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Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions'

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On 14 March 1996 the Council decided to consult the Economic and Social Committee, under Article 100a of the Treaty establishing the European Community, on the above-mentioned proposal.

The Section for Industry, Commerce, Crafts and Services, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 19 June 1996. The Rapporteur was Mr Malosse.

At its 337th Plenary Session (meeting of 11 July 1996), the Economic and Social Committee adopted the following Opinion by 106 votes to one, with three abstentions.

1. Introduction

1.1. Justification for a European Directive 1.1.1. The initial 1988 proposal was based on EEC Treaty Article 100a which deals with the establishment and functioning of the European internal market. But as early as 1985 the Commission's White Paper on completion of the internal market had noted that differences in existing intellectual property laws were an obstacle to the development of the internal market.

1.1.2. These differences are the cause of legal uncertainty for inventors and consequently hamper the movement of products spawned by these inventions; they may also give rise to additional costs for businesses. However, even when use is made of the European patent procedure via the Munich Office (18 European states, including 15 from the European Union are currently party to the Munich Convention), the practice of referring back to different Member State rules if appeals procedures need to be instigated makes harmonization necessary. The introduction of common rules throughout the European Union would also be a way of ensuring that the practices of the European Office develop along the same lines.

1.2. The need to adapt patent law to biotechnological innovations 1.2.1. The 1985 White Paper on completion of the internal market also underlined the need to adapt intellectual property rights to recent technological changes in a variety of areas, including biotechnology, and made the point that 'The Commission accordingly intends to propose to the Council measures concerning patent protection of biotechnological inventions`.

1.2.2. When European patent law was introduced thirty years ago it was not possible to discern the scope of biotechnological research and even less foresee the range of possible applications and the various ethical and other problems that might arise. However, as a result of intensive scientific research and major inventions over the last few years, biotechnology has emerged as one of the most innovative and promising of technologies, particularly in the medical and veterinary fields, stockbreeding and the agro-food sector. As a technique applicable to biological matter (cells, genetic information), biotechnology has enabled researchers to make significant progress in understanding the mechanisms of numerous illnesses such as cancer and Alzheimer's disease, in isolating certain bacterial and viral agents of infection (AIDS virus, hepatitis, etc.), and in finding weapons to fight against such diseases. Biotechnology is therefore a source of hope and progress.

1.3. Technological and industrial challenges for Europe 1.3.1. It goes without saying that there are also industrial, economic and commercial challenges and opportunities created by biotechnologies, as well as possibilities for job-creation. It is up to the European Union to meet these challenges and opportunities since the market today is dominated by the USA, as is demonstrated by the recent Ernst and Young studies taken over by the European Patents' Office. The United States, for example, holds 65 % of the patents arising out of biotechnological research in the pharmaceuticals industry, as against only 15 % in the European Union. The US also has 1 300 biotechnology firms compared with 485 in the Union, whilst for every ten genetically modified plants placed on the market in the USA there is on average only one in the European Union.

1.3.2. Hence the brain drain from Europe to America, spurred on by the fact that the level of investment in biotechnologies on the other side of the Atlantic is three times higher than in Europe. The European Union visibly suffers from being over-compartmentalized in its research activities, its industrial fabric and its markets.

The harmonization of legal protection systems is therefore one of the ways to develop this sector in the European Union so that European researchers can see their labours rewarded, industry can make the necessary investment in research and development, legal certainty can be improved and the potential job spin-off realized.

1.4. Information and ethical challenges 1.4.1. Like any new scientific area, and particularly because it affects living matter, biotechnology raises legitimate moral questions. This is true even though it is not the task of patent law to approve the direction of basic research or to authorize the marketing of products arising out of such research.

1.4.2. It is legitimate in this context a) to clarify ethical questions by removing all possible ambiguity, and b) to provide every assurance regarding the citizen's legitimate right to information. Here it needs to be pointed out that the patent system is an excellent tool for disseminating know-how and information.

1.5. The rejection by the European Parliament of the first proposal for a Directive 1.5.1. The first European Commission proposal of 1988 was essentially technical and legal in nature and did not tackle all the problems, particularly those relating to ethics. The Economic and Social Committee's Opinion of 26 April 1989 () likewise stated that the proposed Directive did not 'face up to all the issues` and regretted that 'human beings per se are not expressly mentioned in the Directive as not being patentable`.

