

## ***The Patents Act 1977 (Isle of Man) Order 2003***

2003 No. 1249

PATENTS

The Patents Act 1977 (Isle of Man) Order 2003

Made 8th May 2003

Laid before Parliament 20th May 2003

Coming into force 10th June 2003

At the Court at Buckingham Palace, the 8th day of May 2003

Present,

The Queen's Most Excellent Majesty in Council

Her Majesty, in exercise of the powers conferred upon Her by sections 124(3) and 132(2) of the Patents Act 1977, is pleased, by and with the advice of Her Privy Council, to order, and it is hereby ordered, as follows:

### **Citation and commencement**

1. This Order may be cited as the Patents Act 1977 (Isle of Man) Order 2003 and shall come into force on 10th June 2003.

### **Modification of the Patents Act 1977 in its application to the Isle of Man**

2. The provisions of the Patents Act 1977 specified in the Schedule to this Order shall, in their application to the Isle of Man, have effect subject to the modifications specified in that Schedule.

3. The Patents Act 1977 shall, in its application to the Isle of Man, be construed -

- a. as if references to the Crown included the Crown in right of the Government of the Isle of Man;
- b. as if references to a government department included references to a Department of the Government of the Isle of Man, and in relation to such a Department as if references to the Treasury were references to the Treasury of the Isle of Man, and
- c. for the purposes of any arbitration in pursuance thereof and of the application thereto of the Arbitration Act 1976 (an Act of Tynwald), as if it were an Act of Tynwald.

## **Revocations**

4. The Patents Act 1977 (Isle of Man) Order 1978 and the Patents Act 1977 (Isle of Man) (Variation) Order 1990 are revoked.

A. K. Galloway

Clerk of the Privy Council

## **SCHEDULE**

Article 2(1)

Modifications of specified provisions of the Patents Act 1977 in their application to the Isle of Man

1. In section 1, for subsections (3) and (4) substitute -

3. "A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.
4. For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it."

2. In section 5, after subsection (5) insert -

6. "References in subsection (5) above to a convention country include references to a country, other than the United Kingdom, which is a member of the World Trade Organisation."

3. In sections 22(9)(b) and 23(3)(b), for "indictment" substitute "information".

4. In section 41, add the following subsection: -

12. "In the Isle of Man an order made under section 40 above by the comptroller for the payment of any sums may be enforced in like manner as an execution issued out of the court."

5. Omit sections 44 and 45.

6. For section 48 substitute -

"Compulsory licences: general

48. -

1. At any time after the expiration of three years, or of such other period as may be

prescribed, from the date of the grant of the patent, any person may apply to the comptroller on one or more of the relevant grounds -

- a. for a licence under the patent;
  - b. for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or
  - c. where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent.
2. Subject to sections 48A and 48B below, if he is satisfied that any of the relevant grounds are established, the comptroller may -
- a. where the application is under subsection (1)(a) above, order the grant of a licence to the applicant on such terms as the comptroller thinks fit;
  - b. where the application is under subsection (1)(b) above, make such an entry as is there mentioned;
  - c. where the application is under subsection (1)(c) above, order the grant of a licence to the person specified in the application on such terms as the comptroller thinks fit.
3. An application may be made under this section in respect of a patent even though the applicant is already the holder of a licence under the patent; and no person shall be estopped or barred from alleging any of the matters specified in the relevant grounds by reason of any admission made by him, whether in such a licence or otherwise, or by reason of his having accepted a licence.
4. In this section "the relevant grounds" means -
- a. in the case of an application made in respect of a patent whose proprietor is a WTO proprietor, the grounds set out in section 48A(1) below;
  - b. in any other case, the grounds set out in section 48B(1) below.
5. A proprietor is a WTO proprietor for the purposes of this section and sections 48A, 48B, 50 and 52 below if -
- a. he is a national of, or is domiciled in, a country which is a member of the World Trade Organisation; or
  - b. he has a real and effective industrial or commercial establishment in such a country.
6. A rule prescribing any such other period under subsection (1) above shall not be made unless a draft of the rule has been laid before, and approved by a resolution of, each House of Parliament.

