

**Annex One**  
**Text of the**  
**Agreement on Trade-Related Aspects of**  
**Intellectual Property Rights 1994 (TRIPS)**

Contents

Preamble

PART I GENERAL PROVISIONS AND BASIC PRINCIPLES

PART II STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS:

1. Copyright and Related Rights
2. Trademarks
3. Geographical Indications
4. Industrial Designs
5. Patents
6. Layout-Designs (Topographies) of Integrated Circuits
7. Protection of Undisclosed Information
8. Control of Anti-Competitive Practices in Contractual Licences

PART III ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

1. General Obligations
2. Civil and Administrative Procedures and Remedies
3. Provisional Measures
4. Special Requirements Related to Border Measures
5. Criminal Procedures

PART IV ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED INTER-PARTES PROCEDURES

PART V DISPUTE PREVENTION AND SETTLEMENT

PART VI TRANSITIONAL ARRANGEMENTS

PART VII INSTITUTIONAL ARRANGEMENTS; FINAL PROVISIONS

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Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual

property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

- (a) the applicability of the basic principles of [GATT 1994](#) and of relevant international intellectual property agreements or conventions;
- (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and
- (e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

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## **PART I: GENERAL PROVISIONS AND BASIC PRINCIPLES**

### Article 1 Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is

required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of [Part II](#).

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members. [1](#) In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions. [2](#) Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

#### Article 2 Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

#### Article 3 National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection [3](#) of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and

where such practices are not applied in a manner which would constitute a disguised restriction on trade.

#### Article 4 Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

#### Article 5 Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under [Articles 3](#) and [4](#) do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

#### Article 6 Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of [Articles 3](#) and [4](#) nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

#### Article 7 Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

## Article 8 Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

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## **PART II: STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS**

### SECTION 1: COPYRIGHT AND RELATED RIGHTS

#### Article 9 Relation to the Berne Convention

1. Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6bis of that Convention or of the rights derived therefrom.
2. Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

#### Article 10 Computer Programs and Compilations of Data

1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).
2. Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.

#### Article 11 Rental Rights

In respect of at least computer programs and cinematographic works, a Member shall provide authors and their successors in title the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works. A Member shall be excepted from this obligation in respect of cinematographic works unless such rental has led to widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and

their successors in title. In respect of computer programs, this obligation does not apply to rentals where the program itself is not the essential object of the rental.

#### Article 12 Term of Protection

Whenever the term of protection of a work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

#### Article 13 Limitations and Exceptions

Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

#### Article 14 Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations

1. In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.
2. Producers of phonograms shall enjoy the right to authorize or prohibit the direct or indirect reproduction of their phonograms.
3. Broadcasting organizations shall have the right to prohibit the following acts when undertaken without their authorization: the fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same. Where Members do not grant such rights to broadcasting organizations, they shall provide owners of copyright in the subject matter of broadcasts with the possibility of preventing the above acts, subject to the provisions of the Berne Convention (1971).
4. The provisions of [Article 11](#) in respect of computer programs shall apply mutatis mutandis to producers of phonograms and any other right holders in phonograms as determined in a Member's law. If on 15 April 1994 a Member has in force a system of equitable remuneration of right holders in respect of the rental of phonograms, it may maintain such system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.
5. The term of the protection available under this Agreement to performers and producers of phonograms shall last at least until the end of a period of 50 years computed from the end of the calendar year in which the fixation was made or the

performance took place. The term of protection granted pursuant to paragraph 3 shall last for at least 20 years from the end of the calendar year in which the broadcast took place.

6. Any Member may, in relation to the rights conferred under paragraphs 1, 2 and 3, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention. However, the provisions of Article 18 of the Berne Convention (1971) shall also apply, *mutatis mutandis*, to the rights of performers and producers of phonograms in phonograms.

## SECTION 2: TRADEMARKS

### Article 15 Protectable Subject Matter

1. Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.

2. Paragraph 1 shall not be understood to prevent a Member from denying registration of a trademark on other grounds, provided that they do not derogate from the provisions of the Paris Convention (1967).

3. Members may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.

4. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark.

5. Members shall publish each trademark either before it is registered or promptly after it is registered and shall afford a reasonable opportunity for petitions to cancel the registration. In addition, Members may afford an opportunity for the registration of a trademark to be opposed.

### Article 16 Rights Conferred

1. The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not

prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

2. Article 6bis of the Paris Convention (1967) shall apply, *mutatis mutandis*, to services. In determining whether a trademark is well-known, Members shall take account of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Member concerned which has been obtained as a result of the promotion of the trademark.

3. Article 6bis of the Paris Convention (1967) shall apply, *mutatis mutandis*, to goods or services which are not similar to those in respect of which a trademark is registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use.

#### Article 17 Exceptions

Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

#### Article 18 Term of Protection

Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely.

#### Article 19 Requirement of Use

1. If use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will of the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other government requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use.

2. When subject to the control of its owner, use of a trademark by another person shall be recognized as use of the trademark for the purpose of maintaining the registration.

#### Article 20 Other Requirements

The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods

or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

#### Article 21 Licensing and Assignment

Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.

### SECTION 3: GEOGRAPHICAL INDICATIONS

#### Article 22 Protection of Geographical Indications

1. Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

- (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;
- (b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967).

3. A Member shall, ex officio if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.

4. The protection under paragraphs 1, 2 and 3 shall be applicable against a geographical indication which, although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

#### Article 23 Additional Protection for Geographical Indications for Wines and Spirits

1. Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation" or the like. [4](#)

2. The registration of a trademark for wines which contains or consists of a geographical indication identifying wines or for spirits which contains or consists of a geographical indication identifying spirits shall be refused or invalidated, ex officio if a Member's legislation so permits or at the request of an interested party, with respect to such wines or spirits not having this origin.

3. In the case of homonymous geographical indications for wines, protection shall be accorded to each indication, subject to the provisions of paragraph 4 of [Article 22](#). Each Member shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled.

4. In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

#### Article 24 International Negotiations; Exceptions

1. Members agree to enter into negotiations aimed at increasing the protection of individual geographical indications under [Article 23](#). The provisions of paragraphs 4 through 8 below shall not be used by a Member to refuse to conduct negotiations or to conclude bilateral or multilateral agreements. In the context of such negotiations, Members shall be willing to consider the continued applicability of these provisions to individual geographical indications whose use was the subject of such negotiations.

2. The Council for TRIPS shall keep under review the application of the provisions of this Section; the first such review shall take place within two years of the entry into force of the WTO Agreement. Any matter affecting the compliance with the obligations under these provisions may be drawn to the attention of the Council, which, at the request of a Member, shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral or plurilateral consultations between the Members concerned. The Council shall take such action as may be agreed to facilitate the operation and further the objectives of this Section.

3. In implementing this Section, a Member shall not diminish the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement.

4. Nothing in this Section shall require a Member to prevent continued and similar use of a particular geographical indication of another Member identifying wines or spirits in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either (a) for at least 10 years preceding 15 April 1994 or (b) in good faith preceding that date.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either:

(a) before the date of application of these provisions in that Member as defined in Part VI; or

(b) before the geographical indication is protected in its country of origin;

measures adopted to implement this Section shall not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to goods or services for which the relevant indication is identical with the term customary in common language as the common name for such goods or services in the territory of that Member. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to products of the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Member as of the date of entry into force of the WTO Agreement.

7. A Member may provide that any request made under this Section in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Member or after the date of registration of the trademark in that Member provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Member, provided that the geographical indication is not used or registered in bad faith.

8. The provisions of this Section shall in no way prejudice the right of any person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public.

9. There shall be no obligation under this Agreement to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country.

#### SECTION 4: INDUSTRIAL DESIGNS

##### Article 25 Requirements for Protection

1. Members shall provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Member shall ensure that requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection. Members

shall be free to meet this obligation through industrial design law or through copyright law.

#### Article 26 Protection

1. The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.
2. Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.
3. The duration of protection available shall amount to at least 10 years.

#### SECTION 5: PATENTS

#### 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. [5](#) 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<sup>6</sup> 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 Conferred

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<sup>7</sup> 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 semi-conductor 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;

(k) 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;

(l) 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; and

(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. [8](#)

#### 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.

### SECTION 6: LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

#### Article 35 Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and

paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

#### Article 36 Scope of the Protection

Subject to the provisions of paragraph 1 of [Article 37](#), Members shall consider unlawful the following acts if performed without the authorization of the right holder:<sup>9</sup> importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

#### Article 37 Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding [Article 36](#), no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.

2. The conditions set out in subparagraphs (a) through (k) of [Article 31](#) shall apply mutatis mutandis in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

#### Article 38 Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.

2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.

3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

## SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

### Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.
2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices<sup>10</sup> so long as such information:
  - (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
  - (b) has commercial value because it is secret; and
  - (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.
3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

## SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

### Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

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## **PART III: ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS**

### **SECTION 1: GENERAL OBLIGATIONS**

#### Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

## SECTION 2: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

### Article 42 Fair and Equitable Procedures

Members shall make available to right holders<sup>11</sup> civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

### Article 43 Evidence

1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.

2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

### Article 44 Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of [Part II](#) specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of [Article 31](#). In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

#### Article 45 Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

#### Article 46 Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

#### Article 47 Right of Information

Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

#### Article 48 Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.
2. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

#### Article 49 Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

### SECTION 3: PROVISIONAL MEASURES

#### Article 50

1. The judicial authorities shall have the authority to order prompt and effective provisional measures:
  - (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;
  - (b) to preserve relevant evidence in regard to the alleged infringement.
2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.
3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.
4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the

notification of the measures, whether these measures shall be modified, revoked or confirmed.

5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.

6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

#### **SECTION 4: SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES [12](#)**

##### Article 51 Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures [13](#) to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods [14](#) may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

##### Article 52 Application

Any right holder initiating the procedures under [Article 51](#) shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is prima facie an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have

accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

#### Article 53 Security or Equivalent Assurance

1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in [Article 55](#) has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

#### Article 54 Notice of Suspension

The importer and the applicant shall be promptly notified of the suspension of the release of goods according to [Article 51](#).

#### Article 55 Duration of Suspension

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of [Article 50](#) shall apply.

#### Article 56 Indemnification of the Importer and of the Owner of the Goods

Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any

injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to [Article 55](#).

#### Article 57 Right of Inspection and Information

Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

#### Article 58 Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired prima facie evidence that an intellectual property right is being infringed:

- (a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;
- (b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, mutatis mutandis, set out at [Article 55](#);
- (c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

#### Article 59 Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in [Article 46](#). In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

#### Article 60 De Minimis Imports

Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.

## SECTION 5: CRIMINAL PROCEDURES

### Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

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## **PART IV: ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED INTER-PARTES PROCEDURES**

### Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.
2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.
3. Article 4 of the Paris Convention (1967) shall apply mutatis mutandis to service marks.
4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and inter partes procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of [Article 41](#).
5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

## **PART V: DISPUTE PREVENTION AND SETTLEMENT**

### Article 63 Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6ter of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

### Article 64 Dispute Settlement

1. The provisions of Articles XXII and XXIII of [GATT 1994](#) as elaborated and applied by the [Dispute Settlement Understanding](#) shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of [GATT 1994](#) shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of [GATT 1994](#) made pursuant to this

Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

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## **PART VI: TRANSITIONAL ARRANGEMENTS**

### Article 65 Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than [Articles 3, 4](#) and [5](#).
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

### Article 66 Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than [Articles 3, 4](#) and [5](#), for a period of 10 years from the date of application as defined under paragraph 1 of [Article 65](#). The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.
2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer

to least-developed country Members in order to enable them to create a sound and viable technological base.

#### Article 67 Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

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### **PART VII: INSTITUTIONAL ARRANGEMENTS; FINAL PROVISIONS**

#### Article 68 Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

#### Article 69 International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

#### Article 70 Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.
2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection

under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of [Article 14](#) of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of [Article 11](#) and of paragraph 4 of [Article 14](#) with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply [Article 31](#), or the requirement in paragraph 1 of [Article 27](#) that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under [Article 27](#), that Member shall:

(a) notwithstanding the provisions of [Part VI](#), provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with [Article 33](#) of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of [Part VI](#), for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

#### Article 71 Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of [Article 65](#). The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the [WTO Agreement](#) on the basis of a consensus proposal from the Council for TRIPS.

#### Article 72 Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

#### Article 73 Security Exceptions

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

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**Footnotes:**

1. When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

2. In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

3. For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

4. Notwithstanding the first sentence of Article 42, Members may, with respect to these obligations, instead provide for enforcement by administrative action.

5. For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

6. This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

7. "Other use" refers to use other than that allowed under Article 30.

8. It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

9. The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPICT Treaty.

10. For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

11. For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

12. Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

13. It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

14. For the purposes of this Agreement:

(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

## Annex Two

### Biotechnology and Intellectual Property Law in APEC economies

This annex provides information on particular IP practices relating to biotechnology in various APEC economies. Generally, it consists of publicly-available information, mostly on the web site of the intellectual property offices. Hence it varies widely in its scope and content. It is provided to give further insight into the range of approaches taken in the APEC region. The range is not complete, but reflects material made available to the editors at the time of compilation.

Following is information on:

- Australia
- Japan
- Republic of Korea
- New Zealand
- Singapore
- United States

Three other useful resources are:

- Intellectual Property Practices in the Field of Biotechnology  
OECD Document TD/TC/WP(98)15/FINAL  
Available on the OECD website ([www.oecd.org](http://www.oecd.org))
  - Trilateral Project: Comparative study on biotechnology patent practices  
Japanese, European and US patent offices  
Available on the JPO website ([www.jpo.go.jp](http://www.jpo.go.jp))
  - Submissions to the WTO TRIPS Council on TRIPS Article 27.3b  
Documents in the series IP/C/W/125  
Available on the WTO website ([docsonline.wto.org](http://docsonline.wto.org))
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## AUSTRALIAN PATENTS FOR: Microorganisms; Cell lines; Hybridomas; Related biological materials and their use; & Genetically manipulated organisms

### Patentable subject matter

The range of patentable inventions involving microorganisms, cell lines, hybridomas and other related biological materials includes:

- bacteria and other prokaryotes, fungi (inc. yeast), algae, protozoa, plasmids, viruses, prions;
- DNA, RNA, genes, viruses, vectors, chromosomes, prions, cell organelles and other nonliving material existing in, and reproducible from, microorganisms or like biological material;
- non-living material existing in and reproducible from a living cell, such as, monoclonal antibodies produced from hybridomas, DNA, RNA, genes, viruses, vectors, chromosomes, prions, cell organelles;
- purified nucleic acids.
- apparatus or processes for enzymology or microbiology;
- compositions of microorganisms or enzymes;
- propagating, preserving or maintaining microorganisms;
- mutation or genetic engineering;
- fermentation or enzyme using processes to synthesize a desired chemical compound or composition;
- measuring or testing processes involving enzymes or microorganisms;
- processes using enzymes or microorganisms to liberate, separate, purify or clean;
- the use of microorganisms to produce food or beverages.

Patent protection can also be obtained for inventions involving:

- genotypically or phenotypically modified living organisms. For example, genetically modified bacteria, plants and non-human organisms. Patenting of plant varieties is described in our information sheet *Australian Patents for Plants*;
- the building blocks of living matter, such as DNA and genes (including human DNA and genes) which have for the first time been identified and copied from their natural source and then manufactured synthetically as unique materials with a definite industrial use. DNA or genes in the human body are not patentable as such, however, a DNA or gene sequence which has been separated from the human body and manufactured synthetically for reintroduction into the human body for therapeutic purposes would be patentable. The treated human body is not patentable.
- products of such living matter eg. food supplements, drugs, and processes for synthesising the material or making the products.

The range of patentable inventions involving genetic manipulation found in Australian patent applications includes:

- synthetic genes or DNA sequences;
- mutant forms and fragments of gene sequences;
- the DNA coding sequence for a gene. This is claimed in either the isolated or recombinant state (otherwise it is claiming something which occurs in nature);
- the protein expressed by the gene;
- vectors (such as plasmids or bacteriophage vectors or viruses) containing the gene;
- probes for the gene;
- methods of transformation using the gene;
- anti-sense DNA (the opposite sequence to the gene, used for regulation of the gene);
- host cells carrying the gene;
- higher plants/animals carrying the gene;
- organisms for expression of the gene (making the protein from the DNA). There are many types of expression

systems:

- bacterial, yeast, viral;
- plant or animal cell cultures
- higher plants or animals per se;
- DNA sequences can also include regulatory sequences such as promoters.
- general recombinant DNA methods such as PCR and novel expression systems.

"Human beings, and the biological processes for their generation" are not patentable, as they are specifically excluded under subsection 18(2) of the Patents Act 1990.

## Patents

A patent is granted for an invention that is an innovative idea which provides a practical solution to a technological problem. In this context, a patent would only be granted for subject matter which meets all the following tests:

- involves the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from the natural source material. (A patent cannot be granted for a mere discovery of biological material);
- is new in the sense of not previously being publicly available. That is, a patent cannot be granted for materials in their naturally occurring state or for materials which have previously been made publicly available;
- has been fully described in the sense that sufficient information is provided to allow the technologist to make the product or perform the process without having to resort to invention.
- has a demonstrated industrial use. The use to which the invention is to be put, for example, for the treatment of human diseases such as cancer or multiple sclerosis, must also be fully described. This means that there must be an actual use for an invention rather than speculation as to future uses.

## The written description

The specification must include a full description of the microorganism, hybridoma, enzyme or transgenic material (including the organisms in which the transgenic products are expressed), and their use, as well as the best method of performing the invention known to the applicant.

Where the invention is a microorganism, enzyme or related material or a specific method to produce or use these materials, there should be sufficient details in the specification for a specialist in the field to identify and repeat the invention.

Applicants often have difficulty in satisfying the requirement to reproduce or repeat the invention and to fully describe biological materials such as microorganisms. To enable an applicant to meet this requirement applicants may choose to deposit the biological material under the provisions of the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". This Treaty was devised to enable applicants to comply with this requirement by including references, in the patent specification, to Deposits under the Budapest Treaty.

Deposits of microorganisms must be made at an International Depositary Authority (IDA) in accordance with the rules of the Treaty on or before the filing date of the complete patent application. For more information on the Budapest Treaty see the information sheet *The Budapest Treaty and Australian Patents*.

Full description of the microorganism means an inclusion of the full morphological, biochemical and taxonomic characteristics of the organism known to the applicant. It also includes a full description of any scientific testing characteristics (e.g. isozyme analysis, DNA profiling, etc.), if available.

Where the invention is a plant or animal product or a specific method to produce such a product, there should be sufficient details in the specification for a specialist in the field to identify and repeat the invention (e.g. an isolated gene or a specific method to produce a transgenic product).

There must be sufficient clear information to enable the specialist to fill in any missing gaps in the description of the invention without conducting lots of experimentation or resorting to invention to discover the conditions necessary for the invention to work. Where the invention resides in a complete plant or animal (e.g. a mutated or transgenic plant variety) the entire organism must be described fully, with particular emphasis on the characteristics or combination of characteristics which are significantly different from known and related plants or animals.

Such a description would enable the plant or animal to be clearly identified and distinguished from known close relatives.

The description should also describe the method of selecting the invention from the other organisms produced in the transformation or mutation process.

