



Polish Patent Office



Patentability Issues in Biotechnology

- Law and Practice in Europe

Practice of the Polish Patent Office



Banská Bystrica, 2-3 may 2007



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Industrial Property Law and other Laws necessary for examining the biotechnological inventions:

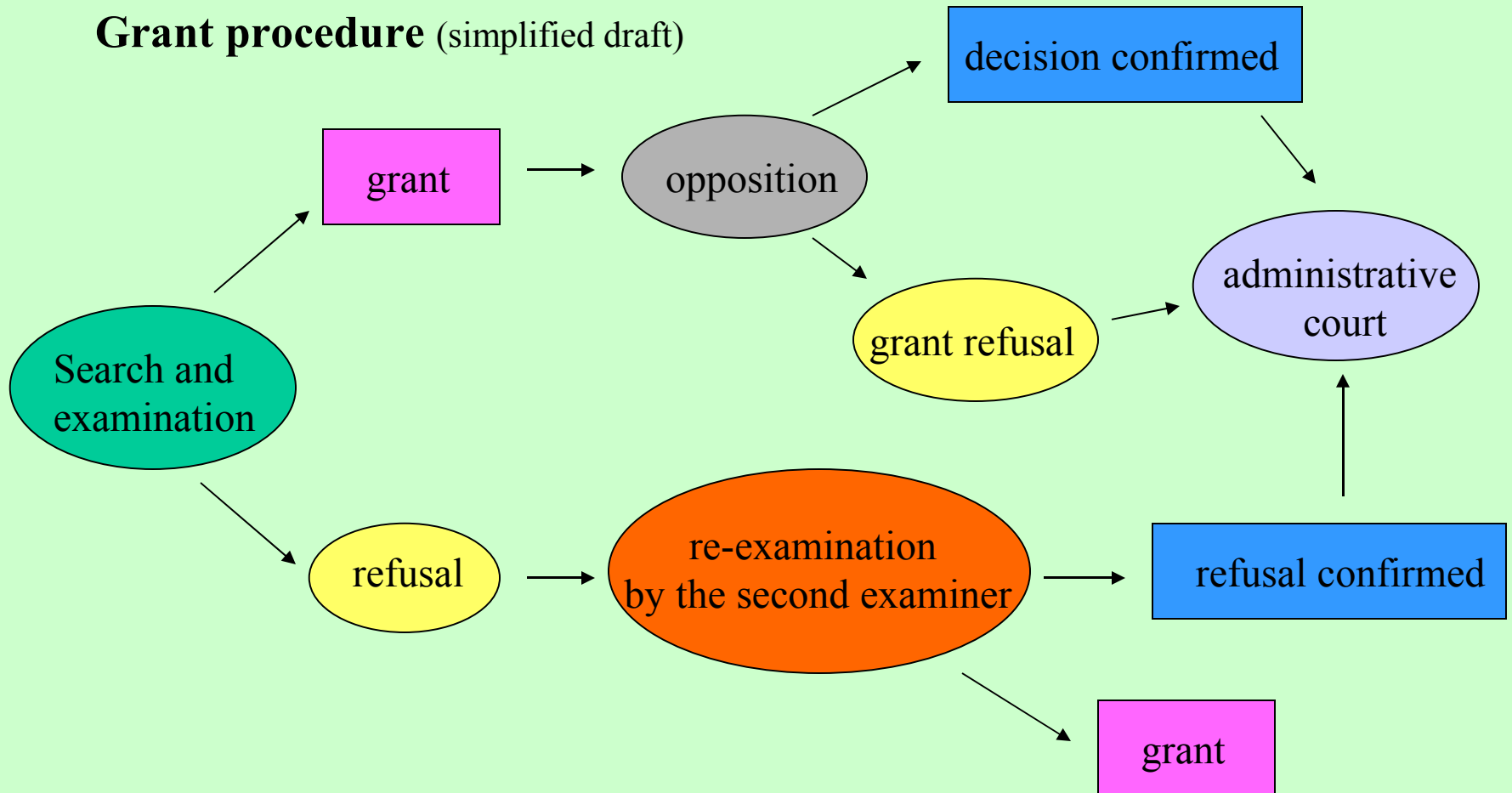
- Budapest Treaty (1977)
- The Seed Act (1995)
- Biotechnology Directive (1998)
- Industrial Property Law (2000) with further amendments
- Regulation on filing and processing of patent and utility model applications (2001)
- Transgenic Organisms' Law (2001)
- Inventor's Guides - Patent and utility model specifications - rules and tips (2005-2006)