1.5.2. The Commission's proposed Directive, which came under the codecision procedure after the Maastricht Treaty entered into force, was finally rejected by the European Parliament at its Plenary Session of 1 March 1995 after the conciliation procedure had been exhausted. The reasons for the rejection essentially boiled down to different interpretations of ethical problems, and particularly the question of the patentability of parts of the human body and the genetic manipulation of the human body. This also happens to be the first text rejected by Parliament under the conciliation procedure.

1.5.3. Following this rejection, the European Commission considered it appropriate to present an amended proposal soon after. This was because, despite the 1 March 1995 vote, substantial amendments had already been made to the initial proposal during the conciliation procedure and the Commission was of the view that one further attempt to clarify the text would draw the whole exercise to a successful conclusion.

1.5.4. The Commission justifies the speed with which it has submitted this amended Directive by the continually widening gap between American and European biotechnological firms at a time when prospects for the world market in biotechnologies are looking increasingly optimistic. A 1988 study anticipated a market of around US$ 40 bn. by the year 2000, whereas the most recent estimates indicate that it might even exceed US$ 90 bn.

2. Gist of the amended proposal for a Directive

According to the explanatory part of the document, the new European Commission proposal is expected to improve on the initial draft in four key areas:

2.1. A clearer distinction between invention and discovery. In a discovery, there is no intervention by man to modify and make use of a phenomenon or an existing law of nature. A discovery is therefore not patentable. An invention on the other hand is obtained after a technical process and may therefore be patentable, notably in respect of its industrial applications, provided certain conditions are met.

2.2. Exclusion from patentability of the human body and the parts thereof in their natural state. The new proposal no longer uses the words 'as such`, which had originally caused misunderstandings. Thus a gene or microorganism cannot be patented in their own right. Such materials are only patentable if they have a precise, purposeful function in a technical process susceptible of industrial application and accordingly constitute the starting point for such a process.

2.3. Exclusion from patentability of germ line gene therapy on humans out of respect for human dignity. The methods used in this therapy might make it possible to correct and/or modify the genetic code of a future human being during 'in vitro` fertilization.

2.4. Extension of farmer's privilege to the livestock breeder. This privilege allows the breeder to use the patented animals for breeding purposes on his own farm, or to replenish the size of his herd.

3. General comments

3.1. The Committee urges the Council and European Parliament to rapidly adopt the Directive on the legal protection of biotechnological inventions for the following reasons:

3.1.1. The Committee recognizes that pursuit of harmonization via a European Directive is justified. The Directive will lead to the greater approximation of EU Member States' laws and will strengthen the unity of the European single market.

3.1.2. The Committee endorses the need to harmonize patent law in this promising sector in order to stimulate European research. Biotechnology today makes a key contribution to the marketing of a new generation of medicines which will help to generate considerable progress in the prevention and treatment of serious and at present incurable diseases.

3.1.2.1. Furthermore, in the agricultural sector, progress in biotechnologies makes it possible to increase yields and develop crops resistant to unfavourable climatic conditions, disease, harmful insects and selective herbicides. Such applications may be particularly important in third-world countries.

3.1.3. The Committee feels it should draw attention to the major economic and social implications of the proposed Directive. According to the European Commission the biotechnology sector today is responsible for the direct employment of more than 200 000 people in the European Union. The lack of a clear legal framework curbs the industrial exploitation on our continent of research findings. The first victims of this circumstance are researchers, as well as small and medium-sized enterprises which do not at present have the means to guard against the risk of their inventions being commercially exploited without protection.

3.1.4. Biotechnology nowadays lies at the heart of pharmaceutical research. However, according to the European Patents' Office, 76 % of the pharmaceutical patents filed today originate in the United States, which has clear legislation on the protection of biotechnological inventions. The consequences of Europe's backwardness in this domain may also have repercussions on the public at large. Thus, for example, a large American laboratory marketing a new treatment for AIDS is thinking of initially reserving its products for the American market because of limited production capacity.

3.2. The Committee would like to see an improved text The Committee recognizes that the Commission's new text, which is more comprehensible and better argued than the initial proposal of 1988, is an appropriate starting point for the rapid adoption of a European Directive by the legislative authority. It nevertheless proposes clarifications on ethical questions, more detailed explanations in connection with plant varieties and additional information regarding breeders' rights.

