01/10/01

OR

MOTION FOR A RESOLUTION with request for inclusion in the debate on topical and urgent subjects of major importancepursuant to Rule 50(1) of the Rules of Procedure by Paul Lannoye, Hiltrud Breyer, Nuala Ahern on behalf of the Group Verts/ ALE

B5-663/01

Resolution on Patenting of Human Genes

The European Parliament,

recalling its resolution of 30 March 2000 on the decision by the European Patent Office with regard to patent No EP 695 351 granted on 8 December 1999, calling on the EPO "to ensure that all ... patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural emvironment ...",

having regard to Article 21 of the 1997 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, according to which "the human body and its parts shall not, as such, give rise to financial gain",

having regard to the "Advice on the patentability of the human genome", adopted by consensus by the International Bioethics Committee of UNESCO (IBC) at the outcome of its Eighth Session on 14 September 2001 which states "that there are strong ethical grounds for excluding the human genome from patentability" and further recommends "that the World Trade Organization (WTO), in its review of the TRIPS Agreement, clarify that, in accordance with the provision of Article 27(2)1, the human genome is not patentable on the basis of the public interest considerations set out therein, in particular, public order, morality and the protection of human life and health",

having regard to the European Patent Convention (EPC), in particular Article 52.2(a) according to which no patents shall be granted for discoveries, and Article 53 (a) which excludes inventions the publication or exploitation of which would be contrary to ``ordre public'' or morality from patentability,

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

having regard to the European Patent No. 699 754 and European Patent No. 705 903,

A. whereas the European Patent Office has granted on 10 January 2001 European Patent 699 754 to the US biotechnology corporation Myriad Genetics Inc. for a method for diagnosing a predisposition for breast and ovarian cancer associated with the BRCA 1 gene; and whereas this patent covering all diagnostic technologies and products using the BRCA 1 gene grants de facto monopoly rights over such tests to Myriad Genetics,

B. whereas the European Patent Office granted a second patent (EP 705 903) to Myriad Genetics Inc. on 25 May 2001 which covers mutations in the 17q-linked breast cancer and ovarian cancer susceptibility gene,

C. whereas Myriad Genetics holds further patents in the field of human genetics, in particular with regard to the BRCA 2 gene in the United States of America and has applied for similar patents to the European Patent Office,

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D whereas Myriad Genetics, according to the Institut Curie, does not intend to grant licences for initial family mutation searches; whereas this would mean that all European laboratories engaged in genetic testing would be obliged to send their DNA samples obtained from high risk individuals to Myriad's testing laboratories in Salt Lake City, where all such tests would have to be performed; whereas the price charged by Myriad is estimated to be between half and three and a half times higher than the price currently charged by European testing laboratories;

E. whereas several Member States have reported major difficulties with the implementation of Directive 98/44/EC and, in particular, its Article 5 which on the hand excludes from patentability "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene" (Art. 5.1), while on the other hand stating that "an element isolated from the human body (...), including the sequence or partial sequence of a gene, may constitute a patentable invention" (Art. 5.2);

Is deeply shocked at the granting by the European Patent Office of patents on human genes;

Notes that the Commission is required to produce every five years a report on any problems encountered with regard to the relationship between Directive 98/44/EEC and international agreements on the protection of human rights to which the Member States have acceded and to publish annually a report on the development and implications of patent law in the field of biotechnology and genetic engineering (Art. 16 of Directive 98/44/EC); that being the case, calls on the Commission to ensure that it submits the first annual report which was due on 30 July 2001, uses that opportunity to report the results of expert meetings, including consultations held by the Commission, on the issue of patenting of genetic sequences in the field of human genetics and to report about any communication between the Commission and the Member States regarding the difficulties to implement the Directive and, in particular, its Article 5;

Notes the concerns of many public research and medical insitutions and private companies that the patenting of genes of human origin may slow down and hinder basic research in human genetics and thereby slow down scientific progress and development of genuine preventive care for high risk patients ;

Maintains that, as regards the possibility of patenting biological material, it is vital to make a clear distinction, which, moreover, already exists in European patent law, between a 'discovery' and an 'invention' to the effect that the former is not patentable; and concludes that while naturally occuring biological materials, whether isolated from their natural surroundings or not, are discoveries and should therefore not be patentable, novel and inventive applications of these materials, should be eligible for process patent protection;

Underlines its position that in the interest of the individual human beings concerned and in the interest of society as a whole, human beings, their genes and cells shall be excluded from patentability;

Calls on the European Patent Office to revise its policy towards patenting of human genes and associates itself with those filing notices of opposition against such patents;

Reiterates its demand for a review of the operations of the European Patent Office to ensure that it becomes publicly accountable in the exercise of its functions, and for amendment

of the European Patent Convention to ensure that the EPO may revoke patents on its own initative;

Undertakes to file without delay an objection to the European patents No. 699 754 and No. 705 903 if legally possible, and calls on the other institutions of the European Union and Member State governments to do likewise;

Calls on the Commission to clarify either by amendment of Directive 98/44/EC or by additional legislation that in the light of Article 5 (1) of the Directive, which excludes "the human body" from patentability, elements isolated from the human body, such as the BRCA 1 gene, shall likewise be considered as being excluded from patentability;

Notes that the status of genetic information should be regulated comprehensively and coherently, reiterates its call on the European Union to defend the principles laid down in the 1992 Convention on Biodiversity and reiterates that it supports a ban on the patenting of animals, plants, micro-organisms and biological and microbiological processes[1];

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

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1 See Resolution **A5-0076/2001** "WTO: Built-in Agenda", *Recommendation 37.*