Is My Project Patentable?
(and what does that really mean?)

By Jay DeYoung and Peter Fasse

Presented to Boston Children's Hospital

June 23, 2015

FISH.

FISH & RICHARDSON

Agenda

- What is a Patent?
- Patent Process
- US Patent Prosecution
- Patent-Eligible Subject Matter
- Nature-Based Product Examples
- Diagnostic Methods and Patenting Biological Inventions
- Inventorship and Ownership

What is a Patent?

A document that provides to the patent owner the right **to prevent others** from making, using, offering to sell, selling or importing the invention(s) claimed in the patent.

A “ticket to court”

What is a Patent? (cont.)

- Negative (or exclusive) right — gives its owner the right to prevent others from using his invention. However, ***it does not give its owner the right to make, use, sell, or offer to sell his invention. It only gives the owner the right to exclude others.***
  - Compare real property claim
- Territorial — must obtain patent in every country where protection is desired
- Personal property — can be bought, sold, licensed, bequeathed, etc.

Benefits of a Patent Portfolio

Generation of revenue by way of licensing/royalty payments

Increase visibility of, and attract funding for, research and development

Exclude competitors from best products or most efficient processes

Increase competitors' risks and levels of uncertainty

Types of US Patent Applications

- Provisional
- Utility
- Patent Cooperation Treaty (PCT) application
- Design
- Plant

Provisional Application

- Never examined, never will issue as a patent
- Automatically expires in 12 months
- Think “place holder” for priority date
- Provides 12 months to further refine the invention BUT(!!) added matter only gets new date, so SHOULD BE AS COMPLETE AS POSSIBLE
- Must be “re-filed” as a utility or PCT application within 12 months of filing date to maintain priority date

US Utility Application

- This is the document that is examined by the U.S. Patent & Trademark Office (USPTO)
- This is the text that may ultimately be granted as a patent (after possible amendments to claims)
- After filing, no changes can be made to the specification without risking a “new matter” rejection

PCT Application

- International clearing house (World Intellectual Property Office, “WIPO”); does not issue patents
- “Place holder” for priority date – US and most of world
- “As if” you filed an application in each of the countries that are members of the PCT
- Preliminary search for prior art and review of claims; results then communicated to various national patent offices
- Applicant can ***later*** choose whether to proceed with actual filings in countries of interest

Typical Life Science Patent Process

- File a Provisional Application in the US
- 12 months later:
  - file a PCT Application, then file US national stage application within 18 months from provisional filing date

  -AND/OR-
  - Directly file a US Utility Application
- Prosecution begins within 1-3 years

Prosecution in the US

- Typically, a multi-year process
- One or more office actions in which all claims are rejected on multiple bases
  - -prior art (novelty, obviousness)
  - -written description
  - -enablement
  - -patentable subject matter
  - -clarity/indefiniteness
- Each action gives the opportunity to amend the claims/argue the rejection

