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BIO TECH PATENTS

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The EPO published

61.000 EP Patents and EP Patent applications

in IPC class C12

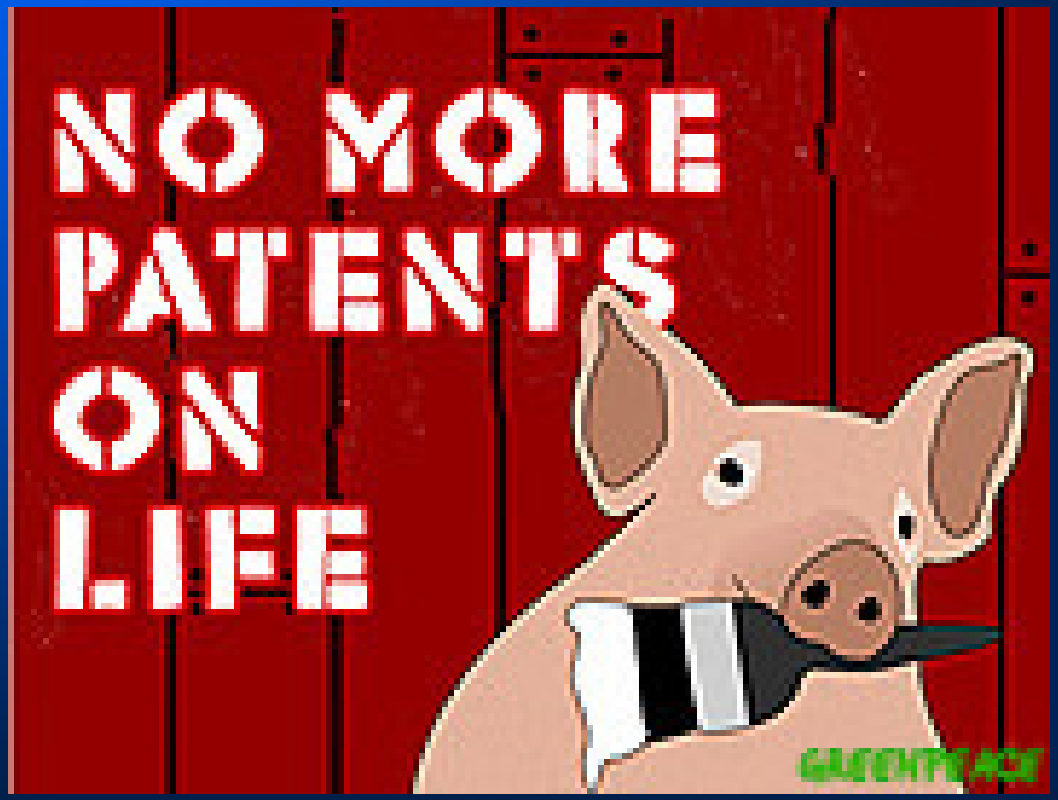

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Fig. 9

Anmeldestärkste technische Gebiete
Technical fields with the most filings
Domaines techniques dans lesquels le plus g

IPC-Klassen IPC classes Classes de la CIB		2003 Summe Number Total	= %	2004 Summe Number Total	= %	Wachstum 2003-2004 Growth Progression Summe Number Total	in % in % en %
A 61	Medizin oder Tiermedizin; Hygiene	12 276	10.5%	13 770	11.1%	1 494	12.2%
H 04	Elektrische Nachrichtentechnik	11 012	9.4%	12 120	9.8%	1 108	10.1%
G 06	Datenverarbeitung	7 597	6.5%	8 134	6.6%	537	7.1%
H 01	Elektrische Bauteile	7 162	6.1%	7 385	6.0%	223	3.1%
G 01	Messen; Prüfen	6 195	5.3%	6 700	5.4%	505	8.2%
C 07	Organische Chemie	6 126	5.2%	6 188	5.0%	62	1.0%
C 12	Biochemie; Gentechnik	4 163	3.6%	3 975	3.2%	-188	-4.5%
B 60	Fahrzeugtechnik	3 745	3.2%	3 901	3.2%	156	4.2%
F 16	Maschinenelemente	3 044	2.6%	3 238	2.6%	194	6.4%
C 08	Org. makromolekulare Verbindungen	3 234	2.8%	3 113	2.5%	-121	-3.7%
	Zwischensumme	64 554	55.3%	68 524	55.4%	3 970	6.1%
	Andere	52 237	44.7%	55 182	44.6%	2 945	5.6%
	Summe	116 791	100.0%	123 706	100.0%	6 915	5.9%

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Part I
WHAT IS A PATENT OF INVENTION?

