ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Intellectual property and biotechnological innovation

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My professional background

- Law Degree from the University of Bari (2002)
- LLM in Information Technology Law from the University of Bologna (2003)
- PhD in Information Technology Law from the University of Bologna (2008)
- Visiting Researcher at the Benjamin N. Cardozo School of Law (New York, 2007) and at the Max Plank Institute for Innovation and Competition (Munich, 2011)
- Post-doc at the University of Bologna (2008-2014)

- Founding Partner of the Law Firm MPSLAW (2009-)
- Senior Researcher in Commercial Law at the University of Bologna (2015-)
- Adjunct Professor in Intellectual Property Law and Competition Law at the University of Bologna (2015-)

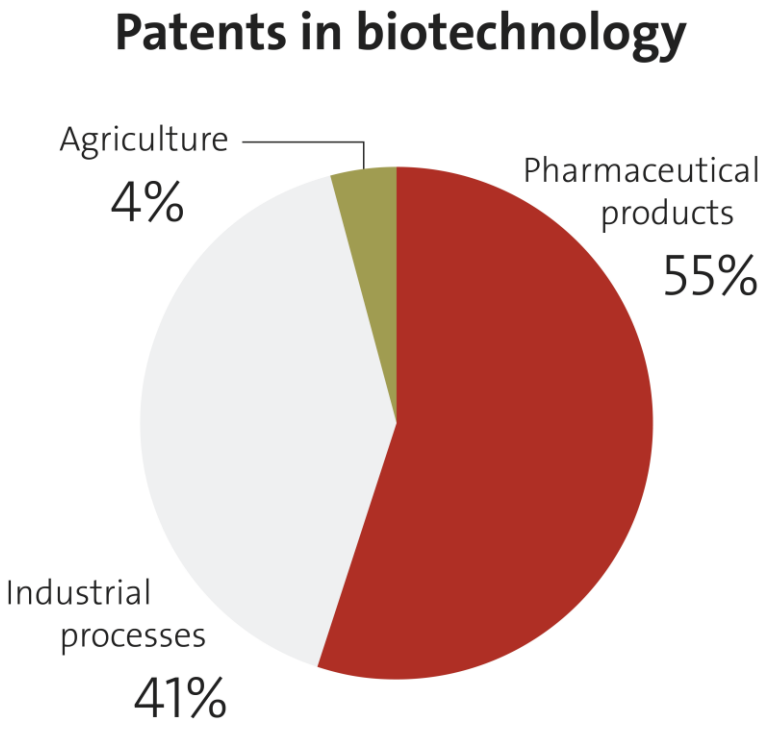
Why Intellectual Property

It is enormously expensive and time-consuming to develop a new drug and obtain market approval, and the necessary funds are largely provided by venture capital supplied by investors.

Drug companies would not be able to fund costly clinical trials and research without being able to claim exclusive rights to recoup these investments. Patents are also an effective barrier to illicit copying of medicines and the health risks associated with unauthorised copycat versions.

[Source: EPO, Biotechnology patents at the EPO]

Patents in biotechnology: a few numbers



[Source: EPO, Biotechnology patents at the EPO]

Patentable inventions

Art. 52 EPC

1. European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

2. […]

Patentable inventions and biotechnology

Art. 3(1) of the Directive 98/44/EC

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

What is not an invention

Art. 52 EPC

1. […]

2. The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) **discoveries**, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

3. Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities **as such**.

Discoveries not-as-such = inventions

A European patent shall be granted for a **specific technical application** of a discovery

An inventions is always a technical solution to a technical problem

When a biological material is not a discovery as such

Art. 3(2) of the Directive 98/44/EC

1. […]

2. Biological material which is **isolated** from its natural environment or **produced by means of a technical process** may be the subject of an invention even if it previously occurred in nature.

