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Patenting Biotechnology and Bioinformatics

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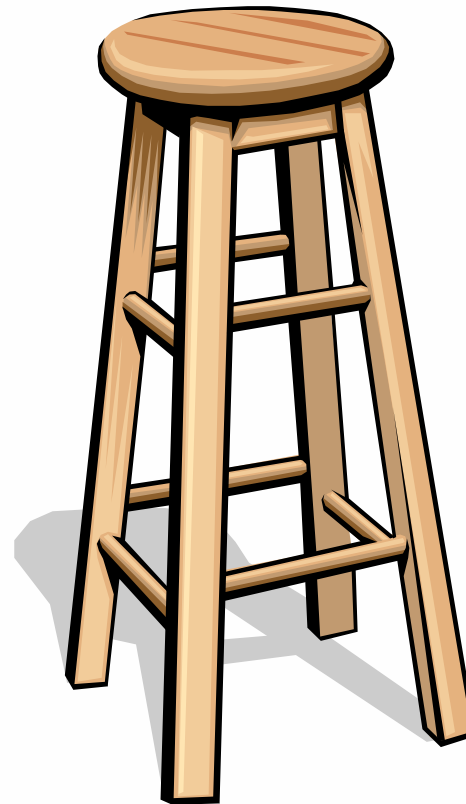
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Alternative IP Assets

Patents

Copyrights



Trademarks

Trade secrets

What is a patent?

Dictionary Definition: A writing securing to an inventor for a term of years the exclusive right to make, use or sell his invention.

- A patent does not give the patent holder the affirmative right to do anything. Rather, the patent confers a “negative” right - only allowing the patent holder to PREVENT OTHERS from making using or selling. 35 USC Section 154 .

35 USC Section 154: The right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.

What is a patent?

- **A patent is “intangible property” which may be assigned, licensed, and given as security.**
- **Persons or entities violating the patentee’s exclusive right can be prevented from practicing the patented invention and/or forced to pay damages to the patent owner.**
- **The scope of the property is defined by the claims of the patent.**

INTRODUCTION TO PATENTS

- **What is a patent?**
- **What is patentable?**
 - what can be protected?**
- **compositions, products of manufacture**
- **methods / processes of making and using**

What is patentable?

- **Whoever invents or discovers any new and useful process, machine, product of manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent ... (section 101)**

=> “the hand of man”

The Supreme Court acknowledged that Congress, through legislative history, intended statutory subject matter to *“include anything under the sun that is made by man.”* See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

What is patentable?

**Isolated or recombinant nucleic acids,
polypeptides - their sequences**

Cells, cell lines, transgenic animals

Chemical compounds, small molecules

Methods of making, Methods of treating

Databases and libraries

- as data stored in a computer:

algorithms – for example, for:

- **predicting function or structure**
- **comparing structures**

What is patentable?

- **Medicine**
Computer aided disease diagnosis, prognosis and patient monitoring
- **Pharmacogenomics**
 - matching drugs, genes and patients, diseases
 - genetic screening data
- **Business Methods Patents**
Information/ database Management
Interactions between databases

What is patentable?

Despite the wide scope of Section 101, the Supreme Court has specifically identified three categories of nonstatutory subject matter: (not patentable)

- laws of nature
- natural phenomena, and
- abstract ideas.

These are not categories of invention. See *Diamond v. Diehr*, 450 U.S. at 175, 209 USPQ 1 (1981).

INTRODUCTION TO PATENTS

- **What is a patent?**
- **What is patentable?**
- **What is the purpose of the patent system?**

Purpose of the patent system?

- **To reward inventors and thereby encourage innovation.**
- **To make it financially feasible to invest money in research and development.**
- **To provide a technology “database” available to all.**

or,

government-issued “monopoly” in exchange for full public disclosure of your invention

REQUIREMENTS FOR PATENTABILITY

- **What must a patent application include?**
 - Written description (specification) must describe
 - the full scope of the claimed (protectable) invention
 - how to make and use the claimed invention

Contents of a patent application

- The specification shall contain a written description of the invention, and of the manner and process of **making and using it**, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, **to make and use** the same, **and shall set forth the best mode contemplated by the inventor of carrying out his invention.** (35 U.S.C. §112)

REQUIREMENTS FOR PATENTABILITY: Written Description

- **What must a patent application include?**
 - Written description : inventor had possession of the invention
 - Description must be enabling : how to make and use the invention
 - Description must teach a “best mode”

