



# One size fits all?

How unitary is the present European patent system?



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# Overview

*Take stock of European framework with regard to*

- Eligible subject matter
- Patentability requirements
- Scope of protection
- Exercise of rights
- Patent term
- Patent use

*of differentiation [which is technology specific]*



# Eligible subject matter

- General rule

- art. 52 (1) EPC

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

<b>No</b> protection for	in
– Pharmaceutical products	49/92
– Animal varieties	45/92
– Plant varieties	44/92
– Biological methods	42/92
– Therapeutic methods	44/92
– Food	35/92
– Software	32/92
– Chemical compounds	22/92 PC member states

WIPO, *Existence, Scope and Form of Generally Accepted and Applied Standards/Norms for the Protecting of Intellectual Property*, September 1988 (Doc. WO/INF/29)

**End of differentiation?**



# Eligible subject matter

- Exclusion of inventions
  - Too abstract in nature
    - discoveries, scientific theories and mathematical methods (article 52-2) [NEL!]
  - Non technical in nature [technology specific]
    - aesthetic creations; schemes, rules and methods for performing mental acts, playing games or doing business, and programs computers; presentation of information (art.52-2) [NEL!]
  - Policy [health] reasons
    - methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human and animal body (article 52-4)
  - Ethical reasons [technology specific]
    - inventions the publication or exploitation of which would be contrary to 'OP' or morality
    - processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes [NEL!]  
human embryonic stem cells? (article 53 a + Rule 23)
  - Legal reasons
    - [prohibition double protection]: plant and animal varieties (article 53 b)

**Differentiation! Non-exclusive lists + interpretation problems = legal uncertainty. Do we need more?**



# Patentability requirements

- General rule

- art. 52 (1) EPC

- “European patents shall be granted for *any* inventions which are susceptible of industrial application, which are new and which involve an inventive step”

- Differentiation

- Inventive step

- “person skilled in the art” in the respective field of technology

- Disclosure requirement

- Somewhat looser in the field of software?

**Hardly any differentiation! Do we want more?**



# Scope of protection

- General rule

- Article 69 EPC

- Article 69 (1) EPC: ‘The extent of the protection conferred by a European patent or a European patent application shall be *determined by the terms of the claims*’
- Protocol on the Interpretation of Article 69 EPC: “Article 69 should *be interpreted* as defining a position which combines a *fair protection for the patentee* with a *reasonable degree of certainty for third parties.*”

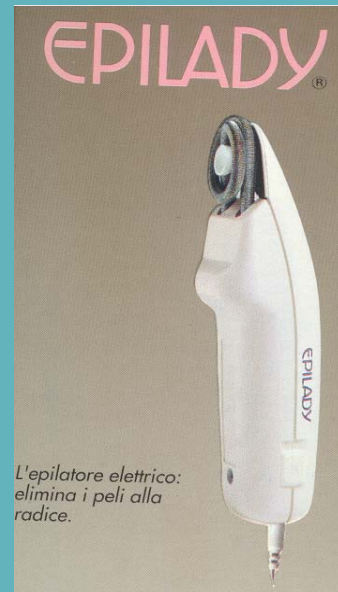
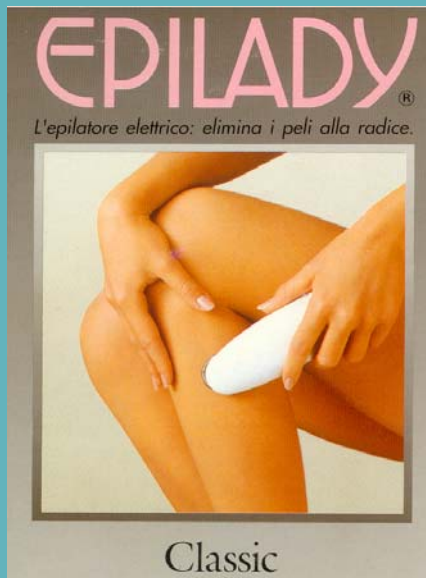