Patent-Eligible Subject Matter

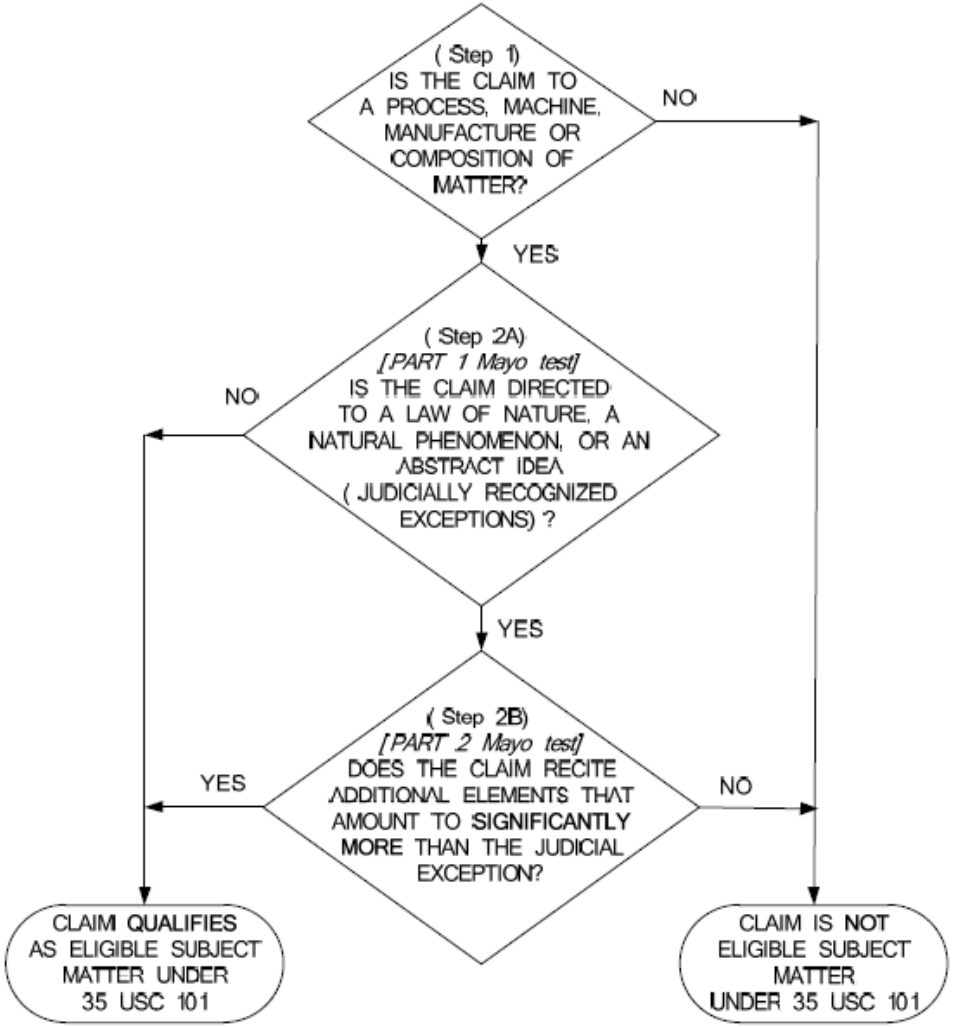
In the wake of decisions by the Supreme Court over the past 3 years, what is considered patent-eligible subject matter has drastically changed

- Case Law:
  - *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. __, 134 S.Ct. 2347, 110 USPQ2d 1976 (2014)
  - *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S.Ct. 2107, 106 USPQ2d 1972 (2013)
  - *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. __, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012)

Interim Eligibility Guidance

In December 2014, the USPTO issued Interim Eligibility Guidance for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101 in view of recent decisions by the Supreme Court

Patent-Eligible Subject Matter



Patent-Eligible Subject Matter

What are the “Judicial Exceptions”?

Abstract Ideas

- Mathematical Formulae

Natural Products

Laws of Nature/Natural Phenomena

- Correlations that are a consequence of biology (diagnostics/prognostics)
- Chemical principal underlying union between fatty elements and water

Patent-Eligible Subject Matter

- Natural Products – Markedly Different?
- Naturally occurring products and some man-made products that are essentially no different from a naturally occurring product are "products of nature"
- To determine if a nature-based product is a "product of nature" (and thus a JE), markedly different characteristics analysis is required
  - **Structure, Function and/or Other Properties**
- "Care should be taken not to overly extend the markedly different characteristics analysis to products that when viewed as a whole are not nature-based"
- A process claim is not subject to the markedly different analysis for nature-based products used in the process

Nature-Based Product Examples

Amazonic Acid

1. Purified amazonic acid
   - **Ineligible**, no evidence is markedly different
2. Purified 5-methyl amazonic acid
   - **Eligible**, different chemical structure
3. Deoxyamazonic acid
   - **Eligible**, diff. chemical structure, even though no evidence of different activity – it doesn't pre-empt the natural product
4. A composition comprising an acid produced by a process which comprises: providing amazonic acid; and replacing the hydroxyl group of the amazonic acid with a hydrogen
   - **Eligible**, product differs from what is in nature

Nature-Based Product Examples

Amazonic Acid

5. A pharmaceutical composition comprising: a core comprising amazonic acid; and a layer of natural polymeric material enveloping the core
   - **Eligible** – structurally different from naturally occurring substances, and
   - this structural difference results in the claimed composition having different functional characteristics *in vivo*
   - So it's markedly different
6. A stable aqueous composition comprising: amazonic acid; and a solubilizing agent
   - **Eligible** - In nature, amazonic acid is insoluble in water. As explained in the specification, however, when amazonic acid is combined with a solubilizing agent, it becomes soluble in water and forms a stable solution. This changed property (solubility) between amazonic acid as a part of the claimed stable aqueous composition and amazonic acid in nature is a marked difference

