II

(Preparatory Acts)

COMMISSION

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

(96/C 296/03)

COM(95) 661 final — 95/0350(COD)

(Submitted by the Commission on 25 January 1996)

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,

Having regard to the opinion of the Economic and Social Committee,

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

(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 be guaranteed effectively 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 [1], 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;

(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

[1] OJ No C 68, 20. 3. 1995, p. 26.

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 intervention;

(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 putting 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 in so far 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 Council Regulation (EC) No 2100/94 [1];

(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,

[1] 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 on 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 mateial 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 a 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 20 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 accom-

panied 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 20th day following that of its publication in the *Official Journal of the European Communities.*

Article 20

This Directive is addressed to the Member Sates.

Proposal for a Council Regulation (EC) protecting against the effects of the application of certain legislation of certain third countries, and actions based thereon or resulting therefrom

(96/C 296/04)

COM(96) 420 final — 96/0217(CNS)

(Submitted by the Commission on 31 July 1996)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 113 and 235 thereof,

Having regard to the proposal of the Commission,

Having regard to the opinion of the European Parliament,

Whereas it is an objective of the EC that there should be an open system of international trade and capital investment,

Whereas certain third countries have enacted or are likely to enact certain laws, regulations, and other legislative instruments which purport to regulate the activities of natural and legal persons under the jurisdiction of the Member States of the European Community;

Whereas by their extra-territorial application such laws, regulations and other legislative instruments violate international law;

Whereas these laws and actions based thereon or resulting therefrom, including regulations and other legislative instruments, affect or are likely to affect the established legal order and have adverse effects on the external economic interests of the EC and the interests of natural and legal persons exercising their rights in accordance with the common import and export regimes and on the principle of free movement of capital between the Community and third countries;

Whereas, under these exceptional circumstances, it is necessary to take action at the Community level protecting the established legal order and the external economic interests of the Community and the interests of these persons, in particular by removing, neutralizing, blocking or otherwise countering the effects of the foreign legislation concerned;

Whereas the Commission, in the implementation of this Regulation, should be assisted by a committee composed of representatives of the Member States;

Whereas this action takes the form of measures ancillary to the achievement of the objectives set out above;

Whereas the Treaty does not provide for the adoption of certain provisions of this Regulation powers other than those of Article 235,

HAS ADOPTED THIS REGULATION:

Article 1

Scope of protection

This Regulation provides protection against and counteracts the effects of the extra-territorial application of the laws specified in the Annex and of actions based