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Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

on the legal protection of biotechnological inventions

(presented by the Commission)

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I. BACKGROUND

A. THE NEED FOR ACTION

THE JUSTIFICATION FOR THE INITIAL PROPOSAL

1. In 1985, the Commission White Paper on completing the internal market stated: *"Differences in intellectual property laws have a direct and negative impact on intra-Community trade and on the ability of enterprises to treat the common market as a single environment for their economic activities [...] The picture has recently been further complicated by the need to adapt existing trademark systems to technological change in a number of areas including [...] biotechnology [...] The Commission accordingly intends to propose to the Council measures concerning patent protection of biotechnological inventions ...".*[1]

   As a result of intensive scientific research and major discoveries over the past four decades in molecular biology, biotechnology has emerged as one of the most promising and crucial technologies. Modern biotechnology constitutes a growing range of techniques, procedures and processes, such as cell fusion, r-DNA technology, biocatalysis, that can be substituted for and complement classical biotechnologies of selective breeding and fermentation. It is science-based, the scientific input being the most crucial element of the technology trajectory. The gap between developments in basic science and their research and development applications is small and diminishing. The impact of the processes, techniques and hardware represented by biotechnology is felt across a number of sectors: health care, agriculture, environmental protection, foodstuffs and industry.

2. Consequently, when publishing its initial proposal in 1988[2], the Commission noted: "The primary purpose of the modern patent system is to promote technical innovation as the major factor of economic growth by encouraging inventive activity through rewarding inventors for their creative efforts. The patent system thus secures costly investment in research and development and industrial exploitation of research results. Simultaneously, the patent system encourages an early and beneficial dissemination of knowledge in the field of activity involved which, without such protection, might be kept secret"[3].

3. The initial proposal highlighted a number of specific problems regarding the application of the patent system to biotechnology. These concerned the interpretation to be given to the conventional patent-law concepts to be applied from now on to biological material that is self-reproducible or reproducible within a biological system. In other words, how should animate material be treated compared with inanimate material? The questions raised concerned the definitions of the terms "subject-matter of the patent", "invention", "novelty", "adequacy of description", "scope of protection", etc.

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(1) Commission White Paper for the European Council in Milan (28-29 June 1985) "Completing the internal market", COM(85) 310 final of 14 June 1985, paragraph 145 *et seq.*

(2) COM(88) 496 final - SYN 159, 17 October 1988; OJ No C 10, 13.1.1989, p. 3.

(3) *Op. cit.*, paragraph 11, p. 6.

4. The applicable patent law is based on the Convention on the unification of certain points of substantive law on patents for invention, concluded in Strasbourg at the Council of Europe on 27 November 1963. Among other things, the Convention defines the conditions governing patentability and determines a number of exceptions to patentability[4]. The content of the Convention was incorporated into the Convention on the grant of European patents, concluded in Munich on 5 October 1973. Seventeen European countries are now party to the Munich Convention (referred to below as the European Patent Convention - EPC), fourteen of which are Member States[5].

5. The Member States' laws on patents for invention have gradually been harmonized in line with the EPC, i.e. they have incorporated the content of the Convention. This process is the result of a Declaration on the adjustment of national patent law, adopted by the governments of the Member States when the Agreement relating to Community patents was signed[6].

6. Thus the Member States' laws on patents for invention and the EPC contain provisions written over thirty years ago, at a time when the scope offered by biotechnology could not be imagined.

7. In the absence of a clear response to the questions outlined above, uncertainty will increase. That uncertainty will hamper the free movement of biotechnological products and investment in research and development for new biotechnological products and processes. How can we be certain that the Member States' patent offices will all react in the same way when confronted with patent applications relating to the same biotechnological invention? And how can we be sure that the national courts to which relevant questions may be referred will all reach the same decision - for example, as regards the scope of protection offered by a patent.

8. Consequently, the Commission's initial proposal contained a number of definitions and rules of interpretation designed to clarify exactly what is patentable and what is not, and to resolve the problems of demarcation with plant variety rights. The proposal also contained provisions whereby patent offices would have had to follow a uniform practice as regards granting patents and assessing applications. Lastly, the scope of protection conferred by a patent for a biotechnological invention was defined.

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(4) The conditions are: novelty, involvement of an inventive step, and industrial application. The exceptions are: *ordre public* or morality, plant or animal varieties, and essentially biological processes for the production of plants or animals.

(5) Finland will be acceding to it very shortly.

(6) The first version of the Convention for the European Patent for the common market, known as the Community Patent Convention (CPC), was signed in Luxembourg on 15 December 1975. It now forms part of the Agreement relating to Community patents, concluded in Luxembourg on 15 December 1989, which has not yet entered into force (OJ No L 401, 30.12.1989, p. 1).

9. The initial proposal was, therefore, largely technical in character. Not that the ethical dimension was ignored but, at that time, it appeared that the exclusion from patentability of inventions the publication or exploitation of which would be contrary to public policy or morality, which was common to all the Member States' legislation on patents for invention and to the EPC[7], met the need to take into account the ethical dimension of biotechnological inventions. Further harmonization of national laws did not appear justified, given that they were already based on a common principle and that each case had to be assessed on its merits[8].

REJECTION OF THE INITIAL PROPOSAL

10. On 1 March 1995 the European Parliament concluded the codecision procedure by rejecting the joint text, approved by the Conciliation Committee on 23 January 1995, for a European Parliament and Council Directive on the legal protection of biotechnological inventions[9]. The measure is thus deemed not to have been adopted, and the legal environment regarding biotechnological inventions is unchanged.

THE CURRENT SITUATION WITHOUT A DIRECTIVE: GREATER LEGAL UNCERTAINTY

11. The vote on 1 March 1995 shows that the plenary sitting of the European Parliament was, ultimately, not able to accept the outcome of the negotiations within the Conciliation Committee.[10] The Commission has, therefore, to acknowledge that the issues raised by the legal protection of biotechnological inventions have still not been resolved in a sure and uniform manner for all Member States. The legal uncertainty that constituted the justification for the 1988 proposal remains.

12. National patent offices and the national courts may always refer to existing legislation that indisputably applies to biotechnological inventions. No technological field is excluded *a priori* from patentability, provided that the conditions governing protection are satisfied. The vote on 1 March may not, therefore, be interpreted as requiring a moratorium - either *de jure* or *de facto*.

13. But patent law now appears even more incomplete and uncertain than in 1988, and it is not realistic to hope that this can always be remedied through an unambiguous and equitable interpretation shared by all the courts in all the Member States. The most important thing is to assess the ethical dimension of certain biotechnological inventions which, unless otherwise clarified by the legislature, could turn out to be a Pandora's box from which emotive issues are constantly likely to emerge.

14. Matters will not resolve themselves with time. An increasing number of patent applications, including in genetic engineering, are being deposited and granted. Consequently, there will be more and more questions to resolve. The European Patent Office's statistics are illuminating in this respect (see Annex).

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(7) Article 53(a).

(8) The classic example of an invention that must be excluded on grounds of public policy or morality is the letter-bomb.

(9) C4-0042/95 - 94/0159(COD), doc PE-CONS 3606/1/95, 21.2.95, OJ No C 68, 20.3.95, p. 26.

(10) See paragraphs 27 to 32 below for a summary of the joint text.

15. Reference to the European Patent Office's activities is justified because, even if - by definition - a directive harmonizing Member States' legislation may not directly influence the EPC and the European Patent Office's rulings, Article 2(2) of the EPC states that "*The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless otherwise provided in this Convention.*" Also, Article 138 of the EPC states, among other things, that "*(1) Subject to the provisions of Article 139, a European patent may only be revoked under the law of a Contracting State, with effect for its territory, on the following grounds: (a) if the subject-matter of the European patent is not patentable within the terms of Articles 52 to 57 ...*"[11].