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Grant procedure (simplified draft)





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Relevant Articles and Rules of the EU Biotech Directive 98/44, the EPC and the Polish Industrial Property Law

	the EU Biotech Directive	the EPC	the Polish Industrial Property Law
Definitions	Art. 2	Rule 23b	Art. 93 ¹
Exclusions in biotechnology	Art. 4, art. 5	Art. 53 Rule 23d	Art. 29 Art. 93 ³
Morality + public order	Art. 6	Art. 53(a)	Art. 29.1(1)
Plant varieties and rases + biological methods	Art. 4	Art. 53(b) Rule 23c(b)	Art. 29.1(2) Art. 29.2



A few examples of law harmonization

Article 5 – EU Biotech Directive

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.

Rule 23e - EPC

The human body and its elements

- (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.

Article 93³ - the Polish Industrial Property Law

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.



Article 5 – EU Biotech Directive

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.

Rule 23e - EPC

The human body and its elements

(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.

Article 93² - the Polish Industrial Property Law

1. The following, in particular, shall be considered as biological inventions eligible for patent protection:

(ii) elements isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element,



Article 5 – EU Biotech Directive

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

Rule 23e - EPC

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

Article 93² - the Polish Industrial Property Law

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



Rule 23d - EPC

Exceptions to patentability

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- (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.

Article 93³ - the Polish Industrial Property Law

2. The following, in particular, shall be considered as biotechnological inventions, whose exploitation would be contrary to Public order or morality within the meaning of Article 29(1)(i), or with public morality:

- (i) processes for cloning human beings,
- (ii) processes for modifying the germ line genetic identity of human beings,
- (iii) uses of human embryos for industrial or commercial purposes,
- (iv) 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.



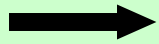
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Main reasons of changing approaches of the Polish Patent Office



Harmonization of law (EU Biotech Directive, EPC)



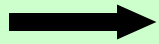
New law



Opinions of applicants



Opinions of examiners



New information from scientific world



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Main changes

- Transgenic organisms
- Antibodies
- Product by process
- Product defined by its **function**

- **Unity**
- Complex applications
- Search - examination
- Re-examination
- Administrative court (no patent court)



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Patenting of DNA

- sequences
- restriction maps
- deposits
- homologies
- hybridising sequences
- elements-components
- modifications



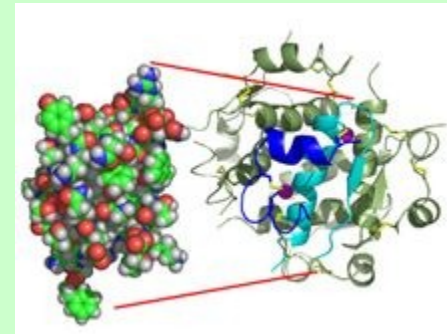


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Patenting of proteins

- sequences
- physical and chemical data
- homologies
- deposits
- elements-components
- product by process
- modifications





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Patenting of transgenic plants and animals



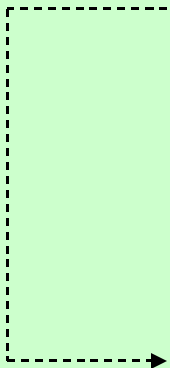
past

- Plants and animals - NO!: new variety and new race
- Methods of producing - NO!: the results of introducing them into the natural environment can be unexpected and unpredictable - contrary to public order



present

Yes,
if the technical feasibility of the invention
is not confined to a particular plant or animal variety.