## Compulsory licences: WTO proprietors

48A. -

1. In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are -
  - a. where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;
  - b. that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms -
    - i. the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or
    - ii. the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
  - c. that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.
2. No order or entry shall be made under section 48 above in respect of a patent whose proprietor is a WTO proprietor unless -
  - a. the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions; and
  - b. his efforts have not been successful within a reasonable period.
3. No order or entry shall be so made if the patented invention is in the field of semi-conductor technology.
4. No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(b)(i) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.
5. A licence granted in pursuance of an order or entry so made shall not be assigned except to a person to whom the patent for the other invention is also assigned.
6. A licence granted in pursuance of an order or entry made under section 48 above in

respect of a patent whose proprietor is a WTO proprietor -

- a. shall not be exclusive;
- b. shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part;
- c. shall be predominantly for the supply of the market in the United Kingdom;
- d. shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence; and
- e. shall be limited in scope and in duration to the purpose for which the licence was granted.

Compulsory licences: other cases

48B. -

1. In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are -
  - a. where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;
  - b. where the patented invention is a product, that a demand for the product in the United Kingdom -
    - i. is not being met on reasonable terms, or
    - ii. is being met to a substantial extent by importation from a country which is not a member State;
  - c. where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked -
    - i. where the invention is a product, by the importation of the product from a country which is not a member State,
    - ii. where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;
  - d. that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms -

- i. a market for the export of any patented product made in the United Kingdom is not being supplied, or
    - ii. the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or
    - iii. the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
  - e. that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced.
2. Where -
  - a. an application is made on the ground that the patented invention is not being commercially worked in the United Kingdom or is not being so worked to the fullest extent that is reasonably practicable; and
  - b. it appears to the comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked,

he may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.
3. No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(a) above if -
  - a. the patented invention is being commercially worked in a country which is a member State; and
  - b. demand in the United Kingdom is being met by importation from that country.
4. No entry shall be made in the register under section 48 above on the ground mentioned in subsection (1)(d)(i) above, and any licence granted under section 48 above on that ground shall contain such provisions as appear to the comptroller to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.
5. No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(d)(ii) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms."

7. -

1. In section 50(1), after "in respect of a patent" insert "whose proprietor is not a WTO proprietor".
2. In section 50(2), for "such an application" substitute "any application under section 48 above".

8. In sections 51(1) and 53(2), for "Monopolies and Mergers Commission" substitute "Competition Commission".

9. For section 52 substitute -

" Opposition, appeal and arbitration.

52. -

1. The proprietor of the patent concerned or any other person wishing to oppose an application under sections 48 to 51 above may, in accordance with rules, give to the comptroller notice of opposition; and the comptroller shall consider any opposition in deciding whether to grant the application.
2. Where an order or entry has been made under section 48 above in respect of a patent whose proprietor is a WTO proprietor -
  - a. the proprietor or any other person may, in accordance with rules, apply to the comptroller to have the order revoked or the entry cancelled on the grounds that the circumstances which led to the making of the order or entry have ceased to exist and are unlikely to recur;
  - b. any person wishing to oppose an application under paragraph (a) above may, in accordance with rules, give to the comptroller notice of opposition; and
  - c. the comptroller shall consider any opposition in deciding whether to grant the application.
3. If it appears to the comptroller on an application under subsection (2)(a) above that the circumstances which led to the making of the order or entry have ceased to exist and are unlikely to recur, he may -
  - a. revoke the order or cancel the entry; and
  - b. terminate any licence granted to a person in pursuance of the order or entry subject to such terms and conditions as he thinks necessary for the protection of the legitimate interests of that person.
4. Where an appeal is brought -
  - a.

from an order made by the comptroller in pursuance of an application under sections 48 to 51 above;

- b. from a decision of his to make an entry in the register in pursuance of such an application;
- c. from a revocation or cancellation made by him under subsection (3) above; or
- d. from a refusal of his to make such an order, entry, revocation or cancellation,

the Attorney General, the appropriate Law Officer within the meaning of section 4A of the Crown Suits (Scotland) Act 1857, the Attorney General for Northern Ireland or the Attorney General for the Isle of Man or such other counsel as any of them may appoint, shall be entitled to appear and be heard.

- 5. Where an application under section 48 to 51 above or subsection (2) above is opposed, and either -
  - a. the parties consent, or
  - b. the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot in the opinion of the comptroller conveniently be made before him,

the comptroller may at any time order the whole proceedings, or any question or issue of fact arising in them, to be referred to an arbitrator agreed on by the parties or, in default of agreement, appointed by the comptroller.