Applicants should be wary of subjective descriptive characteristics (e.g. for plants - robust, tall, extensive, bright; or for micro-organisms - large, small, distinctive colonies, etc.). If there is no point of reference or objective standard, these terms will be meaningless.

## Best method of performance

In order to satisfy full description requirements for an invention involving:

- new microorganisms,
- a process involving microorganisms, or
- products of microorganisms,

in addition to the broad description of the invention, all specific steps required to reproduce the microorganism, to carry out the processes or prepare the products must be disclosed in the specification. In other words, there may be a number of ways to achieve the desired result but the best way of obtaining the invented product or performing the invented process, must be described in detail.

## For genetically manipulated organisms

In order to satisfy full description requirements, for example, in the case of an invention involving a transgenic plant or animal, in addition to the broad description of the invention all specific steps required to reproduce the genetic materials and the transgenic plants or animals must be disclosed in the specification. In other words, there may be a number of ways to achieve the desired result but the best way of obtaining the invented product or performing the invented process, must be described in detail.

## Repeatability

A patent monopoly is granted in return for a full written description of an invention. Such a description is required to ensure that other people are able to make a product or repeat a process once the patent period is over. A specialist in the particular technology must be able to repeat the process or reproduce the product from the directions given in the written description.

The main difference between inventions involving living and non-living systems is that many processes involving living systems are not repeatable 100% of the time. In some cases the probability of repeating the invention, even using the best method known to the applicant, can be very low.

Each technological area has its own standard of repeatability and this must be taken into consideration when assessing repeatability of an invention. The issue when considering repeatability is not the numerical probability of achieving the specified result, but whether the result can be reproduced to a practical level acceptable to the person skilled in that particular technology.

In a case involving the "Scarlet Queen Elizabeth" rose, the method of production was a chance genetic mutation. It has been estimated that the chance of such a variety occurring is 1 in 100,000,000. If the unfortunate plant breeder who was trying to repeat the invention, had to rely on chance alone, he/she might have to examine up to 100,000,000 plants before he/she found the same variety again. The Patent Office would consider the process essentially unrepeatable and would not grant the patent.

However, in the last 40 odd years, we have learnt a lot more about genetic engineering. This means that although the chances of such a sport occurring remains the same, we are a lot better at:

- making such an event happen (mutagenesis); and
- finding the plant, once the sport has occurred from amongst all the other plants (selection).

On the other hand, some microbiological work done under automation and/or computer control over a period of time involves millions of trials, and such a number is clearly practical in the fields involved. In situations where the repeatability would be low (for example, production of plant varieties using standard breeding techniques), it is our practice to accept that there is a best method of performance, if there is a description of the process and a statement in the description such as:

"It is practical to repeat the invention using current state of the art techniques to carry out the number of trials necessary to achieve the desired result."

Repeatability is not likely to be an issue where the description of an invention, such as a novel organism, relies on a

deposit made under the Budapest Treaty.

The issue of repeatability is best considered through examples.

## **Mutagenesis**

With our increased understanding of molecular inheritance of, for example, plant and animal characteristics, breeders now have an armoury of techniques to make mutational events occur more frequently - irradiation, drugs that alter the genetic coding for the characters, and sometimes manipulation of the genes for the characters themselves.

The use of these techniques means that repeatability is rarely an issue provided the inventor gives sufficient clear instructions for the specialist to follow and repeat the invention. The description would need to clearly identify the organisms used, the type and amount of mutagenic agent, and how the organism was treated and how the mutants were subsequently recovered.

## **Mutagenic chemicals**

Under this umbrella, breeders have found that including the drug colchicine in the plant growth medium results in an increase in the number of plant chromosomes and often leads to an increase in flower size - a technique that rose breeders are now using. This change is readily described, is heritable and repeatable.

Other drugs have been used which specifically alter the genetic code of plants and such treatments have the effect of "hotting up" the rate of mutational events. One example of this from the patent literature is the treatment of wheat seed with several chemical mutagens, followed by screening the seedlings that survived the treatment for resistance to herbicide. Such wheat lines are of interest as farmers would then be able to spray their crops with the herbicide and specifically eradicate weed.

## **Genetic engineering**

Another exciting approach has been through genetic engineering where genes are taken from one quite unrelated organism and put into a second. The use of genetic engineering requires that the plant breeder, for example, knows a great deal about the genes for the characters he/she wants to manipulate. Fortunately such knowledge is increasing rapidly. This approach permits not only the exquisitely accurate introduction of characteristics into plants but also the introduction of characteristics from unrelated species - impossible by the normal routes of sexual propagation. The description requires additional details about the genes used, such as for example, the sequence of the gene used to transform the organism. Repeatability is rarely an issue in genetic engineering inventions, provided the invention is fully described.

Other ingenious methods make use of unrelated characters, for example, a gene for a blue seed coat may be linked to a wanted characteristic so that if the plant receives the gene for one character, it also generally receives the other to the extent that the seed can be simply sorted by machine!

One important feature of this type of genetic manipulation is that instead of the breeder having to sift through the 100,000,000 plants, he/she can design his/her experiments so that the mutagenic events are no longer scattered throughout the plant genome but are concentrated only in the specific genes he/she wishes to alter.

## **Selection**

The importance of selection is that instead of having to look at all 100,000,000 plants produced, the breeder can design breeding programs to eliminate over 90% of the unwanted plants and if he/she is really tricky, he/she can screen out almost all the unwanted plants. One example is the breeding of herbicide resistant wheat - the potentially disease resistant cultivars can be identified from their resistance to the herbicide when it is included in their culture medium. Susceptible plant cells die, resistant ones survive - the breeder manipulates the odds spectacularly in his/her favour by simply killing off the few million or so plant cells that don't have the specific characteristic he/she wants.

The ability to select the required mutant organism generally obviates the issue of repeatability.

Some species are amenable to tissue culture techniques and this confers the added advantage that a very large number of "plants" can be examined on a culture plate the size of a saucer. A large array of crop plants are amenable to this technique, including both wheat and barley.

## Patenting microorganisms and other biological materials

Patent claims to inventions relating to microorganisms may be directed to the microorganism itself, its products or processes, depending on where the novelty and inventive concept lie. The claims must be fairly based on a full description of the invention in the body of the specification.

The specific details required in a description of a new microorganism or related invention will vary depending on the nature of the particular invention claimed and must include information (data) clarifying the repeatability issue. The following is intended only as a guide to the applicant and is not an all-inclusive list of the sort of information needed.

### New microorganisms, cell lines, hybridomas, etc.

If the invention is a microorganism per se, such as a bacterium or fungus, or a new cell line, etc, which may produce a desired product or have some desired effect (for example the ability of a microorganism to digest oil-spills), as much as is known of its features should be described.

This includes

- the taxonomic description
- morphological characteristics such as shape, size, stain ability, motility, etc
- colony characteristics, for example, colour, shape, size, swarming and any distinguishing features in appearance, such as shininess
- metabolic characteristics including substrate requirements, products or by-products, isozyme characteristics, etc
- genetic characterisation of any known genes relevant to the use or the characterisation of the organisation or the inventive concept. The characterisation may be at the level of gene sequence, function or restriction pattern.

### Processes involving microorganisms, cell lines, hybridomas, etc.

When the invention lies in a process, such as fermentation, which makes use of a microorganism, the description of the invention should provide details including the particular organism used for the process as well as its required nutrient and culture conditions (temperature, aeration, etc.). If special incubation, mixing apparatus, or particular separation or isolation techniques are necessary to perform the invention, then they must be described in detail.

### Products of microorganisms, cell lines, hybridomas, etc.

A microbial product, such as a novel antibiotic is best characterised by its structure. However, this is not always known so the product may be defined in terms of the organism from which it is produced and/or as many physical or chemical characteristics as are known and which are sufficient to distinguish it from other known compounds. Such information may be UV or IR absorption spectra, NMR spectrum, elemental analysis, molecular weight, melting point, solubility characteristics and HPLC analysis.

In all the above cases resort may be made to a deposit made under the Budapest Treaty in order to assist in fully describing the invention.

## Patenting modified plants and animals

Patent claims which are directed to parts of inventive mature plants, animals or to plant seeds which grow into inventive mature organisms, must be limited by the characteristics of the mature organism. However, it may be possible to correlate certain characteristics of an organism (e.g. isoenzyme or DNA profiling analysis) with the inventive characteristics of the mature organism.

For example, where the invention claimed is a seed or a plant part of a material, such as, hybrid seed, transgenic plants, mutant plants and plant varieties, the full description must include information (data) clarifying the repeatability question and, at least, the following information:

### Transgenic plants and animals

The characteristics of the gene introduced into the organisms must be described (preferably including the complete sequence of the gene) as well as the best method of transformation, regeneration and selection of the transformed materials, eg. protoplast, pollen or embryo. The parent strains or the source of the host material must also be fully described and readily available to the public.

## Mutant plants and animals

The parent strains must be fully described and readily available to the public. The method of mutagenesis (e.g. chemical or UV radiation) and the method of selecting or obtaining the mutant organisms must be disclosed. Finally, there must be a full written description of the mutant produced. A deposit made under the Budapest Treaty may assist in this regard.

Where the invention is a component of a plant seed (e.g. an improved oleic/linoleic acid ratio) or is an improved characteristic of the seed (e.g. germination rates, viability, storability).

The method of manufacture of the seed must be disclosed in the specification and the source of the seed material must be fully described and readily available to the public. The description will not need to include the characteristics of the mature plant where these are not relevant. If breeding techniques are utilised then the description will require information similar to that required for plant varieties.

Any relevant characteristics of the seed must also be provided. The specification must also provide information (data) clarifying the repeatability question.

Similar requirements apply to transgenic or mutant animals and cell lines.

## Seek professional advice

This sheet provides only basic information. Patenting biotechnology can sometimes involve complex legal issues and it may be in your best interests to obtain professional advice.

## Example Patent Applications

(Application number and subject)

- 11198/92 Physiologically active Kanglemycin C, process for preparing the same and its use.
- 13186/92 Bioleaching of cobalt and copper containing pyritic concentrates.
- 13654/92 Biological reaction process.
- 17165/92 Method for detection of Dichelobacter Nodosus.
- 21122/92 Method for the rapid determination of the microorganism content of liquids and fluid solutions, and apparatus for implementing this method.
- 30088/92 Tumour associated monoclonal antibody 88BV59.
- 31277/93 Bacillus Thuringiensis isolates active against cockroaches and genes encoding cockroach-active toxins.
- 36856/93 Novel macrocyclic lactones and a productive strain thereof.
- 38200/93 Novel toxin producing fungal pathogen and uses.
- 35853/93 Biochemical purification of simvastatin.
- 36052/93 Mycobacterial species-specific reporter mycobacteriophages.
- 36709/93 Integrative gene-expression in food-grade microorganisms.
- 36925/93 Protein having nitrile hydratase activity and the gene encoding the same and a method for producing amides from nitriles via a transformant containing the gene.
- 36959/93 Fungal protease.
- 37166/93 Method for producing a microorganism which is natural enemy to a nematode.
- 62066/94 New Bacillus Thuringiensis strains and their insecticidal proteins.
- 66810/94 Method for addressing proteins in yeast.
- 72119/94 Glycolate oxidase production.
- 11019/95 Aspergillus expression system.
- 21913/95 Novel mutated virus and novel methods of making vaccines.
- 41569/96 Insecticidal compositions containing heterorhabditis nematodes.
- 47637/96 Human retinoid X receptor - gamma (hRXR - gamma)
- 57576/90 transgenic animal producing modified human granulocyte macrophage-colony stimulating factor.
- 81063/91 transgenic animals generated using embryos passaged in culture medium containing Lif.
- 13703/92 gene construct for transgenic fish
- 17429/92 non-human animal carrying non-infectious HIV genome.
- 19530/92 genetic sequences encoding flavonoid pathway enzymes
- 26766/92 Transgenic plants.
- 34025/93 Virus resistant animals using pseudorabies virus polynucleotides.

36303/93 Transgenic Wheat  
51356/93 Transgenic animal models for neurodegenerative disease.  
62558/94 Animals with disrupted colony stimulating factors production.  
76194/94 Plants with a DNA construct to modify expression of senescence gene.  
80226/94 Novel cruciferous plant having a high carotene content.  
10758/95 Double knockout transgenic mammal as a model for sepsis.  
19770/95 Production of fibrinogen in transgenic animals.  
20022/95 Recombinant saccharomyces for decreased hydrogen sulfide formation in beer production.  
46884/96 Genetically modified plant with modulated flower meristem.  
47028/96 Plant transformed with bacterio-opsin gene for pathogen resistance.  
47851/96 Transgenic animals with defective thyroid hormone receptor gene.  
52245/96 Plants with a disrupted stamen cell function or development.  
17257/97 Parapoxviruses containing foreign DNA.  
17502/97 Humanised green fluorescent protein genes.  
17559/97 Raspberry promoters for expression of transgenes in plants.  
63837/98 Mammalian melanocyte stimulating hormone receptors.  
78438/98 Culturing algae such as Spirulina.

You can read these applications at any IP AUSTRALIA State Office. Or you can order a copy from our Examination Support and Sales Unit in Canberra, phone (02) 6283 2355 for more information.

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## JAPAN PROVISIONAL TRANSLATION<sup>1</sup>

### Implementing Guidelines for Inventions in Specific Fields

#### Chapter 2 Biological Inventions

In this chapter, matters requiring special judgment and handling in examining patent applications relating to biological inventions are mainly explained.

Here, the term "organisms" means microorganisms, animals as well as plants, including reproducible animal or plant cells.

In this chapter, "Implementing Guidelines" means "Section 1. Implementing Guidelines for 1994-Revised Section 36 of the Patent Law" in "Practices in Examination and Appeals under 1994-Revised Patent Law (May 1995, the Japanese Patent Office)."

#### 1. GENETIC ENGINEERING

This section deals with inventions relating to genetic engineering in biological inventions. The term "genetic engineering" here means the technology which manipulates genes artificially by gene recombination, cell fusion, etc. Inventions relating to genetic engineering include those of a gene, a vector, a recombinant vector, a transformant, a fused cell, a protein which are obtained by transformation (hereinafter, referred to as "a recombinant protein"), a monoclonal antibody, etc.

Inventions relating to microorganisms, plants and animals, and which are obtained using genetic engineering are treated here in this section, in principle.

#### 1.1 Description Requirements for the Specification

##### 1.1.1 Scope of Claim (See Implementing Guidelines, Chapter 1-2.2.2.)

According to Section 36(6)(ii) of the Patent Law, the invention for which a patent is sought shall be clear, therefore, scope of claim shall be described that an invention shall be clearly identified on the basis of statements of each claim.

In a claim, a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein and a monoclonal antibody should be described as indicated below.

##### (1) Genes

- 1) A gene may be described by specifying its base sequence.
- 2) A structural gene may be described by specifying an amino acid sequence of the protein encoded by the said gene.

**Example:** A gene encoding a protein consisting of an amino acid sequence represented by Met-Asp-?????-Lys-Glu.

- 3) A gene may be described by a combination of the terms "substitution, deletion or addition" or "hybridize" and functions of the gene, and if necessary, origin or source of the gene in a generic form as follows (provided that the claimed invention is clear and the enablement requirement is met (See 1.1.2.1 below)).

##### **Example 1:**

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<sup>1</sup> When any ambiguity of interpretation is found in this translation the Japanese text shall prevail

A gene encoding a protein of (a) or (b) as follows:

(a) a protein whose amino acid sequence is represented by Met-Tyr-?????-Cys-Leu

(b) a protein derived from the protein of (a) by substitution, deletion or addition of one or several amino acids in the amino acid sequence defined in (a) and having the activity of enzyme A.

Note: The protein (a) has the activity of enzyme A.

The gene encoding the protein (b) is described in the detailed description of the invention in such a manner that a person skilled in the art can make the said gene without large amount of trials and errors or complicated experimentations beyond the reasonable extent that can be expected from a person skilled in the art who is supposed to have ordinary skill.

**Example 2:**

A gene selected from the group consisting of:

(a) a DNA whose nucleotide sequence is represented by ATGTATCGG???TGCCCT

(b) a DNA which hybridizes under stringent conditions to the DNA defined in (a) and encodes the human protein having the activity of enzyme B.

Note: A protein encoded by the DNA (a) has the activity of enzyme B.

"Stringent conditions" are described in the detailed description of the invention.

4) A gene may be described by specifying functions, physiochemical properties, origin or source of the said gene, a process for producing the said gene, etc. (provided that the claimed invention is clear and the enablement requirement is met (See 1.1.2.1 below)).

**(2) Vector**

A vector should be described by specifying a base sequence of its DNA, a cleavage map of DNA, molecular weight, number of base pairs, source of the vector, process for producing the vector, function or characteristics of the vector, etc.

Note: A cleavage map is a map which shows the relative location and distance of the cleavage sites by various restriction enzymes.

**(3) Recombinant vector**

A recombinant vector may be described by specifying at least one of the gene and the vector.

**Example:** A recombinant vector containing a DNA whose base sequence is represented by ACAGCA?????AGTCAC.

**(4) Transformant**

A transformant may be described by specifying at least one of 1) its host and 2) the gene which is introduced (or the recombinant vector) (provided that the claimed invention is clear and enablement requirement is met (See 1.1.2.1 below)).

**Example 1:**

A transformant comprising a recombinant vector containing a gene encoding a protein whose amino acid sequence is represented by Met-Asp-?????Lys-Glu.

**Example 2:**

A plant wherein a toxin gene having a base sequence of ATGACT????? is inserted and the said gene is expressed.

**Example 3:**

A transgenic non-human mammal, having a recombinant DNA obtained by linking a structural gene encoding any protein to the regulatory region of a gene involved in the production of milk protein, and secreting the said protein into milk.

**(5) Fused cell**

A fused cell may be described by specifying parent cells, function and characteristics of the fused cell, or a process for producing the fused cell, etc.

**(6) Recombinant protein**

1) A recombinant protein may be described by specifying an amino acid sequence or a base sequence of structural gene encoding the said amino acid sequence.

**Example:**

A recombinant protein consisting of an amino acid sequence represented by Met-Tyr-?????-Cys-Leu.

2) A recombinant protein may be described by a combination of the terms "substitution, deletion or addition" and functions of the recombinant protein, and if necessary, origin or source of the recombinant protein in a generic form as follows (provided that the claimed invention is clear and the enablement requirement is met (See 1.1.2.1 below)).

**Example:**

A recombinant protein of (a) or (b) as follows:

(a) a protein whose amino acid sequence is represented by Met-Tyr-.....-Cys-Leu

(b) a protein derived from the protein of (a) by substitution, deletion or addition of one or several amino acids in the amino acid sequence in(a) and having the activity of enzyme A.

Note: A protein (a) has the activity of enzyme A.

The protein (b) is described in the detailed description of the invention in such a manner that a person skilled in the art can make the said protein without a large amount of trials and errors or complicated experimentations beyond the reasonable extent that can be expected from a person skilled in the art who is supposed to have ordinary skill.

3) A recombinant protein may be described by specifying functions, physiochemical, origin or source of the said recombinant protein, a process for producing the said recombinant protein, etc. (provided that the claimed invention is clear and the enablement requirement is met (See 1.1.2.1 below)).