16. Consequently, the Commission has been forced to acknowledge that it is no use believing that, in the absence of harmonization of national laws on patents for invention, the EPC and the rulings of the European Patent Office would prove sufficient.

17. Nor does the case-law of the European Patent Office yet appear to be very firmly established, and it will take several more years before it can become the first point of reference[12].

18. At present, therefore, it cannot be claimed that all European patents granted and entering the national stage in the designated Contracting States will be interpreted in the same way, regardless of the national court involved. Not only must a decision be taken as to whether an invention may be patented or not; the precise scope of the protection conferred by a patent must also be ascertained if the holder institutes infringement proceedings. In the absence of clear reference points, national courts may react differently. At present, national courts are accustomed to deferring judgment pending the European Patent Office's final decisions. But that will take a long time yet and will not, ultimately, be binding on national courts: the latter will always be free to decide on the basis of the interpretation they regard as correct.

19. As a result of this uncertainty and confusion, some national legislatures may wish to react by adopting differing national legislative solutions. The objective of harmonizing Member States' legislation in order to ensure the smooth functioning of the internal market so as to promote a more competitive economy could thus be directly called into question once again[13].

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(11) Article 139 of the EPC concerns rights of earlier date or the same date. Articles 52 to 57 lay down the conditions governing patentability. Article 53 stipulates the exceptions to patentability: "*European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.*"

(12) For example, on 29 July 1995 the President of the EPO referred a point of law to the EPO's Enlarged Board of Appeal in order to ensure uniform application of the law and, in particular, of Article 53(b) EPC (OJ EPO 9/95, p. 595).

(13) Commission White Paper *Growth, competitiveness, employment*, Bulletin EC, Supplement 6/93, p. 14, Making the most of the single market. Paragraphs 35 and 36 of the Court of Justice's judgment in Case C-350/92, supplementary protection certificate for medicinal products.

20. The Commission is also obliged to note that the French legislature has introduced a new law: Law No 94-653 of 29 July 1994 on respect for the human body[14]. Article 7 of the Law amends the first two subparagraphs of Article L 611-17 of the intellectual property code: "*The following shall not be patentable: (a) Inventions whose publication or implementation would be contrary to "ordre public" or morality, provided that the implementation of such an invention is not considered so contrary merely on the grounds of a legislative or regulatory provision; consequently, the human body, its elements and products and knowledge relating to the overall structure of a human gene or element thereof may not, as such, form the subject-matter of patents.*"

THE NEED FOR FURTHER COMMUNITY ACTION

21. Following the vote by the European Parliament on 1 March 1995, the objective of harmonizing national patent law - by introducing provisions to ensure the free movement of biotechnological products and the smooth functioning of the internal market - still remains to be achieved as regards the legal protection of biotechnological inventions. Thus practical shape has still not been given to this measure, which was announced by the White Paper on completing the internal market.

22. The observations made in 1988 with regard to the shortcomings of the legal environment for biotechnological inventions are all the more valid today. The evident legal uncertainty is bound to prevent the necessary answers being given to the questions now arising with increased urgency.

23. French Law No 94-653 of 29 July 1994 is a sign that the Member States' legislatures will not be able to put up with the current situation for very much longer.

24. It should also be noted that economic forecasts regarding the world market for biotechnological products have become more specific and refined since the initial proposal was published. In 1988, following a study carried out in 1986, the world market by the year 2000 was estimated to be worth USD 40 billion[15]. According to the latest estimates, the world market in the year 2000 is valued at ECU 83.3 billion (see Annex). Accordingly, the Molitor group stresses that: "*The Commission should put forward as soon as possible a new proposal for the legal protection of biotechnological inventions in order to avoid further increasing the gap between the legislative framework for investment in the EU and its main competitive countries*"[16].

25. The industry that invests the most in perfecting new products based on biotechnologies is the pharmaceutical industry. In this connection, the Commission should mention Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products. The Regulation is designed precisely to promote, in Europe, the long and costly research involved in perfecting medicinal products. The aim is to provide equitable compensation for the effective reduction in the protection offered by the patent, which is caused by granting authorization to place medicinal products on the market.[17] The supplementary protection certificate for medicinal products confers

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(14) French Official Gazette of 30 July 1994.

(15) COM(88) 496, *op. cit.*, paragraph 19, p. 8.

(16) Report of the group of independent experts on legislative and administrative simplification, Brussels, 21.6.1995, COM(95) 288 final/2, proposal 5, p. 18.

(17) OJ No L 182, 2.7.1992, p. 1. The fourth recital of the Regulation refers to the present situation leading to a lack of protection which penalizes pharmaceutical research.

the same rights as conferred by the basic patent (Article 5 of Regulation 1768/92). It would be paradoxical to accept a measure which, while designed to increase the European pharmaceutical industry's competitiveness, merely confirms a system of protection that - as regards medicinal products made using biotechnological processes - will become increasingly unsatisfactory unless it is clarified and adjusted.

26. A number of medicinal products are indeed being produced using biotechnology (see figures quoted in the Annex), as is noted in Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. Part A of the Annex to the Regulation specifically refers to the possibility that certain medicinal products may be derived from elements of the human body and points out that some biotechnological processes make it mandatory for the Community to grant authorization for placement on the market[18]. The industry therefore needs to know to what extent it will be able to protect its investments in perfecting new medicinal products.

B. ASSESSMENT OF THE JOINT TEXT APPROVED BY THE CONCILIATION COMMITTEE ON 23 JANUARY 1995

27. The conciliation procedure was initiated because, on 19 September 1994, the Council was unable to accept the amendments supported by the European Parliament at second reading[19].

28. On 23 January 1995 the Conciliation Committee approved a joint proposal. Discussion centred on new wording for the tenth recital of the Council's common position (which became the twelfth recital of the joint text). It had to be determined whether the words "as such" in point (a) of the second subparagraph of Article 2(3) differentiated sufficiently between a discovery and an invention as regards body elements of human origin:[20] "*On this basis, the following inter alia shall be unpatentable: (a) the human body or parts of the human body as such ...*". Eventually a compromise was reached within the Conciliation Committee: the words "*as such*" were retained in the twelfth recital, which was reworded. But there is still some doubt, since the Council and the European Parliament have made contradictory statements regarding the interpretation of that recital.

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(18) OJ No L 214, 24.8.1993, p. 1. The Annex is on page 21, and Part A refers to recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods. Part B of the Annex lists the types of medicinal products that may be placed on the market once the Commission has granted authorization. The list includes new medicinal products derived from human blood or human plasma.

(19) The opinion (first reading) was delivered on 29.10.1992, OJ No C 305, 23.11.1992. The Commission presented an amended proposal on 16.12.1992, COM(92) 589 SYN 159, OJ No C 44, 16.2.1993, p. 36. The Council adopted a common position on 7.2.1994 (Common position (EC) No 4/94, OJ No C 101, 9.4.1994, p. 65). The Commission communicated its views on the common position to the European Parliament on 17.2.1994, SEC(94) 275 final - COD 159. The three amendments supported by Parliament at the second reading are included in Parliament's decision of 5.5.1994, OJ No C 205, 25.7.1994, p. 307. The Commission's opinion on those three amendments is given in document COM(94) 245 final - COD 159, 9.6.1994.

(20) See explanatory memorandum to the report by Parliament's delegation to the Conciliation Committee, 23.2.1995, PE 211.520/déf.

29. The other problem to which a solution seemed to have been found in the joint text was the deletion of *"automatic"* in the thirteenth recital (which became the fifteenth recital of the joint text). That recital explained the limits of the exception to patentability in point (b) of the second subparagraph of Article 2(3) regarding *"processes for modifying the genetic identity of the human being contrary to human dignity"*. The thirteenth recital of the common position stated that, even if it were possible to obtain a patent for a process for modifying the genetic identity of the human being, *"that would in no way imply automatic recognition of the patentability and legitimacy of what is known as germ line gene therapy ..."*. The use of the adjective "automatic" could suggest that there might be non-automatic cases permitting recognition of the patentability and legitimacy of what is known as germ line gene therapy[21].