REQUIREMENTS FOR PATENTABILITY - Enablement

- **Description must be “enabling” to the skilled artisan (one skilled in the art)**
(how to make and use)
 - Prevent need for undue experimentation to make and use:
need for more testing ?
 - e.g.: vaccines, gene therapy, antisense.
 - Effect of not teaching how to make and use full scope invention: narrow claims

REQUIREMENTS FOR PATENTABILITY – Best Mode

- **Description must teach “best mode”**
 - Best mode known to inventor
(subjective)
 - At time the application was filed
 - Effect of failure to disclose best mode:
patent invalid

REQUIREMENTS FOR PATENTABILITY - Drawings

- **What must a patent application include?**
 - Written description
 - Description must be enabling
 - Description must teach “best mode”
 - Drawings
 - the applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented.

Software patents: flow diagrams

Software Flow Diagrams

- **Software inventions can be supported by a flow diagram functionally representing the operation of the software**
 - **definitions used for significant data, and inputs and outputs for the system.**
 - **software applications should include representative examples for the operation of the software in addition to the functional (flow diagram) description.**

Software Flow Diagrams

- **Focus on the most relevant parts of the software program;**
- **Describe (define) relevant parts in terms of their function(s);**
- **How much detail needed:**
 - **Is it possible to write a program that performs the function(s) ?**
 - ... by a skilled artisan, using standard modules for, e.g., networking, parsing and database management.

REQUIREMENTS FOR PATENTABILITY - Claims

- **What must a patent application include?**
 - Written description
 - Description must be enabling
 - Description must teach “best mode”
 - Drawings
- **Claims – defining property borders**
- **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. (35 U.S.C. §112)**

The claims = protectable invention

- **Claims define what patentee can prevent others from making, using, selling, importing.**
- **Claimed invention must be “new,” i.e., novel (no anticipation) and non-obvious (must have inventive step).**
- **Claims must be clear enough to determine whether a process or product is the same (i.e., infringes).**

NOVELTY - § 102

- **§ 102 Conditions for patentability; novelty and loss of right to patent**
- **A person shall be entitled to a patent unless-**
 - (a) the invention was known or used by others in this country, patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

§ 102 REQUIREMENTS FOR PATENTABILITY - NOVELTY

- (b) the invention was known or used by others in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) the person has abandoned the invention, or

§ 102 REQUIREMENTS FOR PATENTABILITY - NOVELTY

- (d) the invention was first patented [...] in a foreign country prior to the date of the application for patent in this country on an application [...] filed more than twelve months before the filing of the application in the United States, or

§ 102 REQUIREMENTS FOR PATENTABILITY - NOVELTY

- (e) the [other person's] invention [the same or similar to yours] was described in a patent [...] filed in the United States before [you conceived your invention],....,

=> “secret prior art”

or

§ 102 REQUIREMENTS FOR PATENTABILITY - NOVELTY

- (f) the person did not himself invent the subject matter sought to be patented, or
 - (g) before applicant's invention the [same] invention was made in this country by another who had not abandoned, suppressed, or concealed it.
 - who was first to conceive?
 - last to reduce to practice ?
- => two applications for same invention
- United States PTO: "interference"

§ 103 REQUIREMENTS FOR PATENTABILITY - Obviousness

- **§ 103 Conditions for patentability; non-obvious subject matter**
- A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102
... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

REQUIREMENTS FOR PATENTABILITY – Novelty and Obviousness.

- **What constitutes prior art?**
 - Publications (journals, abstracts, on-line)
 - Commercial products (in the U.S.)
sales, offers for sale
 - Prior independent invention by another
 - Patents, published patent applications (“secret prior art”)

REQUIREMENTS FOR PATENTABILITY - Utility

- **Utility – to be useful**

“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.”

What is required for a claimed invention to be “useful”?

What is useful?

When an abstract idea is reduced to a practical application, the abstract idea no longer stands alone if ... the practical application of the abstract idea produces a useful, concrete and tangible result.

- *In re Alappat.*, 31 USPQ 2d 1545, 1558 (Fed. Cir. 1994).
- statute is 35 USC §101.

What is useful? example

A machine (computer) programmed to transform data which represents discrete dollar amounts into a final share price through mathematical calculations.

- This is a practical application of a mathematical algorithm, formula, or calculation, because:

the programmed computer produces “a useful, concrete and tangible result”

i.e., the final share price upon which investors and their brokers can make investment decisions.

What is useful?

A process, machine, manufacture, or composition of matter employing a law of nature, natural phenomenon, or abstract idea may be patentable subject matter even though a law of nature, natural phenomenon, or abstract idea would not, by itself, be entitled to such protection.