3.3. Ethical questions 3.3.1. The Committee approves in particular the European Commission's intention to provide clear guidance on the legitimate ethical questions raised by Parliament. It calls upon the Council and Parliament to study carefully the Opinion to be delivered by the group of Councillors for Ethics in Biotechnology.

3.3.2. It is essential here for the legislative authority to be quite clear that a legal patent protection system cannot in any way condone practices or processes that are deemed by law to be contrary to public policy and morality, notably as laid down by the Munich Patent Convention.

3.3.3. It is also necessary to make quite clear to the general public that a legal protection system merely confers negative rights (i.e. a ban on use without the consent of the patentee) and does not grant any positive rights regarding the invention. It does not therefore interfere in procedures for examining compatibility with existing rules on ethics, such procedures applying in particular to upstream research activities and to downstream marketing of the products.

3.3.4. Whilst making a clear distinction between aspects of legal protection and the ethical debate, the Committee urges that the Directive should reaffirm the right of the public at large to receive information at all stages of the preparation of new biotechnology products, from the drawing-board via the legal protection phase to final marketing.

3.4. Plant varieties, farming and livestock breeding 3.4.1. In matters pertaining to plant varieties, the text should be clearer about the relationship between plant variety rights and protection by patent. This is particularly important when questions arise about the patentability of plants and the combination of the two forms of protection. A reference to the concept of plant varieties would make it possible to remove potential sources of conflict.

3.4.2. To make it easier to understand the text, the Committee proposes the addition of a new recital to the introductory part of the text reading as follows: 'it is important to make clear that the exclusion from patentability of plant varieties and animal breeds concerns varieties and breeds per se and is without prejudice to the patentability of plants or animals when the application of the underlying invention is not technically limited to specific plant or animal varieties.` 3.4.3. The Committee approves the extension of the farm seed right to livestock breeders (somewhat unhelpfully called the 'farmer's privilege`). It would however help to make clear exactly how this system would work. Without explicit details, the provision might be subject to conflicting interpretations in different Member States.

3.4.4. The Committee shares the concern expressed by many representatives of the farming community on the dangers of the sector becoming over-dependent on industry. It calls upon the Commission to study this question.

4. Specific comments

4.1. Article 1 4.1.1. This Article indicates that the proposal fits into the existing framework of general patent legislation on inventions. It makes clear that it only confers a negative right, i.e. the possibility of prohibiting third parties from using the invention without authorization, and not a positive right, i.e. the right of exploitation and commercialization.

The Committee proposes that this Article be rendered even more explicit by stating that 'this Directive shall be without prejudice to national and Community laws covering the monitoring of research applications and the use or commercialization of research results, particularly with ethical considerations in mind, for the purpose of defining what may be authorized`.

4.1.2. It is also important to point out that when filing an application, proof must be furnished of an invention's function and usefulness, and hence its potential application in industry, and such proof must be verified in the course of the examination of the application.

4.1.3. Both the public's right to information on patents filed, and the many appeals procedures available in the event of a challenge or even a simple doubt, might also be mentioned at this stage. The Committee proposes that the following recital be added:

4.1.3.1. 'Patenting offices already publish all applications for patents, thereby providing the public with general information. However, transparency is essential to the European citizen in order to establish his long-term confidence in scientific innovations and to enable the consumer to choose according to his personal opinion.

Consequently, in cooperation with national authorities, scientific committees, the European agency for the Evaluation of Medicinal Products, the group of Councillors for Ethics in biotechnology, agrobusiness, pharmaceutical industries and European consumer and environmental associations, the Commission should take an initiative to ensure that the citizen's right to information on biotechnological innovations, their applications, the risks, and existing safeguards is fully enforced.` 4.2. Article 2 4.2.1. This Article is new and was not in the previous text. It gives a precise definition of 'biological material`, 'a microbiological process`, and an 'essentially biological process for the production of plants or animals`. Precise definitions are indeed highly important to avoid misunderstandings.

4.2.2. As far as animal breeds are concerned, there exists at present no specific law containing a precise definition. The Committee would underline the arguments in favour of the Community carrying out work to draw up such a definition.