30. The Conciliation Committee also brought point (c) of the second subparagraph of Article 2(3), which concerns the exclusion from patentability of transgenic animals where certain conditions are not met, into line with the fifteenth recital of the common position (which became the seventeenth recital of the joint text). The aim was to incorporate into the article itself the criterion of proportionality set out in the recital, in order to assess correctly the acceptability of the *"suffering or physical handicaps inflicted on the animals"* in relation to the substantial benefit represented by the invention.

31. The Commission should point out that the criterion of proportionality is justified particularly in view of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[22].

32. Lastly, the European Parliament's delegation to the Conciliation Committee stressed the need to provide for a derogation in respect of breeding stock, analogous to that provided for in respect of farmers in Article 12 of the common position. By way of compromise, the Commission had proposed a declaration [unofficial translation]: "Once a provision has been introduced, under Community law concerning the production of animal varieties, that will enable farmers to use protected livestock for breeding purposes on their own farms in order to replenish their stock, the Commission undertakes to take due account of that provision with a view to incorporating a corresponding derogation into the Directive."

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(21) The purpose of this therapy is to remedy genetic changes that cause serious diseases, thereby preventing them from being passed on to future generations (Opinion No 4 of the Commission's group of advisers on biotechnological ethics, "The ethical aspects of gene therapy").

(22) OJ No L 358, 18.12.1986, p. 1. Article 3 of the Directive states that: *"This Directive applies to the use of animals in experiments which are undertaken for one of the following purposes:*

(a) the development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products:

(i) for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in man, animals or plants;

(ii) for the assessment, detection, regulation or modification of physiological conditions in man, animals or plants;

(b) the protection of the natural environment in the interests of the health or welfare of man or animal."

C. THE LEGAL BASIS

33. Since the objectives of the present proposal are the same as those of the original 1988 proposal, namely to ensure the free movement of patented biotechnological products by harmonizing Member States' laws so as to clarify the legislative environment for such products, the Commission proposes retaining Article 100a of the EC Treaty as the legal basis[23].

34. In drawing up the proposal, the Commission took due account of the provisions of Article 7c of the Treaty and noted that there is currently no need to lay down special provisions or to provide for exceptions.

35. Similarly, the Commission examined the question of the high level of protection required with regard to health, safety, environmental protection and consumer protection under Article 100a(3) of the Treaty. In this connection the Commission wishes to emphasize, in particular, that harmonization of national laws on patents for invention may be carried out only in accordance with a legal framework that already exists or is to be devised concerning health, safety, environmental and consumer protection[24]. A patent for invention does not confer the right to exploit an invention without restriction. A patent merely enables the holder to prohibit third parties from using the invention without authorization. In terms of competition rules, a patent confers a purely negative right of exclusion and not a positive right of exploitation.

The proposal takes into account the Community's international commitments and, in particular, is compatible with Articles 27 and 30 of the Agreement on trade-related aspects of intellectual property rights, annexed to the Agreement establishing the World Trade Organization[25].

The proposal is also compatible with the Convention on Biological Diversity, in particular Article 16(5)[26].

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(23) Paragraph 59 of Court of Justice Opinion 1/94 of 15 November 1994. Paragraph 33 of Court of Justice judgment in Case C-350/92, *op. cit.*

(24) For example, Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms and Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ No L 117, 8.5.1990), Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ No L 214, 24.8.1993), Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (OJ No L 374, 31.12.1990) as amended by Directive 93/88/EEC of 12 October 1993 (OJ No L 268, 29.10.1993).

(25) Council Decision 94/800/EC of 22 December 1994 concerning the conclusion of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ No L 336, 23.12.1994, p. 1).

(26) Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (OJ No L 309, 13.12.1993, p. 1).

II. THE MAIN POINTS OF THE NEW PROPOSAL

A. INVENTIONS AND DISCOVERIES

36. The essential aim of the new proposal is to clarify the distinction between what is patentable and what is not. In other words, its purpose is to confirm that discoveries may not be regarded as patentable inventions. Clarification has proved necessary following the discussions regarding the twelfth recital of the Conciliation Committee's joint proposal, which concerned the patentability of inventions "*incorporating industrially applicable elements obtained in a technical manner from the human body in such a way that they can no longer be ascribed to a particular individual*"[27].

37. Clearly, on no account may harmonization of national laws on patents for invention depart from the basic principles of patent law. In order to qualify for protection, the conditions governing patentability - novelty, involvement of an inventive step, and potential for industrial application - must be satisfied[28]. The consistent application of patent law highlights two further conditions deriving directly from the essential requirement to comply with the three conditions governing patentability:

- the invention must be such that a person skilled in the art can reproduce it (on the information contained in the patent application), and

- the invention must be of a technical nature, in the sense that it must relate to a technical field, must concern a technical problem and must possess technical characteristics that can be set out in the form of claims that define the subject-matter for which protection is sought.

38. The patent law currently applicable in Europe, whether it be the Convention on the grant of European patents (EPC) or the Member States' laws, does not define an invention as such: an invention is identified by reference to the conditions listed in the previous paragraph. However, the patent law currently applicable in Europe does contain a non-exhaustive list of what may not be regarded as an invention: the exclusions are either abstract in character (e.g. discoveries, scientific theories, etc.), or non-technical (e.g. aesthetic creations or presentations of information). Thus an invention must be both practical and technical.

39. Accordingly, as regards the concept of a discovery, the Directives on the examinations carried out by the European Patent Office contain an interpretation based on the consistent application of patent law in Europe: "*If a man finds out a new property of a known material or article, that is mere discovery and unpatentable. If, however, a man puts that property to practical use he has made an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable. To find a substance freely occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters and it is*

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(27) Doc. PE-CONS 3606/1/95, 21.2.1995, p. 4.

(28) Article 1 of the Strasbourg Convention clearly states that: "... An invention which does not comply with these conditions shall not be the subject of a valid patent."

'new' in the absolute sense of having no previously recognised existence, then the substance per se may be patentable"[29].

40. Scientific theories constitute a general instance of discovery: for example, while the physical theory of semiconductivity is not patentable, new semiconductor devices and processes for their manufacture may well be.

41. To sum up, it is fair to say that an invention is something that provides a technical solution to a technical problem. The technical solution may include elements that are excluded from patentability, but that will entail the whole invention being unpatentable only where the application for protection confines itself to elements that are excluded from patentability.[30] The essential factor is the technological contribution, given that this constitutes the human input and that the same result cannot possibly be achieved simply through the interplay of the laws of nature.

42. Assessment of the technological contribution is carried out objectively under patent law. The benchmark for assessing the extent of this contribution is the state of the art as comprised by "*everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application*"[31].

43. In accordance with the principles explained above, a element of the human body that has not been obtained with the aid of a technological process, but simply detached, removed or collected, may not be regarded as a patentable invention. Thus a limb, an organ or a bodily fluid (e.g. sperm, blood, tears or sweat) cannot be patentable. Regardless of whether the limb, organ or bodily fluid concerned ranks as a discovery, the question arises as to what constitutes the technical solution applied to a technical problem. Moreover, that question must be answered with reference to the state of the art. In this instance, a sensible answer to these questions that refers to technology is not possible.

44. The question as to the patentability of sequences of nucleotides of human origin must be understood in the light of the above-mentioned principles. Clearly, DNA - which is made up of some three billion basic pairs (adenine (A) with thymine (T) guanine (G), with cytosine (C)) - is not patentable in its natural state in the human body, since it is a naturally occurring substance. But what about individual genes?

45. DNA is the chemical basis for some 100 000 genes in the genetic code. The order in which the basic pairs occur constitutes the genes' coded information. All the genes gather together in the form of chromosomes representing the genetic inheritance of a cell or of a living organism. That inheritance is passed on to descendent cells and organisms.

