

Texts adopted by Parliament

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Patents on
biotechnological
inventions

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► European Parliament resolution on patents for biotechnological inventions

The European Parliament,

- having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions⁽¹⁾ ("the Directive"),
- having regard to the Council's Statement of reasons annexed to Common Position (EC) No 19/98 adopted by the Council on 26 February 1998 with a view to adopting Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions⁽²⁾,
- having regard to the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, signed in Oviedo in 1997,
- having regard to the Convention on the Grant of European Patents of 5 October 1973 (European Patent Convention),
- having regard to its resolution of 30 March 2000 on the decision by the European Patent Office with regard to patent No EP695351 granted on 8 December 1999⁽³⁾,
- having regard to the Report from the Commission to the Council and the European Parliament entitled 'Development and implications of patent law in the field of biotechnology and genetic engineering', COM(2005)0312 final,
- having regard to Rule 103(4) of its Rules of Procedure,
 - A. whereas biotechnology is one of the most important technologies for the future and has to be supported by a suitable political framework, also taking account of ethical, environmental and health aspects,
 - B. whereas patents are necessary to promote innovation,
 - C. whereas biotechnology is 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,
 - D. whereas specific problems exist in the area of biotechnology, resulting in a need for general patent law to be fleshed out by appropriate specific rules,
 - E. whereas the definition of ethically motivated limits is of particular importance in biotechnology,
 - F. whereas the European Patent Office granted a patent on 2 February 2005 (EP1257168) that includes a method of selection of human germ cells and of the germ cells themselves,
 - G. whereas opposition has been made to this decision, so that the legal situation is still unclear,
 - H. whereas the European Patent Office has also granted European Patents EP1121015 and EP1196153, which also cover human germ cells, and EP1121015 covering frozen human embryos,
 - I. whereas the European Patent Office accepted the opposition to patent EP695351 (the Edinburgh Patent) and made it clear that patents on human embryonic stem cells cannot be granted,

J. whereas the Directive allows the patenting of human DNA only in connection with a function, but it is unclear whether a patent on DNA covers only the application in this function or whether other functions are also covered by the patent,

K. whereas the issue to be reviewed, according to the first report submitted under Article 16(c) of the Directive, is the question 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 may be claimed ("purpose-bound protection"),

L. whereas over-generous granting of patents can stifle innovation,

M. whereas the public must be fully informed and the European Union must play a leading role in promoting public debate,

N. whereas for the creation of embryonic stem cells embryos have to be destroyed and the patenting of technologies where human embryos are destroyed or used for commercial or industrial purposes is excluded according to Article 6(2)(c) of the Directive,

O. whereas Article 6 of the Directive excludes the cloning of human beings and the Council made it clear in its explanatory statements to Parliament that this ban on patenting does not cover only reproductive cloning and that the term 'human being' in this regard includes the embryonic phase,

1. Supports biotechnology as a future technology and considers that an appropriate political framework is important to support this technology, also taking account of ethical, environmental and health aspects;
2. Considers the patenting of biotechnological inventions in accordance with common rules throughout Europe to be an important precondition for the provision in Europe of appropriate support for this future technology;
3. Supports further stem-cell research and other alternatives to promote human health but underlines its fundamental position regarding the application of biotechnology to human beings, especially the rejection of interventions in the human germ line, the rejection of cloning of the human being in all phases of its development and the rejection of research on human embryos, which destroys the embryo;
4. Considers that the Directive provides the framework for this in most cases, but that it still leaves important questions open, such as the patenting of human DNA;
5. Calls on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection);
6. Calls on the Commission to examine whether this interpretation of the Directive can be achieved by means of a recommendation to the Member States or whether it requires an amendment to Article 5 of the Directive;
7. Reaffirms that no consideration of research can be allowed to override that of the dignity of human life;
8. Notes the setting up of an informal Group of Advisers on the Ethical Implications of Biotechnology, as announced in the first report submitted under Article 16(c) of the Directive, which is mandated to analyse important issues surrounding biotechnological inventions and to advise the Commission on the preparation of future reports;
9. Points out that germ cells are not patentable as part of the human body and certainly not an invention, and that patent EP1257168 therefore constitutes an infringement of the Directive;
10. Points out its deep concern about any plan to introduce methods for the selection of sex in humans;
11. Notes that any person may file a notice of opposition to the patent according to Article 99(1) of the European Patent Convention;
12. Asks the Commission to file a notice of opposition to patent EP1257168 without delay;

13. Calls on the European Patent Office, the Commission and the competent authorities in the Member States to work together with Parliament to confirm that all kinds of human cloning are excluded from patenting under the Directive;

14. Insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive;

15. Takes note of the conclusions of the second report concerning the scope of patents and the patentability of stem cells;

16. Calls on the Commission in the next report to consider carefully the proper implementation of Article 4(1)(a) of the Directive;

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

18. Requests the European Patent Office to set up a further body which, because of the sensitivity of the issue, checks patents that are sensitive from an ethical point of view before they are granted;

19. Instructs its President to forward this resolution to the Council, the Commission, the governments of the Member States and the European Patent Office.

(1) OJ L 213, 30.7.1998, p. 13.

(2) OJ C 110, 8.4.1998, p. 17.

(3) OJ C 378, 29.12.2000, p. 95.