Article 27: Patentable Subject Matter
1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28: Rights Conferred
1. A patent shall confer on its owner the following exclusive rights:
   (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
   (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29: Conditions on Patent Applicants
1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.
Article 30: Exceptions to Rights Conferrered

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent;

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32: Revocation/Forfeiture
An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33: Term of Protection
The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

Article 34: Process Patents: Burden of Proof
1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.
DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 July 1998 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,
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, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;
(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;
(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, the European Parliament and the Council have determined that the legal protection of biotechnological inventions requires clarification;
(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;
(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or whereas national case-law interpreting such legislation develops differently;
(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;
(8) Whereas 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 given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;
(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety
conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty;

(10) Whereas regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground; whereas the patent system should be used to encourage research into, and the application of, such processes;

(11) Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world; whereas the patent system should likewise be used to encourage research in these fields; whereas international procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned should be promoted;

(12) Whereas the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology;

(13) 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, to the scope of protection conferred by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions and lastly to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely;

(14) Whereas a patent for invention does not authorise 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 replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation 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;

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

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the
human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;

(18) Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the community and the Member States have a duty to respond adequately to this problem;

(19) Whereas account has been taken of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission;

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of 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;

(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

(25) Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms;

(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;

(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;
Whereas this Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a patented product;

(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;

(30) Whereas the concept 'plant variety' is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties;

(31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;

(32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;

(33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological;

(34) Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent law;

(35) Whereas this Directive shall be without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability;

(36) Whereas the TRIPS Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;

(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive;

(38) 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 ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

(39) Whereas ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;
(40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against *ordre public* and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;

(41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;

(44) Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law;

(45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability;

(46) 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 encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself;

(47) 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 authorise 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 of 27 July 1994 on Community plant variety rights;

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

(49) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against a breeder who has developed a plant variety incorporating the protected invention if the latter fails to adhere to his commitments;
(50) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use protected livestock for agricultural purposes;
(51) Whereas the extent and the conditions of that second derogation must be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;
(52) 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 the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;
(53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;
(54) Whereas Article 34 of the TRIPS Agreement contains detailed provisions on the burden of proof which is binding on all Member States; whereas, therefore, a provision in this Directive is not necessary;
(55) Whereas following Decision 93/626/EEC the Community is party to the Convention on Biological Diversity of 5 June 1992; whereas, in this regard, Member States must give particular weight to Article 3 and Article 8(j), the second sentence of Article 16(2) and Article 16(5) of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive;
(56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPS Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity'.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER-I
Patentability

Article 1
1. Member States shall protect biotechnological inventions under national patent law. They 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 the obligations of the Member States pursuant to international agreements, and in particular the TRIPS Agreement and the Convention on Biological Diversity.

Article 2
1. For the purposes of this Directive,
(a) 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
(b) 'microbiological process' means any process involving or performed upon or resulting in microbiological material.
2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
3. The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3
1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4
1. The following shall not be patentable:
   (a) plant and animal varieties;
   (b) essentially biological processes for the production of plants or animals.
2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5
1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6
1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public 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, in particular, shall be considered unpatentable:
   (a) processes for cloning human beings;
   (b) processes for modifying the germ line genetic identity of human beings;
   (c) uses of human embryos for industrial or commercial purposes;
   (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
Article 7

CHAPTER-II
Scope of protection

Article 8
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 propagation or multiplication 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 directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9
The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

Article 10
The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 11
1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.
2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.
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 12

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 the 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 concerning 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) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

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

Article 13

1. Where an invention involves the use of or concerns 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 recognised 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 microorganisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty', shall be recognised;
   (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 depository 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 authorised 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 material derived from it available to third parties; and
(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, 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 14

1. If the biological material deposited in accordance with Article 13 ceases to be available from the recognised depositary institution, 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 depositor certifying that the newly deposited biological material is the same as that originally deposited.

CHAPTER-V
Final provisions

Article 15

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof.
When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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

Article 16

The Commission shall send the European Parliament and the Council:
(a) every five years as from the date specified in Article 15(1) a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded;
(b) within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable;
(c) annually as from the date specified in Article 15(1), a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

Article 17
This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 18
This Directive is addressed to the Member States.

