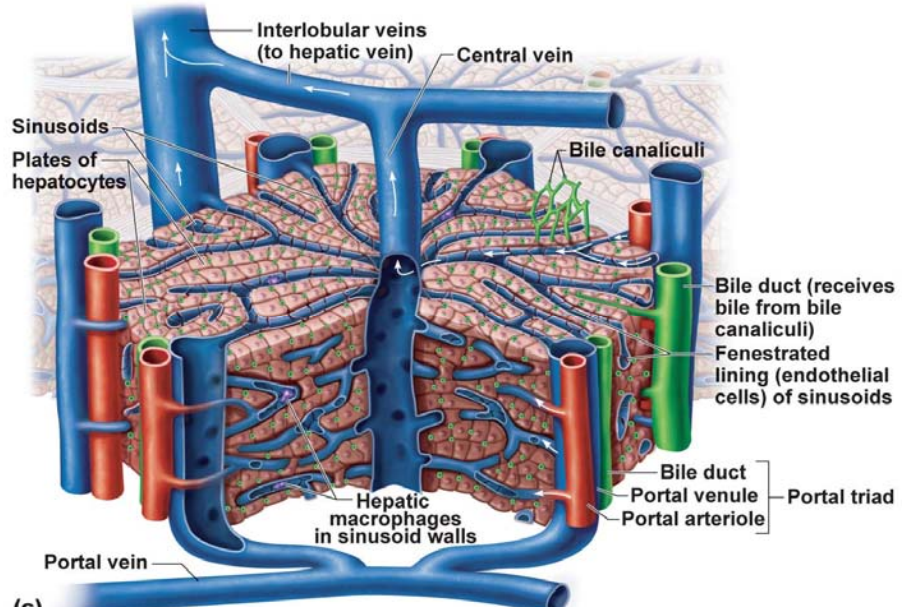
University of Utah Research Foundation vs Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014)

Any patent claims survived?

http://www.patents4life.com/2015/06/ariosa-v-sequenom-novel-genetic-analysis-fails-the-mayo-test/

Natural-based Claims - U.S.

***Rapid Litigation Management v. CellzDirect*, No. 15-1570 (Fed. Cir. July 5, 2016)**



https://herbsforhealthandwellbeing.wordpress.com/tag/physiology-of-the-liver/

Rapid Litig. Mgmt. v. CellzDirect, Inc., 2016 U.S. App. LEXIS 12352 (Fed. Cir. 2016)

- July 5, 2016, CAFC held that claimed methods of U.S. Patent No. 7,604,929 (the '929 patent) directed to cryopreserving hepatocyte cells are **patent eligible.**
- Previously, “cryopreservation” techniques to preserve hepatocytes for later use, which could damage the hepatocytes, leading to poor recovery numbers of viable cells.
- Hepatocytes could be frozen only once and then had to be either used or discarded.

Rapid Litigation Management v. CellzDirect, No. 15-1570 (Fed. Cir. July 5, 2016)

Claim 1 of "'929 patent"

1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:

(A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non- viable hepatocytes,

(B) recovering the separated viable hepatocytes, and

(C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

Step 2A - whether the claims at issue were directed to a patent ineligible concept

Method of preserving hepatocytes, comprising

1) separating viable and non-viable hepatocytes from the first freeze-thaw cycle,
2) recovering the viable hepatocytes, and
3) cryopreserving the recovered viable hepatocytes

Different from

- *Ambry Genetics* (screening genome sequence in BRCA1 gene for mutation)
- Here, the end result is not simply an observation or detection of the hepatocytes' ability to survive multiple freeze-thaw cycles.

Rapid Litigation Management v. CellzDirect, No. 15-1570 (Fed. Cir. July 5, 2016)

Step 2B - whether additional elements embodied an inventive step

Method of preserving hepatocytes, comprising

1) separating viable and non-viable hepatocytes from the first freeze-thaw cycle,
2) recovering the viable hepatocytes, and
3) cryopreserving the recovered viable hepatocytes

Different from

- *Mayo* (administering the drug, measuring metabolite levels, and adjusting dosage were routine)
- Here, running multiple cycles was far from routine and conventional, prior art taught away from multiple freezings.