# Scop

- Application Article 69

EP 101656	DE	NL	GB	HK	IT	AT	BE
Prio 20.08.82 AT 29.07.83 Erl. 05.11.86							
E I 19.06.87 E II 01.07.87	19 07 88 EVI + I, 90, 471		14 07 88 EVI - II, 90, 474		18 07 88 EVI + XI, 93, 249		16 06 88 EVI + VII, 92, 385
E III 24.08.86 (Art.105 EPÜ)	27 10 88 EVII - I, 90, 471	16 09 88 EVI + IV, 90, 478	12 08 88 EVII + II, 90, 474	02 11 88 EVI + III, 90, 477		13 03 89 EVI - V, 92, 53	
	30 12 88 HSI + VIII, 93, 242	29 06 89 EVII IV, 90, 478	16 05 89 HSI - IX, 93, 245	02 10 89 HSI - X, 93, 248		31 07 89 EVII - V, 92, 53	
12.10.89 Widerruf Beschwerde		13.11.89 Einstellung Zwangsvoll- streckung					
	01.03.90 Einstellung Zwangsvoll- streckung	28.11.89 Gutachten Bijzonder Afdeling		04 09 90 HSII - I, 93, 248			25 06 90 EVI + VI, 92, 385
24.04.91 Patent aufrecht	21.11.91 HSII + VIII, 93, 242	20 02 92 EVII + XII, 93, 252			04 05 92 HSII + XI, 93, 249		

EV = Einstweilige-Verfügung, HS = Hauptsache,  
I = 1. Instanz, II = 2. Instanz,  
\*+ bzw. \*- Entscheidung für bzw. gegen Patentinhaber  
VIII, 93, 242 = Epilady VIII, GRUR Int. 93, 242



Differentiation! Not desirable – we want reduce it!



# Scope of protection

- Deviations
  - Technology specific: genetics: absolute protection/purpose bound protection
    - Germany, France

Differentiation! Is it legitimate?



COMMISSION OF THE EUROPEAN COMMUNITIES

## 2.1. Scope of patents on gene sequences

The issue to be reviewed according to the first paragraph is whether patents on gene sequences (DNA sequences) are in line with the classical model of patent claim, whereby a first disclosure covers all possible future uses of that sequence, or whether the protection is limited to the specific use disclosed in the patent application (“purpose bound protection”).

TO THE  
Development at

On examination of the detailed provisions of the Directive, articles 4 and 11 make up Chapter 2 of the Directive which contains none of these articles addresses the concept of a limited scope of protection for a specific use identified for the gene sequence compared to the protection conferred by a patent extends to the product or in which the claimed product

information expresses its function. This might be seen as arguing for a broad scope of protection rather than a restricted one, subject of course to the exclusion under Article 5(1) of claims to the human body in its entirety.

On the other hand, it might be thought from Article 5(3) and Recitals 23 and 25 that the Community legislator had intended to at least raise the possibility of a limited scope of protection covering only the specific industrial application identified in the patent, as far as this particular type of invention is concerned. Otherwise Article 5(3), which requires the industrial application of a gene sequence to be disclosed in the patent application, merely repeats a standard requirement of general patent law, as can be seen from Recital 22.

is entitled Scope of protection. However

Against this background, the Commission does not at present intend to take a position on the validity of transposition according to the choice between classical and limited scope of protection for gene sequences. The Commission will, nonetheless, continue to monitor whether there are any economic consequences of possible divergences between Member States' legislation.



# Exercise of rights

- General practice
  - Exploitation
  - Licensing/cross licensing
- Models facilitating licensing
  - Conventional models: “license of right”

The patent proprietor files a written statement with the patent authority that he is prepared to allow any person to use the invention as a licensee in return for appropriate compensation. In that case, a reduction of annual fees will be applied.

