

Article 9 of the  
Biotechnology Directive 98/44/EC:  
The End of Absolute Product Protection?

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Young EPLAW Congress, Brussels, May 11, 2009

Daily IP Life In EPC Countries

- The EPO grants tens of thousands of patents per annum with claims to chemical products or compositions per se
- Article 69 EPC
- **All EPC countries have the concept of absolute product protection**
- Hundreds of court decisions in EU countries based on (non)-infringement of chemicals per se based on the doctrine of absolute product protection

## Biotech Directive 98/44/EC

What is it?



- Guideline on (non)-patentable biotech subject matter in EU
- Guideline on scope of protection in EU
- Provision on disclosure/availability of biological matter
- Intention to harmonize EU IP law for biotech inventions
- Intention to provide legal certainty for biotech inventions

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## History

What is it?



- Conceived by a European Commission in October 1988
- Born in the European Parliament in July 1998
- A difficult birth - NL/IT/NO brought suit in 1998 before the ECJ to annul Directive - rejected by ECJ in 2001
- Ratification was due by 30.7.2000 - actually ratified in EU States from 2000 to 2006 and 2007 in CH

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## Subject matter of Directive



Regulates controversial subject matter such as: cloned humans, human and animal embryos, organs, stem cells, hereditary material, etc.

## Biotech Directive 98/44/EC

### Preamble

(1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;

(2) Whereas, in particular, in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

## Biotech Directive 98/44/EC

### Preamble

(3) Whereas effective and harmonized protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

(5) Whereas, differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;

## Biotech Directive 98/44/EC

### Preamble

(8) Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;

## Biotech Directive 98/44/EC

(15) Whereas no prohibition or exclusion exists in national or European patent law which precludes a priori the patentability of biological matter;

(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;

## Biotech Directive 98/44/EC

(46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself;

## Biotech Directive 98/44/EC

### Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

### Article 2

1. For the purposes of this Directive,

(a) "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

## Biotech Directive 98/44/EC

### Article 3

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

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.

## Biotech Directive 98/44/EC

### Article 8

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

## Biotech Directive 98/44/EC

### Article 9

The protection conferred by a patent on an product containing or consisting of genetic information shall **extend** to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

(Art. 5(1) states that the human body at its various stages of formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be patentable)

## Scope of Protection of EP Patents

- 1) Absolute product protection for chemicals/biochemicals including DNA or material comprising DNA.
- 2) Protection for a product containing or consisting of genetic information **extends** to all material in which the product is incorporated and in which the genetic information is contained and performs its function.