Different kind of inventions

Patens are granted for a:

- **Novel product** (→ also a product consisting of or containing biological material)
- **Novel process** (→ also a process by means of which biological material is produced, processed or used)
- **Novel use of existing products**

Patent requirements

In order to grant a patent and invention must:

- Be new
- Involve an inventive step
- Be susceptible of industrial application
- Be disclosed (in the patent application) in a manner sufficiently clear and complete

Novelty

Art. 54 EPC

1. An invention shall be considered to be new if it does not form part of the **state of the art**.

2. The state of the art shall be held to comprise **everything made available to the public** by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

3. Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

The novelty requirement in patent law is geographically absolute (at least in the EU)

Novelty and biotechnology

Art. 3(2) of the Directive 98/44/EC

1. […]

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention **even if it previously occurred in nature**.

How do you find out if your invention is novel?

How do you find out if your invention is novel?

The nearly impossible quest for prior art…

Prior art does not need to exist physically or be commercially available. It is enough **that someone, somewhere, sometime previously** has described or shown or made something that contains a use of technology that is very similar to your invention.

A prehistoric cave painting can be prior art. A piece of technology that is centuries old can be prior art. A previously described idea that cannot possibly work can be prior art. **Anything can be prior art**.

[Source: EPO, Inventor's Handbook]

Inventive step

Art. 56 EPC

1. An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is **not obvious to a person skilled in the art**. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.

What is obvious?

Thus the question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim, having regard to the art known at the time, it **would have been obvious** to the person skilled in the art to arrive at something falling within the terms of the claim. […]

The term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art.

[Source: EPO, Guidelines for Examination]

'Would' approach: OK
'Could' approach: NOT OK

The person skilled in the art

The "person skilled in the art" should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date […].

He should also be presumed […] to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question.

[Source: EPO, Guidelines for Examination]

Industrial Application

Art. 57 EPC

1. An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Industrial application and gene sequences

Art. 5(3) of the Directive 98/44/EC

1. […]

2. […]

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

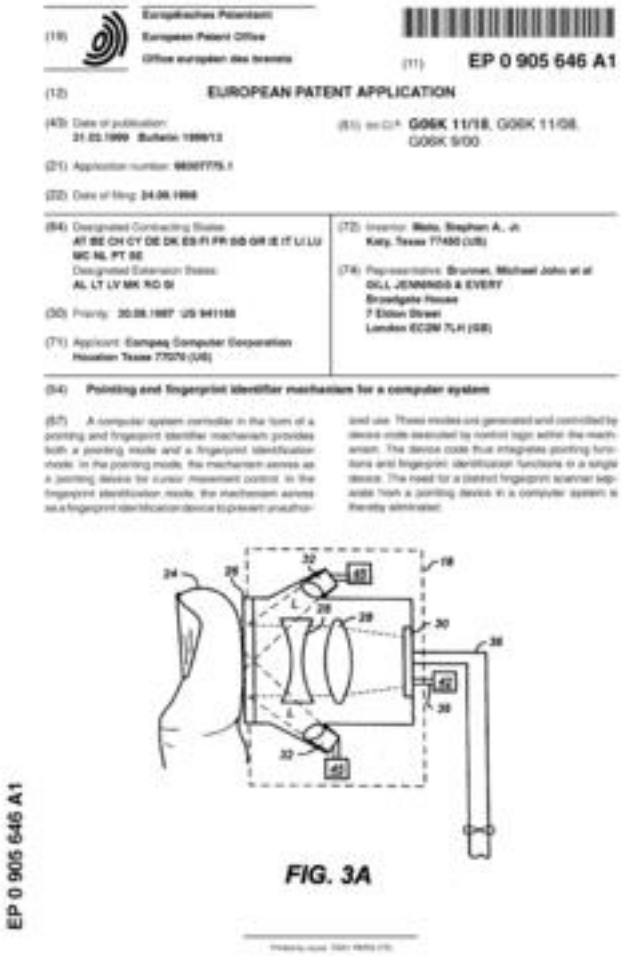
The importance of indicating a function

Recitals of the Directive 98/44/EC

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

The patent application



(19) European Patent Office
Office européen des brevets

(11) EP 0 905 646 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication: 31.03.1999 Bulletin 1999/13