- 6. Where the whole proceedings are so referred, unless the parties otherwise agree before the award of the arbitrator or arbiter is made, and appeal shall lie from the award to the court.
- 7. Where a question or issue of fact is so referred, the arbitrator shall report his findings to the comptroller."

10. In section 54(2), after "means a country other than a member State" insert "or a member of the World Trade Organisation".

11. In section 58(12), after "Wales" insert ", the Isle of Man".

12. -

- 1. In section 60(5), after paragraph (f) insert -
  - g. "it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;
  - h.



it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention."

2. After section 60(6) insert -

" (6A) Schedule A1 contains -

- a. provisions restricting the circumstances in which subsection (5)(g) applies; and
- b. provisions which apply where an act would constitute an infringement of a patent but for subsection (5)(g).

(6B) For the purposes of subsection (5)(h), use for an agricultural purpose -

- a. includes making an animal or animal reproductive material available for the purposes of pursuing the farmer's agricultural activity; but
- b. does not include sale within the framework, or for the purposes, of a commercial reproduction activity.

(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation."

3. In section 60(7) -

- a. in the definitions of "relevant ship" and "relevant aircraft, hovercraft or vehicle", after "1983" insert "or which is a member of the World Trade Organisation";
- b. in the definition of "exempted aircraft", for "section 53 of the Civil Aviation Act 1949" substitute "section 89 of the Civil Aviation Act 1982".

13. After section 76 insert -

" Biotechnological inventions

76A. -

1. Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.
2. Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent."

14. In section 93, at the end insert -

- d. "in the Isle of Man, the order may be enforced in like manner as an execution issued out of the court."

15. Omit section 96.

16. In section 97(2), omit the words from "and the Patents Court" onwards.

17. In section 107, at the end insert -

6. "In the Isle of Man, any order under this section for the payments of costs may be enforced in like manner to an execution issued out of the court."

18. In section 109, for "indictment" substitute "information".

19. After section 124 insert -

" Use of electronic communications

124A. -

1. The comptroller may make directions as to the form and manner in which documents to be delivered to the comptroller -
  - a. in electronic form; or
  - b. using electronic communications,are to be delivered to him.
2. A direction under subsection (1) may provide that in order for a document to be delivered in compliance with the direction it shall be accompanied by one or more additional documents specified in the direction.
3. If a document to which a direction under subsection (1) applies is delivered to the comptroller in a form or manner which does not comply with the direction the comptroller may treat the document as not having been delivered.
4. Subsection (5) applies in relation to a case where -
  - a. a document is delivered using electronic communications, and
  - b. there is a requirement for a fee to accompany the document.
5. The comptroller may make directions specifying -
  - a. how the fee shall be paid;

- b. when the fee shall be deemed to have been paid.
6. The comptroller may make directions specifying that a person who delivers a document to the comptroller in electronic form or using electronic communications cannot treat the document as having been delivered unless its delivery has been acknowledged.
7. The comptroller may make directions specifying how a time of delivery is to be accorded to a document delivered to him in electronic form or using electronic communications.
8. A direction under this section may be given -
  - a. generally;
  - b. in relation to a description of cases specified in the direction;
  - c. in relation to a particular person or persons.
9. In a case falling within subsection (8)(a) or (b), the direction must be published in such manner as the comptroller considers appropriate for the purpose of bringing it to the attention of the persons affected by it.
10. In a case falling within subsection (8)(c), the direction must be notified to that person or those persons in such manner as may be agreed between that person or those persons and the comptroller.
11. A direction under this section may be varied or revoked by a subsequent direction under this section.
12. A direction under this section may include incidental, supplementary, saving and transitional provisions.
13. Where the comptroller delivers a document using electronic communications then, unless the contrary intention has been specified by the comptroller, the delivery is deemed to be effected by the comptroller properly addressing and transmitting the electronic communication.
14. Where the comptroller makes a direction under this section which applies in addition to or in place of rules, to the extent that the direction applies -
  - a. "prescribed" in this Act includes prescribed by the direction;
  - b. references in this Act to compliance with rules or requirements of rules include compliance with the direction or requirements of the direction.
15. In this section -
  - a. references to a document include anything that is or may be embodied in paper

form;

- b. references to delivery to the comptroller include delivery at, in, with or to the Patent Office;
- c. references to delivery by the comptroller include delivery by the Patent Office;

and cognate expressions must be construed accordingly."