**(7) Monoclonal antibody**

A claim directed a monoclonal antibody may be defined by specifying any of antigen recognized by it, hybridoma which produces it, or cross-reactivity, etc.

**Example 1:**

A monoclonal antibody to antigen A.

[Note] Antigen A is necessary to be defined by specifying as a substance.

**Example 2:**

A monoclonal antibody to antigen A, produced by a hybridoma having ATCC Deposit No. HB-xxxx.

[Note] Antigen A is necessary to be defined by specifying as a substance.

**Example 3:**

A monoclonal antibody which binds not to antigen B but to antigen A.

[Note] Antigen A and antigen B are necessary to be defined by specifying as substances.

### **1.1.2 The Detailed Description of the Invention (See Implementing Guidelines, Chapter 1-3.)**

The detailed description of the invention shall be stated in such a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains (the enablement requirement), and shall be stated that the problem to be solved by the invention and its solution, or other matters necessary for a person having ordinary skill in the art to understand the technical significance of the invention (the Ministerial Ordinance Requirement).

The detailed description of the invention which does not meet the above requirements violates Section 36(4) of the Patent Law.

### 1.1.2.1 Enablement Requirement (See Implementing Guidelines, Chapter 1-3.2.)

Section 36(4) of the Patent Law states that "the detailed description of the invention shall be stated .... in such a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains."

This means that "the detailed description of the invention shall be described in such a manner that a person who has ability to use ordinary technical means for research and development (including comprehension of document, experimentation, analysis and manufacture) and to exercise ordinary creativity in the art to which the invention pertains can carry out the claimed invention on the basis of matters described in the specification (excluding claims) and drawings taking into consideration the common general knowledge as of the filing."

Therefore, if "a person skilled in the art" who is supposed to have ordinary skill cannot understand how to carry out the invention on the basis of teachings in the specification (excluding claims) and drawings taking into consideration the common general knowledge as of the filing, then, such a description of the invention should be deemed insufficient for enabling such a person to carry out the invention. For example, if a large amount of trials and errors or complicated experimentations are needed to find a way of carrying out the invention beyond the reasonable extent that can be expected from a person skilled in the art who is supposed to have ordinary skill, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to carry out the invention.

#### 1.1.2.1.1 An Invention of a Product (See Implementing Guidelines, Chapter 1-3.2.1(2).)

For an invention of a product, the definition of carrying out the invention is to make and use the product. That a product can be used is interpreted as meaning that a product can be used in an industrially applicable way. Also, the said invention of a product should be explained clearly in the detailed description of the invention.

Therefore, an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc. should be described as follows.

##### (1) "An invention of a product" being explained clearly

If an invention of a product can be identified by a person skilled in the art based on the statements of a claim and can be understood from the statements and implications in the detailed description of the invention, then, the invention will be deemed as being explained clearly.

##### (2) "Can be made"

For an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein or a monoclonal antibody, the way of making the product shall be described in the detailed description of the invention except where the product could be made by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

##### 1) Gene, vector or recombinant vector

A process for producing a gene, a vector or a recombinant vector should be described by respective origin or source, means for obtaining a vector to be used, an enzyme to be used, treatment conditions, steps for collecting and purifying it, or means for identification, etc.

If genes are claimed in a generic form (See 1.1.1(1)3)) and a large amount of trials and errors or complicated experimentations are needed to produce those genes beyond the reasonable extent that can be expected from a person skilled in the art, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to make the product.

For example, in case that a claimed invention includes the gene actually obtained and many of genes whose identity is extremely low to the said gene obtained and is specified by their function and that as a result, many of genes which do not have the same function as the said gene obtained are included in the genes whose identity is extremely low, a large amount of trials and errors or complicated experimentations are generally needed to select the genes with the same function as the said gene obtained among the genes whose identity is extremely low beyond the reasonable extent that can be expected from a person skilled in the art, and therefore, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to make the product.

**Example:** A gene selected from the group consisting of:

- (a) a DNA whose nucleotide sequence is represented by ATGTATCGG...TGCCT

(b) a DNA whose nucleotide sequence has more than X% identity to that of (a) and which encodes the protein having the activity of enzyme B.

Note: A protein encoded by the DNA (a) has the activity of enzyme B.  
X% represents extremely low identity.

**Explanation:** Genes whose identity is extremely low to the gene actually obtained are included in the (b), although (b) is specified by its function. In case that "A DNA whose nucleotide sequence has more than X % identity to that of (a)" includes many of genes which do not have the activity of enzyme B, a large amount of trials and errors or complicated experimentations are generally needed to select the genes with the activity of enzyme B beyond the reasonable extent that can be expected from a person skilled in the art. Therefore, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to make the product.

#### 2) Transformant

A process for producing a transformant should be described by a gene or a recombinant vector introduced, a host (a microorganism, a plant or an animal), a method of introducing gene or the recombinant vector into the host, a method of selectively collecting the transformant, or means for identification, etc.

If the transformant is the one described by a generic taxonomical unit (e.g., a transformed plant, a transformed non-human vertebrate, a transformant (including microorganisms, plants and animals)), and if a large amount of trials and errors or complicated experimentations are needed to produce those transformants beyond the reasonable extent that can be expected from a person skilled in the art, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to make the product.

#### 3) Fused cell

A process for producing a fused cell should be described by stating pretreatment of the parent cells, fusion condition, a method of selectively collecting the fused cell, or means for identification, etc.

#### 4) Recombinant protein

A process for producing a recombinant protein should be described by stating means for obtaining a gene encoding the recombinant protein means for obtaining, an expression vector used, means for obtaining a host, a method for introducing the gene into the host, steps for collecting and purifying the recombinant protein from the transformant into which the gene has been introduced, or means for identification of the obtained recombinant protein, etc.

(See "1) Gene, vector or recombinant vector" for the treatment of enablement requirement in case that recombinant proteins are claimed in a generic form.)

#### 5) Monoclonal antibody

A process for producing a monoclonal antibody should be described by stating means for obtaining or producing immunogen, a method for immunization, a process for selectively obtaining antibody producing cells, or means for identification of the monoclonal antibody, etc.

#### 6) Deposit of microorganisms, etc. (For the detail of deposit and furnishing of microorganisms etc., see 2.1.3.1.1 (2) 1) Deposit and Furnishing of Microorganisms.)

(a) For an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc. produced by the use of a microorganism, etc. ("a microorganism, etc." here includes a microorganism, a plant and an animal), a process for producing the said product should be described in the specification as filed so that a person skilled in the art can make it. Further, the microorganism used in the process should be deposited and its accession number should be described in the specification as filed unless the microorganisms readily available to a person skilled in the art (See 2.1.3.1.1(2) 1)(ii)).

(b) For an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc., when it is not possible to describe a process for producing the said product in the specification in such a manner that a person skilled in the art can make it, the obtained transformant (including a transformant which produces a recombinant protein) or the fused cell (including a hybridoma which produces a monoclonal antibody) into which the gene, the vector, the recombinant vector has been introduced, should be deposited and its accession number should be described in the specification as filed.

(c) Generally, the obtainment of a hybridoma producing a monoclonal antibody which satisfies limitative conditions, (e.g., a monoclonal antibody whose affinity to the antigen A is specified by the limitative coupling constant,) is not reproducible. Therefore, in case that the claimed invention is related to a monoclonal antibody

which satisfies limitative conditions or a hybridoma producing the said monoclonal antibody, the said hybridoma should be deposited and its accession number should be described in the specification as filed, except where the hybridoma can be created by a person skilled in the art on the basis of the description in the specification.

(3) "Can be used"

For an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc., in order to show the industrial applicability of the product, the way of industrial application of it shall be described in the detailed description of the invention except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

For instance, in order to show the industrial applicability of the invention of a gene, it should be described in the detailed description of the invention that the gene has the specific function (in case of a structural gene, the protein encoded by the said gene has the specific function).

In case that genes are claimed in a generic form and the function is not specified in the claim (genes specified only by "substituted, deleted or added," "hybridized" or "having more than X% identity," etc.), the genes claimed in a generic form contain the ones which do not have the said function and the part of the said genes cannot be used, and therefore, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to use the product.

#### **1.1.2.1.2 An Invention of a Process (See Implementing Guidelines, Chapter 1-3.2.1(3).)**

For an invention of a process, the definition of carrying out the invention is to use the process and that a process can be used is interpreted as meaning that a process can be used in an industrially applicable way. Further, the said invention of a process should be explained clearly in the detailed description of the invention. In order to describe the invention of the process in such a manner that the process can be used in an industrially applicable way, the enablement requirement in "1.1.2.1.1 An Invention of a Product" should be referred to, if necessary. For instance, "1.1.2.1.1(2) 6) Deposit of microorganisms, etc." should be referred to if deposit of microorganisms, etc. is necessary.

#### **1.1.2.1.3 An Invention of a Process for Manufacturing a Product<sup>2</sup>**

Where an invention of a process is directed to "a process for manufacturing a product," the definition of "the process can be used" means that the product can be manufactured by the process and either the process or the product shall be industrially applicable to meet industrial application. Further, the said invention of a process for manufacturing a product should be explained clearly.

Therefore, for an invention of a process for producing a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc., the said process should be explained clearly and the description shall be stated so as to enable a person skilled in the art to produce the product by using the said process. In order to be stated so as to enable a person skilled in the art to produce the product by using the said process, the enablement requirement in "1.1.2.1.1 An Invention of a Product" should be referred to, if necessary. For instance, "1.1.2.1.1(2) 6) Deposit of microorganisms, etc." should be referred to if deposit of microorganisms, etc. is necessary.

Further, it is necessary to describe the industrial applicability of the said process or at least one use of the said product.

#### **1.1.2.1.4 How Specifically the Detailed Description of the Invention Must Be Described?<sup>3</sup>**

It is necessary for the applicant to describe at least one mode for showing how to carry out the claimed invention in the detailed description of the invention. When embodiments or working examples are necessary in order to explain the invention in such a way that a person skilled in the art can carry out the invention, "the mode for carrying out the invention" should be described in terms of embodiments or working examples. Embodiments or working examples are those which specifically show the mode for carrying out the invention (in case of an invention of a product, for instance, those which specifically show how to make the product, what structure it has, or how to use it, etc.)

In the case of inventions in technical fields where it is generally difficult to infer how to make and use a product on the basis of its structure, normally one or more representative embodiments or working examples are necessary which enable a person skilled in the art to carry out the invention.

<sup>2</sup> (See Implementing Guidelines, Chapter 1-3.2.1(4).)

<sup>3</sup> (See Implementing Guidelines, Chapter 1-3.2.1(5).)

Since this technical field (i.e., genetic engineering) is the one where it is difficult to infer how to make and use a product on the basis of its structure, normally one or more representative embodiments or working examples are necessary.

#### 1.1.2.1.5 Balance of the Claim and the Detailed Description of the Invention<sup>4</sup>

In the detailed description of the invention, at least one mode for carrying out the invention needs to be described in terms of "claimed invention." For not all embodiments nor all alternatives within the extent (or the metes and bounds) of the claimed invention, the mode for carrying out the invention needs to be described.

However, when the examiner can show well-founded reasons that a person skilled in the art would be unable to extend the particular mode for carrying out the invention in the detailed description of the invention to the whole of the field within the extent (or the metes and bounds) of the claimed invention, the examiner should determine that the claimed invention is not described in such a manner sufficiently clear and complete to be carried out by a person skilled in the art. In such a case, the examiner should specifically point out a concrete reason and preferably the reason above should be supported by reference documents.

#### 1.1.2.2 Ministerial Ordinance Requirement (See Implementing Guidelines, Chapter 1-3.3.)

Matters required under the Ministerial Ordinance are (1) technical field to which an invention pertains and (2) problem to be solved by the invention and its solution.

##### (1) Technical field to which an invention pertains

As "technical field to which an invention pertains," at least one technical field to which a claimed invention pertains shall be stated in a specification, in principle.

In the inventions of genetic engineering, "technical field to which an invention pertains" should be described such as pharmaceuticals, analytical agents, production of plants, for example.

##### (2) Problem to be solved by the invention and its solution

As "problem to be solved by the invention," an application shall state at least one technical problem to be solved by a claimed invention, in principle. As "its solution," an application shall explain how the technical problem has been solved by the claimed invention.

For example, in the case of the invention of the process for the production of a plant resistant to disease A by using a vector into which disease A-resistant gene B has been inserted, the problem to be solved by the invention should be described as "to produce a plant resistant to disease A" and the means for solving the problem should be described as "cloning disease-resistant gene B from the chromosomal DNA of another plant resistant to disease A, obtaining a recombinant vector inserted by the said gene, and regenerating the plant body from the plant cell transformed by the said vector."

#### 1.1.2.3 Prior Art and Advantageous Effects (See Implementing Guidelines, Chapter 1-3.3.2(3).)

##### (1) Prior art

An applicant should describe background prior art, as far as he knows, which is deemed to contribute to understanding the technical significance of the claimed invention and examination of patentability of the invention, because such descriptions of prior art could teach the problem to be solved and could substitute the descriptions of the problems.

Also, documents related to prior art are one of the important means for evaluating the patentability of the claimed invention. Therefore, when there exist any documents relevant to the claimed invention, it is strongly recommended to cite such documents.

##### (2) Advantageous effects over prior art

It is an applicant's advantage to describe an advantageous effect of a claimed invention over the relevant prior art because such advantageous effect, if any, is taken into consideration as a fact to support to affirmatively infer the existence of an inventive step. Therefore, an applicant should describe an advantageous effect of a claimed invention over the relevant prior art, if any, as far as he knows.

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<sup>4</sup> (See Implementing Guidelines, Chapter 1-3.2.1(6) and 3.2.3.)

### 1.1.3 Sequence Listing

(1) When a nucleotide sequence consisting of 10 or more nucleotides, or an amino acid sequence of a protein or peptide consisting of 4 or more L-amino acids is described in a specification, a "Sequence Listing" of the sequence prepared in accordance with "Guidelines for the preparation of specifications which contain nucleotide and/or amino acid sequence" published by the Public Notice of Japanese Patent Office should be described at the end of the detailed description of the invention as a part of it (See Note 15e of Form 29, Section 24 of Regulations under the Patent Law, and Note 12e of Form 14, Section 11 of Regulations under the Law concerning the Special Provisions to the Procedure, etc. relating to the Industrial Property Right). The "Sequence Listing" should be submitted in coding data.

(2) When a nucleotide sequence or an amino acid sequence is described in the scope of claim, the sequence described in the "Sequence Listing" prepared in accordance with "Guidelines for the preparation of specification which contain nucleotide and/or amino acid sequence" may be cited.

### 1.2 Unity of Invention

-applicable to applications filed on or after January 1, 1988-  
(See Implementing Guidelines, Chapter 3-2.)

A single application may be filed for a set of claims describing inventions shown in the following examples.

#### [Example 1]

- 1) An invention of a chemical substance produced with the use of a transformant (referred to as the "specified invention")
- 2) An invention of a structural gene
- 3) An invention of a recombinant vector containing the structural gene; and
- 4) An invention of a transformant containing the structural gene

#### [Explanation]

A structural gene has an inherent function of determining the amino acid sequence of a specific chemical substance. Therefore, in providing the specific chemical substance, inventions of a structural gene, a recombinant vector containing the structural gene and a transformant containing the structural gene have a very close relationship with the chemical substance. Thus, since it may be considered that the inventions of the structural gene, the recombinant vector and the transformant provide means to obtain the specific chemical substance, these inventions and the invention of the chemical substance produced with the use of the transformant are considered to solve the same problem. Accordingly, the specified invention and inventions 2 to 4 above meet the relationship under Section 37(i) of the Patent Law.

In such a case, a claim directed to a process for producing the structural gene, the recombinant vector, or the transformant having the relationship provided in Section 37(iii) of the Patent Law with the inventions 2 to 4, for instance, may be included in a single application in accordance with the provision of Section 37(v) of the Patent Law.

#### [Example 2]

- 1) An invention of a parent cell (specified invention); and
- 2) An invention of a fused cell prepared from the parent cell

#### [Explanation]

Since a fused cell contains, in general, the characters of its parent cell as a part of its characters, the substantial part of the matters being to be stated in the claim of both inventions is considered to be the same. Accordingly, the specified invention and the invention 2 above meet the relationship under Section 37(ii) of the Patent Law.

#### [Example 3]

- 1) An invention of a transformant (specified invention)
- 2) An invention of a process for manufacturing a chemical substance using the transformant

#### [Explanation]

An invention of a process for producing a chemical substance using a transformant falls within the "invention directed to a process using the product" provided in Section 37(iii) of the Patent Law, because it utilizes functions and characteristics of the transformant.

[Example 4]

- 1) An invention of a gene (specified invention),
- 2) An invention of a process for producing a recombinant vector using the said gene; and
- 3) An invention of a process for producing a transformant using the said gene

[Explanation]

The invention 2 and invention 3 above fall within the "invention of a process using the product" under Section 37(iii) of the Patent Law, because it utilizes functions and characteristics of the gene.

[Example 5]

- 1) An invention of an antigenic protein (specified invention); and
- 2) An invention of a monoclonal antibody against the antigenic protein

[Explanation]

It is obvious that the above-mentioned protein is antigenic and an antigen is associated with a monoclonal antibody. An invention of the antigenic protein has a very close relationship with the monoclonal antibody in providing the monoclonal antibody against the antigenic protein. Since the invention of the antigenic protein is considered to aim at providing the monoclonal antibody against the antigenic protein, both inventions have the same problem to be solved. Accordingly, the specific invention and the invention 2 above fall within the relationship under Section 37(i) of the Patent Law.

However, the patent application does not meet the requirements of Section 37 of the Patent Law in the following case.

[Example 6]

- 1) An invention of a transformant (specified invention); and
- 2) An invention of a process using a chemical substance produced with the use of the transformant

[Explanation]

The specified invention and the invention 2 above do not fall within any of the relationships provided in Items of Section 37 of the Patent Law.

However, when a claim directed to the chemical substance produced with the use of the transformant is added, the invention 2 above has the relationship provided in Section 37(iii) of the Patent Law with the invention described in the added claim having the relationship provided in Section 37(i) of the Patent Law with the specified invention, and these inventions may be included in a single application in accordance with the provision of Section 37(v) of the Patent Law.

### 1.3 Requirements for Patentability

#### 1.3.1 Invention Not Falling within "Industrially Applicable Invention"

Inventions of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein and a monoclonal antibody whose utility is not described in a specification or cannot be inferred, do not meet the requirements set forth in the first sentence in Section 29(1) of the Patent Law.

#### 1.3.2 Novelty (See Implementing Guidelines, Chapter 2-1.)

##### (1) Recombinant protein

1) Where a protein X as an isolated and purified single substance is publicly known, a claimed invention concerning a recombinant protein X specified by a process of production, the said recombinant protein being identical as a chemical substance with the publicly known protein X, is not novel.

2) In case where a recombinant process inevitably leads to a different product, for example in its sugar chain or the like, due to the difference of the host cells, even though the recombinant protein has the same amino acid sequence as the publicly known one, a claimed invention concerning the recombinant protein specified by a process of production is novel.