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1. Background
2. Principles
3. Requirements
   1. Industrial application
   2. Novelty
   3. Inventive step
4. Exceptions

Contract

between two parties

The proprietor of the invention and **The State**

This contract has

A first part and **A counterpart**

The proprietor of the invention:

discloses his invention to the State &
authorises the State to publish the invention after a certain time

The State:

grants to the proprietor of the invention a monopoly on his invention (normally for a period of 20 years); provided that the invention is patentable

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DISCLOSURE OF THE INVENTION

against a

MONOPOLY

THAT ’S THE DEAL

1. Background
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However beware:

I.

If the inventor does not sufficiently disclose his invention

⇓

the State will not be prepared to grant him the monopoly.

II.

If the inventor has already published his invention

⇓

the State has no reason to grant him the monopoly.

Why should the State pay for something, that is already available to the public?

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1. Background
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Principles:

On the one hand:

- give the inventor moral recognition for his feat
- give the proprietor of the invention the chance to make profit

↓

monopoly of exploitation limited in time;

- make technical knowledge easily tradable

On the other hand:

- promotion of the disclosure of technical knowledge
- documentation of technical knowledge
- promotion of innovation & investments in R&D
- promotion of technology exchange

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3. The requirements for patentability

No State will grant an inventor a monopoly - a patent - if the invention does not fulfil certain requirements for patentability.

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Article 52(1) of the

EUROPEAN **P**ATENT **C**ONVENTION (**EPC**)

"European patents shall be granted for any inventions which are susceptible of ***industrial application*** *which are* ***new*** *and which involve an* ***inventive step.***"

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Requirements:

1. **Industrial application**
2. **Novelty**
3. **Inventive step**

All three requirements must be fulfilled to obtain a patent

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Definition of industrial application

Article 57 of the EPC:

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

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Definition of Novelty

Article 54, paragraph 1, of the EPC:

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

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Definition of the State of the Art

Article 54, paragraph 2, of the EPC:

*"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."*

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The "**State of the Art**" or the "**Prior Art**"

=

Any subject-matter a member of the public **could** get access

to prior to the date of filing of the patent application and

without a bar of confidentiality restricting the use or dissemination of such knowledge.

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In conclusion:

Novelty of a patentable invention is destroyed by any disclosure

(even the one made by the inventor himself)

in any way and in any place or country of the world,

if such disclosure has taken place

"before the date of filing of the patent application".

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Definition of the inventive step

Article 56 of the EPC:

*"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."*

In a Nutshell

A claimed invention is held to lack inventive step basically in two situations:

a) A single prior art reference almost anticipates the claim, except for a minor feature which is known in a different context.

b) The claimed invention corresponds to the combination of the teaching of two prior art references.

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Costs for a Patent application in the first 2 1/2 years

- First Application +/- 4000 EUR (0-12 months)
- PCT Application +/- 6000 EUR (12-30 months)

Total Costs

to maintain an option on a patent in

122 countries

+/- 10.000 EUR

(less than 350 EUR/month)

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4. Inventions excluded by law from patenting

Article 52 of the EPC

a) Discoveries, scientific theories and mathematical methods

b) Aesthetic creations

c) Schemes, rules, methods for performing mental acts, for playing games, for doing business

d) Programs for computers

e) Presentations of information

f) Methods for treatment of the human and animal body by surgery or therapy and diagnostic methods practised on the human or animal body

shall not be patentable as such.

Other exceptions to patentability are :

a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality

b) plants or animal varieties or essentially biological processes for the production of plants or animals excluding „microbiological“ processes and the products thereof

Article 53 of the EPC

Part II
PROTECTING BIOTECH INVENTIONS

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LEGAL BASIS

- TRIPS
- Convention on Biological Diversity (93/626/EEC)
- Directive 98/44/EC

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Directive 98/44/EC

Article 3 (object)

1. 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.

Directive 98/44/EC

Article 3 (object)

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.