(51) Int Cl.: G06K 11/18, G06K 11/08, G06K 9/00

(21) Application number: 98307775.1

(22) Date of filing: 24.09.1998

(84) Designated Contracting States: AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States: AL LT LV MK RO SI

(30) Priority: 30.09.1997 US 941168

(71) Applicant: Compaq Computer Corporation
Houston Texas 77070 (US)

(72) Inventor: Weiss, Stephen A., Jr.
Katy, Texas 77450 (US)

(74) Representative: Brunner, Michael John et al
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Broadgate House
7 Eldon Street
London EC2M 7LH (GB)

(54) Pointing and fingerprint identifier mechanism for a computer system

(57) A computer system controller in the form of a pointing and fingerprint identifier mechanism provides both a pointing mode and a fingerprint identification mode. In the pointing mode, the mechanism serves as a pointing device for cursor movement control. In the fingerprint identification mode, the mechanism serves as a fingerprint identification device to prevent unauthorized use. These modes are generated and controlled by device code executed by control logic within the mechanism. The device code thus integrates pointing functions and fingerprint identification functions in a single device. The need for a distinct fingerprint scanner separate from a pointing device in a computer system is thereby eliminated.

FIG. 3A

EP 0 905 646 A1

Main parts

- Title of the invention
- Name of the inventor
- Name of the applicant
- Abstract of the invention
- Description of the invention
- Claims
- Drawings

The patent application

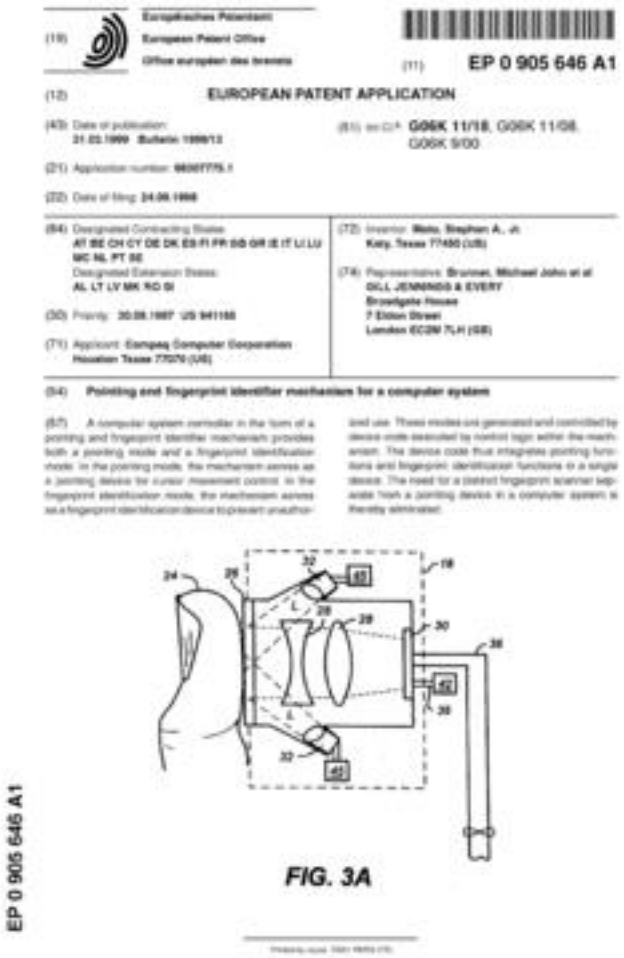

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FIG. 3A

EP 0 905 646 A1

Main parts

- Title of the invention
- Name of the inventor
- Name of the applicant
- **Abstract of the invention**

Art. 85 EPC

The abstract shall serve the purpose of technical information only; it may not be taken into account for any other purpose, in particular for interpreting the scope of the protection sought or applying Article 54, paragraph 3.