35 U.S.Code 100-105

35 U.S.C. 100:
When used in this title unless the context otherwise indicates—
(a) The term "invention" means invention or discovery.
(b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.
(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.
(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.
(e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 or inter partes reexamination under section 311 who is not the patent owner.

35 U.S.C. 101:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 102:
A person shall be entitled to a patent unless—
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
(c) he has abandoned the invention, or
(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
(e) the invention was described in
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or
(f) he did not himself invent the subject matter sought to be patented, or
(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or
(2) before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.
35 U.S.C.103:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
(b) (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—
(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and
(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.
(2) A patent issued on a process under paragraph (1)—
(A) shall also contain the claims to the composition of matter used in or made by that process, or
(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.
(3) For purposes of paragraph (1), the term “biotechnological process” means—
(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—
(i) express an exogenous nucleotide sequence,
(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
(iii) express a specific physiological characteristic not naturally associated with said organism;
(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c) (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.
(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if—
(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
(3) For purposes of paragraph (2), the term “joint research agreement” means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

35 U.S.C. 102: (a) In General.—
(1) Proceedings.— In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country, except as provided in sections 119 and 365 of this title.
(2) Rights.— If an invention was made by a person, civil or military—
(A) while domiciled in the United States, and serving in any other country in connection with operations by or on behalf of the United States,
(B) while domiciled in a NAFTA country and serving in another country in connection with operations by or on behalf of that NAFTA country, or
(C) while domiciled in a WTO member country and serving in another country in connection with operations by or on behalf of that WTO member country, that person shall be entitled to the same rights of priority in the United States with respect to such invention as if such invention had been made in the United States, that NAFTA country, or that WTO member country, as the case may be.
(3) Use of information.— To the extent that any information in a NAFTA country or a WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Director,
court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.

(b) Definitions.— As used in this section—

(1) the term “NAFTA country” has the meaning given that term in section 2(4) of the North American Free Trade Agreement Implementation Act; and

(2) the term “WTO member country” has the meaning given that term in section 2(10) of the Uruguay Round Agreements Act.

35 U.S.C.105

(a) Any invention made, used or sold in outer space on a space object or component thereof under the jurisdiction or control of the United States shall be considered to be made, used or sold within the United States for the purposes of this title, except with respect to any space object or component thereof that is specifically identified and otherwise provided for by an international agreement to which the United States is a party, or with respect to any space object or component thereof that is carried on the registry of a foreign state in accordance with the Convention on Registration of Objects Launched into Outer Space.

(b) Any invention made, used or sold in outer space on a space object or component thereof that is carried on the registry of a foreign state in accordance with the Convention on Registration of Objects Launched into Outer Space, shall be considered to be made, used or sold within the United States for the purposes of this title if specifically so agreed in an international agreement between the United States and the state of registry.

European Patent Convention Art.52-57

Art.52: Patentable Inventions:

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53: 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.

Article 54: Novelty
(1) An invention shall be considered to be new if it does not form part of the state of the art.
(2) The state of the art shall be held to comprise 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.
(3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art.
(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.
(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

Article 55: Non-prejudicial disclosures
(1) For the application of Article 54 a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of:
(a) an evident abuse in relation to the applicant or his legal predecessor, or
(b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.
(2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application, that the invention has been so displayed and files a supporting certificate within the period and under the conditions laid down in the Implementing Regulations

Article 56: Inventive step:
An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.

Article 57: Industrial application:
An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.
CHAPTER II: INVENTIONS NOT PATENTABLE

3. What are not inventions
The following are not inventions within the meaning of this Act,

a. an invention which is frivolous or which claims anything obvious contrary to well established natural laws;

b. an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;

c. the mere discovery of a scientific principle or the formulation of an abstract theory;

d. the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

e. a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

f. the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

g. a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;

h. a method of agriculture or horticulture;

i. any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

4. Inventions relating to atomic energy not patentable
No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of Section 20 of the Atomic Energy Act, 1962.

5. Inventions where only methods or processes of manufacture patentable
(1) In the case of inventions-

a. claiming substances intended for use, or capable of being used, as food or as medicine or drug, or

b. relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

(2) Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section 2, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA.]