State Street Bank & Trust Co. v. Signature Financial Group Inc., 149

F. 3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998)

Steps carried Out in the Human Mind OK

A method or process patentable even if some or all of the steps can be carried out:

- ❖ in the human mind
- ❖ with the aid of the human mind, or
- ❖ because it may be necessary for one performing the method or process to think.

In re Musgrave, 167 USPQ 280, 289 (CCPA 1970)

The Test for Patent Eligibility

An abstract idea by itself never satisfies statutory requirements.

However...

...an abstract idea when practically applied to produce a useful, concrete and tangible result, is patentable.

Utility requirements

- the utility need not be expressly recited in the claims, it may be inferred;
 - if the utility is not asserted in the written description, then it must be well established;
 - a specific, substantial and credible utility must be accomplished.
- => only need to disclose one “real” utility

What is Concrete?

- **Does the invention produce a “concrete” result ?**
- **Usually, this question arises when a result cannot be assured, a lack of enablement, because the invention cannot operate as intended without undue experimentation.**

What is Tangible?

Is there is simply a mathematical construct claimed, such as a disembodied data structure and/or method of making it ?

If so, the claim involves no more than a manipulation of an abstract idea and therefore, is not patentable.

What is Tangible?

In contrast,

a claimed computer-readable medium, encoded with a data structure, defines structural and functional interrelationships between the data structure and the computer software and hardware components which permits the data structure's functionality to be realized,

this is patentable.

Example of Useful, Concrete and Tangible

A method for convening a group of people in a room to generate ideas for reducing the number of patent applications physically located in a particular area.

After the ideas are generated, the best ideas are determined by multivoting within the group.

Then, multivoting is again used to sequence the best ideas into a series of steps forming a scheme to reduce the number of applications located in a particular area.

Finally, the steps of the scheme are implemented.

Example of Useful, Concrete and Tangible

Claim 1. A method comprising the steps of:

- (a) convening people in a room; and**
- (b) brainstorming to generate a series of steps forming a scheme for reducing the number of patent applications in a particular area.**

Example of Useful, Concrete and Tangible

Analysis of claim 1:

The claim merely manipulates an abstract idea without producing a “useful, concrete and tangible result.”

Claim 1 would be rejected as being directed to nonstatutory (unpatentable) subject matter.

***In re Wamerdam*, claims drawn to a method of making a disembodied data structure not patentable.**

Example of Useful, Concrete and Tangible

Claim 2. A method comprising steps of:

(a) convening people in a room;

(b) brainstorming to generate a series of steps forming a scheme for reducing the number of patent applications in a particular area; and,

(c) prioritizing ideas in formulating the scheme.

Example of Useful, Concrete and Tangible

Analysis of claim 2:

Claim 2 does not produce a useful, concrete and tangible result. The claim is nonstatutory.

Example of Useful, Concrete and Tangible

- Claim 3. A method comprising steps of:**
- (a) convening people in a room;**
 - (b) brainstorming to generate a series of steps forming a scheme for reducing the number of patent applications in a particular area;**
 - (c) prioritizing ideas in formulating the scheme; and,**
 - (d) implementing the steps of the scheme.**

Example of Useful, Concrete and Tangible

Analysis Claim 3:

By implementing the steps of the scheme, the method produces a concrete, tangible and useful result.

If the result is speculative and it would require undue experimentation to produce the concrete result, claim 3 would be rejected both for lack of utility and for lack of enablement.

Patentable: Computer readable mediums

- **A claim to a computer readable medium encoded with functional descriptive material that can function with a computer to effect a practical application that results in a useful, concrete and tangible result.**
Running screening assay, comparing symptoms to a medical database, associating a SNP to a disease.

Software Patents and the European Patent Convention

- **To be patentable, an invention must be technical in some way.**
- **The technical effect must go beyond the "normal" physical interactions between program and computer.**
- **A computer program that, when run on a computer, causes the computer to:**
 - **activate a peripheral device,**
 - **display items on screen, or**
 - **store a particular pattern in a memory⁷**

Software Patents in the EPO

- **Examples acceptable technical effects:**
 - a reduced memory access time,
 - a better control of a robotic arm,
 - an improved reception or decoding of a radio signal,
 - reduced hard disk access time,
 - an enhanced user interface.