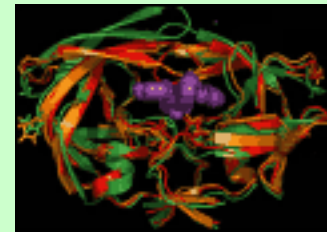
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Antibodies

past

Only structural data



present

- structure - sequences
- deposits
- by new sufficiently disclosed antigen recognised by this antibody
- method of preparing



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Product by process

Art. 64 - A patent granted for a process of manufacture shall also cover products directly obtained by means of that process.

Rather - product by structure, components

If there is no other possibility. It is some kind of necessity.



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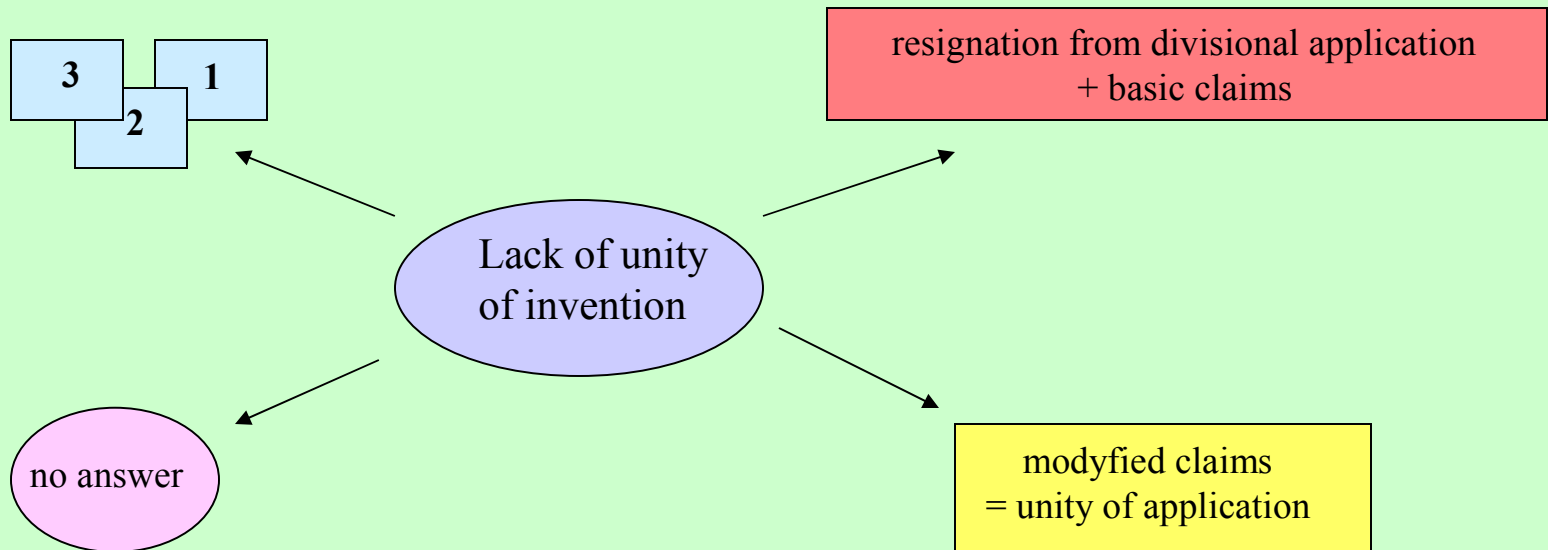
Product defined by its function

NO



Unity

**In the case of lack of unity - we decide.
Additional fees do not change anything.
The application must be separated.**





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Search - examination

Two processes but not separated like in the European Patent Office.

We process both of them together .



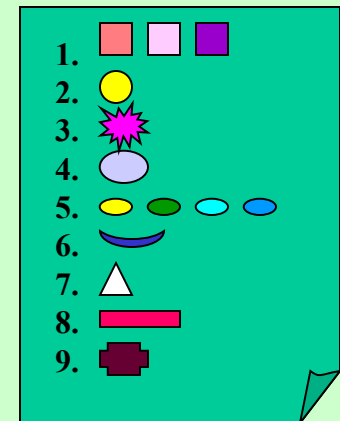
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Complex applications

- very high number of claims
- no clear
- very large number of combinations and different possibilities
- reach-through claims