Nature-Based Product Examples

Amazonic Acid

7. 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
   - **Eligible!!** the claim is focused on a process of practically applying the product to treat a particular disease (colon cancer), and not on the product *per se*
8. A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer
   - **Eligible!!** the claim is focused on a process of practically applying the product to treat a particular disease (breast or colon cancer), and not on the product *per se*

Nature-Based Product Examples

Nucleic Acids

1. Isolated nucleic acid comprising SEQ ID NO: 1
   - **Ineligible** – no marked differences
2. Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1
   - **Eligible** – structural differences are marked, even if no functional difference
3. The isolated nucleic acid of claim 1, further comprising a fluorescent label attached to the nucleic acid
   - **Eligible** – structural and functional differences
4. A vector comprising the nucleic acid of claim 1 and a heterologous nucleic acid sequence
   - **Eligible** – non-natural combination, so a different structure, and may have a different function

Nature-Based Product Examples

Purified Proteins

1. Antibiotic L
   - **Ineligible** - Natural product, no differences in characteristics
2. Purified Antibiotic L
   - **Eligible** – definition in spec provides different form, doesn't encompass naturally occurring, "may" result in different functional properties
3. The Antibiotic L of claim 1, which is in a tetrahedral crystal form
   - **Eligible** – different form from naturally occurring substance

Nature-Based Product Examples

Purified Proteins

4. The Antibiotic L of claim 1, which is expressed by recombinant yeast
   - **Eligible** - different glycosylation from naturally occurring substance, and different properties (reduced immunogenicity and different half-life)
5. A purified antibiotic comprising an amino acid sequence that has at least 90% identity to SEQ ID NO: 2 and contains at least one substitution modification relative to SEQ ID NO: 2
   - **Eligible** – even though for some conservative modifications there may be no observable functional difference, because not tying up the natural product

Nature-Based Product Examples

Antibodies

1. An antibody to Protein S
   - **Ineligible** – spec shows that some are naturally occurring in mice and wild coyotes
2. The antibody of claim 1, wherein the antibody is a human antibody
   - **Eligible** – no naturally occurring human Abs
3. The antibody of claim 1, wherein the antibody is a murine antibody comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12
   - **Eligible** - unless the examiner can show that this particular murine antibody exists in nature, the mere possibility that it might exist does not bar the eligibility of this claim

Nature-Based Product Examples

Antibodies

4. The antibody of claim 1, wherein the antibody is a chimeric or humanized antibody
   - **Eligible** – structurally different from natural, may have different functional characteristics as well
5. The antibody of claim 1, wherein the antibody comprises a variant Fc domain
   - **Eligible** - structurally different from natural, may have different functional characteristics as well

Nature-Based Product Examples

Cells

1. An isolated man-made human pacemaker cell
   - **Ineligible** – no markedly different characteristics from natural cells
2. An isolated man-made human pacemaker cell expressing marker Z
   - **Eligible** - No human pacemaker cells expressing marker Z are naturally occurring, and
   - phenotypically different than natural pacemaker cells, in that they express marker Z and have increased oxygen utilization efficiency
3. A population of human pacemaker cells, wherein the population is about 10-15% positive for marker Z, and 85-90% positive for marker P
   - **Eligible** – Spec describes an altered growth rate for naturally occurring cells in this mixture

Nature-Based Product Examples

Cells

4. A composition comprising a population of isolated man-made human pacemaker cells in a container
   - **Ineligible** - no indication in the specification that placing the cells in a generic container results in the cells having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring cells, so it's a JE
   - Not "substantially more" than the JE: use of a container to hold cells is not only well-understood, routine and conventional activity already engaged in by the scientific community, it is also required for growing and using the cells
   - Container recited at a high level of generality: "tells a scientist to use whatever container she wishes to use"

Nature-Based Product Examples

Cells

5. A composition comprising a population of isolated man-made human pacemaker cells in a biocompatible three-dimensional scaffold.