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Directive 98/44/EC

Article 2 (Definitions)

1. (a) 'biological material` = any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

(b) 'microbiological process` = any process involving or performed upon or resulting in microbiological material.

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Directive 98/44/EC

Article 2 (Definitions)

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of 'plant variety` is defined by Article 5 of Regulation (EC) No 2100/94.

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Directive 98/44/EC

Article 1

1. biotechnological inventions to be protected under national patent law.
2. without prejudice to the obligations to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

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Directive 98/44/EC

Article 4

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

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Directive 98/44/EC

Article 4

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

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Directive 98/44/EC

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

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Directive 98/44/EC

Article 5

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

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

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Directive 98/44/EC

Article 6

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.

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Directive 98/44/EC

Article 6

2. On the basis of §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.

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Directive 98/44/EC

Article 8

1. The protection conferred by a patent on a biological material … shall extend to any biological material derived from (the patented) ... biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

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Directive 98/44/EC

Article 8

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

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Directive 98/44/EC

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, …, in which the product in incorporated and in which the genetic information is contained and performs its function.

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Directive 98/44/EC

Article 10

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

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Directive 98/44/EC

Article 11

- 1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

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Directive 98/44/EC

Article 11

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

Part III
PATENT RIGHTS AND PATENT INFRINGEMENT

Most patent laws explicitly specify the acts that are prohibited to third parties

TRIPs Agreement ⇒ minimum rights

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Subject matter of the patent is **a product**:

Patentee has the right

to prevent third parties from

→ making the patented product

→ using the patented product

→ offering for sale the patented product

→ selling the patented product

→ importing for these purposes the patented product

Subject matter of a patent is **a process**:
Patentee has the right
to prevent third parties from:

→ using the patented process

→ using, offering for sale, selling or importing for these purposes **the product obtained directly by the patented process**

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Exceptions to patent rights

- acts done privately and for non-commercial purposes
- the making of the patented product for the sole purpose of scientific research and experiment
- the use of the patented product in vehicles in transit in the country
- the prior use or prior possession rights
- compulsory license granted by the State (very rare!)

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Exhaustion of rights provision:

The rights conferred by a patent do not extend to acts concerning a product covered by a patent

after that product has been put on the market

→ by the patentee or

→ with the patentee's express consent.

European Union

Exhaustion of patent rights

in all the member States

if the patented product has been put on the market in any member State

by the patentee or with his express consent.

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2.2. Interpretation of the Claims

The scope of protection of the patent is determined by the claims

The meaning of the claims is ultimately interpreted by the courts

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2. Establishment of Infringement

The patentee must prove:

1. that a prohibited act has been carried out
2. that the prohibited act has been done after the grant of the patent; or at least after the publication of the patent application, if the latter provides provisional protection until grant
3. that the prohibited act has been done within the territory of the State for which the patent has been granted and
4. that the prohibited act is in relation to a product or process falling within the scope of a claim of the patent

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3. Enforcing the Patent Rights

Initiative to enforce the patent rests exclusively with Patentee

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Patent owner is responsible

→ for detecting infringements of his patent,

→ for collecting evidence and

→ bringing it to the infringer's attention.

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Remedies available to Patentee

→ the grant of an injunction

→ the award of damages

→ the seizure and destruction of the infringing products or the tools used by the infringe

In case of an intentional infringement the sanctions may also include:

- punitive damages or even
- criminal sanctions
  such as a fine or imprisonment

Part IV
PATENTS AS A SOURCE OF INFORMATION

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More than 20% of the R&D funds

in the European Union

are spent to invent things that have already been invented.

The fact that a product doesn't exist on the market, does not necessarily mean that the product has not yet been described in the patent literature

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According to a study of the O.E.C.D:

80% of the technical information is exclusively available through the patent literature.

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1. Introduction
2. Exploit Literature
3. International Patent Classification

Advantages of the patent literature as source of information:

- → covers all technologies;
- → world-wide contribution;
- → up to date with technological development (time lag not more than 18 months)
- → detailed classification according to areas of technology;
- → information easily usable by technicians;
- → very easy and quick access.

A search is generally performed as follows:

1. Scan the patent data bases by technology classes and/or key words
2. Study the abstracts of the patent documents which are the result of the search.
3. Order those documents that seem to interesting
4. Review the ordered documents
   Do not forget to have a look at the cited prior art.
5. Refine your search if necessary.