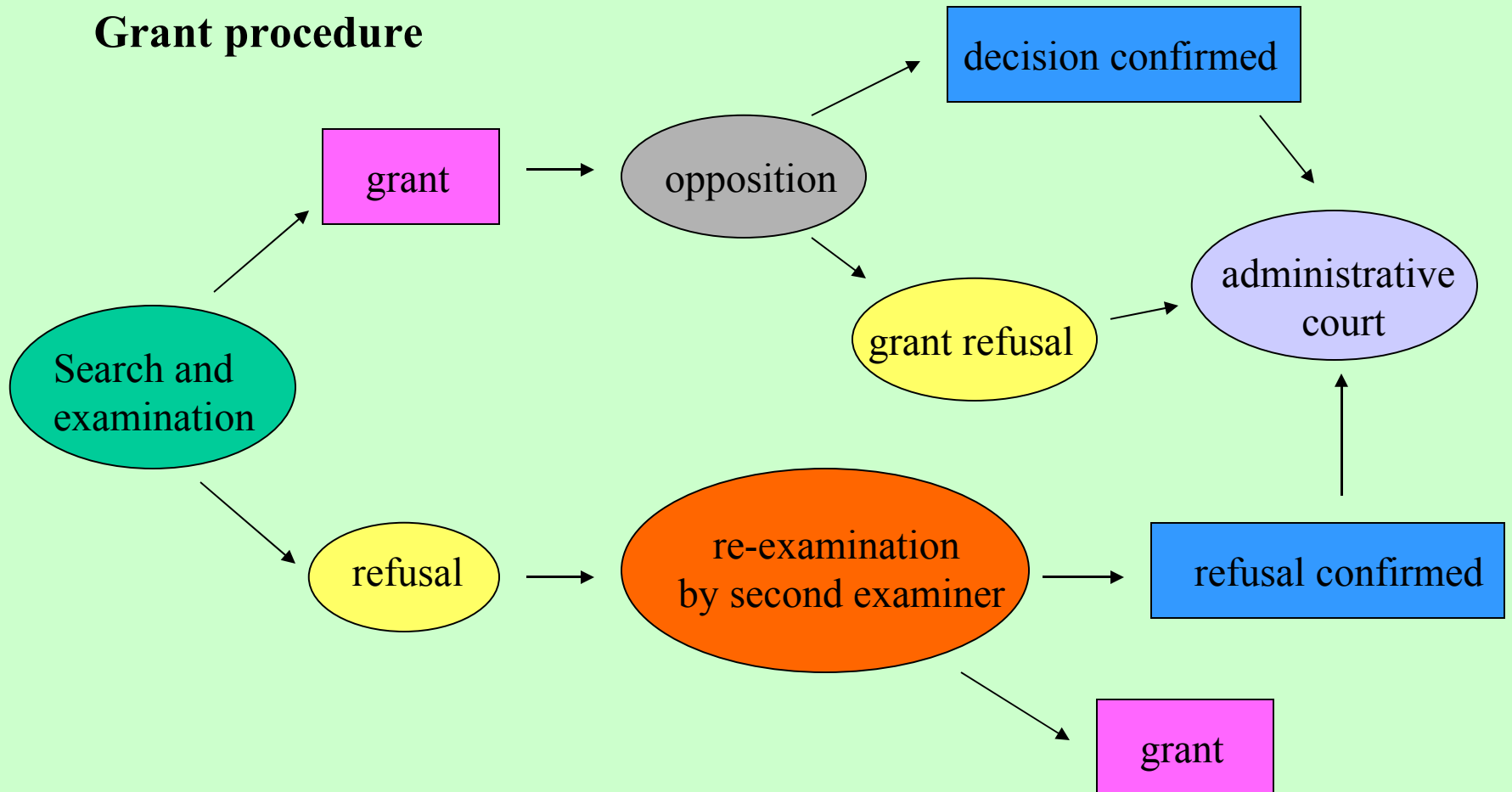
- lack of unity
- no support in the description
- novelty / inventive step



No partial search report



Grant procedure





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Re-examination

Separated procedure



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Administrative court

No Patent Court

No essential discussion in the court



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THANK YOU !