##### (2) Monoclonal antibody

1) If antigen A is novel, a monoclonal antibody to the antigen A is generally considered novel. However, if a monoclonal antibody to publicly known antigen A' is publicly known and if the antigen A has the same epitope as that of A' because the antigen A is partially modified from publicly known antigen A' or the like, a monoclonal antibody to antigen A' also binds to antigen A. Therefore, in such a case, the claimed invention of "a monoclonal antibody to antigen A" is not novel.

2) The claimed invention of a monoclonal antibody specified by a cross-reactivity, such as "a monoclonal antibody which binds not to antigen B but to antigen A" is not novel, if a monoclonal antibody to antigen A is publicly known and if there is no particular technical significance to specify the monoclonal antibody described by such a cross-reactivity (e.g., when it is clear that the publicly known monoclonal antibody to antigen A does not bind to antigen B either, because antigen B has no similarities to antigen A in the function, structure, etc.).

### 1.3.3 Inventive Step (See Implementing Guidelines, Chapter 2-2.)

#### (1) Gene

1) An invention of a gene encoding Protein A has an inventive step, if Protein A has novelty and an inventive step.

2) Where Protein A is publicly known but its amino acid sequence is not publicly known, an invention of a gene encoding Protein A does not have an inventive step, provided that a person skilled in the art could determine the amino acid sequence easily at the time of filing. However, when it is considered that the gene is specified by a specific base sequence and has advantageous effects that a person skilled in the art cannot foresee in comparison with other genes having a different base sequence encoding the Protein A, the invention of the said gene has an inventive step.

3) When an amino acid sequence of Protein A is publicly known, an invention of a gene encoding the Protein A does not have an inventive step. However, when it is considered that the gene is specified by a specific base sequence and has advantageous effects that a person skilled in the art cannot foresee in comparison with other genes having a different base sequence encoding the Protein A, the invention of the said gene has an inventive step.

4) When a structural gene is publicly known, an invention relating to a structural gene of naturally obtainable mutant (allelic mutant, etc.) of the said publicly known structural gene and which is derived from the same species as the said structural gene and has the same properties and functions as the said structural gene does not have an inventive step. However, if the claimed structural gene has advantageous effects that a person skilled in the art cannot foresee in comparison with the said publicly known structural gene, the claimed invention of the structural gene has an inventive step.

#### (2) Recombinant vector

In case where both a vector and a gene to be introduced are publicly known, a claimed invention concerning a recombinant vector obtained by a combination of them does not have an inventive step.

However, even if both a vector and a gene to be introduced are publicly known, a claimed invention concerning a recombinant vector with a specific combination of them, which leads to an advantageous effect that a person skilled in the art cannot foresee, has an inventive step.

#### (3) Transformant

If both a host and a gene to be introduced are publicly known, a claimed invention concerning the transformant obtained by a combination of them does not have an inventive step.

However, even if both of a host and a gene to be introduced are publicly known, a claimed invention concerning a transformant with a specific combination of them, which leads to an advantageous effect that a person skilled in the art cannot foresee, has an inventive step.

#### (4) Fused cell

If both of parent cells are publicly known, a claimed invention concerning a fused cell produced by fusing both of the parent cells does not have an inventive step. However, if the fused cell has advantageous effects that a person skilled in the art cannot foresee, the claimed invention of the fused cell has an inventive step.

#### (5) Monoclonal antibody

If antigen A is publicly known and it is clear that the antigen A has immunogenicity (for example, antigen A clearly has immunogenicity because a polyclonal antibody to the antigen A is publicly known or because the antigen A is a polypeptide with a large molecular weight, etc.), the claimed invention of "a monoclonal antibody to the antigen A " does not have an inventive step. However, if the claimed invention is further specified by other features, etc. which leads to an advantageous effect that a person skilled in the art cannot foresee, the claimed invention has an inventive step.

#### 1.4 Amendment of Specification

Amendment of the specification relating to the deposit of microorganisms, etc. is handled as described in "2.3 Amendment of Specification" below.

## 2. Microorganisms

This section deals with inventions related to microorganisms per se as well as those related to the use of microorganisms, etc. Inventions relating to the use of microorganisms include not only those using a novel microorganism but also those based on finding of a method for using a publicly known microorganism (e.g., an invention of a process for producing a publicly known substance using a publicly known microorganism, an invention of a process for treating a material (e.g., water treatment, soil improvement) using a publicly known microorganism, an invention of use for a publicly known microorganism as a treating agent (e.g., water treating agent, soil improving agent).

The term "microorganisms" means yeasts, molds, mushrooms, bacteria, actinomyces, unicellular algae, virus, protozoa, etc. and further includes undifferentiated animal or plant cells as well as animal or plant tissue cultures. Matters relating to genetic engineering are referred to "1. Genetic Engineering" even if they are inventions relating to microorganisms.

### 2.1 Description Requirements for the Specification

#### 2.1.1 Designation of Microorganisms

In principle, microorganisms should be specified by scientific names in accordance with microbiological nomenclature. In case of designating a strain of a microorganism, it should be specified by the strain name following the species name (in accordance with microbiological nomenclature). When a microorganism cannot be specified by the species name, it may be specified by the strain name along with the genus name.

In case that a strain of a microorganism has been deposited, the said strain may be specified by the description of the accession number in addition to the species name or the strain name following the species name.

Example:

*Bacillus subtilis* FERM P-xxxxx strain

Undifferentiated animal or plant cells should be specified, in principle, by scientific names in accordance with zoological or botanical nomenclature or standard Japanese names, respectively.

#### 2.1.2 Scope of Claim (See 1.1.1 above.)

According to Section 36(6)(ii) of the Patent Law, the invention for which a patent is sought shall be clear, therefore, scope of claim shall be described that an invention shall be clearly identified on the basis of statements of each claim.

#### 2.1.3 The Detailed Description of the Invention (See 1.1.2 above.)

##### 2.1.3.1 Enablement Requirement (See 1.1.2.1 above.)

###### 2.1.3.1.1 An Invention of a Product (See 1.1.2.1.1 above.)

As to an invention of a product, a microorganism to be created or a microorganism to be used should be described as follows.

##### (1) A microorganism being explained clearly

In order to explain a microorganism clearly, the microorganism should be described as indicated below.

As to a new microorganism, the microorganism should be specified by the species name or the strain name following the species name in accordance with microbiological nomenclature, and also the microbiological characteristics should be described. As microbiological characteristics, it is desirable that taxonomic characteristics generally used in the field (Appendix 1) are described, however, other microbiological characteristics (e.g., selective productivity of metabolites) may be described.

A microorganism which cannot be specified by the species name should be specified by the strain name along with the genus name, after clarifying the reason why the species name cannot be specified.

Microbiological characteristics of a microorganism should be described as follows, depending on whether it is a new strain or a new species.

##### 1) New strain

It should be clearly described that the characteristics of the strain as well as the difference in the microbiological characteristics of the strain from the publicly known strains within the same species to which the new strain belongs.

## 2) New species

The taxonomic characteristics of the species should be described in detail, and the reason why the microorganism is judged to be a new species should be clarified. That is, the difference of the species from the existing similar species should be expressly described, and the relevant literature used on the basis of the judgement should be indicated.

## (2) "Can be made"

As to an invention relating to a microorganism per se or relating to the use of a novel microorganism, means for creating the microorganism should be described so that a person skilled in the art can create the said microorganism. Means for creating microorganisms includes means for screening, means for mutagenesis, means for gene recombination, etc.

If the means for creating the microorganism cannot be described in the detailed description of the invention so that a person skilled in the art can create the said microorganism, it is necessary to deposit the microorganism in accordance with Section 27<sup>b15</sup> of Regulations under the Patent Law (the detail is as follows).

## 1) Deposit and Furnishing of Microorganisms

### Section 27<sup>b15</sup> of Regulations under the Patent Law (Deposition of microorganisms)

1 A person desiring to file a patent application for an invention involving or using a microorganism shall attach to the request a copy of the latest receipt referred to in Rule 7 of the Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (hereinafter referred to as "Treaty") for the deposit of the microorganism issued by the international depository authority defined in Article 2(viii) of the Treaty, or a document certifying the fact that the microorganism has been deposited with an institution designated by the Commissioner of the Patent Office, except where the microorganism is readily available to a person skilled in the art to which the invention pertains.

2 Where an accession number is newly given after the filing of a patent application to the deposit of a microorganism under the preceding paragraph, the applicant for a patent or the patentee shall notify the Commissioner of the Patent Office without delay.

3 The notification under the preceding paragraph shall be made in accordance with Form 32 with respect to a patent application, or Form 33 with respect to an International Patent Application.

### Section 27<sup>c17</sup> of Regulations under the Patent Law (Furnishing of microbiological samples)

1 A person who intends to work for the purpose of tests or experiments an invention involving or using a microorganism deposited in accordance with the preceding section may be furnished with a sample of the microorganism provided that:

(i) registration for the establishment of a patent right to the invention involving or using the microorganism has been made;

(ii) the person received a warning given in the form of a document describing the contents of the invention involving or using the microorganism in accordance with Section 65(1) of the Patent Law; or

(iii) such is necessary in order to prepare a written argument referred to in Section 50 of the Patent Law (including its application under Section 159(2) (including its application under Section 174(2)) and Section 163(2)).

2 A person who has been furnished with a sample of the microorganism in accordance with the preceding paragraph shall not permit a third party to utilize the sample of the microorganism.

(i) A person desiring to file a patent application for an invention involving or using a microorganism, shall deposit the microorganism with a depository institution designated by the Commissioner of the Patent Office or international depository authorities (hereinafter, the both are referred to as "depository institution for the purposes of patent procedure"), unless a person skilled in the art can easily obtain the microorganism, shall state the accession number in the specification as filed, and shall attach to the request a document certifying the fact that the microorganism has been deposited.

When a new accession number is given to the microorganism after filing, for the reason that, e.g., re-deposit was made, samples of the microorganism were transferred to another international depository authority, or the deposit was converted from the deposit under the national law to that under the Budapest Treaty, the applicant or the patentee shall give a notice to that effect to the Commissioner of the Patent Office without delay.

Where a microorganism which was deposited with a depository institution designated by the Commissioner of the Patent Office and was confirmed to be viable is found to be no longer viable, the depositor, upon receipt of the "Notice that the microorganism cannot be furnished" (Official Gazette of MITI No.178 Section 15) from the depository institution, should deposit immediately the same microorganism as that originally deposited. Where the

microorganism is related to a patent application or a patent, the applicant or the patentee should give a notice to that effect to the Commissioner of the Patent Office without delay. In such a case, the newly deposited microorganism is treated as having been deposited without intermission since the original deposit was made.

The deposited microorganism can be furnished simultaneously with the registration for establishment of a patent right. Even prior to the registration for establishment of a patent right, though, in the case where Section 27<sup>ter</sup> (1)(ii) or (iii) of Regulations under the Patent Law is applied, the microorganism can be furnished.

The deposit of a microorganism should be maintained at least during the term of the patent for the invention related to the microorganism so that the microorganism can be furnished.

For reference, a list of International Depositary Authorities and kinds of microorganisms accepted by the IDAs is shown in Appendix 2.

(ii) Microorganisms excluded from obligation to be deposited

(a) Microorganisms which cannot be stored or maintained by the depositary institution for the purpose of patent procedure for technical reasons or the like

In such a case, however, furnishing of the microorganisms provided in Section 27<sup>ter</sup> of Regulations under the Patent Law should be guaranteed by the applicant. (Such microorganisms should be preferably deposited with a reliable cultural collection.)

(b) Microorganisms readily available to the persons skilled in the art stated in "Section 27<sup>bis</sup> of Regulations under the Patent Law"

More specifically, the following microorganisms are included for example:

(b-1) Commercially available microorganisms, such as baker's yeast, koji (*Aspergillus oryzae*), *Bacillus natto*, etc.

(b-2) A stored microorganism in the case where it has been confirmed, prior to filing, that the microorganism has been stored at a reliable cultural collection and is freely accessible from a catalog or the like issued by the said cultural collection

In this case, the storage number of the microorganism should be described in the specification as filed.

(b-3) Microorganisms which can be created by a person skilled in the art on the basis of the description in the specification

(iii) Where a claimed invention in an application claiming priority relates to a microorganism which is not readily available to a person skilled in the art, the application can enjoy advantages of the priority provided that the microorganism has been deposited with a depositary institution for the purpose of patent procedure or a reliable public cultural collection and that the accession number or storage number of the microorganism is stated in the specification contained in the first application which has served as a basis for claiming a right of priority or in the specification contained in the earlier application which has served as a basis for claiming a right of internal priority.

(3) "Can be used"

For the invention of a microorganism per se or of the use of a microorganism, in order to show the industrial applicability of it, the way of industrial application of the product shall be described in the detailed description of the invention except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

2.1.3.1.2 An Invention of a Process (See Implementing Guidelines, Chapter 1-3.2.1 (3).)

Of those inventions related to the use of a microorganism, an invention of a process for the use of a microorganism (e.g. an invention of a process for treating a material with a microorganism) should be described as follows.

For an invention of a process, the definition of carrying out the invention is to use the process and that a process can be used is interpreted as meaning that a process can be used in an industrially applicable way. Further, "the said invention of a process" should be explained clearly in the detailed description of the invention.

Accordingly, for the invention of a process for the use of microorganism, in order to show the industrial applicability of it, the way of industrial application of the process shall be described in the detailed description of the invention except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing. In order to describe the industrial applications, the enablement requirement described in

"2.1.3.1.1 An Invention of a Product" should be referred to, if necessary. For instance, "2.1.3.1.1 An Invention of a Product (2) Deposit and furnishing of microorganisms" should be referred to, if the deposit of microorganisms is necessary.

2.1.3.1.3 An Invention of a Process for Manufacturing a Product (See Implementing Guidelines, Chapter 1-3.2.1(4).)

Of those inventions related to the use of a microorganism, an invention of a process for producing a substance using a microorganism should be described as follows.

Where an invention of a process is directed to "a process for manufacturing a product," the definition of "the process can be used" means that the product can be manufactured by the process and either the process or the product shall be industrially applicable to meet industrial application. Further, the said invention of a process for manufacturing a product should be explained clearly in the detailed description of the invention.

Accordingly, for the invention of a process for producing a substance by using a microorganism, a process for producing the said substance shall be described in the detailed description of the invention so that a person skilled in the art can produce the said substance taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing. In order to describe the process in such a manner that a person skilled in the art can produce the said substance by the process, the enablement requirement described in "2.1.3.1.1 An Invention of a Product" should be referred to, if necessary. For instance, "2.1.3.1.1 An Invention of a Product (2) Deposit and furnishing of microorganisms" should be referred to, if the deposit of microorganisms is necessary.

Further, it is necessary to describe the industrial applicability of the said process or at least one use of the said substance.

As to "How Specifically the Detailed Description of the Invention Must Be Described?" and "Balance of the Claim and the Detailed Description of the Invention," see the relevant portions (1.1.2.1.4 and 1.1.2.1.5) in "1. Genetic Engineering."

2.1.3.2 Ministerial Ordinance Requirement (See 1.1.2.2 above.)

Matters required under the Ministerial Ordinance are (1) technical field to which an invention pertains and (2) problem to be solved by the invention and its solution.

(1) Technical field to which an invention pertains

As "technical field to which an invention pertains," at least one technical field to which a claimed invention pertains shall be stated in a specification, in principle.

In the inventions related to a microorganism, "technical field to which an invention pertains" should be described such as pharmaceuticals, feed, food, water treatment, for example.

(2) Problem to be solved by the invention and its solution

As "problem to be solved by the invention," an application shall state at least one technical problem to be solved by a claimed invention, in principle. As "its solution," an application shall explain how the technical problem has been solved by the claimed invention.

As to "Prior Art and Advantageous Effects," see 1.1.2.3 in "1. Genetic Engineering."

## 2.2 Requirements for Patentability

### 2.2.1 Invention Not Falling within "Industrially Applicable Invention"

The following inventions do not meet the requirement provided in the first sentence in Section 29(1) of the Patent Law.

(1) A mere discovery which is not a creation

Example: A merely discovered microorganism existing in nature.

However, an invention of a microorganism which is isolated from nature artificially involves creativity.

(2) Inventions incapable of industrial application

An invention of a microorganism per se whose utility is not described or cannot be inferred.

### 2.2.2 Inventive Step (See Implementing Guidelines, Chapter 2-2.)

#### (1) Invention of a microorganism per se

An inventive step of an invention of a microorganism per se should be examined based on taxonomic characteristics of the microorganism as well as effects produced by the use of the microorganism.

- 1) An invention of a microorganism whose taxonomic characteristics are remarkably different from those of publicly known species (i.e., a new species) has an inventive step.
- 2) An invention involving a microorganism producing advantageous effects that a person skilled in the art cannot foresee, though the taxonomic characteristics of the microorganism are not substantially different from those of publicly known species, has an inventive step.

Example:

A microorganism which was obtained by mutating a publicly known species and which has remarkably high productivity of metabolite.

#### (2) Invention relating to the use of a microorganism

- 1) An invention relating to the use of a microorganism (e.g., an invention of a process for producing a substance) does not have an inventive step, if the microorganism used in the invention is a taxonomically known species and belongs to the same genus as another microorganism for which the same mode of use (e.g., producing the aimed substance) is known. However, if it is found that the invention using the former microorganism has advantageous effects that a person skilled in the art cannot foresee in comparison with the invention using the latter microorganism, the invention using the former microorganism has an inventive step.

(Explanation)

Between publicly known species in the same genus, it is usually easy for a person skilled in the art to culture each microorganism and confirm its utility (e.g., substance productivity) and its effects.

- 2) An invention relating to the use of a microorganism (e.g., an invention of a process for producing a substance) has an inventive step, if the microorganism used in the invention is remarkably different from publicly known species in taxonomic characteristics (i.e., a new species), even if the mode of use (e.g., the aimed substance) is the same.

(Explanation)

Since the used microorganism per se has an inventive step as described (1) 1) above, a process using the microorganism has also an inventive step.

### 2.3 Amendment of Specification

- applicable to applications filed on or after January 1, 1994 -

(See "Implementing Guidelines for Amendment of Specification and Drawings" (Nov. 1993, the Japanese Patent Office) Chapter 1-1.)

- (1) An amendment of an accession number of a microorganism is not regarded as addition of a new matter, where microbiological characteristics of the microorganism are described to the extent that the microorganism can be specified in the specification as filed and deposit of the microorganism can be specified based on the name of the depositary institution, etc.

In such a case, the applicant should make an amendment of the accession number without delay.

- (2) An amendment converting a storage number of a microorganism to an accession number based on the deposit of the microorganism with a depositary institution for the purpose of patent procedure is not regarded as addition of a new matter, where the microorganism used is stored at a reliable public cultural collection and the storage number of the microorganism is explicitly stated in the specification as filed and that it is clear that the identity of the microorganism is not lost.

In such a case, the applicant should make an amendment of the accession number without delay.

- (3) An amendment adding microbiological characteristics of a microorganism is regarded as addition of a new matter unless a person skilled in the art can directly and unambiguously derive those characteristics from what is described in the specification and drawings as filed, even if the accession number of the microorganism stated in the

specification as filed is not changed and microbiological characteristics of the microorganism are described in the specification as filed to the extent that the taxonomic species of the microorganism can be specified.