- **Eligible** – even though this is a JE –
  - no indication in the specification that placing the cells into a biocompatible three-dimensional scaffold results in the cells or the scaffold having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring cells, so still a JE
  - Substantially more: the biocompatible three-dimensional scaffold in combination with the pacemaker cells is **not required** for growing or using the cells, because the cells can be grown or used in other containers, and is not recited at a high level of generality
  - Adding these cells to the scaffold confines the claim to **a particular useful application** of the scaffold (repair of cardiac tissue), because the pacemaker cells are not routinely required for all practical uses of the scaffold
  - the combination of these elements does more than generally link these two judicial exceptions together; as described in the specification, this combination improves the technology of regenerative medicine

Nature-Based Product Hypotheticals

- CRISPR
  - tracrRNA vs single guide RNA?
  - Specific sequences?
- Gene Therapy
  - Vectors? Methods?
- Natural Products
  - Specific natural products?
  - SAR-modified analog of the specific natural products?
- Methods of using Natural Products

What About Diagnostic Methods?

USPTO's Interim Guidance did not provide any examples

Two recent court cases from the Federal Circuit:

- Myriad II, December 17, 2014
- Sequenom v Ariosa, June 12, 2015

“Myriad II”

- Claim 7 of 5,753,441 to a “method for screening … for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA … 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.”
- **REJECTED**
- Analyzed under *Alice*, not *Mayo*, as an ABSTRACT IDEA
- Held the second part of the claim was conventional and routine, did not add enough to make the claim patentable
- Despite S.Ct. language in *Mayo* that claims to methods were not implicated by that decision…

"*Sequenom v Ariosa*"

- Claim 1 of 6,258,540 recites a "methods for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."
- **REJECTED**
- 2-step analysis under *Mayo*
  - Step 1: directed to a natural phenomenon: the existence of paternally-inherited cell-free fetal DNA (cffDNA) in the maternal bloodstream.
  - Step 2: "*For process claims that encompass natural phenomenon [sic], the process steps are the additional features that must be new and useful.*"
  - Methods of amplifying DNA were well-known at the time of the invention, so the claims disclosed only well-understood, routine, conventional activity beyond the underlying natural phenomenon

Patenting Biological Inventions

- Federal Circuit's interpretation seems to go beyond the Supreme Court; the USPTO has not issued any new examples yet
- Include concrete steps of what to do once you have the result (easiest for companion diagnostics)
- Novel probes (sequence not found in nature)/antibodies still OK (though narrow claims likely)
- Get what you can now and file a continuation. The law may (hopefully will) change for the better in the next few years…
- Still patent-eligible outside the US!

Inventorship and Ownership of Patents

- Default rule: **Inventor** is owner of the patent
- Transfer of ownership: **assignment**
- Circumstances where employer may own patent:
  - Employment agreement may prospectively assign inventions to employer
  - Local law may make employer owner of invention made by employee during the course of employment
- Collaboration/consulting agreements should address ownership of resulting patents

Inventorship

- Determining inventorship correctly is important in the US
-
- Can impact enforceability, validity, ownership, and standing (ability to sue)
- A *legal* determination based on the claims (often decision made by patent lawyer, not investigators or applicant/hospital)
- Should not be over-inclusive or under-inclusive in listing inventors

Inventorship Basics

- An inventor is someone who **conceives** of the subject matter claimed in the patent
  - Depends on what is **claimed** in the issued patent
  - Inventorship may change between filing and issuance if application is amended
- Criteria are **not** the same as criteria for authorship
- Joint inventors
  - Amount of inventive contribution irrelevant
  - Only need to contribute in more than insubstantial manner to **conception of at least one claim** to be an inventor
- Liabilities of inventorship - legal duties

Who Qualifies as a Joint Inventor?

- Did the person make a contribution to at least one **claim**?
- Was the person in a **collaboration** working on the subject matter of the claims?
- Did the person make some contribution to the **conception** of the claimed subject matter?
- Was the person's contribution sufficiently **significant**, amounting to more than what is already well known in the state of the art and amounting to more than a general restatement of the problem or goal at hand?

Thank You

Jay DeYoung
617-594-3826
deyoung@fr.com

Peter Fasse
617-521-7802
fasse@fr.com