The patent application

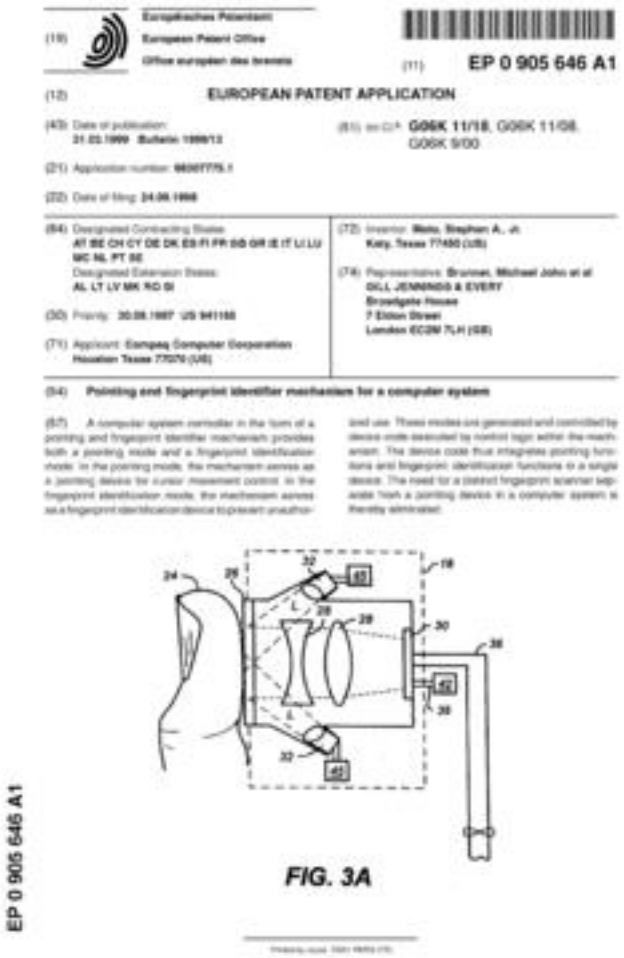

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FIG. 3A

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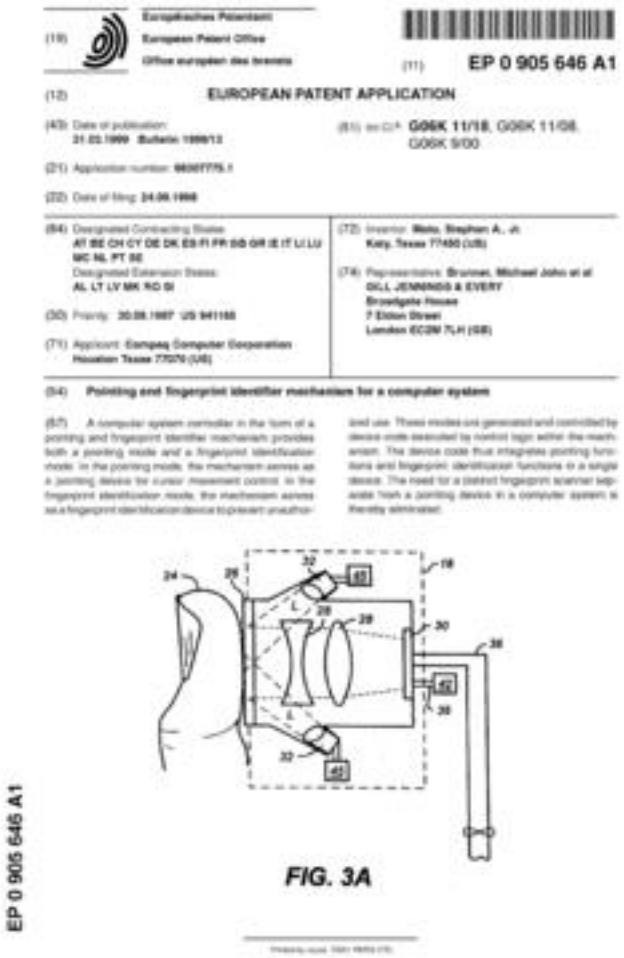
Main parts