### 3. Plants

This section deals with inventions of plants per se, those relating to parts of plants (e.g., a fruit), those of a process for creating plants, those relating to use of plants, etc. The term "plants" means the plants under the classification where organisms are classified into three groups, namely microorganisms, plants and animals.

As to undifferentiated plant cells as well as plant tissue cultures, which are treated as microorganisms, reference should be made to relevant parts in "2. Microorganisms."

Matters relating to genetic engineering are referred to "1. Genetic Engineering" even if they are inventions relating to plants.

#### 3.1 Description Requirements for the Specification

##### 3.1.1 Designation of Plants

In principle, plants should be specified by scientific names in accordance with the botanical nomenclature or standard Japanese names.

##### 3.1.2 Scope of Claim (See 1.1.1 above.)

As to an invention relating to a plant, a claim should be described as follows.

In the case of an invention of a plant per se, the plant should be specified by, for example, a combination of any of the species, the distinctive gene of the plant, characteristics of the plant, etc. and may be further specified by the process for creating the plants.

##### Example 1:

A plant belonging to *Castanea crenata* (Japanese chestnut) having the ATCC Accession No. xxxx whose bark contains catechol tannin and pyrogallol tannin in the ratio of  $X_1 - X_2 : Y_1 - Y_2$  and has a catechol tannin content of  $z_1 - z_2$  ppm (weight ratio), or its mutant having the said characteristics.

##### Example 2:

A watermelon obtained by crossing a diploid watermelon with a tetraploid watermelon obtained by polyploidizing a diploid watermelon, whose somatic cell has 33 chromosomes.

As to an invention of a process for creating a plant, the process for creating the plant should be described in the claim step by step. In the case where selection is performed as one step of creation based on characteristics or the like, the characteristics or the like necessary for the selection should be additionally described. Where conditions such as environment are necessary for creating the plant, such conditions should be also described.

##### Example:

A process for creating a cabbage characterized by crossing a cabbage strain having the ATCC Accession No. xxxx as a seed parent with another cabbage as a pollen parent by having resistance for the herbicide X.

##### 3.1.3 The Detailed Description of the Invention (See 1.1.2 above.)

As to an invention of a plant per se or that of a process for creating a plant, the detailed description of the invention should be described as follows.

##### 3.1.3.1 Enablement Requirement (See 1.1.2.1 above.)

##### 3.1.3.1.1 An Invention of a Product (See 1.1.2.1.1 above.)

An invention of a plant per se should be described as follows.

- (1) A plant being explained clearly

In order to explain a plant clearly, for example, 1) matters regarding species of the plant created and 2) matters relating to characteristic properties of the created plant should be described.

#### 1) Species of the plant created

In principle, the created plant should be specified by the scientific name in accordance with the botanical nomenclature or standard Japanese name.

#### 2) Characteristic properties of the plant created

In the case that properties of the created plant are characteristic, they should be described specifically stating by numeric values actually obtained by measuring or the like and it is desirable that they are described in comparison with those of publicly known plants, if necessary.

For instance, it should be described not by a mere statement that the plant is high-yielding, but concrete numeric values commonly used in conventional yield surveys, such as total number of fruits produced per stock, total weight of fruits produced per stock, gross yield per are, etc., and they should be described in comparison with those of publicly known plants, if necessary.

Colors, such as leaf color, fruit color, and flower color should be expressed in accordance with official standards, such as the color atlas JIS Z8721 which is a specification of colours according to their three attributes, JIS Z8102 concerning color names and the R.H.S. color chart.

Where characteristic properties of the created plant cannot be expressed by a conventional cultivation method which a person skilled in the art usually conducts, or where characteristic properties of the created plant are expressed only in specific environments and under specific cultivation method though the method is conventional, such specific cultivation conditions should be specifically described.

#### (2) "Can be made"

As to an invention of a plant per se, a process for creating the plant should be described step by step including species of parent plant(s), a step of selecting the plant to be aimed at based on objective indicators or the like.

(a) Where a person skilled in the art cannot carry out the invention because of unavailability of the parent plant(s) even if the process for creating the plant is described in the specification step by step, its parent plant(s) (seeds, cells, etc.) should be deposited with a depositary institution prior to filing and its accession number should be described in a specification as filed similarly to the deposit under Section 27<sup>bis</sup> of Regulations under the Patent Law.

(b) Where it is not possible to describe a process for creating the plant in the specification in such a manner that enables a person skilled in the art to create the plant, the created plant which is reproducible (seeds, cells, etc.) should be deposited with a depositary institution prior to filing and its accession number should be described in a specification as filed similarly to the deposit under Section 27<sup>bis</sup> of Regulations under the Patent Law.

However, where the above-mentioned plant cannot be deposited with the depositary institute for the purpose of patent procedure due to some technical reasons or the like, means for obtaining the above should be described in the specification and the applicant should guarantee the furnishing of the samples similarly to the furnishing of samples under Section 27<sup>ter</sup> of Regulations under the Patent Law. (Such a plant should be preferably deposited with a reliable cultural collection.)

For the details of the deposit and furnishing of microorganisms, etc., see "2.1.3.1.1 (2) Deposit and Furnishing of Microorganisms in 2. Microorganisms"

#### (3) "Can be used"

For an invention of a plant per se, in order to show the industrial applicability of it, the way of industrial application of the product shall be described in the detailed description of the invention except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

#### 3.1.3.1.2 An Invention of a Process for Manufacturing a Product (See 1.1.2.1.3 above.)

An invention of a process for creating a plant should be described as follows.

An invention of a process for creating a plant should be described in such a manner that enables a person skilled in the art to create the plant by the said process.

In order to describe the process in such a manner that a person skilled in the art can produce the said plant by the process, the enablement requirement described in "3.1.3.1.1 An Invention of a Product" should be referred to, if necessary. For example, in case that deposit of a plant is necessary, "3.1.3.1.1 (2) Can be made" should be referred to.

Further, in an invention of a process for creating a plant, how the process or the plant created by the process is industrially applicable should be described in the detailed description of the invention, except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

As to "How Specifically the Detailed Description of the Invention Must Be Described?", "Balance of the Claim and the Detailed Description of the Invention," " Ministerial Ordinance Requirement" and "Prior Art and Advantageous Effects," see the relevant portions (1.1.2.1.4, 1.1.2.1.5, 1.1.2.2 and 1.1.2.3) in "1. Genetic Engineering."

### 3.1.4 Drawings

When photographs are attached as drawings, black -and-white photographs should be used. Color photographs may be submitted as reference materials.

## 3.2 Requirements for Patentability

### 3.2.1 Invention Not Falling within "Industrially Applicable Invention"

The following inventions do not meet the requirement provided in the first sentence in Section 29(1) of the Patent Law.

#### (1) Mere discovery which is not a creation

Mere recognition of a plant existing in nature as it is does not involve creativity and is nothing but a discovery. Example: A newly discovered plant per se.

In order to show that an invention involves creativity, how the invention has been created should be described in the detailed description of the invention.

#### (2) Inventions incapable of industrial application

Inventions whose utility is not described or cannot be inferred.

### 3.2.2 Inventive Step

(1) An invention of a plant per se does not have an inventive step, where characteristics of the plant created can be easily predicted from the characteristics of publicly known plants within the species to which the plant belongs and where the invention does not have advantageous effects that a person skilled in the art cannot foresee.

#### Example 1:

A plant whose shape or color is similar to that of publicly known plants within the species to which the plant belongs.

#### Example 2:

Mere combination of the characteristics of publicly known plants within the species to which the plant belongs.

(Plants obtained by mere crossing: for instance, suppose that it is publicly known that *Pisum sativum* A (pea A) has a single-locus-controlling characteristics that the legume is yellow when premature and *Pisum sativum* B has a single-locus-controlling characteristics that it bears blossoms at each knot through the full length. In such a case, a new *Pisum sativum*, obtained by merely crossing *Pisum sativum* A and *Pisum sativum* B and fixing their characteristics, having characteristics that the legume is yellow when premature and it bears blossoms at each knot, does not have an inventive step.)

(2) An invention of a process for creating a plant does not have an inventive step, where the selection of parent plants, means, conditions or the like is not considered to be difficult and where the created plant does not have advantageous effects that a person skilled in the art cannot foresee.

### 3.3 Amendment of Specification

Amendment of the specification relating to the deposit of plants is handled as described in "2.3 Amendment of Specification" above.

## 4. Animals

This section deals with inventions of animals per se, those relating to parts of animals, those of a process for creating animals, those relating to use of animals, etc. The term "animals" means the animals (excluding humans) under the classification where organisms are classified into three groups, namely microorganisms, plants and animals.

As to undifferentiated animal cells as well as animal tissue cultures, which are treated as microorganisms, reference should be made to relevant parts in "2. Microorganisms."

Matters relating to genetic engineering are referred to "1. Genetic Engineering" even if they are inventions relating to animals.

### 4.1 Description Requirements for the Specification

#### 4.1.1 Designation of Animals

In principle, animals should be specified by scientific names in accordance with the zoological nomenclature or standard Japanese names.

#### 4.1.2 Scope of Claim (See 1.1.1 above.)

As to an invention relating to an animal, a claim should be described as follows.

In the case of an invention of an animal per se, the animal should be specified by, for example, a combination of any of the species, the distinctive gene of the animal, characteristics of the animal, etc. and may be further specified by the process for creating the animals.

Example:

A mouse having DSM Accession No.xxxxx characterized by the occurrence of degeneration and swelling of anterior lens cortical fibers at 8 weeks of age, appearance of opacity of the lens at 5 or 6 months of age and rapid completion of cataract immediately after that, or its mutant having the said characteristics.

As to an invention of a process for creating an animal, the process for creating the animal should be described in the claim step by step. In the case where selection is performed as one step of creation based on characteristics or the like, the characteristics or the like necessary for the selection should be additionally described. Where conditions such as environment are necessary for creating the animal, such conditions should be described.

#### 4.1.3 The Detailed Description of the Invention (See 1.1.2 above.)

As to an invention of an animal per se or that of a process for creating animals, the detailed description of the invention should be described as follows.

##### 4.1.3.1 Enablement Requirement (See 1.1.2.1 above.)

##### 4.1.3.1.1 An Invention of a Product (See 1.1.2.1.1 above.)

An invention of an animal per se should be described as follows.

##### (1) An animal being explained clearly

In order to explain an animal clearly, for example, 1) matters regarding species of the animal created and 2) matters relating to characteristic properties of the created animal should be described.

##### 1) Species of the animal created

In principle, the created animal should be specified by the scientific name in accordance with the zoological nomenclature or standard Japanese name.

## 2) Characteristic properties of the animal created

In the case that properties of the created animal are characteristic, they should be described specifically stating by numeric values actually obtained by measuring or the like and it is desirable that they are described in comparison with those of publicly known animals, if necessary.

Where characteristic properties of the created animal cannot be expressed by a conventional breeding method which a person skilled in the art usually conducts and they are expressed only in specific environments or only under specific breeding method, such specific conditions should be specifically described.

### (2) "Can be made"

As to an invention of an animal per se, the process for creating the animal should be described step by step including species of parent animal(s), a step of selecting an animal to be aimed at based on objective indicators or the like.

(a) Where a person skilled in the art cannot carry out the invention because of unavailability of the parent animal(s) even if the process of creating the animal is described in the specification step by step, its parent animal(s) (fertilized ovum, etc.) should be deposited with a depositary institution prior to filing and its accession number should be described in a specification as filed similarly to the deposit under Section 27<sup>bis</sup> of Regulations under the Patent Law.

(b) Where it is not possible to describe the process for creating the animal in the specification in such a manner that enables a person skilled in the art to create the animal, the created animal which is reproducible (fertilized ovum, etc) should be deposited with a depositary institution prior to filing and its accession number should be described in a specification as filed similarly to the deposit under Section 27<sup>bis</sup> of Regulations under the Patent Law.

However, where the above-mentioned animal cannot be deposited with the depositary institute for the purpose of patent procedure due to some technical reasons or the like, means for obtaining the above should be described in the specification and the applicant should guarantee the furnishing of the samples similarly to the furnishing of samples under Section 27<sup>ter</sup> of Regulations under the Patent Law. (Such an animal should be preferably deposited with a reliable cultural collection.)

For the details of the deposit and furnishing of microorganisms etc., see "2.1.3.1.1 (2) Deposit and Furnishing of Microorganisms in 2. Microorganisms"

### (3) "Can be used"

For an invention of an animal per se, in order to show the industrial applicability of it, the way of industrial application of the product shall be described in the detailed description of the invention except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

#### 4.1.3.1.2 An invention of a Process for Manufacturing a Product (See 1.1.2.1.3 above.)

An invention of a process for creating an animal should be described as follows.

An invention of a process for creating an animal should be described in such a manner that enables a person skilled in the art to create the animal by the said process.

In order to describe the process in such a manner that a person skilled in the art can produce the said animal by the process, the enablement requirement described in "4.1.3.1.1 An Invention of a Product" should be referred to, if necessary. For example, in case that deposit of an animal is necessary, "4.1.3.1.1 (2) Can be made " should be referred to.

Further, in an invention of a process for creating an animal, how the process or the animal created by the process is industrially applicable should be described in the detailed description of the invention, except where it could be understood by a person skilled in the art without such description when taking into account the overall descriptions of the specification (excluding claims), drawings and common general knowledge as of the filing.

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As to "How Specifically the Detailed Description of the Invention Must Be Described?", "Balance of the Claim and the Detailed Description of the Invention," " Ministerial Ordinance Requirement" and "Prior Art and Advantageous Effects," see the relevant portions (1.1.2.1.4, 1.1.2.1.5, 1.1.2.2 and 1.1.2.3) in "1. Genetic Engineering."

#### 4.1.4 Drawings

When photographs are attached as drawings, black -and-white photographs should be used. Color photographs may be submitted as reference materials.

### 4.2 Requirements for Patentability

#### 4.2.1 Invention Not Falling within "Industrially Applicable Invention"

The following inventions do not meet the requirement provided in the first sentence in Section 29(1) of the Patent Law.

##### (1) Mere discovery which is not a creation

Mere recognition of an animal existing in nature as it is does not involve creativity and is nothing but a discovery. Example: A newly discovered bird per se.

In order to show that an invention involves creativity, how the invention has been created should be described in the detailed description of the invention.

##### (2) Inventions incapable of industrial application

Inventions whose utility is not described or cannot be inferred.

#### 4.2.2 Invention Contravening Public Order, Morality or Public Health

When working of an invention inevitably contravenes public order, morality or public health, the invention falls under the invention as provided in Section 32 of the Patent Law.

#### 4.2.3 Inventive Step (See Implementing Guidelines, Chapter 2-2.)

(1) An invention of an animal per se does not have an inventive step, where characteristics of the animal created can be easily predicted from the characteristics of publicly known animals within the species to which the animal belongs and where the invention does not have advantageous effects that a person skilled in the art cannot foresee.

(2) An invention of a process for creating an animal does not have an inventive step, where the selection of parent animal(s), means, conditions or the like is not considered to be difficult and where the created animal does not have advantageous effects that a person skilled in the art cannot foresee.

### 4.3 Amendment of Specification

Amendment of the specification relating to the deposit of animals is handled as described in "2.3 Amendment of Specification" above.

Appendix 1:  
The Guidelines for Describing Taxonomic Characters

Appendix 2:  
The List of International Depository Authorities and Kinds of Microorganisms Accepted by the IDAs

[Reference]

The application of these guidelines should be as follows.

#### 1. Genetic Engineering

(i) New practices under the 1994-Revised Japanese Patent Law to be applicable to applications filed on and after July 1, 1995.

1.1 Description Requirements for Specification

1.1.1 Scope of Claim

1.1.2 The Detailed Description of the Invention (1.1.2.2 Ministerial Ordinance Requirement)

(ii) Clarification of the ambiguity of some current practices to be applicable to all pending applications.

1.1 Description Requirements for Specification

1.1.2 Description of the Invention (1.1.2.1 Enablement Requirement)

1.1.3 Sequence Listing

1.2 Unity of Invention

1.3 Requirements for Patentability

2. Microorganisms

Ditto

3. Plants

Ditto

4. Animals

Ditto

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**Examples of examinations on the inventions related to genes (DNA fragments, full-length cDNAs, and Single Nucleotide Polymorphisms)" (abridged translation)**

The original version of the "Examples of examinations on the inventions related to genes (DNA fragments, full-length cDNAs, and Single Nucleotide Polymorphisms)" is available from the JPO homepage. When any ambiguity of interpretation is found in this translation, the Japanese original text shall prevail.

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1. Unity of Invention

Case 1 (Unity of Invention : No) DNA fragments

Case 2 (Unity of Invention : Yes) DNA fragments

2. Enablement Requirement: No

Case 3 Full-length cDNA

Case 4 Full-length cDNA

Case 5 Full-length cDNA

3. Inventive Step: No

Case 6 Full-length cDNA

4. Inventive Step: No, Enablement Requirement : No

Case 7 DNA fragment

Case 8 SNPs

5. Inventive Step: Yes, Enablement Requirement : Yes

Case 9 DNA fragment

Case 10 Full-length cDNA

Case 11 SNP

## 1. Unity of Invention

### Case 1 DNA fragments (Unity of invention: no)

#### **Claims**

1. A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:1.
2. A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:2.

#### **Description of the invention**

Both of the claimed 500bp polynucleotides were derived from the same cDNA library constructed from human liver. Both of the claimed polynucleotides are part of structural genes, and they can be used as probes in one of the steps to obtain the full-length DNAs. The nucleotide sequence of SEQ ID NO:1 showed 5% homology to the nucleotide sequence of SEQ ID NO:2.

#### **Result of the prior-art search**

The nucleotides derived from human liver are known.

#### **Reason for rejection (Unity of invention)**

As there are so many known polynucleotides derived from human liver, the mere fact that these DNA sequences have the same source does not mean that these sequences have the same technical problem to be solved because the technical problem must be the one which is unsolved before the filing.

Furthermore, it cannot be said that substantial parts of the matters stated in the claims are the same since the nucleotide sequence of SEQ ID NO:1 showed 5% homology to the nucleotide sequence of SEQ ID NO:2.

In this case, therefore, unity of invention cannot be acknowledged.

#### **(Attention)**

If the application does not comply with the requirement of unity of invention, the invention set forth in the first claim (and those inventions having unity with the said invention) should be examined in respect of other requirements (novelty, inventive step, enablement requirement, etc.)

Please refer to the case 7 in respect of other requirements.

### **Case 2 DNA fragments (Unity of Invention: yes)**

#### ***Claims***

1. A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:3.
2. A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:4.

#### ***Description of the invention***

These polynucleotides are the 500bp cDNAs which were found in cDNA library derived from hepatocyte of patients with disease Y but not found in those of normal persons. It was confirmed by northern hybridization that the corresponding mRNAs were expressed only in the patients' hepatocyte.

Therefore, these polynucleotides can be used as probes to diagnose disease Y. The nucleotide sequence of SEQ ID NO:3 showed 5% homology to the nucleotide sequence of SEQ ID NO:4.

#### ***Result of the prior-art search***

There is no known polynucleotide or protein which are unique in the patients with disease Y.