- CPC (art. 20)
- German Patent Act (art. 23). Between 1949 – 2002 more than 100.000 statements [Krasser]. Effect on subsequent licensing relations?

**Differentiation! Further research needed!**

- New models: collaborative rights management
  - Success is technology related
    - ICT: successful [industry standard]
    - Genetics: difficult, cumbersome [incentive?]



SCIENCE AND SOCIETY

# Models for facilitating access to patents on genetic inventions

Geertrui Van Overwalle, Esther van Zimmeren, Birgit Verbeure and Gert Matthijs

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Review

TRENDS in Biotechnology Vol.24 No.3 March 2006

Full text provided by www.scie



## Patent pools and diagnostic testing

Birgit Verbeure<sup>1,2</sup>, Esther van Zimmeren<sup>1</sup>, Gert Matthijs<sup>2</sup> and Geertrui Van Overwalle<sup>1</sup>

<sup>1</sup>Centre for Intellectual Property Rights, Faculty of Law, University of Leuven, Belgium

<sup>2</sup>Centre of Human Genetics, Faculty of Medicine, University of Leuven, Belgium

VAN ZIMMEREN, E., VERBEURE, B., MATTHIJS, G., & VAN OVERWALLE, G.,  
'A Clearinghouse for Diagnostic Testing: the Solution to Ensure Access to and Use of Patented Genetic Inventions?', *Bulletin of the World Health Organization*, 2006, 352-359

Differentiation desirable! How to realize?



# Exercise of rights

Patent licensing in human genetics within the European Union: a survey on common and new licensing approaches

2007-2008

Drs. Esther van Zimmeren, LL.M

Collaborative rights mechanisms: 'markets for lemons'?

2007-2001

Prof. Dirk Czarnitzky

**Project: "Gene Patents and Public Health"**  
**Centre for Intellectual Property Rights, University of Leuven**





# Exercise of rights

- Limitations. Compulsory licenses
  - *Non technology specific*
    - Non use
    - Dependancy
  - *Technology specific*
    - Public health

**Differentiation! Do we want more?**



# Patent term

- General rule
  - High quality [*inv st*], fully fletched patent
  - High cost
  - 20 years
- Alternative: “petty patent” “utility model”  
“Gebrauchsmuster”
  - “Lower” quality [*inv st*], restricted patent
  - Lower cost
  - 6 years

**Differentiation! Technology tailored? [Life cycle product]**



# Patent use

- General rule
  - High quality [*inv sf*]
  - High cost
  - Plethora of uses: exploitation, licensing, monetisation..

- Need for alternative

- Current proposal floating around: “Social patent”
    - Low/No cost
    - No use for exclusionary commercial purposes

[Cf. Arti RAI & James BOYLE, Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons, *PLoS*, March 2007]

- My proposal
    - High quality
    - Moderate cost
    - Differentiation in use and subsequent differentiation in maintenance fees

[example: *exploitation*: high fee; *exclusive* license: relatively high fee; *non-exclusive* licenses: low fee]

**Differentiation use of the patent – Welcome! Feasible?**



# Conclusion

## 1. Eligible subject matter:

Differentiation! Non-exclusive lists + interpretation problems! Do we need more?

## 2. Patentability requirements

Hardly any differentiation! Do we want more?

## 3. Scope of protection

*Application Protocol:* Differentiation! Not desirable – we want reduce it!

*Purpose bound:* Differentiation! Is it legitimate? Do we want to apply it beyond genetics?

## 4. Exercise of rights

*“License of right”:* Differentiation! Further research needed!

*Collaborative rights models:* Differentiation desirable! How to realize?

*Limitation of rights (compulsory licensing):* Differentiation! Do we want more?

## 5. Patent term

*Petty patents:* Differentiation! Technology tailored? [Life cycle product]

## 6. Patent use

Differentiation *use of the patent* – Welcome! Feasible? Differentiation of maintenance fees!