46. A cell's DNA is an inert store of information that does not renew or destroy itself. When a gene's information is to be expressed, it must first be copied in the form of a messenger RNA molecule. Proteins are the decoding products of these RNAm's. The genetic information is expressed in the course of the line of descent from gene to RNAm to protein. Proteins are the molecules that actually carry out the genes' instructions. The code that makes it possible to determine a protein's structure (the amino-acid sequence) functions according to a system of universal correspondence. This applies equally to bacteria and mammals: one amino acid corresponds to three successive bases. Nature has selected just twenty amino acids as the building blocks of life, and these are present in all living organisms.

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(29) Guidelines for Examination in the European Patent Office, Part C, Chapter IV, point 2.3.

(30) Article 52(4) EPC, which has been incorporated into legislation in all the Member States.

(31) Article 54(2) EPC, which has been incorporated into legislation in all the Member States.

47. The points set out in the preceding three paragraphs are laws of nature that cannot possibly be covered by patent law. Beyond that, in the case of genes the question is whether the conditions governing patentability may be satisfied as regards certain products or processes related to the processes of life itself.

48. The answer is provided by the conditions governing patentability set out in paragraph 37 and the Directive on the examination referred to in paragraph 39: if the coding region of a gene is identified[32], if a process for obtaining it is perfected[33], if it can be distinguished by its structure[34] and if this biological material provides a technical solution to a technical problem[35], then it is patentable. Clearly, all these operations are highly technical and can be carried out only in accordance with the laws of nature applicable in the case concerned, just as the new molecules that go to make up patentable medicinal products are subject to the laws of organic chemistry applying to compounds of carbon.

49. The state of the art regarding DNAc provides an objective criterion. The additional DNA containing the copy of the genes' coding regions in the form of RNAm is cloned in bacteria. Those bacteria may constitute a genomic bank or a bank of DNAc. Those banks provide an accurate measure of the state of the art so that an assessment can be made as to whether the conditions of novelty, involvement of an inventive step, and industrial application have been met.

50. Accordingly, since nucleic acids obtained from the human body do not have a specific technical purpose, they cannot be patented. How are the criteria inventive step and industrial application to be applied to the subject-matter of an application for a patent for invention if there is no ready measure of their extent? An invention is deemed to involve an inventive step if "*having regard to the state of the art, it is not obvious to a person skilled in the art*". Industrial application is deemed to be possible if the invention "*can be made or used in any kind of industry, including agriculture*". If the specific technical purpose of an invention is not known, then these two conditions cannot be satisfied because there is no state of the art against which to make an assessment.

51. As regards the conventional principles of patent law, there is thus no difficulty in distinguishing between a discovery and an invention with reference to elements of human origin. Elements isolated from the human body by means of a technical process are artificial and thus qualify as inventions, since they are technical solutions invented by man in order to solve technical problems. Nature is incapable of producing this type of element by itself. The techniques employed in order to isolate such elements from the human body work only by means of human intervention.

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(32) In a gene there is only one part that provides the code for the protein. There are other parts that regulate expression, known as regulatory or instigator regions and located mainly upstream from the coded messages defining the structure of the coded protein.

(33) With the aid of restricting enzymes and the PCR technique, enabling a specific region of a whole genome to be detected on the basis of a single cell by replicating it in large quantities *in vitro*.

(34) That is to say the succession of ATGC bases determined by sequencing.

(35) For example, if the coded protein is known, recombinant bacteria can be cloned (i.e. bacteria carrying extraneous DNA and capable of breeding in the form of colonies), along with DNAc (copies of RNAm from cells representing genuinely functional genetic information) in order to obtain a recombinant protein. The recombinant protein is artificial, as is the DNAc taken as a basis. In the case in point, the technical solution to a technical problem is the possibility of reproducing *ex vivo* a substance that nature normally produces only via human beings: e.g. erythropoietine, factor VIII, etc.

52. In the course of the discussions within the Conciliation Committee, Parliament stressed that the words "*as such*" - the aim of which was to distinguish the natural elements of the human body to be excluded from patentability - gave the impression of making discoveries patentable, which they cannot be. Accordingly, in order to clarify the question of the patentability of elements of human origin, it appears sensible not to include the words "*as such*" in the present proposal. At the same time, a clarification has been included in order to highlight the technical possibilities offered by an invention in respect of a element of human origin.

53. The technical discussion concerning the difference between a discovery and an invention as regards elements of human origin took place against the background of interpretative guidelines as to exclusion from patentability on grounds of being contrary to public order or public morality. But the aspects explained above make it possible to establish that this question of difference is a technical one. Thus patent law may not, in itself, affect the fundamental principle excluding all rights of ownership in respect of the human being. A gene or a cell, in their natural state, must be excluded from patentability because they cannot be regarded as patentable inventions. In this respect, patent law does not have to adopt an ethical stance for reasons of public policy or morality. It has only to observe its own principles. In the Commission's view, in the interests of clarity the rule of law relating to this question of excluding from patentability elements of the human body that cannot be regarded as inventions should be tackled within a more appropriate framework. Thus the conventional system of patent law established by the laws of all the Member States and by the EPC will be observed.

B. A CLEAR EXCLUSION FROM PATENTABILITY OF GERM LINE GENE THERAPY ON HUMANS

54. Point (b) of the second subparagraph of Article 2(3) of the Conciliation Committee's joint text excluded from patentability "*processes for modifying the genetic identity of the human being contrary to human dignity*". Two criticisms were made of this Article. Firstly, it was considered that it would introduce an exception to the exclusion provided for by Article 52(4) of the EPC, under which methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not to be regarded as inventions which are susceptible of industrial application. Secondly, the article was criticized for not adopting a clear stance on principle against germ line gene therapy.

55. As regards this position of principle against germ line gene therapy that should have been or should be taken when harmonizing national laws on patents for invention in respect of biotechnological inventions, the Commission can only emphasize that patent law cannot allow itself to adopt a position on principle *erga omnes*. Two important recent statements by committees on ethics serve to stress the complexity of the issue and the difficulty of taking a final decision[36]. While it may not be possible to adopt an ethical stance on principle that may extend beyond the scope of a directive harmonizing legislation on biotechnological inventions, there is no doubt that the present proposal may clearly exclude from patentability germ line gene therapy on humans.

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(36) Opinion No 4 of the Commission's group of advisers on biotechnological ethics, regarding ethical aspects of gene therapy, and the August 1994 report by the sub-committee on human gene therapy of the UNESCO International Bioethics Committee, concerning therapeutic applications of genetic engineering.

C. FARMER'S PRIVILEGE AS REGARDS BREEDING STOCK

56. The Conciliation Committee's joint text did not provide for the direct introduction into patent law of farmer's privilege as regards breeding stock: it referred to the future introduction of Community legislation on animal variety rights, which would include a derogation similar to that contained in Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights[37]. Consequently, when the time came the Commission would have been in a position to propose a specific derogation to be incorporated into legislation on patents for invention, as had been done for the product of a harvest in Article 12 of the Conciliation Committee's joint text.

57. To clarify the situation, the Commission proposes that preferential treatment for farmers in respect of breeding stock be introduced directly into patent law.

D. NEW PRESENTATION

58. In order to make the proposal for a Directive clearer, it seems appropriate to alter its structure. Definitions are now given at the beginning of the text, followed by provisions on patentability. In accordance with the structure of Member States' legislation and the EPC, the first description given is of what may not be regarded as a patentable invention. The extent of, and exclusions from, patentability are then specified. Finally, exclusion from patentability on grounds of public policy or morality is clarified.

III. EXAMINATION OF THE PROVISIONS

Article 1

59. This Article now comprises two paragraphs.

The first is taken over from Article 1 of the Conciliation Committee's joint text (referred to below simply as the joint text)[38]. It states that the proposal fits into the existing framework of legislation on patents for invention and is not intended to introduce patent law applying specifically to living matter.