#### ***Reason for rejection (unity of invention)***

No reason for rejection

(Attention)

Since both of the claimed inventions are related to specific DNAs in the patients with disease Y, the field of industrial application is considered to be the same. And both of the claimed inventions have the same problem to be solved that they provide for the first time multiple group of polynucleotides which are specific to patients with disease Y because no such DNA was known before the time of filing. Therefore, these claims have unity of invention.

Please refer to case 9 in respect of other requirements.

## **2. Enablement Requirement :No**

### **Case 3 Full-length cDNA**

#### ***Claim 1***

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 5.

#### ***Description of the invention***

The claimed polynucleotide is 3000bp cDNA obtained from human liver cDNA library. It encodes a polypeptide of amino acid sequence of SEQ ID NO:6. As a result of similarity search, no known sequences showed over 30% similarity to the nucleotide sequence of SEQ ID NO:5 or the amino acid sequence of SEQ ID NO:6. The amino acid sequence of SEQ ID NO:6 was proved to have a potential site of glycosylation.

Therefore, the claimed polynucleotide is assumed to be a structural gene encoding a new glycoprotein, whose specific function is unknown, and may be used for obtaining a new drug.

**Result of the prior-art search**

There is no known nucleotide sequence with over 30% similarity to that of SEQ ID NO:5.  
There is no known amino acid sequence with over 30% similarity to that of SEQ ID NO:6.

**Reason for rejection**

Even if the claimed polynucleotide encodes glycoprotein, the corresponding glycoprotein's specific function cannot be recognized because there are so many glycoproteins whose specific function differs from each other. The specific function of the claimed polynucleotide also cannot be assumed with the common general knowledge. As the specific function of the claimed polynucleotide is not clear, it is not clear how to use the claimed polynucleotide.

Therefore, there is no disclosure concerning the use of the claimed polynucleotide, thus, the description of the invention is deemed insufficient for enabling a person skilled in the art to carry out the invention.

(Attention)

The above mentioned reason for rejection normally shall not be overcome.

**Case 4 Full-length cDNA****Claim 1**

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:7.

**Description of the invention**

The claimed polynucleotide is 2400bp cDNA obtained from human liver cDNA library. It encodes a polypeptide of 800 amino acids of SEQ ID NO.8. As a result of similarity search using a known DNA and amino acid database, the claimed polynucleotide showed 20 to 30% homology to the polynucleotides encoding factor WW1 of mammals such as rats. The polynucleotides are written in document A, document B, etc. And the amino acid sequence of SEQ ID NO.8 showed 20 to 30% homology to the amino acid sequences of factor WW1 of mammals such as rats. The amino acid sequences are also written in document A, document B, etc.

Therefore, the claimed polynucleotide was assumed to encode human factor WW1 and to be useful.

**Result of the prior-art search**

There is no known sequence with over 40% similarity to the nucleotide sequence of SEQ ID NO:7 or the amino acid sequence of SEQ ID NO:8.

**Reason for rejection**

The given reason by the applicant that this polynucleotide encodes human factor WW1 is only based on the fact that the claimed polynucleotide has 20 to 30% homology to other mammalian polynucleotides encoding factor WW1 and that the amino acid sequence of SEQ ID NO:8 has 20 to 30% homology to amino acid sequences of factor WW1 of other mammals.

In general, when two polynucleotides (polypeptides) show only 20-30% homology to each other, they probably do not have any specific function in common. And there is no common general knowledge that the human polynucleotide, with only 20-30% homology to the polynucleotide of factor WW1, encodes human factor WW1. As the claimed polynucleotide probably does not

encode human factor WW1, the specific function of the claimed nucleotide is not clear and no one can assume the specific function of the protein encoded by the nucleotide.

Therefore, we consider there is no disclosure concerning the use of this polynucleotide in an industrial applicable way, thus the description of the invention is deemed insufficient for enabling a person skilled in the art to carry out the invention.

(Attention)

If the claimed polynucleotide is proved as encoding human factor WW1 by written argument or certified experiment results, the above mentioned reason for rejection may be overcome. But other reasons for rejection (inventive step) will be examined.

### **Case 5 Full-length cDNA**

#### ***Claim 1***

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:9.

#### ***Description of the invention***

The claimed polynucleotide is 2400bp cDNA obtained from human liver cDNA library. It encodes a polypeptide of 800 amino acids of SEQ ID NO:10. As a result of similarity search using a known DNA and amino acid database, the claimed polynucleotide showed 20 to 30% homology to the polynucleotide encoding factor ZZ1 of rat, factor ZZ2 of pig and an antagonist of factor ZZ1 receptor of monkey. And the amino acid sequence of SEQ ID NO:10 showed 20 to 30% homology to factor ZZ1 of rat, factor ZZ2 of pig and an antagonist of factor ZZ1 receptor.

Therefore, this polynucleotide encodes a human protein related to factor ZZ and may be used to diagnose patients with disease related to factor ZZ.

#### ***Result of the prior-art search***

There is no known sequence with over 40% similarity to the nucleotide sequence of SEQ ID NO:9 or the amino acid sequence of SEQ ID NO:10.

#### ***Reason for rejection***

As factor ZZ1, factor ZZ2, and antagonist of factor ZZ1 receptor have a different specific function to each other, mere description that the claimed polynucleotide encodes protein relating to factor ZZ does not indicate any specific function of the claimed polynucleotide. And the specific function of the corresponding protein cannot be assumed considering the state of the art as of the filing.

Therefore we consider there is no disclosure concerning the use of this polypeptide in an industrial applicable way, thus the description of the invention is deemed as insufficient for enabling a person skilled in the art to carry out the invention.

***(Attention)***

Even if the claimed polynucleotide is proved as encoding human protein ZZ1 by written argument or certified experiment results, the reason for rejection above may not be overcome.

### **3. Inventive Step : No**

## Case 6 Full-length cDNA

### **Claim 1**

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:11.

### **Description of the invention**

The claimed polynucleotide is 2700bp cDNA obtained from human liver cDNA library. It encodes a polypeptide of 900 amino acids of SEQ ID NO:12. As a result of similarity search, the amino acid sequence of SEQ ID NO:12 showed 85% homology to rat factor XX1(written in document A) and the polynucleotide sequence of SEQ ID NO:11 showed 80% homology to the polynucleotide encoding rat factor XX1(written in document A).

Therefore, this polynucleotide was assumed to encode human factor XX1 and to be useful.

### **Result of the prior-art search**

There was no other sequence detected with over 80% similarity to that nucleotide sequence or polypeptide sequence except for rat polynucleotide encoding rat factor XX1 or the amino acid sequence of rat factor XX1. It is a well-known fact that mammals including human have factor XX1.

### **Reason for rejection**

It is a well-known object to prepare human DNAs encoding proteins. It is also common general knowledge to isolate the human DNA encoding a certain protein by using a partial nucleotide sequence of a mammal other than human encoding the same protein as a primer probe. Since polynucleotide encoding proteins with the same biological activities are in general highly homologous between mammalian species.

Therefore, it is obvious that the DNA encoding human factor XX1 can be isolated from human cDNA library using the partial polynucleotide encoding rat factor XX1 written in document A as a primer. And any advantageous effect cannot be acknowledged from document A or common general knowledge, hence this invention cannot be regarded as involving an inventive step.

(Attention)

The reasons for rejection above shall be determined to overcome if the applicant show specific difficulty to obtain the claimed polynucleotide with the state of the art as of the filing.

## **4. Enablement Requirement : No, Inventive Step : No**

### Case 7 DNA fragment

### **Claim 1**

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:13.

### **Description of the invention**

A cDNA library was constructed from human liver using oligo (dT) primers. The nucleotide sequence of SEQ ID NO:13 is one of the sequences (500 bp) which were analyzed using an automated DNA sequencer. The polynucleotide consisting of the nucleotide sequence of SEQ ID NO:13 is part of a structural gene, and it can be used as a probe in one of the steps to obtain the full-length DNA.

However, there is no working example indicating that the full-length DNA was actually obtained, and there is no description of the function or biological activity of the DNA and its corresponding protein.

### ***Result of the prior-art search***

There is no known sequence with over 30% similarity to the nucleotide sequence of SEQ ID NO:13 or the amino acid sequence of SEQ ID NO:14.

### ***Reason for rejection***

#### 1. Inventive Step: No

It is a well-known object to obtain cDNAs from human cells and sequence them. It is also a well-known art to construct cDNA libraries from human organs, such as the liver, and to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer.

Therefore, for a person skilled in the art, it would have been easy to prepare cDNA library and to sequence cDNAs derived from the library using conventional methods. And the obtained DNA does not have an unexpected advantageous effect.

Hence, this invention cannot be regarded as involving an inventive step.

#### 2. Enablement Requirement: No

An invention of a product should be described in a way enabling for a person skilled in the art to make and to use the product in an industrially applicable way (except where the product could be made and used by a person skilled in the art without such explicit description by taking into account the overall descriptions of the specification, drawings and common general knowledge as of the filing.) There is a description that the claimed DNA can be used as a probe in one of the steps to obtain a full-length DNA. However, there is no description on function or biological activity of the protein encoded by the corresponding full-length DNA. Moreover, function or biological activity of the full-length DNA cannot be assumed with common general knowledge as of the filing. The use of a DNA fragment in obtaining the full-length DNA, whose corresponding protein's function and biological activity are unknown, is not considered to be an industrially applicable use. We consider there is no disclosure concerning the use of the DNA fragment in an industrially applicable way, thus the description of the invention is deemed insufficient for enabling a person skilled in the art to carry out the invention.

(Attention)

The reasons for rejection 2 above normally shall not be overcome.

## **Case 8 SNPs**

### ***Claim 1***

A polynucleotide of between 20 and 100 bases including position 100 (polymorphic site) of the nucleotide sequence of SEQ ID NO:14 or SEQ ID NO:15.

### ***Description of the invention***

The polynucleotide of the locus of the human genome DNAs derived from 10 persons were compared to each other. Six of 10 polynucleotide were SEQ ID NO:14 and four of 10 were SEQ ID NO:15. The nucleotide at position 100 of SEQ ID NO:14 is g. On the other hand, that of SEQ ID NO:15 is c. These two nucleotide sequences are the same except for the nucleotide at position 100. The claimed polynucleotide can be used as a forensic marker.

**Result of the prior-art search**

The nucleotide sequence of SEQ ID NO:14 and NO:15 are unknown. The claimed polynucleotide is also unknown.

**Reason for rejection**

1. Inventive step: No

It is a well-known object to detect polymorphic site in human genome DNA. It is a well-known art to analyze and compare the sequences of genome DNAs of many persons, to detect a polymorphic site.

Therefore, for a person skilled in the art, it would have been easy to analyze and compare the sequences of a certain part of genome DNAs of several persons and to detect the polymorphic site.

And any unexpected advantageous effect cannot be acknowledged, hence this invention cannot be regarded as involving an inventive step.

2. Enablement requirement: No

An invention of a product should be described in a way enabling for a person skilled in the art to make and to use the product in an industrially applicable way. (except where the product could be made and used by a person skilled in the art without such explicit description by taking into account the overall descriptions of the specification, drawings and common general knowledge as of the filing.) Though, there is a description that the claimed nucleotide can be used as a forensic marker, only one SNP itself is not usually utilized as a forensic marker. Therefore, the mere description that the polynucleotide can be used as a forensic marker does not indicate any industrial applicable use of the claimed polynucleotide.

**Attention**

The reasons for rejection 2 above normally shall not be overcome.

**5. Enablement Requirement : Yes, Inventive Step : Yes****Case 9 DNA fragment****Claim 1**

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:16.

**Description of the invention**

The polynucleotide is one of the 500bp cDNAs which were found in a cDNA library derived from the hepatocyte of patients with disease Y, but not found in those of normal persons. It was confirmed by northern hybridization that the corresponding mRNAs were expressed only in the patients' hepatocyte. Therefore, the polynucleotide can be used to diagnose disease Y.

**Result of the prior-art search**

There is no known DNA and polypeptide which are unique in the patients with disease Y. There is no known sequence with over 30% similarity to the nucleotide sequence of SEQ ID NO:16.

**Reason for rejection**

No reason for rejection

### Case 10 Full-length cDNA

**Claim 1**

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:17.

**Description of the invention**

The claimed polynucleotide is 2700bp cDNA obtained from human liver cDNA library. It encodes a polypeptide of 900 amino acids of SEQ ID NO:18. This polypeptide was expressed and it showed the activity of human factor YY1.

**Result of the prior-art search**

There is no known sequence with over 80% similarity to the nucleotide sequence of SEQ ID NO:17 or the amino acid sequence of SEQ ID NO:18. And no prior art was found about the human factor YY1.

**Reason for rejection**

No reason for rejection

**Attention**

The specific function of the factor YY1 is known.

### Case 11 SNP

**Claim 1**

A polynucleotide of between 20 and 100 bases including position 50(g) (polymorphic site) of the nucleotide sequence of SEQ ID NO:19.

**Description of the invention**

The polynucleotide of SEQ ID NO:20 is known. The nucleotide at position 50 of SEQ ID NO:19(500 length DNA) is g. On the other hand, that of SEQ ID NO:20 is c. These two nucleotides are the same except for the nucleotide at position 50. The nucleotide at position 50 of the polynucleotide of SEQ ID NO:19 is proved to be polymorphic site. A polynucleotide of between 20 and 100 bases including position 50 (g) of the nucleotide sequence of SEQ ID NO:19 is experimentally proved to be used to diagnose disease Z.

**Result of the prior-art search**

The polynucleotide sequence of SEQ ID NO:19 was not known. The claimed polynucleotide was neither known. Relationship between the polymorphic site at position 50 and disease Z was not known. Though the polynucleotide of SEQ ID NO:20 is known to be a part of structural gene, the relationship between the protein encoded by the structural gene and disease Z was not known.

**Reason for rejection**

No reason for rejection

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## Biotech-related Patent System in Korea

### 1. LEGISLATION SYSTEM

#### A. Patent Law

With the exception of plant invention, there is no any special provision just for biotech-related inventions in Patent Law.

*Requirement of Disclosure and Claims, Industrial Applicability, Novelty, Inventive step, Unity of Invention, etc*

The patent of plant invention can be granted if it satisfies the provision of Patent Law Article 31 ("*Plant Invention*").

*A variety of plant which reproduces itself asexually may obtain a plant patent.*

In addition, Seed Industry Law was enforced on December, 1997 to protect plant varieties by *sui generis* system. (According to TRIPs Article 27.3(b))

An ethical restriction on the patentability of biotech-related inventions is judged under the provision of Patent Law Article 32 ("*Unpatentable Inventions*").

*Inventions liable to contravene public order or morality or to injury public health shall not be patentable.*

#### B. "Patent Examination Guideline for Biotechnological Inventions"

To examine the patentability of biotechnological inventions more efficiently, **Patent Examination Guideline for Biotechnological Inventions** was established in 1998.

*4 Sectors: Genetic Engineering Inventions, Microorganism Inventions, Plant Inventions and Animal Inventions*

This Guideline is amended to reinforce specific standards for the product of Human Genome Project, such as EST or SNP. The amended one is enforced on January, 2001.

### 2. EFFICIENT EXAMINATION SYSTEM AT KIPO

Genetic Engineering Examination Division at KIPO is in charge of examination of Biotech-related invention. Besides, Pharmaceutical Examination Division and Agricultural Forestry & Fishery Examination Division also take part in examining biotech-related inventions.

Biotechnology Patent Sequence Search System (BIOPASS) has been established in '99. for nucleotide or amino acids sequence search. It is open to the public from Jan. 2000.

### **3. DEPOSITORY SYSTEM FOR MICROORGANISM**

#### **A. Backgrounds**

In invention where a starting material or final product includes biological materials such as a microorganism, as a creature whose structure is complicated becomes an essential constitutional factor of the invention, frequently, the claimed invention may not be easily reproduced only based on the disclosure of the specification.

Therefore, if a starting material may not easily be obtained, the starting material should be deposited, and in an invention where a final product cannot be readily produced by only the disclosure of the specification, the final products should be deposited, thereby providing that a person having ordinary skill in the art can easily practice the invention.

#### **B. Deposit of microorganism and disclosure by specification**

Any person desiring to file a patent application in connection with an invention related to a microorganism shall be deposit the microorganism with a deposit agency or an international depository authority approved by the director of KIPO and state the deposit number in the specification at the time of filing.

Furthermore, when a new deposit number is assigned to the prior-deposited microorganism by redepositing after filing, delivery to other international depository authority, or a change from domestic deposit to that under the Budapest Convention, the applicant or patentee should immediately notify the Director of KIPO of the same and new deposit number.

#### **C. Depository Authorities in Korea**

There are 2 Domestic Depository Authorities.

- Korean Research Institute of Bioscience & Biotechnology
- Korean Culture Center of Microorganism

There are 3 International Depository Authorities.

- Korean Research Institute of Bioscience & Biotechnology
  - Korean Culture Center of Microorganism
  - Korean Cell Line Research Foundation
-

## **Brief Outline of *Patent Examination Guideline* for *Biotechnological Inventions in Korea***

### **1. Genetic Engineering Inventions**

#### **A. Description Method for Specification**

##### **A-1. Patent claims**

###### (1) Gene

- A gene is, in principle, described by specifying a base sequence.
- A structural gene can be described by specifying an amino acid sequence of proteins which a base sequence encodes.
- When the expression, "being deleted, replaced or added", is used along with a base sequence of a gene, the position thereof should be clarified.

###### (2) Vector

- A vector should be described in combination of a DNA base sequence, cleavage map of DNA, molecular weight, number of base pairs, origin, production method, function, characteristics, etc.

###### (3) Recombinant Vector

- A recombinant vector should be described by specifying the inserted gene and a vector

###### (4) Transformants

- Transformants should be described specifying a host designed by its species name or generic name according to nomenclature for microorganism, plants or animals and the introduced recombinant vector (or a gene).

###### (5) Proteins and recombinant protein

- Proteins and recombinant proteins should be described by specifying amino acid sequence or base sequence of structural gene encoding said amino acid sequence. However, when an expression such as "deletion", "replacement" or "addition" is used, the position should be clearly disclosed.
- When a protein can not be described by specifying as above, the protein can be described by specifying in combination of function, physiochemical property, origin, source, or production process of the protein.

##### **A-2. Detailed Description of Invention**

- The detailed description of the invention should be the purpose, construction, and effect of the invention in such a manner that it may easily be carried out by a person having ordinary skill in the relevant art.

### **A-3. Sequence Listing**

- When a base sequence of nucleic acid consisting of ten or more nucleotides or an amino acid sequence of protein consisting four or more L-amino acids is described in the detailed description of the invention, the sequence should be prepared in accordance with the preparation guidelines for the specification, and be attached at the end of the detailed description of the invention.
- When a base sequence or amino acid sequence is to be described in the claim, the sequence described in the sequence listing prepared according to above Para. can be cited.

