European Commission

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union.

European Commission

Directive 98/44/EG on the legal protection of biotechnological inventions

Explanatory meeting

8 February 2019

12/04/2019

Internal Market and Services

Genesis of Directive 98/44/EC (1)

October 1988:First proposal

March 1995: Refusal EP

December 1995: Second proposal

Adoption 6 July 1998 → entry into force 30 July 1998

Result: 56 Recitals and 18 Articles!

Genesis of Directive 98/44/EC (2)

October 1998: NL challenged the validity of Directive 98/44/EC

C-377/98 → Court of Justice confirmed the validity of the Directive!

16 (b) report: Com(2002) 2 final

16(c) report: COM(2002) 545 final + COM(2005) 312 final

Objective of the Directive

→ To attract investments and encourage innovations in this field, a harmonised legal framework was necessary in European law to protect such inventions.

See in this regard recitals 5 and 7 of the Preamble

(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;

(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;

Key Principles of Directive 98/44/EC

Directive 98/44/EC lays down principles with regard to:

- Patentability of biological material (Art. 3)
- Patentability of certain elements of human origin (Art. 5(2)(3))
- Exclusions from patentability (Art. 4, Art. 5(1))
- Ethical considerations (Art. 6)
- Scope of protection (Art. 8, 9)
- Limitations (Art. 10, 11)
- Use of deposited biological material (Art. 13)
- Non-exclusive compulsory licensing (Art. 12)

Patentable subject matter

Dir.98/44	EPC
Biological material isolated from its natural environment (Art. 3(2))	Dito Rule 27 (b)
Plants and animals not confined to a plant or animal variety (Art. 4(2))	Dito Rule 27 (a)
Isolated elements of human origin (Art. 5(2))	Rule 29 (2)

Unpatentable subject matter

Dir.98/44	EPC
Plant and animal varieties (Art. 4(1)a)	Dito Art. 53(b)
Essentially biological processes (Art. 4(1)b)	Dito Art. 53(b)
Human body at the various stages of its formation (Art. 5(1)	Dito Rule 29(1)
Inventions contrary to ordre public or morality (Art.6(1))	Dito Art. 53(a)

Ethical considerations

Inventions of which the commercial exploitation would be contrary to ordre public or morality are excluded in particular (Art. 6(2))

(a) Processes for cloning human beings

(b) Processes for modifying the germ line genetic identity of human beings

(c) Uses of embryos for industrial or commercial purposes

However, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.' (Art. 6 (1))

Similar provisions in Paris Convention (Article 4quater) and EPC (Article 53(a)).

Ethical considerations

Reasoning mere prohibition is not sufficient:

- *Restrictions/limitations can be temporary e.g. GMOs*
- *License income*
- *That the exploitation is prohibited does not always necessarily mean that the manufacturing is prohibited as well*

Case Law Court of Justice

C-428/08
Monsanto

Purpose bound protection for DNA sequences

Performing its function at time of infringement

Case Law Court of Justice (2)

C-34/10 Brüstle

Definition of Human Embryo

hESCs leading to destruction human embryo at whatever stage renders invention un patentable

C-364/13 ISC

an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo',

European Commission

Patentability of plants directly obtained by EBP

EBoA (2015): *Patentability of plants directly obtained by EBP*

Commission notice 2016: *the intention of the EU legislator was to exclude such products from patentability*

Feb 2017: *Council counclusions*

July 2018: *changes of rule 28(2) for reflecting this exclusion*

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Thank you for your attention!