4.3. Article 3 4.3.1. This Article concerns the most controversial point of the previous Directive. One of its provisions excludes the human body and its elements in their natural state (replacing the words 'as such`, which had given rise to the conflict with the Parliament) from the scope of legal protection. Another provision of the same Article specifies under what conditions biological material of human origin may be the subject of a patent, i.e. it must be produced by means of a 'technical process`.

4.3.2. The human embryo, which is a special case, should be excluded from patentability under Article 3. The present wording of this Article does not in fact appear to offer this guarantee since the notion of the human body can be interpreted as not including the embryo. The Committee considers that it would be preferable to include this exclusion in Article 3 to give a higher political profile to the argument.

4.3.2.1. The wording 'in their natural state` does not remove all ambiguities even though it is more explicit than the previous phrase. An explanation would help although this seems to be out of the question (How do you define 'the natural world`?). The Committee should therefore aim at clarity by deleting a reference which may only plunge the reader into uncertainty. Article 3 should thus exclude the human body from patentability with the single exception defined precisely in Article 3(2).

4.3.2.2. The Committee suggests that the beginning of Article 3 be reworded as follows:

'1. The human body, including germ cells and notably the human embryo, and all elements of the human body, shall not be considered patentable inventions.

2. Notwithstanding paragraph 1...` 4.3.2.3. Article 3(2), which spells out the derogation from the ban on patentability of the human body, should be rewritten (especially in certain language versions) to remove all ambiguity and should be based on the first paragraph of Article 27 of the TRIPS () agreement which states that a patent can be obtained for any invention, product of process in any biotechnological area, provided that it is new, implies an inventive activity and is capable of being applied in industry.

4.4. Article 4 4.4.1. The aim of Article 4 is to confirm the patentability of biotechnological inventions subject to the exclusions set out in Article 3. For the text to be more easily understood, the Committee suggests that the order of the two Articles be switched around.

4.4.2. As far as plants are concerned, the distinction which has been drawn between plant varieties and elements of plants should be defined more precisely. This definition could be set out in Article 4 or Article 2 which are given over to definitions and refer to the Community Regulation on plant variety rights () (Article 5 of Regulation 2100/94).

4.5. Articles 5 to 7 4.5.1. These Articles determine the scope of the Directive in respect of microbiological processes (patentable), biological processes for the production of plants or animals (not patentable), and uses of plant or animal varieties and processes for their production (patentable).

4.5.2. With regard to plant varieties, clarification is needed on the distinction between patent rights and breeders' rights under Community Regulation 2100/94.

4.5.3. It should be made clear in the text or in the recitals that plant variety and stockbreeding procedures should be covered by the notion of production processes.

4.6. Article 8 4.6.1. This Article is again intended to clarify the distinction between discovery and invention. The wording is unconvincing and the provisions are restrictive as far as use of the term 'discovery` is concerned.

4.6.2. The Committee proposes that the following sentence be added at the end of the Article to clarify this point:

'merely on the grounds that it already formed part of the natural world and was not the subject of a technical process.` 4.6.2.1. The Committee would also like the wording to be clearer. This could be done by splitting the Article up into two paragraphs. The first paragraph would clarify the concept of 'discovery`, as described in the explanatory section of the document, the second the concept of the 'novelty of a product that has already formed part of the natural world`.

4.7. Article 9 4.7.1. The aim of this Article is to exclude from patentability any inventions whose exploitation would be contrary to public policy or morality, with particular reference to a) germ line gene therapy practised on humans, and b) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps, and animals resulting from such processes.

4.7.2. The Committee fully approves the ban on the patentability of eugenic practices which seek to modify the genetic code of the human being. In the interests of clarity once again, and to indicate total opposition to practices involving the misuse of the human embryo, the Committee suggests that this sub-paragraph be replaced by the following text: 'processes for modifying the genetic identity of germ cells of the human being and of future generations, including conception-related products`.

4.7.3. The Committee also approves the ban on the patentability of processes for modifying the genetic identity of animals if the processes are likely to cause them suffering or handicaps without any benefit or which are out of proportion to the objectives pursued.

4.8. Articles 10 and 11 4.8.1. These Articles clearly circumscribe the scope of legal protection, limiting it to any biological material obtained through multiplication or propagation on the basis of an invention.

4.8.2. There is no doubt, on a perusal of this passage, that a patent on a genetically modified plant applies quite logically to the plant variety using the patented genetic information.