Rapid Litigation Management v. CellzDirect, No. 15-1570 (Fed. Cir. July 5, 2016)

Rapid Litig. Mgmt. v. CellzDirect, Inc., 2016 U.S. App. LEXIS 12352 (Fed. Cir. July 5, 2016)

Takeaway:

- For method claims, unconventional step and/or result may establish inventive concept in the eligibility analysis. Simply measuring, detecting and comparing data may be insufficient.

Rapid Litigation Management v. CellzDirect, No. 15-1570 (Fed. Cir. July 5, 2016)

Composition of Matter Claims in China

Article 10.9 Examination of Biotech Invention

Article 10.9 生物技术领域发明专利申请的审查

If the gene or DNA segment is for the first time isolated or extracted from nature, wherein the sequence has not been disclosed and can be clearly characterized, wherein the gene or DNA segment is useful in specific field, the gene or the DNA segment, as well as the method to get them are eligible subject matter.

如果是首次从自然界分离或提取出来的基因或ＤＮＡ片段，其碱基序列是现有技术中不曾记载的，并能被确切地表征，且在产业上有利用价值，则该基因或ＤＮＡ片段本身及其得到方法均属于可给予专利保护的客体。

2010 Chinese Patent Examination Guide

Diagnostic Method in China

Section 2 Article 1 Unpatentable Application (不授予专利权的申请）

Diagnostic and treatment method cannot be granted as patent. The device or apparatus used for disease diagnostic or treatment, and the matter or materials used in the device/apparatus, can be patentable.

疾病的诊断和治疗方法不能被授予专利权。但是，用于实施疾病诊断和治疗方法的仪器或装置，以及在疾病诊断和治疗方法中使用的物质或材料属于可被授予专利权的客体。

2010 Chinese Patent Examination Guide

Eligibility Overview - U.S. *vs* China

Subject matter	U.S.	China
Abstract idea / Mental Activities	No	No
Laws of nature / Scientific discoveries	No	No
Natural phenomena	No	No
Natural products	No	No
Isolated natural products e.g. gene, protein, chemical	No	Yes
Human embryonic stem cells	Yes	No
Diagnostic methods	No – General diagnostic method	No
Treatment methods	Yes	No Yes – Medical use of compositions

Natural-based Claims (Extended)

Subject matter	U.S.	China	Europe	Japan
Abstract idea Mental Activities	No	No	No	No
Laws of nature Scientific discoveries	No	No	No	No
Natural phenomena	No	No	No	No
Natural products	No	No	No	No
Isolated natural products e.g. gene, protein, chemical	No	Yes	Yes	Yes
Human embryonic stem cells	Yes	No	No – if involve destruction of human embryo	Yes
Animal varieties	Yes – Transgenic non-human animals	No	No	Yes – Non-human
Plant varieties	Plant patent – Asexually reproduced Utility patent – Sexually reproduced	No	No	Yes – Invention Patent
Microorganisms	Yes	Yes	Yes	Yes
Diagnostic methods	No – General diagnostic method	No	No Yes – Outside human body	No Yes – in vitro
Treatment methods	Yes	No Yes – Medical use of compositions	No Yes – Medical use of compositions	No Yes – Medical use of compositions

Conclusion

US

- Only protects structure “markedly different” man-synthesized natural products regardless known or not
- Diagnostic/treatment method claims should recite “significant more” to qualify as eligible subject matter.

CN

- Protect firstly discovered and clearly characterized natural products with particular useful application.
- No diagnostic/treatment method patent protection in China; alternatively, it can turn to protect the device or apparatus.

How to protect biomarkers and computer algorithms in both the US and China

Questions?

THANK YOU!

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