### **B. Inventions Corresponding to Unpatentable Reasons**

- Genetic engineering inventions are deemed to be unpatentable under the provision of Patent Law Article 32, when, they are liable to contravene public order or morality or damage public health, as set forth below.
  - Invention liable to destroy the ecosystem
  - Invention liable to cause environmental contamination
  - Invention liable to hurt human beings
  - Invention liable to cause a result denigrating the dignity of human being

### **C. Patent Requirements**

#### **C-1. Establishment of Invention**

(1) The following cases are not acknowledged to be complete as an invention according to the provision of Patent Act Article 29.1

- When corresponding to a mere discovery.
- Inventions directed to a gene, vector, recombinant vector, transformant, fused cell, monoclonal antibody, protein, recombinant protein, where specific production methods thereof are not described in detail in the specification.

(2) However, an invention is deemed to be complete when the gene or protein is artificially isolated and identified from a living thing, and its function is clarified.

#### **C-2. Industrial Applicability**

(1) Utility should be described.

(2) A method of treating or diagnosing a human being is not acknowledged as an [industrial applicable] invention according to the provision of text under the Patent Law Article 29.1.

#### **C-3. Novelty**

(1) Genes, vector, recombinant vector, protein, recombinant protein

- In principle, novelty is determined with priority given to the structure.
- When a gene, vector, recombinant vector, protein, recombinant protein
- is publicly known as an isolated and purified form and is differentiated as a separate material in comparison with known materials by being specified with different specific means, the claimed matter is deemed novel.

- Where a recombinant protein specified by a recombinant process exhibits a difference in its sugar chain, etc. from a publicly known protein due to the use of a different host, even though the recombinant protein cannot be differentiated in the amino acid sequence from the above publicly known protein, the claimed recombinant protein is deemed novel.
- (2) Fused cells
- Novelty of a fused cell is determined based on the mother cell used or the monoclonal antibody produced.
- (3) Monoclonal antibody
- Novelty of a monoclonal antibody is determined based on the antigen and its epitope.

## **2. Microorganism Inventions**

### **A. Description Method for Specification**

- Microorganism means virus, bacteria, protozoa, yeasts, fungi, mushrooms, unicellular algae, actinomycetes, etc. and include non-specialized cells of animals and plants and tissue culture as well.

#### **A-1. Patent claims**

- (1) Inventions of a microorganism
- A microorganism should be described by specifying its scientific name, and a deposit number or mycological property by which the corresponding microorganism is characterized may be added for further specification.
  - Non-specialized cells of animals and plants should be described by specifying with their scientific name based on nomenclature for animals or plants which they were derived from, and the name of deposit agency and deposit number may be added for further specification.
- (2) Inventions using microorganisms
- When using a novel strain, mutant strain or prior art strain, it should be described by its strain name.
  - When using a novel species, mutant species or species, it should be described by its species name.

#### **A-2. Detailed Description of Invention**

- (1) Repetitious reproducibility should be supported.
- When it is difficult to describe a process for producing the microorganism, they should be deposited with the depositary authority appointed by Patent Law Enforcement Ordinance Article 2.
- (2) When a novel microorganism is described, its species name based nomenclature for microorganism, or strain name to which its species name was added should be indicated along with mycological properties.
- (3) In inventions regarding a microorganism or use of microorganism, a manufacturing process thereof such as isolation, purification method, screening method, mutant producing method,

gene recombination process should be described in detail in order for a person having ordinary skill in the art to easily produce the microorganism.

## **B. Patent Requirements**

### **B-1. Establishment of Invention**

The following cases are not recognized to be complete as an invention according to the provision of Patent Law Article 29.1

- (1) When corresponding to a mere discovery.
  - However, an invention is deemed to be complete, when related to a microorganism which was artificially isolated from nature and identified.
- (2) When the microorganism used is unclear, since the microorganism used is novel or its taxonomical properties are insufficiently described in the specification.
- (3) When the material produced by using microorganism is novel or data by which the material may be identified are not sufficiently described.

### **B-2. Industrial Applicability & Novelty**

- Industrial applicability & Novelty are determined according to the provision under the Patent Law Article 29.1.

## **3. Plant Inventions**

### **A. Description Method for Specification**

#### **A-1. Patent claims**

The following must be described to avoid the violation of Article 42.4 of the Patent Law.

- (1) For Inventions to a variety plant or part of a variety plant.
  - The title of the plant, Property of the plant or characteristic genes and Asexual production process
- (2) For Inventions of breeding process for variety plants
  - Order of steps of the breeding procedure, Specific condition such as the environment for the breeding process, and Characteristic which are the standard for selection
- (3) For Inventions of asexual reproduction methods for variety plants
  - Characteristic properties of the plants or a gene, and Asexual reproduction method

#### **A-2. Detailed Description of Invention**

- (1) Repetitious reproducibility should be supported.
- (2) Technical tasks solved by an invention should be described as follows.

- Characteristics of prior art plants to be improved
- Specific method in order to improve specific characteristic
- Specific asexual reproduction method to propagate variety plants

(3) Providing means in order to solve technical tasks, that is, the title of variety plant (scientific name by botanical nomenclature), property, breeding, asexual reproduction method, culture condition, use, etc. should be specifically disclosed.

## **B. Patent Requirements**

### **B-1. Establishment of Invention**

- When corresponding to a mere discovery in an invention of a variety plant, such a invention is not deemed to be complete as an invention under Patent Law Article 29.1.

### **B-2. Industrial Applicability**

- In an invention directed to an asexually variety plant, if utility is not described nor can be inferred therefrom, the invention is not deemed as an industrially applicable invention of under the Article 29.1

### **B-3. Invention Step**

- In determining the inventive step of an invention regarding a bred variety plant, it is determined with priority given to characteristics.
  - Esculent plants : characteristics such as content of nutrient
  - Medicinal plants : characteristics such as content of effective ingredient, quantity
  - Ornamental plants : characteristics such as color, shape, quantity

## **4. Animal Inventions**

### **A. Description Method for Specification**

#### **A-1. Patent claims**

(1) Animals should be described by specifying the title of an animal, a gene or property which becomes the characteristic of the animal and creating process for the animal, and may be specified by adding deposit (such as embryo) authority and deposit number.

(2) Inventions directed to a process for creating an animal should disclose the procedure for creating the animal following the order of steps, property which becomes the standard for selection, and if necessary, production condition such as the environment.

#### **A-2. Detailed Description of Invention**

(1) Repetitious reproducibility should be supported.

(2) Scientific name based on zoological nomenclature and the standard Korean name should be described.

(3) Properties by which the created animal can be characterized should be described.

(4) Where required, specific breeding conditions should be described.

## **B. Patent Requirements**

### **B-1. Industrial Applicability**

- In an invention directed to an asexually variety plant, if utility is not described nor can be inferred therefrom, the invention is not deemed as an industrially applicable invention of under the Article 29.1.

### **B-2. Invention Step**

- Inventive step of inventions directed to an animal is determined based on the characteristics in comparison with those of prior art animals and the effect in terms of the use thereof.
  - Inventive step for a process is determined based on difficulty in selecting means, condition corresponding to respective procedure of the manufacturing process of the novel animal and inventive step of the animal finally made.
-

## **Patentability Criteria of Biotechnological Inventions**

### **Intellectual Property Office of New Zealand (IPONZ)**

Biotechnological inventions are examined under the New Zealand Patents Act 1953. This legislation is presently being reviewed, and this review will take into account the findings of the recent enquiry by the Royal Commission on Genetic Modification (not yet released). This may lead to some restriction being placed on the patentability of inventions involving genetic modification. Also of interest is that the proposed patents bill, if passed, will allow New Zealand to accede to the Budapest Treaty.

At present, claims involving biotechnology may be accepted by IPONZ so long as the established requirements for a patent are satisfied, such as the conditions of a manner of new manufacture are met (including the creation of an artificial state of affairs for which there is a commercial application), novelty, and the technology is fairly and sufficiently described in the specification. It is essential that a clear description of the technology be provided and it is sufficient to distinguish the present technology from all known technology and the best method of performing the invention known to the applicant is disclosed.

Claims involving DNA sequences are viewed by the office in the same light as chemical compounds, in that each variable within the sequences is disclosed; i.e. the scope of the claim is well defined.

Biotechnology applications differ in the blend of objections that are made. Because biotechnological inventions deal more often with naturally-occurring products than other kinds of applications, there are more objections asking the applicant to exclude the product as found in nature by specifying that the product is in isolated or purified form. Biological inventions are often medically applicable so there are more objections that the applications include the medical treatment of humans.

Biotechnology is a new and developing science and does not fit neatly with law here, and in many countries, and with old case law. This means that practice is, and has to be, in a process of development to ensure that the law is applied and that technological developments are protected where appropriate or possible.

Biotechnology is controversial. The implications of the Treaty of Waitangi apply more to these applications. There is a claim before the Waitangi tribunal relating to native flora and fauna. Biotechnology is generally controversial too, from aspects of morality and safety of the research and products developed.

**It should also be noted that NZ patent law and practice complies fully with the TRIPS agreement, especially article 27.3 relating to the patentable subject matter. Article 27.3 (b) of the TRIPS Agreement in 1999 enables members of the Agreement to exclude from patentability:**

***“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”.***

Claims involving method of treatment to humans are currently objected to under Section 17 of the New Zealand Patents Act 1953.

*S17. Refusal of application in certain cases-(1)if it appears to the Commissioner in the case of any application for a patent that the use of the invention in respect of which the application is made would be contrary to morality, the Commissioner may refuse the application.*

*(2) An appeal to the court shall lie from any decision of the Commissioner under this section.*

In *The Commissioner Of Patents v. The Wellcome Foundation Ltd*, Court of Appeal [1983] FSR 593, McMullin J. stated:

*"traditionally patents have not been granted for a method of treatment of disease or illness in human beings" (p603);*

and on change of practice in this area McMullin J. stated:

*"any major thrust should be left to Parliament" (p609).*

In a recent decision on a case including Swiss-type claims, *Pharmaceutical Management Agency Limited v Commissioner of Patents and Others*, it was deemed that methods of treatment involving humans are inventive, therefore allowable under Section 2 as a method of new manufacture. This does not give such claims patentability under Section 17, however.

**Parliament must make any major change in the law on the granting of patents for methods of treating disease or illness in humans to be patentable. However there is scope for minor changes.**

The current practice for IPONZ to continue to refuse claims involving method(s) of treating human under Section 17 pending the outcome of a decision from the courts. There is presently a case on appeal from a decision of the Commissioner waiting to be heard by the court in this regard.

1 May 2001

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## Patenting and Biotechnology

### In Singapore<sup>5</sup>

#### LAW

(a) The main statute on patents in Singapore is the Patents Act (Cap. 221), Revised Edition 1995 and as amended by the Patents (Amendment) Act 1995 (Act 40 of 1995 with effect from 1 January 1996). Copies of the legislation can be purchased from myepb Bookstore Legal Publications at No. 3 Temasek Boulevard, B1-025 Suntec City Mall Singapore 038983 (Tel: 333-9703). The web-site address is: (<http://www.myepb.com/script/legalpub.asp>).

(b) In Singapore, section 13 of our Patents Act states a patentable invention is one that is new, has inventive step and is capable of industrial application. The various concepts of “new”, “inventive step” and “industrial application”, present in this section (and its related provisions in sections 14 to 16), have been developed and discussed in case law before the UK and European courts.

(c) Our Patents Act also contains provisions (sections 14 to 16) that explain the requirements of novelty (novelty destroying matter is anything that had been made anywhere in the world, through any means, before the priority date of the invention), inventive step (the invention must not be obvious to a person skilled in the art), and capable of industrial application (method of treatment of the human or animal body by surgery, or therapy or of diagnosis practiced on the human or animal body shall not be capable of industrial application – section 16(2)).

(d) We would add that in the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body, section 14(7) provides that the fact that the substance or composition is not new shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method is not known.

(e) Over and above the requirements of novelty, inventive step and industrial application, an invention is not patentable if the publication or exploitation of which would generally be expected to encourage offensive, immoral or antisocial behavior (section 13(3)).

(f) As the patents system serves as a *quid pro quo* for the disclosure of inventions, thereby benefiting mankind, there are stringent requirements in place to ensure that this objective is achieved. In most jurisdictions, applicants are required to disclose their inventions in the patent applications in a clear and complete manner so as to enable a person skilled in the art to perform the invention. In Singapore, this requirement is found in section 25 of the Patents Act. Failure to comply with this requirement can serve as a ground for revocation of a granted patent (Section 80 of the Patents Act).

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<sup>5</sup> Information as of 11 April 2001, provided by Assistant Registrar of Patents, Singapore

(g) Our Patents Act does not have a positive definition of what an “invention” is. Our Patents Act also does not have a list of statutory exclusions (unlike the United Kingdom and the European Patent Convention where certain things like discovery, scientific theory, mathematical method and aesthetic creations are expressly excluded from being considered as “inventions”). The question of whether a particular “subject matter” is an invention is therefore left to judicial interpretation on a case-by-case basis, as is the case with other requirements on patentability (e.g. new, inventive step and industrial application).

### ***JUDICIAL INTERPRETATION***

Two Singapore Court of Appeal decisions on patents were released last year i.e. Merck v. Pharmaforte (this case involved a pharmaceutical drug) & Institut Pasteur v. Genelabs (the invention in question relates to a HIV-2 virus) and it would be noted that the case law developed in UK and Europe were discussed and relied upon. It is therefore likely that our courts would continue to find the UK and European case law on similar provisions, to be persuasive.

### ***EXAMINATION GUIDELINES***

In Singapore, section 29 of the Patents Act provides applicants with several options for search and examination. In brief, they can rely on foreign corresponding prescribed search and examination equivalents in lieu of requesting the Registry to conduct a search and examination for them, or file a search and examination request with us.

On search and examination, our Examiners i.e. from the Australian and Austrian Patent Offices, are regularly kept informed of any local statutory or judicial changes on patents. Preliminary objections to patentability could be raised in the written opinions, providing applicants with an opportunity to respond.

In the event where applicants rely on their foreign corresponding prescribed search and examination equivalents in lieu of filing search and examination requests with us, they should take into consideration our Patents Law and any corresponding judicial decisions. We would add that our patents system promotes self-assessment, and applicants are therefore encouraged to make necessary amendments (within the scope of section 84 of the Patents Act) to their specification if any, before they seek for the Grant Certificate.

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## United States Utility Examination Guidelines<sup>6</sup>

**AGENCY:** United States Patent and Trademark Office, Commerce

**ACTION:** Notice

**SUMMARY:** The United States Patent and Trademark Office (USPTO) is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the 'utility' requirement of 35 U.S.C. 101

This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000)

**DATES:** The Guidelines are effective as of January 5, 2001

**FOR FURTHER INFORMATION CONTACT:** Mark Nagumo by telephone at (703) 305-8666, by facsimile at (703) 305- 9373, by electronic mail at 'mark.nagumo@uspto.gov,' or by mail marked to his attention addressed to the Office of the Solicitor, Box 8, Washington, DC 20231; or Linda Therkorn by telephone at (703) 305- 9323, by facsimile at (703) 305-8825, by electronic mail at 'linda.therkorn@uspto.gov,' or by mail marked to her attention addressed to Box Comments, Commissioner for Patents, Washington, DC 20231

**SUPPLEMENTARY INFORMATION:** As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the 'utility' requirement of 35 U.S.C. 101

Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A)

### I. Discussion of Public Comments

The Revised Interim Utility Examination Guidelines published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67, Feb 15, 2000, requested comments from the public. Comments were received from 35 individuals and 17 organizations

The written comments have been carefully considered

#### Overview of Comments

The majority of comments generally approved of the guidelines and several expressly stated support for the three utility criteria (specific, substantial, and credible) set forth in the Guidelines. A few comments addressed particular concerns with respect to the coordinate examiner training materials that are available for public inspection at the USPTO website, [www.uspto.gov](http://www.uspto.gov). The comments on the training materials will be taken under advisement in the revision of the training materials

Consequently, those comments are not specifically addressed below because they do not impact the

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<sup>6</sup> **1092 Federal Register** / Vol. 66, No. 4 / Friday, January 5, 2001 / Notices  
DEPARTMENT OF COMMERCE United States Patent and Trademark Office [Docket No. 991027289-0263-02] RIN 0651-AB09

content of the Guidelines. Comments received in response to the request for comments on the 'Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 'Written Description' Requirement,' 64 FR 71427, Dec. 21, 1999; 1231 O.G. 123, Feb. 29, 2000, which raised issues pertinent to the utility requirement are also addressed below

### Responses to Specific Comments

(1) **Comment:** Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions.

**Response:** The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S. Constitution uses the word 'discoveries' where it authorizes Congress to promote progress made by inventors. The pertinent part of the Constitution is Article 1, section 8, clause 8, which reads: 'The Congress shall have power \* \* \* To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.'

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who 'invents or discovers' a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, which reads: '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.' Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the 'utility' requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

(2) **Comment:** Several comments state that a gene is not a new composition of matter because it exists in nature, and/ or that an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature. These comments urge the USPTO not to issue patents for genes on the ground that genes are products of nature. Others state that naturally occurring DNAs are part of our heritage and are not inventions. Another comment expressed concern that a person whose body includes a patented gene could be guilty of patent infringement.

**Response:** The comments are not adopted. A patent claim directed to an isolated and purified DNA molecule could cover, *e.g.*, a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming '[y]east, free from organic germs of disease, as an article of manufacture.' Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: 'even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call all this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.' *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).

In a more recent case dealing with the prostaglandins PGE2 and PGE3, extracted from human or animal prostate glands, a patent examiner had rejected the claims, reasoning that ‘inasmuch as the ‘claimed compounds are naturally occurring’ \* \* \* they therefore ‘are not ‘new’ within the connotation of the patent statute.’ *In re Bergstrom*, 427 F.2d 1394, 1397, 166 USPQ 256, 259 (CCPA 1970). The Court reversed the Patent Office and explained the error: ‘what appellants claim—pure PGE2 and PGE3—is not ‘naturally occurring.’ Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature’s storehouse, albeit unknown, or what has previously been known to exist.’ *Id.* at 1401, 166 USPQ at 261–62. Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body ‘includes’ a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form

When the patent issued for purified adrenaline about one hundred years ago, people did not infringe the patent merely because their bodies naturally included unpurified adrenaline

(3) **Comment:** Several comments suggested that the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter.

**Response:** The suggestion is not adopted. Congress adopted the current statute defining patentable subject matter (35 U.S.C. 101) in 1952. The legislative history indicates that Congress intended ‘anything under the sun that is made by man’ to be eligible for patenting. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)

The Supreme Court interprets the statute to cover a ‘nonnaturally occurring manufacture or composition of matter—a product of human ingenuity.’ *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, 197 (1980). Thus, the intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability. The genetic sequence data represented by strings of the letters A, T, C and G alone is raw, fundamental sequence data, i.e., nonfunctional descriptive information.

While descriptive sequence information alone is not patentable subject matter, a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting, subject to satisfying the other criteria for patentability.

(4) **Comment:** Several comments state that patents should not issue for genes because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic. Other comments stated that patents should be for marketable inventions and not for discoveries in nature.

**Response:** The comments are not adopted. Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor’s legal right to exclude other people from making, using, offering for sale, selling, or importing the composition for a limited time. That is, a patent owner can stop infringing activity by others for a limited time.