The second is taken over from Article 18 of the joint text. It seems appropriate to point out at the beginning of the proposal that patent law may on no account depart from the general common law on monitoring the applications of research and exploitation or the commercialization of its results.

Article 2

60. This Article is new and not taken over directly from the joint text.

It contains three definitions.

The first defines biological material as any material containing genetic information that is self-reproducible or reproducible within a biological system. This is taken over from Article 2(2) of the joint text.

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(37) OJ No L 227, 1.9.1994, p. 1.

(38) Doc. PE-CONS 3606/1/95, 21.2.1995.

The second defines a microbiological process as any process involving or performed upon or resulting in microbiological material. A process consisting of a succession of steps is to be treated as a microbiological process if at least one essential step of the process is microbiological. This definition is taken from the second sentence of Article 5(1) and from Article 5(2) of the joint text. Microbiological material, therefore, means any biological material made up of micro-organisms or cellular or subcellular biological material derived from plants, animals or the human body.

The third defines an essentially biological process for the production of plants or animals as any process which, taken as a whole, exists in nature or is not more than a natural plant or animal breeding process. This definition is based on the third sentence of Article 6 of the joint text.

Article 3

61. This Article comprises two paragraphs.

The first stipulates that the human body and its elements in their natural state are not to be considered patentable inventions. It places point (a) of the second subparagraph of Article 2(3) of the joint text in a technical context. Article 3 of the proposal is thus intended to fit in with the conventional system of patent law.

The words "*as such*", which gave rise to the difficulty in interpretation regarding the distinction between a discovery and an invention in relation to elements of the human body, have not been included.

The first paragraph states that "The human body and its elements *in their natural state* are not to be considered patentable inventions." The phrase in italics draws the distinction between a discovery and an invention. As already explained above (paragraph 51), patentability applies to something that is artificial in the sense that it is a technical solution to a technical problem and has been invented by man. Conversely, a discovery concerns something natural. The need to draw a clear distinction provides the justification for referring, in the second paragraph, to a technical process in contrast to what is natural. Thus the words "in their natural state" are used to stress that elements of the human body are to be treated as discoveries and not to be considered as inventions.

The second paragraph stipulates that biological material of human origin may form the subject-matter of an invention.

This provision is necessary in order to make clear that elements of human origin must satisfy the conditions governing patentability before they can be considered inventions.

The clearest way of highlighting the requirement for there to be an invention is to stress the fundamental principle of patent law: in order to qualify for protection, the subject-matter must constitute a technical solution to a technical problem. It thus proves essential to stress the industrial application requirement. All technical activity is covered, since patent law defines the condition as follows: "*An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.*"

The industrial application of an invention is specified in the description that must be submitted when the patent application is filed. The description must be sufficiently clear and comprehensive for someone skilled in the art to be able to carry it out. Accordingly, it must:

- specify the technical field to which the invention relates;

- indicate the previous state of the art;

- explain the invention such that the technical problem and the solution can be understood;

- specify in detail at least one way of making or doing the thing invented.

Descriptions of nucleotide and amino-acid sequences in patent applications have now been standardized under World Intellectual Property Organization (WIPO) standard ST.23[39].

There is thus no problem in affirming that patent law places at the disposal of all interested parties the scientific information relating to the invention. All patent applications are published. Consequently, obtaining a patent can in no way be taken as indicative of a wish to stifle research. Patent law is absolutely clear on this point, since it states that it does not extend to "*acts done for experimental purposes relating to the subject-matter of the patented invention*"[40].

An element of human origin that is capable of industrial application must be "*isolated from the human body or otherwise produced by means of a technical process*". This form of words has been chosen in order to show, as clearly as possible, that the patentable element is no longer in its natural state in the human body.[41] It is the result of an artificial process.

The restricting enzymes technique, which enables a nucleotide sequence to be isolated from the genetic code, and ACP, which enables a nucleotide sequence to be replicated *in vitro* in a large quantity, can work only after human intervention. The wording "*isolated from the human body or otherwise produced by means of a technical process*" should therefore be taken in the context of these two techniques.

The second paragraph ends with the words "*even if the structure of that element is identical to that of a natural element*". This wording is taken from the twelfth recital of the joint text, and was suggested by Parliament's delegation to the Conciliation Committee. It needs to be included in the main body of the text because the chemical structure of an element isolated from the human body by means of a technical process that may form the subject-matter of an invention capable of industrial application might be identical to the chemical structure of the element such as it occurs naturally inside the human body. This is so in the case of enzymes, for example.

Article 4

62. The first paragraph is based on Article 2(1) of the joint text, and states that biological material is patentable.

The second paragraph is based on Article 3 of the joint text. It confirms that plants and animals and elements thereof are to be patentable as biological material. There is one exception, however: plant and animal varieties as such, in accordance with Article 53(b) of the EPC.

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(39) Supplement No 2 to EPO Official Journal No 12/1992.

(40) Article 27(b) of the Luxembourg Agreement relating to Community patents. The Agreement has not yet entered into force, but this Article has been incorporated into legislation in all the Member States.

(41) See earlier in paragraph 61.

Article 5

63. This Article is based on the first sentence of Article 5 of the joint text. It states that microbiological processes and products obtained by means of such processes are to be patentable. The latter point was not included in the joint text, but it is helpful to follow the wording of Article 53(b) of the EPC (which has been incorporated into legislation in all the Member States).

Article 6

64. This is based on the first sentence of Article 6 of the joint text, and states that essentially biological processes for the production of plants or animals are not to be patentable.

Article 7

65. This is based on Article 4 of the joint text.

It states that uses of plant or animal varieties and processes for their production, other than essentially biological processes for the production of plants or animals, are to be patentable.

Article 8

66. This is based on Article 7 of the joint text.

It states that the subject-matter of an invention concerning a biological material is not to be considered a discovery or lacking in novelty merely on the grounds that it formed part of a naturally existing material. This Article merely emphasizes the need for an invention to be a technical solution to a technical problem. In order not to be regarded as a discovery (see paragraph 32 of this Explanatory Memorandum) or as lacking novelty, it must constitute a technical advance. The invention may be based on something that already existed in nature which it transforms and distinguishes.

Article 9

67. This is based on points (b) and (c) of the second subparagraph of Article 2(3) of the joint text.

It concerns exclusions from patentability on grounds of public policy or morality. The aim is to establish two general guidelines (rather than three, as there were in the joint text - see paragraph 53) on which to base future interpretations of this possibility for exclusion. Such interpretation should be a genuine reflection of the ethical dimension of biotechnological inventions.

Point (a) restates, in simplified form, point (b) of the second subparagraph of Article 2(3) of the joint text.

Its purpose is to reflect the detailed discussions held on the scope of the joint text as regards the exclusion from patentability of processes that alter the genetic identity of human beings.

To that end, it is proposed to exclude directly from patentability "*methods of germ line gene therapy on humans,*" i.e. therapy that could alter reproductive cells capable of transmitting genetic material to descendants.

Point (b) is identical to point (c) of the second subparagraph of Article 2(3) of the joint text.

Article 10

68. This is based on Article 9 of the joint text.

The first paragraph stipulates that the protection conferred by a patent on a biological material possessing, as a result of the invention, specific characteristics is to extend to any biological material derived from that biological material through multiplication or propagation in an identical or different form and possessing the same characteristics.

The second paragraph provides for the same extent of protection as regards a process enabling a biological material to be produced possessing, as a result of the invention, specific characteristics.

Article 11

69. This is based on Article 10 of the joint text.

It states that the protection conferred by a patent on a product containing or consisting of genetic information is to extend to all material in which the product is incorporated and in which the genetic information is contained and expressed.