20. In section 125A -

- a. in the sidenote, for "micro-organisms" substitute "biological material";
- b. in subsection (1), for "requires for its performance the use of a micro-organism" substitute "involves the use of or concerns biological material";
- c. in subsection (2)(a), for "micro-organism" substitute "biological material".

21. In section 130(1) -

- a. at the end of the definition of "court" insert -
  - d. "as respects the Isle of Man, Her Majesty's High Court of Justice of the Isle of Man;"
- b. at the appropriate places insert -

"biotechnological invention" means an invention which concerns a product consisting of or containing biological material or a process by means of which biological material or a process by means of which biological material is produced, processed or used;"

"electronic communication" has the same meaning as in the Electronic Communications Act 2000;"

"enactment" includes an Act of Tynwald;"

22. Before Schedule 1 insert -

" SCHEDULE A1.

Section 60(5)(g)

Derogation from patent protection in respect of biotechnological inventions

Interpretation

1. In this Schedule -

"the Council Regulation" means Council Regulation (EC) No. 2100/94 of 27th July 1994 on Community plant variety rights;

"farmer's own holding" means any land which a farmer actually exploits for plant growing, whether as his property or otherwise managed under his own responsibility and on his own account;

"the gazette" means the gazette published under section 34 of the Plant Varieties and Seeds Act 1964;

"protected material" means plant propagating material which incorporates material subject to a patent;

"relevant activity" means the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where the product of the harvest constitutes or contains protected material;

"relevant rights holder" means the proprietor of a patent to which protected material is subject;

"seed" includes seed potatoes;

"seed year" means the period from 1st July in one year to 30th June in the following year, both dates inclusive.

Specified species

2. Section 60(5)(g) applies only to varieties of the following plant species and groups:

Name Common Name

Fodder plants

*Cicer arietinum* L. Chickpea milkvetch

*Lupinus luteus* L. Yellow lupin

*Medicago sativa* L. Lucerne

*Pisum sativum* L. (partim) Field pea

*Trifolium alexandrinum* L. Berseem/Egyptian clover

*Trifolium resupinatum* L. Persian clover

*Vicia faba* Field bean

*Vicia sativa* L Common vetch

Cereals

Avena sativa Oats

Hordeum vulgare L. Barley

Oryza sativa L. Rice

Phalaris canariensis L. Canary grass

Secale cereale L. Rye

X Triticosecale Wittm. Triticale

Triticum aestivum L. emend. Fiori et Paol. Wheat

Triticum durum Desf. Durum wheat

Triticum spelta L. Spelt wheat

Potatoes

Solanum tuberosum Potatoes

Oil and fibre plants

Brassica napus L. (partim) Swede rape

Brassica rapa L. (partim) Turnip rape

Linum usitatissimum Linseed with the exclusion of flax

Liability to pay equitable remuneration

3. -

1. If a farmer's use of protected material is authorised by section 60(5)(g), he shall, at the time of the use, become liable to pay the relevant rights holder equitable remuneration.
2. That remuneration must be sensibly lower than the amount charged for the production of protected material of the same variety in the same area with the holder's authority.
3. Remuneration is to be taken to be sensibly lower if it would be taken to be sensibly lower within the meaning of Article 14(3) fourth indent of the Council Regulation.

Exemption for small farmers

4. -

1. Paragraph 3 does not apply to a farmer who is considered to be a small farmer for the

purposes of Article 14(3) third indent of the Council Regulation.

2. It is for a farmer who claims to be a small farmer to prove that he is such a farmer.

Information to be supplied by farmer

5. -

1. at the request of a relevant rights holder ("H"), a farmer must tell H -
  - a. his name and address;
  - b. whether he has performed a relevant activity; and
  - c. if he has performed such an activity, the address of the holding on which he performed it.
2. If the farmer has performed such an activity, he must tell H whether he is -
  - a. liable to pay remuneration as a result of paragraph 3; or
  - b. not liable because he is a small farmer.
3. If the farmer has told H that he is liable to pay remuneration as a result of paragraph 3, he must tell H -
  - a. the amount of the protected material used;
  - b. whether the protected material has been processed for planting; and
  - c. if it has, the name and address of the person who processed it.
4. The farmer must comply with sub-paragraphs (2) and (3) when complying with sub-paragraph (1).
5. If the farmer has told H that he is liable to pay remuneration as a result of paragraph 3, he must (if H asks him to do so) tell H -
  - a. whether he used any protected material with the authority of H within the same seed year; and
  - b. if he did, the amount used and the name and address of the person who supplied it.