- Title of the invention
- Name of the inventor
- Name of the applicant
- Abstract of the invention
- **Description of the invention**

Art. 83 EPC

The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The patent application



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Main parts

- Title of the invention
- Name of the inventor
- Name of the applicant
- Abstract of the invention
- Description of the invention
- **Claims**

Art. 84 EPC

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

Inventions excluded from patentability

Art. 53 EPC

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be **contrary to "ordre public" or morality**; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or **essentially biological** processes for the production of plants or animals; this provision shall not apply to **microbiological** processes or the products thereof;

(c) **methods for treatment** of the human or animal body by surgery or therapy and **diagnostic methods** practised on the human or animal body; **this provision shall not apply to products**, in particular substances or compositions, **for use in any of these methods**.

Ordre public and morality in biotechnology

Art. 6 of the Directive 98/44/EC

1. Inventions shall be considered unpatentable where their commercial exploitation would be **contrary to ordre public or morality**; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

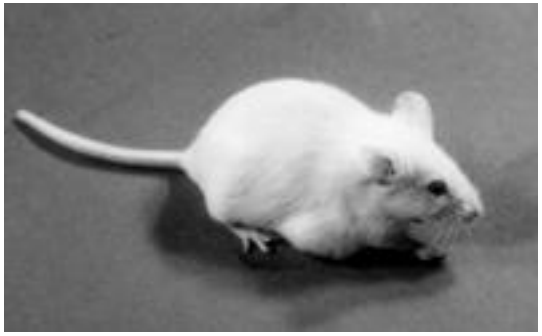
(a) processes for **cloning human beings**;

(b) processes for **modifying the germ line genetic identity of human beings**;

(c) uses of **human embryos** for industrial or commercial purposes;

(d) processes for **modifying the genetic identity of animals** which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The OncoMouse® case



A number of patents requested for a "*a transgenic non-human mammal whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal*"

This case raised fundamental morality issues:

- should patents be granted at all for animals or animal varieties, particularly for higher-order animals such as mammals, even if they do otherwise meet patentablility criteria […]
- how should moral implications be addressed in relation to specific cases, e.g. the question of suffering caused to the transgenic animal?

[Source: WIPO Magazine, *Bioethics and Patent Law: The Case of the Oncomouse*]

Inventions concerning the use of human embryonic stem cells: the *Brüstle* case (1/3)

CJEU, case C-34/10 [Brüstle]

Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that:

- any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo';
- it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of Directive 98/44.

Inventions concerning the use of human embryonic stem cells: the *ISCC* case

CJEU, case C-364/13 [International Stem Cell Corporation]

Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo', within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the **inherent capacity of developing into a human being**, this being a matter for the national court to determine.

Inventions concerning the use of human embryonic stem cells: the *Brüstle* case (2/3)

CJEU, case C-34/10 [Brüstle]

The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for **purposes of scientific research**, only **use for therapeutic or diagnostic purposes which is applied to the human embryo** and is useful to it being patentable.

An example

nature
International journal of science

Article | Published: 02 August 2017

Correction of a pathogenic gene mutation in human embryos

Hong Ma, Nuria Marti-Gutierrez [...] Shoukhrat Mitalipov

Nature **548**, 413–419 (24 August 2017) | Download Citation

Updated online 02 October 2017

Inventions concerning the use of human embryonic stem cells: the *Brüstle* case (3/3)

CJEU, case C-34/10 [Brüstle]

Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

A look to the future researches

What about the patentability of inventions concerning Induced stem cells (iSCs), and, more specifically, induced Totipotent Stem Cells (iTSCs)?

nature
International journal of science

Letter | Published: 02 May 2018

Blastocyst-like structures generated solely from stem cells

Nicolas C. Rivron ✉, Javier Frias-Aldeguer, Erik J. Vrij, Jean-Charles Boisset, Jeroen Korving, Judith Vivié, Roman K. Truckenmüller, Alexander van Oudenaarden, Clemens A. van Blitterswijk & Niels Geijsen

Nature **557**, 106–111 (2018) | Download Citation ⬇

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