It should be noted at this point that the concept of genetic information automatically makes reference to a material substratum on which it is based, namely deoxyribonucleic acid. The order in which the four bases A T G C occur constitutes the genes' coded information. Such information cannot be considered to be the same as the scientific information contained, for example, in scientific publications. But the dissemination of knowledge through the publication of a patent application contributes to the expansion of scientific knowledge concerning biotechnology.

Article 12

70. This is based on Article 11 of the joint text.

It states that the protection referred to in Articles 10 and 11 is not to extend to biological material obtained from the multiplication or propagation of biological material marketed in the territory of a Member State by the holder of the patent or with his consent, if the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the obtained material is not subsequently used for other multiplication or propagation.

Article 13

71. The first paragraph is based on Article 12 of the joint text.

It provides for a derogation from Articles 10 and 11 as regards the scope of the protection conferred by a patent on a biotechnological invention.

The derogation concerns the sale, to farmers, of patented propagating material. Farmers are authorized to use the product of their harvests for propagating purposes on their own farms. The scope of this derogation and detailed rules governing it are confined to those of the corresponding Community plant variety rights, i.e. Article 14 of Regulation (EC) No 2100/94 of 27 July 1994.

The second paragraph is new.

It introduces a derogation from Articles 10 and 11 in respect of the sale, to farmers, of patented breeding stock. Farmers are to be authorized to use the protected livestock for breeding purposes on their own farms, in order to replenish their numbers.

The third paragraph is also new.

It concerns the extent and the conditions of the derogation in respect of breeding stock. Since there are, as yet, no specific Community provisions concerning animal variety rights, the extent and conditions are to be determined by national laws, regulations and practices.

Article 14

72. This is based on Article 13 of the joint text.

It introduces a system of compulsory cross-licensing where a breeder cannot acquire or exploit a variety right without infringing a prior patent, and vice versa.

Two conditions have to be met when submitting a licence application to the competent authority in the Member State concerned:

- the applicant must demonstrate that he has applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence, and

- that exploitation of the plant variety or the invention constitutes significant technical progress.

Article 15

73. This is based on Article 14 of the joint text.

It concerns the deposit of, and access to, a biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art.

In this case, the written description of the invention must be supplemented by a physical component accessible at least to the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure.

At 15 April 1995, 35 countries were party to the Budapest Treaty, including 12 Member States (Ireland, Luxembourg and Portugal are not yet party to it). Recognition has been accorded to 28 international depositary authorities, including 12 in the Member States.

Article 16

74. This is based on Article 15 of the joint text.

It concerns the re-deposit of a biological material which ceases to be available from the recognized depositary institution, either because that institution has lost its status or because the biological material is no longer "live".

Article 17

75. This is based on Article 16 of the joint text.

It confirms that, if the subject-matter of a patent is a process for obtaining a new product, the reversal of the burden of proof also applies to biotechnological inventions.

Anyone other than the holder of the patent will be required to prove that he has not made the new product by means of the patented process.

The principle of reversal of the burden of proof is set out in Article 35 of the Community Patent Convention and must be regarded as a fundamental principle of European patent law on which the Directive has to be based.

Article 18

76. This is based on Article 19 of the joint text.

It is the standard final provision regarding the bringing into force, by Member States, of the laws, regulations and administrative provisions necessary to comply with the Directive. The deadline for doing so will be stipulated at the appropriate stage.

Article 19

77. This is based on Article 20 of the joint text.

It states that the Directive is to enter into force on the day of its publication in the Official Journal of the European Communities, in accordance with Article 191 of the Treaty.

Article 20

78. This is based on Article 21 of the joint text.

It states that the Directive is addressed to the Member States.

79. Article 8 of the joint text has not been incorporated into the draft proposal.

It concerned the patentability of processes comprising a succession of steps, one or more of which involve a method of treatment of the animal body by surgery or therapy or a diagnostic method practised on the animal body.

The original purpose of this Article was to provide for very specific cases involving the transfer of embryos between animals. It has since become clear that this is not a biotechnological problem.

80. Nor has Article 17 of the joint text been incorporated.

It laid down transitional provisions regarding the derogation in respect of the sale, to a farmer, of propagating material by the holder of a patent or with his consent. The transitional arrangements have since been superseded by the full entry into force, on 27 April 1995, of Council Regulation (EC) No 2100/94 on Community plant variety rights.

INFORMATION ON THE INDUSTRIES USING BIOTECHNOLOGY

- While the actual economic prospects of the biotechnology product market have not immediately matched the hopes pinned on the industrial openings for applications of this new technology, the **forecasts for the year 2000 show the market** really taking off (see following table in billions of ecus, source: CEFIC-SAGB, 1994):

	Medicinal products	Chemicals	Agriculture & foodstuffs	Environment	Plant	Total
Current market	1.2	0.1	2.4	0.4	1.0	5.1
Market in 2000	23.9	14.6	40.0	2	2.8	83.3

- The data available for the medicinal products sector make it possible to assess more accurately the position of European firms compared with their competitors from the United States and Japan. **The following table lists the world's top 15 "biopharmaceutical" firms by turnover** generated from medicinal products manufactured using biotechnological processes and products under licence (source: Datamonitor, 1994):

Company	1993 sales (own products) $ millions	1993 sales (+products under licence) $ millions
Amgen	1 306	2 208
Eli Lilly	830	896
Novo Nordisk	797	1 003
J&J	625	625
Schering-Plough	597	597
S-B	479	479
Genentech	457	1 773
Chugai	404	404
Sankyo	377	377
Pharmacia	336	336
Merck & Co	290	290
Roche	250	250
Ares-Serono	199	199
Genzyme	125	125
Hoechst	121	121

As can be seen from the above table, seven US firms are among the top 15, with four among the top five: Amgen, Eli Lilly, J&J, Schering-Plough, Genentech, Merck & Co, and Genzyme.

The six European firms are Novo Nordisk, S-B, Pharmacia, Roche, Ares-Serano and Hoechst.

Two Japanese firms are listed: Chugai and Sankyo.

- The following table showing the **number of entities involved at the clinical and post-clinical development stages in the fields of biotechnology and immunology highlights** the lead that the United States has over the rest of the world (source: Heinz Redwood, 1993):

Origin	No. of entities (clinical stage)	No. of entities (post-clinical stage)
United States	**101**	**29**
Japan	**12**	**16**
Europe	**46**	**10**
Other	**16**	**6**
Total	**175**	**61**

Expressed in percentages, the picture is as follows:

Origin	No. of entities (clinical stage)	No. of entities (post-clinical stage)
United States	**58%**	**48%**
Japan	**7%**	**26%**
Europe	**26%**	**16%**
Other	**9%**	**10%**
Total	**100%**	**100%**

- The above figures show the leading position held by the United States. A similar picture emerges if we look at the European Patent Office (EPO)'s figures for the number of biotechnology patent applications it received and the number of such patents it granted between 1990 and 1994:

Applications for a European patent in the field of biotechnology:

Origin	1990	1991	1992	1993	1994	Total
EPO member countries	176	199	266	231	247	1119
Japan	75	73	73	59	69	349
United States	146	195	219	342	262	1164
Other	30	23	40	49	42	184
Total	427	490	598	681	620	2816

Expressed in percentages:

Europe	United States	Japan	Other
39.7%	41.3%	12.4%	6.6%

The aggregate percentages for all fields of technology over the same period are as follows:

Europe	United States	Japan	Other
48.60%	28%	19.40%	4%

European patents granted in the field of biotechnology:

Origin	1990	1991	1992	1993	1994	Total
EPO member countries	36	44	54	93	106	333
Japan	33	41	41	46	40	201
United States	38	62	77	76	114	367
Other	1	3	5	8	11	28
Total	108	150	177	223	271	929

Expressed in percentages:

Europe	United States	Japan	Other
35.8%	39.5%	21.6%	3.1%

The aggregate percentages for all fields of technology over the same period are as follows:

Europe	United States	Japan	Other
54.2%	23%	19.8%	3%

The above figures show that United States firms have a much stronger presence on the European biotechnology market than in all other fields of technology.