## Biology for Young Lawyers (I)

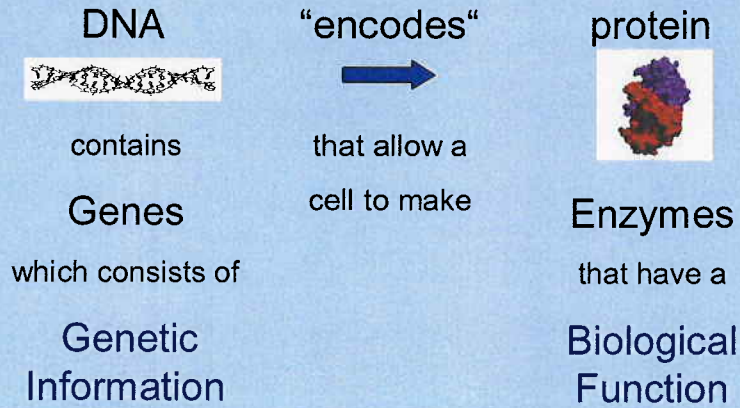
### DNA

DeoxyriboNucleic Acid  
is a chemical polymer  
of 4 repeating units

AGTCATCTACACGTCTCGTTGGCCT

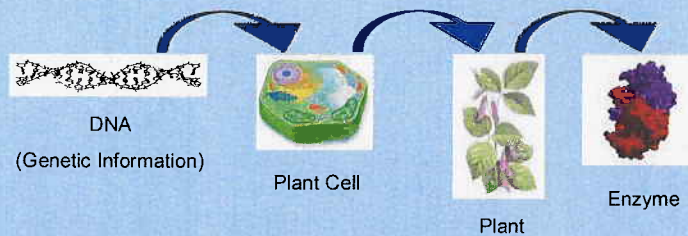


## Biology for Young Lawyers (II)

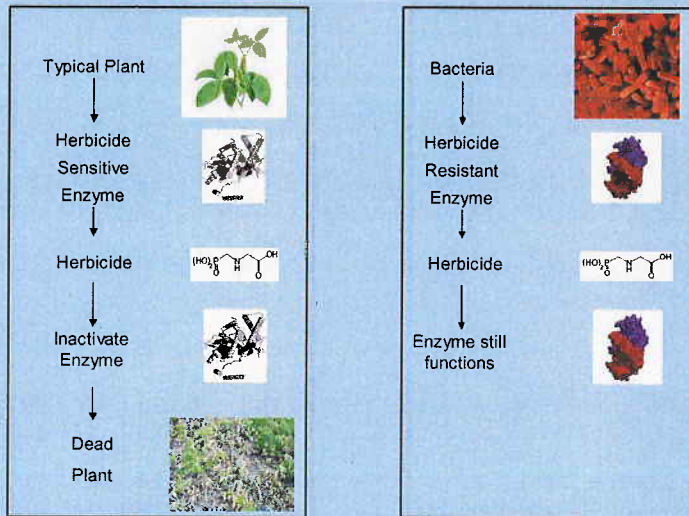


## Biology for Young Lawyers (III)

### Genetic Engineering



## Case Study (I)

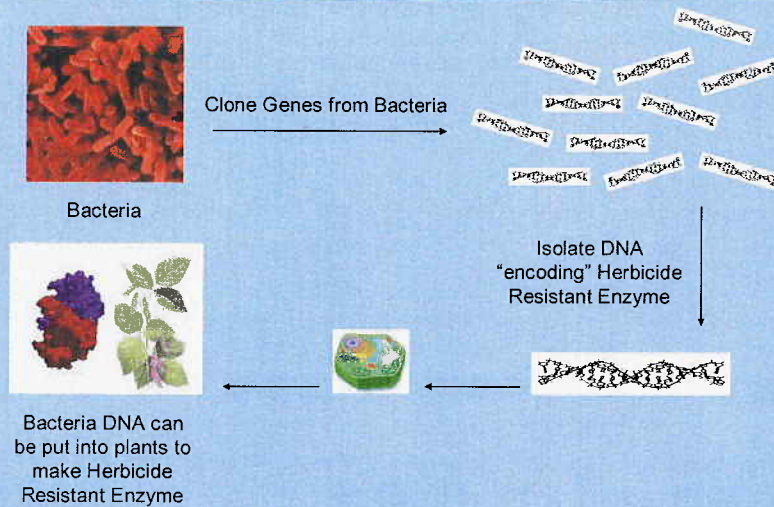


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## Case Study (II)

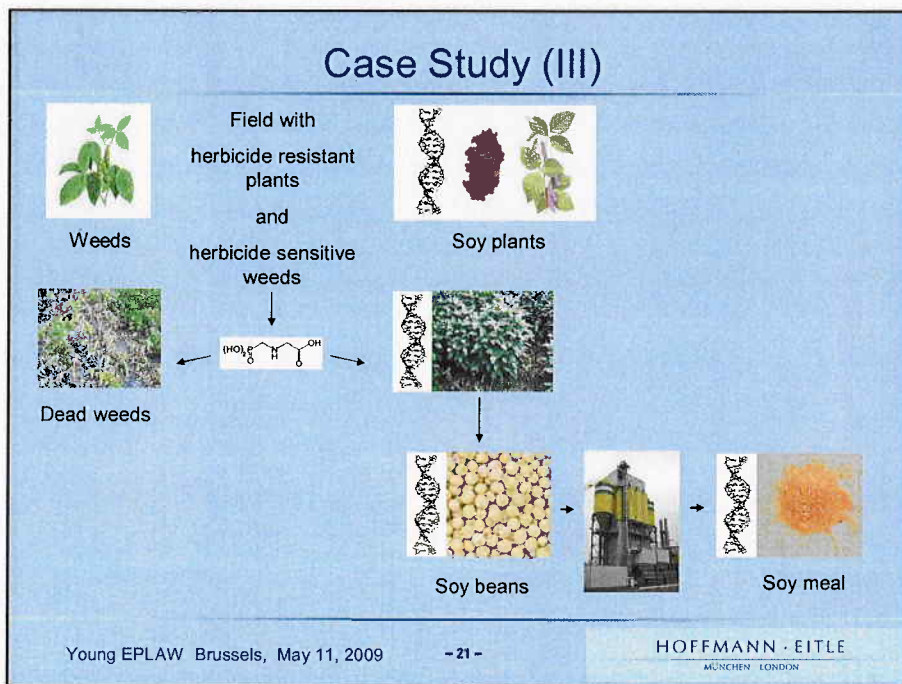


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## Case Study (III)



## Case Study (IV)

EP 546 090 B2

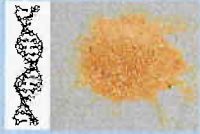
Claimed:

1. DNA encoding herbicide resistant enzyme.
2. Method of producing herbicide resistant soy plant.
3. Herbicide resistant soy plant cell.
4. Method for controlling weeds in a field.

