K.U.Leuven

One size fits all?

How unitary is the present European patent system?

Geertrui Van Overwalle
Centre for Intellectual Property Rights, K.U.Leuven, Belgium

EUPACO
Brussels, 15-16 May 2007

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"

No 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, *Existance, Scope and Form of Generally Accepted and Applied Standards/Norms for the Protecting of Intellectual Property,* Sepember 1988 (Doc. WO/INF/29)

End of differentation?

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)

Differentation! 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?

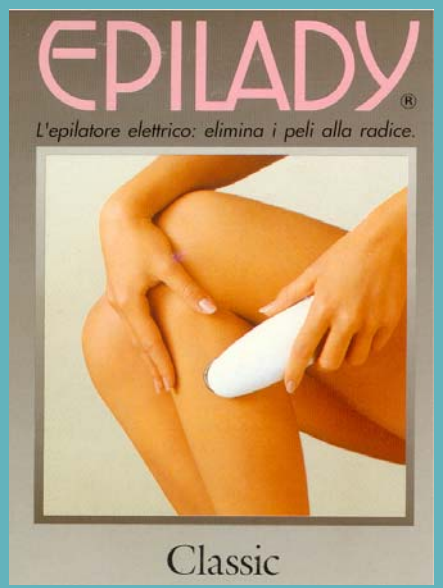
Hardly any differentation! Do we want more?

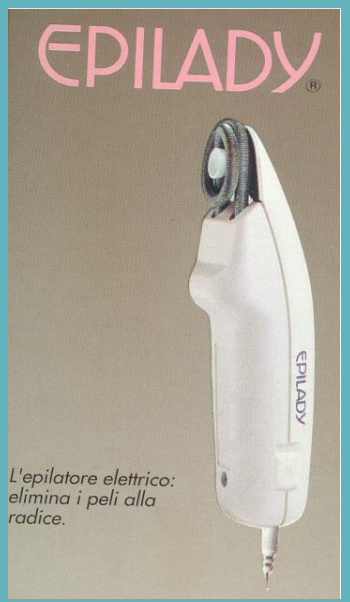
Scope of protection

- 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 Ert. 05.11.86							
E I 19.06.87 E II 01.07.87	19.07.88 EV I + I, 90, 471		14.07.88 EV I - II, 90, 474		18.07.88 EV I + XI, 93, 249		16.06.88 EV I + VII, 92, 385
E III 24.08.88 (Art.105 EPÜ)	27.10.88 EVII - I, 90, 471	16.03.88 EV I + IV, 90, 476	12.06.88 EVII + II, 90, 474	02.11.88 EV I + III, 90, 477		13.03.89 EV I - V, 92, 53	
	30.12.88 HS I + VIII, 93, 242	29.06.89 EVII IV, 90, 476	16.05.89 HS I - IX, 93, 245	02.10.89 HS I - X, 93, 246		31.07.89 EVII - V, 92, 53	
12.10.89 Widerruf Beschwerde		13.11.89 Einstellung Zwangsvollstreckung					
	01.03.90 Einstellung Zwangsvollstreckung	28.11.89 Gutachten Bijzonder Afdeling		04.09.90 HSII - X, 93, 248			25.06.90 EVII + VII, 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

Differentation! Not desirable – we want reduce it!

Scope of protection

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

Differentation! Is it legitimate?

COMMISSION OF THE EUROPEAN COMMUNITIES

TO THE

Development au

2.1. Scope of patents on gene sequences

The issue to be reviewed according to the firs whether patents on gene sequences (DNA seq classical model of patent claim, whereby a first possible future uses of that sequence, or whethe the specific use disclosed in the patent ap protection").

On examination of the detailed provisions of the and 11 make up Chapter 2 of the Directive which is entitled "Scope of protection". However none of these articles addresses the concept of a specific use identified for the gene sequence con the protection conferred by a patent extends t claimed product or in which the claimed pro

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.

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?

    Differentation! 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

NATURE REVIEWS | GENETICS VOLUME 7 | FEBRUARY 2006 | 143

Review *TRENDS in Biotechnology* Vol.24 No.3 March 2006

Patent pools and diagnostic testing

Birgit Verbeure[1,2], Esther van Zimmeren[1], Gert Matthijs[2] and Geertrui Van Overwalle[1]

[1]Centre for Intellectual Property Rights, Faculty of Law, University of Leuven, Belgium
[2]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

Differentation 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, LLM

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

CIR

Exercise of rights

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

Differentation! 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

Differentation! Technology tailored? [Life cycle product]

Patent use

- General rule
  - High quality [*inv st*]
  - High cost
  - Pleithora of uses: exploitation, licensing, monetisation..
- Need for alternative
  - Current proposal floating around: “Social patent”
    - Low/No cost
    - No use for exclusionairy 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]

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

Conclusion

1. Eligible subject matter:
   Differentation! Non-exclusive lists + interpretation problems! Do we need more?
2. Patentability requirements
   Hardly any differentation! Do we want more?
3. Scope of protection
   ***Application Protocol:* Differentation! Not desirable – we want reduce it!**
   ***Purpose bound:* Differentation! Is it legitimate? Do we want to apply it beyond genetics?**
4. Exercise of rights
   ***"License of right":* Differentation! Further research needed!**
   ***Collaborative rights models*: Differentation desirable! How to realize?**
   ***Limitation of rights (compulsory licensing):* Differentation! Do we want more?**
5. Patent term
   ***Petty patents:* Differentation! Technology tailored? [Life cycle product]**
6. Patent use
   Differentation *use* of the patent – Welcome! Feasible? Differentation of maintenance fees!