Information to be supplied by seed processor

6. -

1. On the request of a relevant rights holder, a seed processor shall supply the following information -
  - a. the name and address of the seed processor;
  - b. the address of the seed processor's principal place of business; and
  - c. whether the seed processor has processed seed of a species specified in paragraph 2 above.
2. If the seed processor has processed seed of a species specified in paragraph 2 above he shall also supply the following information with the information referred to in sub-paragraph (1) -
  - a. the name and address of the person for whom the processing was carried out;
  - b. the amount of seed resulting from the processing;
  - c. the date processing commenced;
  - d. the date processing was completed;
  - e. the place where processing was carried out.

Information to be supplied by relevant rights holder

7. On the request of a farmer or a seed processor a relevant rights holder shall supply the following information -
  - a. his name and address; and
  - b. the amount of royalty charged for certified seed of the lowest certification category for seed containing that protected material.

Period in respect of which inquiry may be made

8. A request may be made under paragraph 5, 6, and 7 in respect of the current seed year and the three preceding seed years.

Restriction on movement for processing from the holding

9. No person shall remove or cause to be removed from a holding protected material in order to process it unless -
  - a. he has the permission of the relevant rights holder in respect of that protected



material;

- b. he has taken measures to ensure that the same protected material is returned from processing as is sent for processing and the processor has undertaken to him that the processor has taken measures to ensure that the same protected material is returned from processing as is sent for processing; or
- c. he has the protected material processed by a seed processor on the list of processors referred to in the gazette as being permitted to process seed away from a holding.

#### Confidentiality

10. -

1. A person who obtains information pursuant to this Schedule shall owe an obligation of confidence in respect of the information to the person who supplied it.
2. Sub-paragraph (1) shall not have effect to restrict disclosure of information -
  - a. for the purposes of, or in connection with, establishing the amount to be paid to the holder of rights pursuant to paragraph 3 and obtaining payment of that amount,
  - b. for the purposes of, or in connection with, establishing whether a patent has been infringed, or
  - c. for the purposes of, or in connection with, any proceedings for the infringement of a patent.

#### Formalities

11. -

1. A request for information under this Schedule, and any information given in response to such a request, must be in writing.
2. Information requested under this Schedule must be given -
  - a. within 28 days; or
  - b. if the request specifies a longer period, within the specified period.

#### Remedies

12. -

1. If, in response to a request under this Schedule, a person -

- a. knowingly fails to provide information which he is required by this Schedule to give, or
- b. refuses to provide any such information,

the court may order him to provide it.

2. Sub-paragraph (1) does not affect any of the court's other powers to make orders.
3. A person who knowingly provides false information in response to a request under this Schedule is liable in damages to the person who made the request.
4. In any action for damages under sub-paragraph (3) the court must have regard, in particular to -
  - a. how flagrant the defendant was in providing the false information, and
  - b. any benefit which accrued to him as a result of his providing false information,

and shall award such additional damages as the justice of the case may require.

## SCHEDULE A2

### Section 76A

#### Biotechnological Inventions

1. An invention shall not be considered unpatentable solely on the ground that it concerns -
  - a. a product consisting of or containing biological material; or
  - b. a process by 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.
3. The following are not patentable inventions -
  - a. 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;
  - b. processes for cloning human beings;
  - c. processes for modifying the germ line genetic identity of human beings;
  - d.

uses of human embryos for industrial or commercial purposes;

- e. 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;
- f. any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological or other technical process or the product of such a process.

4. Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

5. 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.

6. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed.

7. 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.

8. 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.

9. The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided for in paragraph 3(a) above, in which the product is incorporated and in which the genetic information is contained and performs its function.

10. The protection referred to in paragraphs 7, 8 and 9 above shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the proprietor 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.

11. In this Schedule -

"essentially biological process" means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;

"microbiological process" means any process involving or performed upon or resulting in microbiological material;

"plant variety" means a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be -

- a. defined by the expression of the characteristics that results from a given genotype or combination of genotypes; and
- b. distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
- c. considered as a unit with regard to its suitability for being propagated unchanged."