(Not claimed: Soy meal obtainable from plant.

Soy meal comprising DNA of claim 1.

## Case Study (V)



Is the importation of DNA and/or soy meal an infringement of:

- 1) Absolute product protection???
- 2) Article 9 of the Biotech Directive ???

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## Biotech Directive 98/44/EC

### *Article 9*

The protection conferred by a patent on an product containing or consisting of genetic information shall **extend** to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

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## Case Study (Spain)

Appeal before the Mercantile Court No.6 of Madrid

### 1. DNA encoding herbicide resistant enzyme.

“... the following can be concluded: ... the genetic information to which the object of the patent is referred to - the complete gene sequence- would be contained, though actually without quantifying its meaning, in the imported flour...”.

So...

infringement due to absolute product protection????

## Case Study (Spain II)

Appeal before the Mercantile Court No.6 of Madrid

“... the key to the lawsuit lies in the scope of application of No.4 of Article 50 of the Patent Act [Article 9 of the Biotech Directive]... which is a **special rule** relating to biotechnological patents... only **subsequently** should it be legally considered if there were infringement that the consequences mentioned in No. 1 of Article 50 of the Patent Act [absolute product protection] would be applicable...”.

## Case Study (Spain III)



### Article 9

The protection conferred by a patent on an product containing or consisting of genetic information shall **extend** to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and **performs its function**.

## Case Study (Spain IV)



Appeal before the Mercantile Court No.6 of Madrid

“...evidence whether the genetic information object of the patent is contained in the soy flour is **not enough**, but the **additional requirement** that it complies a **given function** in it should be met, an unavoidable condition to consider as an infringement...”.

## Case Study (Spain V)

Appeal before the Mercantile Court No.6 of Madrid

“...it is required that the genetic information contained in the product **actually performs a specific biological function** which we understand must be **active and effective**; otherwise, the verb “**perform**” would not be used in the legal provision....

...if said flour is a product where this function is not performed, importation thereof by the defendant could not be considered to be a patent infringement”.

## Case Study (Spain VI)

Infringement denied because:

1. Article 9 of the Biotech Directive is a *lex specialis* that must be evaluated prior to the general law governing absolute product protection, and
2. To infringe Article 9, a DNA per se must actively perform a function other than carrying genetic information.

**The END of absolute product protection**

## Case Study (Netherlands I)



District Court in the Hague

### 1. DNA encoding herbicide resistant enzyme.

“...Through the presented exhibits [Plaintiff] sufficiently demonstrated that the DNA sequence of [claim 1] was, in considerable quantities, present in the shipment....

...Even if it should be assumed that the DNA sequence is only present in the soya meal in limited quantities, this does not alter the fact that the patent of [Plaintiff] is infringed, at least if the scope of protection of the patent comprises the product, the DNA as such...”.

## Case Study (Netherlands II)



District Court in the Hague

“...Articles 8 and 9 of the Directive are, in principle, applicable....

...the question is whether, following processing in another material, the scope of protection is limited to the situation that the DNA performs its function.

...If the marketing of soy meal cannot be prevented on the basis of [Article 9], the question then becomes relevant whether the classic absolute protection of the product still, in addition to the special protection of [Article 9], exists in an instance at stake in the present proceedings”.

## Case Study (Netherlands III)



### District Court in the Hague

“...there seems to be reason to assume that the Directive does not alter the absolute product protection....”

... the formulation of Article 9 of the Directive seems to support this standpoint by using the verb “extends to” and not, for example, “is limited to...”.

## Case Study (Netherlands IV)



### District Court in the Hague

“...if the Directive would not allow a broader protection as considered by the Spanish Court, the Court finds itself facing the preposterous situation that even the isolated DNA, as long as this is not in any material, would not be included in the scope of protection. This kind of limitation, if even yet intended, neither seems justified to the Court in light of the objective and scope of the Directive nor in the light of the protection of the public order”.