What is Non-Functional Descriptive Material

- Music
- Literature
- Art
- Photographs
- Data base *per se*

These are merely stored to be read or outputted by a computer without any functional interrelationship, and thus do not impart functionality to the computer, i.e., they are not computer components.⁴⁹

Non-Functional Descriptive Material

- A data structure encoded on a computer readable medium comprising:**
- a first field having data of the medical condition of a patient;**
 - a second field having data describing the genotype of the patient; and**
 - a third field having a numeric value correlating likelihood an individual with a particular genotype would have a particular disease.**

This is simply a data file – no functional change occurs when an application program uses the structural data.

Computer Program Products

US Patent No. 6,223,186, issued 4/24/01:

A computer program product for a computer system that stores a [your] biomolecular database

comprising a computer readable storage medium and a computer program mechanism embedded therein, ...

a [your] biomolecular database stored on memory media associated with the computer system ...

a data retrieval module that includes instructions for:

receiving a request for data associated with a particular attribute of the particular entry of a particular entity and returning the retrieved data to the requester,

determining a particular [value] associated with the particular entry of the particular entity, and

retrieving data using the particular [value].

Computer Program Products

US Patent No. 6,223,186, issued 4/24/01:

A method of accessing biomolecular data stored in a database, comprising generating a set of entities, each entity storing attributes for a plurality of entries, storing the generated set of entities in a memory; and retrieving data associated with the at least one attribute of a particular entry of one of the entities in the set of entities using an associated entity offset.

Choosing a therapy

A method of choosing a therapy for a patient:

providing [your] database of reference expression profiles each associated with a therapy;

providing a nucleic acid from a patient;

contacting the nucleic acid to [your array];

detecting binding of the nucleic acid to the array to provide a subject expression profile;

selecting a reference profile most similar to the patient's, thereby choosing a therapy.

Selecting a drug or a tx

A method of recommending a drug or a treatment for a patient comprising:

comparing a DNA sequence/ protein expression profile from the patient with [your database profile] of DNA sequences/ SNPs/ protein expression profiles

and each database profile is associated with a drug (or treatment) efficacy

matching the patient's profile with a database profile and

providing the caregiver with a recommendation for a drug or treatment.

In silico drug discovery

A method for identifying a modulator of [your] enzyme, comprising:

comparing 3-D coordinates of the active site of the enzyme to a database of 3-D coordinates of peptides/ small molecules [your algorithm/ database];
selecting a peptide/ small molecule that structurally matches the active site.

Duty of Disclosure

- **Duty of Disclosure**
 - Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [patent] office, which includes a duty to disclose to the office all information known to that individual to be material to patentability. (37 CFR 1.56)

Duty of Disclosure

- If in doubt, DISCLOSE
- Disclose promptly
- Duty does not terminate until patent issues
- Not disclosing may result in an invalid (unenforceable) patent

Patent Office Examines the Patent Application

- **The Office Action**
 - Restriction requirements
 - Substantive rejections
 - Lack of novelty
 - Obviousness
 - Indefiniteness of claims
 - Lack of support or enablement
 - Double patenting

Prosecution of the Patent Application

- **Responding to an Office Action**
 - Written response
 - Interview
 - Must be fully responsive
 - Can amend claims
 - Cannot add new matter
 - Limited time period to respond

Inventorship and Ownership

- **Inventorship is a matter of law**
 - who conceived the invention?
- **For company to own all inventors must assign**
- **Inventorship is determined on a claim by claim basis**
 - Be careful in your collaborations to avoid dual ownership of inventions

Rights of patent co-owners

- . . . each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners.**

(35 U.S.C. §262)

The invention: who is the inventor

- **Inventorship = individuals involved in the “conception” and (sometimes) “reduction to practice” of invention**
- **Conception: formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention**
- **Complete only if ordinary skill is needed to reduce the invention to practice**

Joint inventorship

- **A joint inventor must**
 - (1) contribute in some significant manner to the conception or reduction to practice,**
 - (2) make a contribution to the invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and**
 - (3) do more than merely explain to co-inventor(s) well-known concepts or the current state of the art**

The invention: proof of conception

- **Documentation of the invention**
 - **notebooks, hard copies and electronic**
 - **signed, witnessed, no loose papers**
 - **the electronic notebook can be a legally acceptable document (software available)**
 - **electronic dates and signatures**
 - **Archived imaging of hard drives**

Patent and claiming strategies

- **Patent strategy – claiming strategies**
 - Offensive or defensive patent portfolio?
 - broad or narrow claims
 - Domestic only, or also international protection?
 - timing of filing, secrecy of application
 - “Mapping” your technology and patent space
 - Should the initial filing be a Provisional or a Utility patent application?

Thanks much !!



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