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MOTION FOR A RESOLUTION

to wind up the debate on the statement by the Commission

pursuant to Rule 103(2) of the Rules of Procedure

by Maria Berger

on behalf of the PSE Group

on patents for biotechnological inventions

B6-0552/2005

European Parliament resolution on patents for biotechnological inventions

The European Parliament,

– having regard to Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions,

– having regard to the Commission Communication of 23 January 2002 entitled 'Life Sciences and Biotechnology', which aims to promote biotechnology within a flexible regulatory framework and ensure consistency across policies, sectors and biotech stakeholders,

– having regard to the first report under Article 16(c) of Directive 98/44/EC from the Commission to the European Parliament and the Council of 7 October 2002 on 'The development and implications of patent law in the field of biotechnology and genetic engineering' (COM(2002) 545 final),

– having regard to the second report under Article 16(c) from the Commission to the European Parliament and the Council of 14 July 2005 on 'The development and implications of patent law in the field of biotechnology and genetic engineering' (COM(2005) 312 final) and (SEC(2005)943),

– having regard to Rule 103(2) of its Rules of Procedure,

A. whereas it is essential to implement Directive 98/44/EC quickly, but at the same time we need to keep a close eye on this fast-moving field and to make sure that the European policy framework keeps pace with technical and legal developments on the interface between patent law and the biotechnological sector,

B. whereas, in order to ensure that Europe excels in biotechnology, we need a robust European system for protecting biotechnological inventions,

C. whereas the issue to be reviewed, according to the first report under Article 16(c), is the question of whether patents on gene sequences (DNA sequences) should be allowed in accordance with the classical model of patent claim, whereby a first inventor can claim an invention which covers possible future uses of that sequence, or whether the patent should be restricted so that only the specific use disclosed in the patent application can be claimed ('purpose-bound protection'),

D. whereas the Commission has launched a study analysing the extent of human DNA patenting in Europe and its potential effects on research and innovation, the overall aim of which is to provide an evidence-based analysis of the dynamics of patent applications and grants claiming human DNA sequences, in the form of a project starting on 1 January 2005 and ending on 30 June 2006,

E. whereas the diversity of legal regimes regulating human embryonic stem cell research in

Europe, together with the subsidiarity principle, which devolves competency on legislation concerning ethical aspects, causes uncertainty as to the legal scope of the 'moral exclusion' clause in Article 6 of Directive 98/44EC of 6 July 1998 on the legal protection of biotechnological inventions,

1. Welcomes the setting up of an informal Group of Advisers on the Ethical Implications of Biotechnology, as announced in the first report under Article 16(c), which is mandated to analyse important issues surrounding biotechnological inventions and advise the Commission on the preparation of future reports;

2. Welcomes the Commission proposal to monitor any consequences of possible divergences between Member States' legislation;

3. Welcomes the decision of the Commission to launch a further study looking at the ethical and legal aspects of stem cell patenting, and recommends involving social aspects also;

Scope of patents on gene sequences

4. Shares, with regard to the issue of whether patents on gene sequences (DNA sequences) should be allowed in accordance with the classical model of patent claim or whether the patent should be restricted so that only the specific use disclosed in the patent application can be claimed ('purpose-bound protection'), the Commission's conclusion of not taking a position now, but continuing to monitor developments and awaiting the outcome of the abovementioned study;

Patentability of human embryonic stem cells and cell lines obtained from them

5. Shares the view of the European Group on Ethics that there is no ethical reason for a complete ban on patenting of inventions relating to stem cells or stem cell lines, although the normal requirements of patentability would have to be met;

6. Takes the view, with regard to totipotent stem cells, that it derives from Directive 98/44/EC that the human body at the various stages of its formation and development cannot constitute a patentable invention;

7. Shares the Commission's view, with regard to pluripotent cells, that it is premature to give any further definition or provide for further harmonisation in this area;

Conclusions

8. Supports the conclusions of the second report concerning the scope of patents and the patentability of stem cells;

9. Calls on the European Commission to continue monitoring developments, taking into account both the ethical aspects and the potential impact on accessibility and affordability of health care and competitiveness;

10. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the EU Member States.