4.9. Article 12 This Article introduces a derogation from the two previous Articles. The derogation authorizes multiplication or propagation when this is explicitly provided for at the marketing stage (e.g. a seed).

4.10. Article 13 4.10.1. This Article authorizes, by extension of the previous derogation, a farmer or livestock breeder to use the plant product or livestock obtained for multiplication or propagation for his own production. The previous proposal made no mention of the livestock breeder's rights.

4.10.1.1. With regard to the limitations and scope of the derogation for farmers, reference is made to Regulation No 2100/94 on the plant variety certificate and its implementing provisions for Member States.

4.10.2. There is no European-level provision laying down the conditions under which this derogation is applicable to livestock breeders. The Committee is concerned that interpretations and national provisions will be too divergent to safeguard the rights of patentees or offer them really adequate protection. The Committee proposes that this area, and particularly the question of the size of the herd eligible to benefit from the derogation, be clarified in the directive or in an ad hoc agricultural regulation.

4.10.3. As far as livestock farming is concerned, the Committee considers that the privilege must apply as much to the livestock itself as to propagating materials. Secondly, the Committee considers that in order to put farmers and livestock breeders on the same footing, the privilege must be applicable to the breeder's herd - and not only to the replenishment thereof.

4.10.4. The Committee consequently proposes that the second paragraph of Article 13 be reworded as follows:

'By way of derogation from Articles 10 and 11, the marketing of breeding stock for a farmer by the holder of the patent or with his consent, implies authorization for the farmer to use propagating material and the protected livestock for breeding proposes on his own farm and for his own herd.` 4.10.4.1. These comments should also be incorporated in recital 30.

4.10.5. Article 13(3), as well as recital 31, should make reference to the Community rules which the Committee would like to see drawn up on derogations for stockbreeders.

4.11. Article 14 4.11.1. This Article specifically concerns patents on plant varieties. Its provisions authorize, via a system of licences, the use of selected varieties which have originally been invented or protected. The provisions also include the granting of a cross-licence to the patentee.

4.11.2. The Committee would draw attention to the need to ensure that in any legislation drawn up through international negotiation, the legitimate rights of patentees are compatible with third-world countries' access to new technologies, particularly in the domain of agriculture and stockbreeding.

4.11.3. The Directive should include provisions extending the licensing system where a breeding right is established for animal breeds.

4.12. Articles 15 and 16 4.12.1. The provisions in these Articles cover the description of the invention which must be supplied, particularly in the form of a sample, to the appropriate authorities so that potential purchasers can have access to it. The provisions also cover the duration of the patent.

4.13. Article 17 4.13.1. This Article governs reversal of the burden of proof to the benefit of the patentee, with the other party now having to justify the manner in which he has manufactured a new product identical to a product obtained by means of a patented process.

4.13.2. This provision is in keeping with European patent law (the principle involved being set out in Article 35 of the Community Patent Convention) and with the intellectual property section (TRIPS) of the GATT agreements.

5. Conclusions

5.1. Whereas the European-wide harmonization of patent law is needed to consolidate the single market,

5.2. Whereas the economic and social stakes are exceedingly high in view of biotechnology's achievements and its prospects for development,

5.3. Whereas there is concern about the fact that Europe is lagging further and further behind the USA in biotechnologies, with disastrous effects on employment and the European drug procurement industry,

5.4. Whereas ethical questions must be tackled with the utmost rigour and clearsightedness but cannot be used as a pretext for inaction,

5.5. Whereas legislation governing patents cannot replace instruments for monitoring compliance with the rules on ethics commonly accepted by society,

5.6. The Economic and Social Committee:

5.6.1. calls upon the legislative authority to take on board the amendments and clarifications proposed by the ESC; by doing so, the text of the Directive (Articles and recitals) will be rendered more explicit, errors of interpretation will be avoided, the public will be better informed, and there will be a better balance between the legitimate rights of both inventors and purchasers so that the successful results of inventions can be disseminated as widely as possible;

5.6.2. approves the proposal for a Directive, subject to these reservations, and calls upon the legislative authority to adopt it rapidly.

Done at Brussels, 10 July 1996.

The President of the Economic and Social Committee Carlos FERRER

() OJ No C 159, 26. 6. 1989.

() TRIPS - Trade-Related Aspects of Intellectual Property Rights.

() OJ No L 227, 1. 9. 1994.