- As regards European firms' presence on the United States market, a study published in March 1995 by Pharmaceutical Research and Manufacturers of America entitled "Biotechnology drug research has come of age" states that 140 patents relating to genetic-engineering medicinal products were granted by the United States Patent and Trade Mark Office in 1994. The breakdown of those patents by country of origin was as follows:

United States	Europe	Japan	Other	Total
109	16	10	5	140

Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

on the legal protection of biotechnological inventions

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission[1],

Having regard to the Opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty[3],

(1) Whereas biotechnology and genetic engineering are 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;

(2) Whereas the investments required in research and development, particularly for genetic engineering, are especially high and especially risky and the possibility of recouping that investment can only effectively be guaranteed through adequate legal protection;

(3) Whereas without effective and harmonized protection throughout the Member States such investments might well not be made;

(4) Whereas following the European Parliament's rejection of the joint text, approved by the Conciliation Committee, for a European Parliament and Council Directive on the legal protection of biotechnological inventions[4], the European Parliament and the Council have determined that the legal protection of biotechnological inventions cannot be left as it currently stands;

(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the Member States; whereas such differences could create barriers to trade and to the proper functioning of the internal market;

(6) Whereas such differences in legal protection could well become greater as Member States adopt new and different legislation and administrative practices, or as national case law interpreting such legislation develops differently;

(7) Whereas the uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could result in the creation of new disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;

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(1) OJ No C

(2) OJ No C

(3)

(4) OJ No C 68, 20.3.1995, p. 26.

(8) Whereas the legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions; whereas, however, they must be adapted or added to in certain specific respects in order to take full account of technological developments involving biological material which also fulfil the requirements for patentability;

(9) Whereas harmonization of the laws of the Member States is necessary to clarify certain concepts in national laws originating in certain international patent and plant variety conventions which have led to some uncertainty as to the possibility of protecting biotechnological inventions concerning plant matter and certain microbiological inventions, concepts such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals;

(10) Whereas the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such - such principles being intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin - and can be further limited to defining the scope of the protection accorded by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions, to a reversal of the burden of proof and to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions;

(11) Whereas a patent for invention does not authorize the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to call into question national and Community law on the monitoring of research and of the use or commercialization of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

(12) Whereas no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes a priori the patentability of biological matter;

(13) Whereas it should be specified that knowledge relating to the human body and to its elements in their natural state falls within the realm of scientific discovery and may not, therefore, be regarded as patentable inventions; whereas it follows from this that substantive patent law is not capable of prejudicing the basic ethical principle excluding all ownership of human beings;

(14) Whereas significant progress in the treatment of diseases has already been made thanks to medicinal products derived or otherwise produced from elements isolated from the human body, and medicinal products resulting from a technical process aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, the patent system should promote research aimed at obtaining such elements;

(15) Whereas, therefore, it should be made clear that an invention capable of industrial application and based on an element isolated from the human body or otherwise produced by means of a technical process is patentable, even where the structure of that element is identical to that of a natural element, since no patent may be interpreted as covering an element of the human body in its natural environment forming the basic subject of the invention;

(16) Whereas such an element isolated from the human body or otherwise produced may not be regarded as unpatentable in the same way as an element of the human body in its natural state, that is to say, may not be equated with a discovery, since the element isolated is the result of the technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of puting into practice and which Nature is incapable of accomplishing by itself;

(17) Whereas, in order to determine the extent to which plant and animal varieties are to be excluded from patentability, it should be specified that the exclusion concerns those varieties as such and that, consequently, it does not prejudice the patentability of plants or animals obtained by means of a process at least one stage of which is essentially microbiological, irrespective of the basic biological material to which that process is applied;

(18) Whereas, for the purposes of determining whether or not it is possible to patent essentially biological processes for obtaining plants or animals, human intervention and the effects of that intervention on the result obtained must be taken into account;

(19) Whereas national patent laws for inventions contain provisions as to the criteria for allowing or excluding patentability, including provisions to the effect that a patent may not be granted in respect of inventions whose publication or exploitation would be contrary to public policy or morality;

(20) Whereas such a reference to public policy and morality should be included in the operative part of this Directive in order to bring out the fact that some applications of biotechnological inventions, by virtue of some of their consequences or effects, are capable of offending against them;

(21) Whereas it must be determined whether applications offend against public policy and morality in each specific case, by means of an appraisal of the values involved, whereby the benefit to be derived from the invention, on the one hand, is weighed and evaluated against any risks associated therewith, and any objections based on fundamental principles of law, on the other hand;

(22) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to public policy or morality;

(23) Whereas such moral considerations must be given greater weight in appraising the patentability of biotechnological inventions, both on account of the subject-matter of this branch of science, namely living matter, and because of the often far-reaching implications of the inventions to be examined; whereas these considerations do not, however, change the nature of patent law as a primarily technical body of law and are no substitute for the other legal checks which biotechnological inventions are required to undergo from the start of their development or at the marketing stage, particularly with regard to safety;

(24) Whereas, in view of the importance and the controversial nature of the unprecedented questions raised by germ line gene therapy, it is important to exclude unequivocally from patentability any methods of treatment of human beings based on it;

(25) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and also animals resulting from such processes must be excluded from patentability insofar as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued;

(26) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby to encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducible material in situations analogous to those where it would be permitted to prohibit such use of patented, non-self-reproducible products, namely in respect of the production of the patented product itself;

(27) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorize the farmer to use the product of his harvest for further multiplication or propagation on his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Regulation (EC) No 2100/94[5];

(28) Whereas only the fee envisaged under Community plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer;

(29) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against the breeder who has developed the plant variety incorporating the protected invention if the latter fails to adhere to his commitments;

(30) Whereas a second derogation from the rights of the holder of the patent must authorize the farmer to use the protected livestock for breeding purposes on his own farm, in order to replenish their numbers;

(31) Whereas the extent and the conditions of that second derogation should be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;

(32) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in a Member State in the form of a compulsory licence where, in relation to the genus or species concerned, public interest demands the exploitation of the plant variety for which the licence is requested and the plant variety represents significant technical progress;

(33) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access against a fee must be granted in the form of a compulsory licence where public interest demands the exploitation of the invention for which the licence is requested and where the invention represents significant technical progress,

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[5] OJ No L 227, 1.9.1994, p. 1.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I
Patentability

Article 1

1. Member States shall protect biotechnological inventions under national patent law. Member States shall if necessary adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to national and Community laws on the monitoring of research and of the use or commercialization of its results.

Article 2

For the purposes of this Directive,

1. "biological material" means any material containing genetic information and capable of self-reproduction or of being reproduced in a biological system;

2. "microbiological process" means any process involving or performed upon or resulting in microbiological material; a process consisting of a succession of steps shall be treated as a microbiological process if at least one essential step of the process is microbiological;

3. "essentially biological process for the production of plants or animals" means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal-breeding process.

Article 3

1. The human body and its elements in their natural state shall not be considered patentable inventions.

2. Notwithstanding paragraph 1, the subject of an invention capable of industrial application which relates to an element isolated from the human body or otherwise produced by means of a technical process shall be patentable, even if the structure of that element is identical to that of a natural element.

Article 4

1. The subject of an invention shall not be considered unpatentable merely on the grounds that it is composed of, uses or is applied to biological material.

2. Biological material, including plants and animals, as well as elements of plants and animals obtained by means of a process not essentially biological, except plant and animal varieties as such, shall be patentable.

Article 5

Microbiological processes and products obtained by means of such processes shall be patentable.

Article 6

Essentially biological processes for the production of plants or animals shall not be patentable.

Article 7

Uses of plant or animal varieties and processes for their production, other than essentially biological processes for the production of plants or animals, shall be patentable.

Article 8

The subject of an invention concerning a biological material shall not be considered a discovery or lacking in novelty merely on the grounds that it already formed part of the natural world.