Sources of Patent Literature on the Internet

- http://www.espacenet.com
- http://www.iprhelpdesk.org
- http://www.delphion.com
- http://www.depatisnet.de
- …

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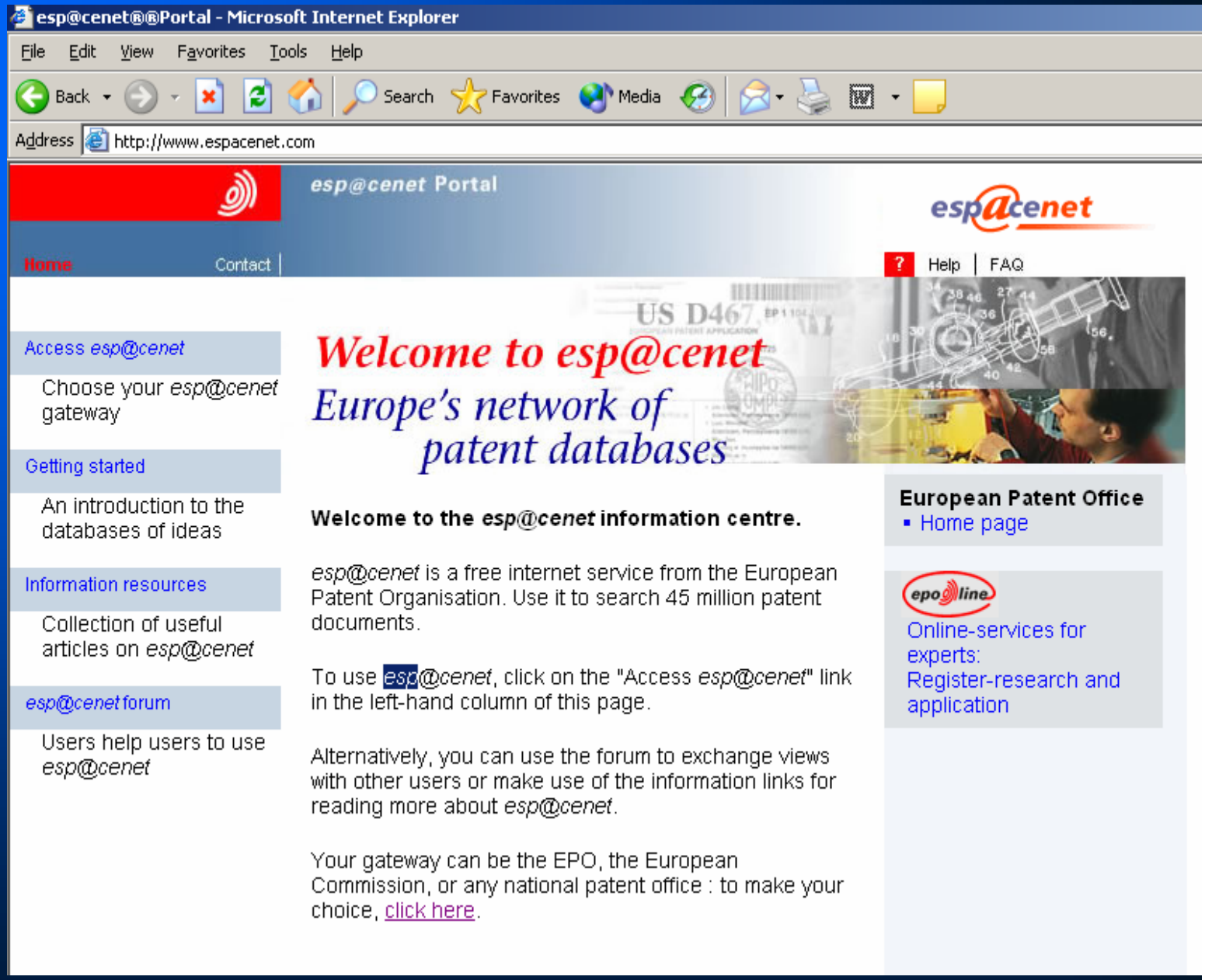
1. Introduction
2. Exploit Literature
3. International Patent Classification



Thank You for Attention

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