Discoveries from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. ‘[D]evelopment of a product to the extent that it is presently commercially salable in the marketplace is not required to establish ‘usefulness’ within the meaning of § 101.’ *In re Langer*, 503 F.2d 1380, 1393, 183

USPQ 288, 298 (CCPA 1974). Inventors are entitled to patents when they have met the statutory requirements for novelty, nonobviousness and usefulness, and their patent disclosure adequately describes the invention and clearly teaches others how to make and use the invention. The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility. As noted in a response to other comments, it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents.

(5) **Comment:** Several comments state that the Guidelines mean that anyone who discovers a gene will be allowed a broad patent covering any number of possible applications even though those uses may be unattainable and unproven. Therefore, according to these comments, gene patents should not be issued.

**Response:** The comment is not adopted. When a patent claiming a new chemical compound issues, the patentee has the right to exclude others from making, using, offering for sale, selling, or importing the compound for a limited time. The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

(6) **Comment:** One comment suggests that the USPTO should not allow the patenting of ESTs because it is contrary to indigenous law, because the Supreme Court's *Diamond v. Chakrabarty* decision was a bare 5-to-4 decision, because it would violate the Thirteenth Amendment of the U.S. Constitution, because it violates the novelty requirement of the patent laws, because it will exacerbate tensions between indigenous peoples and western academic/research communities and because it will undermine indigenous peoples' own research and academic institutions. The comment urges the USPTO to institute a moratorium on patenting of life forms and natural processes.

**Response:** The comments are not adopted. Patents on chemical compounds such as ESTs do not implicate the Thirteenth Amendment. The USPTO must administer the patent statutes as the Supreme Court interprets them. When Congress enacted § 101, it indicated that 'anything under the sun that is made by man' is subject matter for a patent. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court has interpreted § 101 many times without overturning it. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 209 USPQ 1 (1981) (discussing cases construing section 101). Under United States law, a patent applicant is entitled to a patent when an invention meets the patentability criteria of title 35. Thus, ESTs which meet the criteria for utility, novelty, and nonobviousness are eligible for patenting when the application teaches those of skill in the art how to make and use the invention.

(7) **Comment:** Several comments state that patents should not issue for genes because patents on genes are delaying medical research and thus there is no societal benefit associated with gene patents. Others state that granting patents on genes at any stage of research deprives others of incentives and the ability to continue exploratory research and development. Some comment that patentees will deny access to genes and our property (our genes) will be owned by others.

**Response:** The comments are not adopted. The incentive to make discoveries and inventions is generally spurred, not inhibited, by patents. The disclosure of genetic inventions provides new opportunities for further development. The patent statutes provide that a patent must be granted when at least one specific, substantial and credible utility has been disclosed, and the application satisfies the other statutory requirements. As long as one specific, substantial and credible use is disclosed and the statutory requirements are met, the USPTO is not authorized to withhold the patent until another, or better, use is discovered. Other researchers may discover higher, better or more practical uses, but they are

advantaged by the starting point that the original disclosure provides. A patent grants exclusionary rights over a patented composition but does not grant ownership of the composition. Patents are not issued on compositions in the natural environment but rather on isolated and purified compositions.

(8) **Comment:** Several comments stated that DNA should be considered unpatentable because a DNA sequence by itself has little utility.

**Response:** A DNA sequence—*i.e.*, the sequence of base pairs making up a DNA molecule— is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA *molecule* isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, *e.g.*, it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not *per se* unpatentable for lack of utility, and each application claim must be examined on its own facts

(9) **Comment:** One comment states that the disclosure of a DNA sequence has inherent value and that possible uses for the DNA appear endless, even if no single use has been worked out. According to the comment, the ‘basic social contract of the patent deal’ requires that such a discovery should be patentable, and that patenting should be ‘value-blind.’

**Response:** The comment is not adopted. The Supreme Court did not find a similar argument persuasive in *Brenner v. Manson*, 383 U.S. 519 (1966). The courts interpret the statutory term ‘useful’ to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim. The applicant may rebut the Office position by showing that the invention does have a specific, substantial, and credible utility that would have been recognized by one of skill in the art at the time the application was filed

(10) **Comment:** Several comments stated that the scope of patent claims directed to DNA should be limited to applications or methods of using DNA, and should not be allowed to encompass the DNA itself.

**Response:** The comment is not adopted. Patentable subject matter includes both ‘process[es]’ and ‘composition[s] of matter.’ 35 U.S.C. 101. Patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter. If a patent application claims a composition of matter comprising DNA, and the claims meet all the statutory requirements of patentability, there is no legal basis for rejecting the application

(11) **Comment:** Several comments stated that DNA patent claim scope should be limited to uses that are disclosed in the patent application and that allowing patent claims that encompass DNA itself would enable the inventor to assert claims to ‘speculative’ uses of the DNA that were not foreseen at the time the patent application was filed.

**Response:** The comment is not adopted. A patent on a composition gives *exclusive* rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA composition confers the right to exclude others from *any* method of using that DNA composition, for up to 20 years from the filing date. This result flows from the language of the statute itself. When the utility requirement and other requirements are satisfied by the application, a patent granted provides a patentee with the right to exclude others from, *inter alia*, ‘using’ the patented composition of matter. *See* 35 U.S.C.154. Where a new use is discovered for a patented DNA composition, that new use may qualify for its own process patent, notwithstanding that the DNA composition itself is patented. By statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit. If an application fails to disclose one specific, substantial, and credible utility, and the examiner discerns no well-established

utility, the examiner will reject the claim under section 101. The rejection shifts the burden to the applicant to show that the examiner erred, or that a well-established utility would have been readily apparent to one of skill in the art. The applicant cannot rebut the rejection by relying on a utility that would not have been readily apparent at the time the application was filed. *See, e.g., In re Wright*, 999 F.2d 1557, 1562–63, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993) ('developments occurring after the filing date of an application are of no significance regarding what one skilled in the art believed as of the filing date')

(12) **Comment:** Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits biomedical research by allowing a single person or company to control use of the claimed DNA. Another comment expressed concern that patenting ESTs will impede complete characterization of genes and delay or restrict exploration of genetic materials for the public good

**Response:** The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. 'Whoever invents or discovers any new and useful \* \* \* composition of matter \* \* \* may obtain a patent therefor.' 35 U.S.C. 101. Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term.

(13) **Comment:** Several comments suggested that DNA sequences should be considered unpatentable because sequencing DNA has become so routine that determining the sequence of a DNA molecule is not inventive.

**Response:** The comments are not adopted. A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule. An isolated and purified DNA molecule may be patentable because a molecule is a 'composition of matter,' one of the four classes of invention authorized by 35 U.S.C. 101.

A DNA molecule must be *nonobvious* in order to be patentable. Obviousness does not depend on the amount of work required to characterize the DNA molecule. *See* 35 U.S.C. 103(a) ('Patentability shall not be negated by the manner in which the invention was made.'). As the nonobviousness requirement has been interpreted by the U.S. Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular *structure* of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made. *See, e.g., In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ('[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious.');

*see also, In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993)

(14) **Comment:** One comment suggested that genes ought to be patentable only when the complete sequence of the gene is disclosed and a function for the gene product has been determined.

**Response:** The suggestion is not adopted. To obtain a patent on a chemical compound such as DNA, a patent applicant must adequately describe the compound and must disclose how to make and use the compound. 35 U.S.C. 101, 112. 'An adequate written description of a DNA \* \* \* requires a precise definition, *such as* by structure, formula, chemical name, or physical properties.' *Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1556, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (emphasis added, internal quote omitted). Thus, describing the complete chemical structure, *i.e.*, the DNA sequence, is one method of describing a DNA molecule but it is not the only method. In addition, the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a

specific and substantial utility because, *e.g.*, it hybridizes near a disease-associated gene or it has a gene-regulating activity

(15) **Comment:** One comment stated that the specification should ‘disclose the invention,’ including why the invention works and how it was developed.

**Response:** The comment is not adopted. The comment is directed more to the requirements imposed by 35 U.S.C. 112 than to those of 35 U.S.C. 101. To satisfy the enablement requirement of 35 U.S.C. 112, ¶ 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. If all the requirements under 35 U.S.C. 112, ¶1, are met, there is no statutory basis to require disclosure of why an invention works or how it was developed. ‘[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.’ *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989)

(16) **Comment:** One comment suggested that patents should ‘allow for others to learn from and improve the invention.’ The comment suggested that claims to patented plant varieties should not prohibit others from using the patented plants to develop improved varieties. The comment also stated that uses of plants in speculative manners should not be permitted.

**Response:** By statute, a patent provides the patentee with the right to exclude others from, *inter alia*, making and using the claimed invention, although a limited research exemption exists. See 35 U.S.C. 163, 271(a), (e). These statutory provisions are not subject to revision by the USPTO and are not affected by these Guidelines.

Where a plant is claimed in a utility patent application, compliance with the statutory requirements for utility under 35 U.S.C. 101 only requires that a claimed invention be supported by at least one specific, substantial and credible utility. It is somewhat rare for academic researchers to be sued by commercial patent owners for patent infringement. Most inventions are made available to academic researchers on very favorable licensing terms, which enable them to continue their research.

(17) **Comment:** Two comments suggested that although the USPTO has made a step in the right direction in raising the bar in the Utility Guidelines, there is still a need to apply stricter standards for utility.

**Response:** The USPTO is bound by 35 U.S.C. 101 and the case law interpreting § 101. The Guidelines reflect the USPTO’s understanding of § 101.

(18) **Comment:** Several comments addressed specific concerns about the examiner training materials.

**Response:** The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials. Except for comments with regard to whether sequence homology is sufficient to demonstrate a specific and substantial credible utility, specific concerns about the training materials will not be addressed herein as they will not impact the language of the guidelines.

(19) **Comment:** Several comments suggested that the use of computer based analysis of nucleic acids to assign a function to a given nucleic acid based upon homology to prior art nucleic acids found in databases is highly unpredictable and cannot form a basis for an assignment of function to a putatively encoded protein. These comments also indicate that even in instances where a general functional assignment may be reasonable, the assignment does not provide information regarding the actual biological activity of an encoded protein and therefore patent claims drawn to such nucleic acids should be limited to method of use claims that are explicitly supported by the as-filed specification(s). These comments also state that if homology-based utilities are acceptable, then the nucleic acids, and proteins encoded thereby, should be considered as obvious over the prior art nucleic acids. On the other hand,

one comment stated that homology is a standard, art-accepted basis for predicting utility, while another comment stated that any level of homology to a protein with known utility should be accepted as indicative of utility.

**Response:** The suggestions to adopt a *per se* rule rejecting homology based assertions of utility are not adopted. An applicant is entitled to a patent to the subject matter claimed unless statutory requirements are not met (35 U.S.C. 101, 102, 103, 112)

When the USPTO denies a patent, the Office must set forth at least a *prima facie* case as to why an applicant has not met the statutory requirements. The inquiries involved in assessing utility are fact dependent, and the determinations must be made on the basis of scientific evidence. Reliance on the commenters' *per se* rule, rather than a fact dependent inquiry, is impermissible because the commenters provide no scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles. See, e.g., *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (rejection of claims improper where claims did 'not suggest an inherently unbelievable undertaking or involve implausible scientific principles' and where 'prior art \* \* \* discloses structurally similar compounds to those claimed by the applicants which have been proven \* \* \* to be effective')

A patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. '[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient.' *Fujikawa v Wattanasin*, 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996)

The Office will take into account both the nature and degree of the homology. When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C.101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no *per se* rule regarding homology, and each application must be judged on its own merits.

The comment indicating that if a homology-based utility could meet the requirements set forth under 35 U.S.C. 101, then the invention would have been obvious, is not adopted. Assessing nonobviousness under 35 U.S.C. 103 is separate from analyzing the utility requirements under 35 U.S.C. 101. When a claim to a nucleic acid supported by a homology-based utility meets the utility requirement of section 101, it does not follow that the claimed nucleic acid would have been *prima facie* obvious over the nucleic acids to which it is homologous. '[S]ection 103 requires a fact-intensive comparison of the [claim] with the prior art rather than the mechanical application of one or another *per se* rule.' *In re Ochiai*, 71 F.3d 1565, 1571, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995). Nonobviousness must be determined according to the analysis in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). See also, *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc) ('structural similarity between claimed and prior art subject matter, \* \* \* where the prior art gives reason or motivation to make the claimed compositions, creates a prima

facie case of obviousness’) (emphasis added)

Where ‘the prior art teaches a specific, structurally-definable compound [] the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.’ *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995)

(20) **Comment:** Several comments indicated that in situations where a well-established utility is relied upon for compliance with 35 U.S.C. 101, the record should reflect what that utility is. One comment stated that the record should reflect whether the examiner accepted an asserted utility or relied upon a well-established utility after dismissing all asserted utilities. Another comment stated that when the examiner relies on a well-established utility not explicitly asserted by the applicant, the written record should clearly identify this utility and the rationale for considering it specific and substantial

**Response:** The comments are not adopted. Only one specific, substantial and credible utility is required to satisfy the statutory requirement. Where one or more well-established utilities would have been readily apparent to those of skill in the art at the time of the invention, an applicant may rely on any one of those utilities without prejudice

The record of any issued patent typically reflects consideration of a number of references in the prior art that the applicant or the examiner considered material to the claimed invention. These references often indicate uses for related inventions, and any patents listed typically disclose utilities for related inventions. Thus, even when the examiner does not identify a well-established utility, the record as a whole will likely disclose readily apparent utilities. Just as the examiner without comment may accept a properly asserted utility, there is no need for an examiner to comment on the existence of a well-established utility

However, the Guidelines have been revised to clarify that a well-established utility is a specific, substantial, and credible utility that must be readily apparent to one skilled in the art. Most often, the closest prior art cited and applied in the course of examining the application will demonstrate a well-established utility for the invention

(21) **Comment:** Several comments stated that the Guidelines erroneously burden the examiner with proving that a person of skill in the art would not be aware of a well-established utility. One comment states that this requires the examiner to prove a negative. Another comment states that the Guidelines should direct examiners that if a specific utility has not been disclosed, the applicant should be required to identify a specific utility.

**Response:** The comments have been adopted in part. The Guidelines have been revised to indicate that where the applicant has not asserted a specific, substantial, and credible utility, and the examiner does not perceive a well-established utility, a rejection under § 101 should be entered. That is, if a well-established utility is not readily apparent and an invention is not otherwise supported by an asserted specific, substantial, and credible utility, the burden will be shifted to applicant to show either that the specification discloses an adequate utility, or to show that a well-established utility exists for the claimed invention. Again, most often the search of the closest prior art will reveal whether there is a well-established utility for the claimed invention

(22) **Comment:** Several comments suggested that further clarification was required with regard to the examiner’s determination that there is an adequate nexus between a showing supporting a well-established utility and the application as filed. The comments indicated that the meaning of this ‘nexus’ was unclear.

**Response:** The Guidelines have been modified to reflect that evidence provided by an applicant is to be analyzed with regard to a concordance between the showing and the full scope and content of the claimed invention as disclosed in the application as filed. In situations where the showing provides adequate evidence that the claim is supported by at least one asserted specific, substantial, and credible or well-established utility, the rejections under 35 U.S.C. 101 and 112, first paragraph, will be withdrawn. However, the examiner is instructed to consider whether or not the specification, in light of applicant’s

showing, is enabled for the use of the full scope of the claimed invention. Many times prior patents and printed publications provided by applicant will clearly demonstrate that a well-established utility exists.

(23) **Comment:** One comment states that the Office is using an improper standard in assessing ‘specific’ utility

According to the comment, a distinction between ‘specific’ and ‘general’ utilities is an overreaching interpretation of the specificity requirement in the case law because ‘unique’ or ‘particular’ utilities have never been required by the law. The comment states that the specificity requirement concerns sufficiency of disclosure, *i.e.*, teaching how to make and use a claimed invention, not the utility requirement. The comment states that the specificity requirement is to be distinguished from the ‘substantial’ utility requirement, and that the *Brenner v. Manson* decision concerned only a ‘substantial’ utility issue, not specificity.

**Response:** The comment is not adopted. The disclosure of only a general utility rather than a particular utility is insufficient to meet statutory requirements. Although the specificity requirement is relevant to § 112, it is not severable from the utility requirement. [S]urely Congress intended § 112 to presuppose *full satisfaction* of the requirements of § 101. Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention. As this court stated in *Diederich*, quoting with approval from the decision of the board: ‘We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.’ As the Supreme Court said in *Brenner v Manson*: ‘\* \* \* a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’ *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) (affirming rejections under §§ 101 and 112) (emphasis in original)

## II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

### *Introduction*

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable

### *B. Examination Guidelines for the Utility Requirement*

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the 'useful invention' ('utility') requirement of 35 U.S.C. 101 and 112, first paragraph

#### 1. Read the claims and the supporting written description

- (a) Determine what the applicant has claimed, noting any specific embodiments of the invention
- (b) Ensure that the claims define statutory subject matter (*i.e.*, a process, machine, manufacture, composition of matter, or improvement thereof)
- (c) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.*, properties or applications of a product or process), and (2) the utility is specific, substantial, and credible

#### 2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

- (a) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.*, it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility
  - (1) A claimed invention must have a specific and substantial utility. This requirement excludes 'throw-away,' 'insubstantial,' or 'nonspecific' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101
  - (2) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (*e.g.*, test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(b) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well established utility, reject the claim(s) under § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection.

(c) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under § 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The §§ 101 and 112 rejections shift the

burden of coming forward with evidence to the applicant to:

- (1) Explicitly identify a specific and substantial utility for the claimed invention; and
- (2) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above

The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (*e.g.*, scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

- (1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;
- (2) Support for factual findings relied upon in reaching this conclusion; and
- (3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art

(b) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention.

The *prima facie* showing must contain the following elements:

- (1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
- (2) Support for factual findings relied upon in reaching this conclusion; and
- (3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art

(c) Where no specific and substantial utility is disclosed or is well established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a

patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

Dated: December 29, 2000

**Q. Todd Dickinson**, *Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*

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**Annex Three**  
**EU Biotechnology Directive**  
**Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998**  
**on the legal protection of biotechnological inventions**

*Official Journal L 213 , 30/07/1998 p. 0013 - 0021*

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 (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, 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 (4), 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) (5) 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;

(28) 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 (6);

(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 (7) 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 ordre 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**

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

**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 depository institution. At least the international depository 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 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 depository 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.

Done at Brussels, 6 July 1998.

For the European Parliament The President J. M. GIL-ROBLES

For the Council The President R. EDLINGER

(1) OJ C 296, 8.10.1996, p. 4 and OJ C 311, 11.10.1997, p. 12.

(2) OJ C 295, 7.10.1996, p. 11.

(3) Opinion of the European Parliament of 16 July 1997 (OJ C 286, 22.9.1997, p. 87). Council Common Position of 26 February 1998 (OJ C 110, 8.4.1998, p. 17) and Decision of the European Parliament of 12 May 1998 (OJ C 167, 1.6.1998). Council Decision of 16 June 1998.

(4) OJ C 68, 20.3.1995, p. 26.

(5) OJ L 336, 23.12.1994, p. 213.

(6) OJ L 227, 1.9.1994, p. 1. Regulation as amended by Regulation (EC) No 2506/95 (OJ L 258, 28.10.1995, p. 3).

(7) OJ L 309, 31.12.1993, p. 1.