Article 9

1. Inventions shall be considered unpatentable where exploitation would be contrary to public policy or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following shall be considered unpatentable:

   (a) methods of human treatment involving germ line gene therapy;

   (b) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and also animals resulting from such processes, whenever the suffering or physical handicaps inflicted on the animals concerned are disproportionate to the objective pursued.

CHAPTER II
Scope of protection

Article 10

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through multiplication or propagation in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the biological material directly obtained through multiplication or propagation in an identical or divergent form and possessing those same characteristics. That protection shall not affect the exclusion from patentability of plant and animal varieties as such, pursuant to Article 4(2).

Article 11

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided for in Article 3(1), in which the product is incorporated and in which the genetic information is contained and expressed.

Article 12

The protection referred to in Articles 10 and 11 shall not extend to biological material obtained from the multiplication or propagation of biological material marketed in the territory of a Member State by the holder of the patent or with his consent, if the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the obtained material is not subsequently used for other multiplication or propagation.

Article 13

1. By way of derogation from Articles 10 and 11, the sale of propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for reproduction or propagation by him on his own farm, the scope of and procedure for this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 10 and 11, the sale of breeding stock to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the protected livestock for breeding purposes on his own farm, in order to replenish their numbers.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

CHAPTER III
Compulsory cross-licensing

Article 14

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by such patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent on a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

   (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

   (b) exploitation of the plant variety or the invention for which the licence is requested is dictated by the public interest and the plant variety or the invention constitutes significant technical progress.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. The licence shall be granted principally for the supply of the domestic market of the Member State which has granted the licence.

CHAPTER IV
Deposit, access and re-deposit of a biological material

Article 15

1. Where an invention involves the use of or concerns a biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:

   (a) the biological material has been deposited, no later than the date on which the patent application was filed, with a recognized depositary institution. At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure, hereinafter referred to as the "Budapest Treaty", shall be recognized;

   (b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;

   (c) the patent application states the name of the depositary institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:

   (a) up to the first publication of the patent application, only to those persons who are authorized under national patent law;

   (b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

   (c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

   (a) not to make it or any matter derived from it available to third parties; and

   (b) not to use it or any biological matter derived from it except for experimental purposes

   unless the patent holder or applicant, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for twenty years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

Article 16

1. If the biological material deposited in accordance with Article 14 ceases to be available from the recognized depositary institutions, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

2. Any new deposit shall be accompanied by a statement signed by the applicant certifying that the newly deposited biological material is the same as that originally deposited.

CHAPTER V
Burden of proof

Article 17

1. If the subject-matter of a patent is a process for obtaining a new product, then, when the same product is produced by any other party, it shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

CHAPTER VI
Final provisions

Article 18

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 2000. They shall immediately inform the Commission thereof.

   When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 19

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 20

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

FINANCIAL STATEMENT

TITLE OF MEASURE

Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions.

DESCRIPTION

The purpose of the measure is to harmonize national laws on patents for biotechnological inventions, with a view to achieving uniform practices by patent offices and uniform national case-law. Harmonization is necessary in order to ensure the free movement of biotechnological products and the proper functioning of the internal market.

The measure has no financial implications for the Community budget.

IMPACT OF THE PROPOSAL ON BUSINESSES (and particularly SMEs)

1. WHY IS COMMUNITY LEGISLATION NECESSARY?

In order to harmonize, at Community level, Member States' legislation on the legal protection of biotechnological inventions, with a view to achieving the following objectives:

(a) to improve the operation of the internal market for patented biotechnological products, so as to ensure their free movement;

(b) to prevent distortions of competition for firms using biotechnology;

(c) to ensure that research and development in biotechnology enjoy appropriate legal protection thanks to harmonization of Member States' legislation;

(d) to improve the competitiveness of industry using biotechnology;

(e) to take due account of the ethical dimension of biotechnological inventions.

2. WHICH INDUSTRIES WILL BE AFFECTED?

(a) The measure will benefit manufacturers of biotechnological products, and particularly firms that base their activities on research.

(b) According to a study published by Ernst & Young in 1995, 485 firms would be affected in Europe. Of those, 81% employ less than 50 people, and 45% were founded after 1986. They cover a wide range of activities: pharmacy, chemicals, agriculture, foodstuffs, the environment and plant. While investment in the research and development of new biotechnological products is high, the return on that investment is uncertain because the legal protection offered by the system of patents for invention is not as clear-cut as in other areas of technology. The proposed measure is such that it would apply to all firms using biotechnology, whatever their size.

(c) There is no reason to suppose that particular geographical areas will benefit more than others from the measure.

3. WHAT MUST BUSINESSES DO IN ORDER TO COMPLY WITH THE MEASURE?

The firms affected will not be required to take any special steps in order to benefit from the planned legislative harmonization.

4. WHAT ARE THE LIKELY ECONOMIC EFFECTS OF THE MEASURE?

(A) ON EMPLOYMENT

Clarifying the legislative environment for biotechnological inventions will provide innovative firms in the various industries using biotechnology with an incentive to continue or even increase their investment in research. Establishing an appropriate legal framework for the protection of biotechnological inventions will encourage innovation. Consequently, the boost given to employment will be most noticeable in the research field.

(B) ON INVESTMENT AND THE ESTABLISHMENT OF NEW BUSINESSES

Harmonization of legal protection for biotechnological inventions should enable the firms concerned to feel far more certain about recouping their costs and investment. Once it is clear that patent law also applies in full to biotechnological products, patent holders will realize that the possible return on sums invested in perfecting such products enjoys a much greater legal guarantee. Patent law does not, of course, guarantee that there will be a market for any given product, but at least research findings cannot be turned to advantage by those not involved in making the necessary initial investment. This is a powerful incentive for setting up new businesses in order to undertake leading-edge research in biotechnology and then market the results. The sector's great promise is borne out by Ernst & Young's figures, which show that many of the firms concerned are newly established and small.

(C) ON THE COMPETITIVENESS OF BUSINESSES

The Commission White Paper *Growth, competitiveness, employment - The challenges and ways forward into the 21st century*[1] places special emphasis on the responsibility of governments and the Community in creating an environment that is as conducive as possible to businesses' competitiveness. Firms using biotechnology must be able to contribute increasingly to the European Union's balance of payments surplus. In order to do so, they need to be able to occupy a position that accurately reflects both their domestic and international competitiveness, so as not to be left behind by developments in other parts of the world.

5. DOES THE PROPOSAL CONTAIN MEASURES THAT TAKE PARTICULAR ACCOUNT OF SMEs?

The harmonization measures contained in the proposal are not particularly designed to assist small and medium-sized enterprises, although they will be able to benefit equally from them.

6. CONSULTATION

In drawing up the proposal, the Commission departments consulted widely with the sectors concerned and with various interest groups. In line with the wishes expressed by Parliament, the purpose of the consultations was to ensure that the legislation governing patents for invention would be clear and unambiguous, that it would contain precise definitions, and that it would distinguish clearly between unpatentable discoveries and patentable inventions.

The Commission departments were in contact with, or received written submissions from: the European Patent Office (EPO), the Union of Industrial and Employers' Confederations of Europe (UNICE), the European Board of Chemical Industry Federations (EBCIF), the European Federation of Pharmaceutical Industry Associations (EFPIA), the European Secretariat of National Bioindustry Associations (ESNBA), the Seed Committee of the Common Market (COSEMCO), Greenpeace, the Chartered Institute of Patent Agents, the Animal Cell Technology Platform (ACTEP), the Green Industry Biotechnology Platform (GIBiP), the Senior Advisory Group on Biotechnology (SAGB), the Agence Nationale pour la Valorisation de la Recherche (ANVAR), Friends of the Earth (Europe), the BioIndustry Association (BIA) and the British Union for the Abolition of Vivisection (BUAV).

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