Act of April 1, 2004 (No. 2004:159)
Amending the Patents Act (1967:837)

In accordance with the decision by Parliament it is prescribed, as regards the Patents Act (1967:837)

that Articles 1, 3, 8, 8*a*, 22, 25, 45, 46, 49, 52 and 56 shall read as follows, and

that six new Articles shall be inserted in the Act, numbered 1*a*, 1*b*, 1*c*, 3*a*, 3*b* and 46*a* and reading as follows.

1. Anyone who has made an invention that is susceptible of industrial application, or anyone to whom the rights of the inventor have been assigned, may, pursuant to Chapters 1 to 10 of this Act, be granted a patent for the invention in Sweden and thereby acquire an exclusive right to exploit the invention commercially. Provisions concerning European patents are included in Chapter 11.

As an invention shall never be considered what is solely

1. a discovery, scientific theory or mathematical method,

2. an artistic creation,

3. a scheme, rule or method for performing intellectual activities, for playing games or for doing business, or a computer program,

4. a presentation of information.

As an invention shall also not be considered such a method for surgical or therapeutic treatment, or for diagnosing, which is intended for use on humans or animals. A patent may, however, be granted for products, including substances and or compositions of substances, for use in methods of this kind.

1*a*. Patents are not granted on plant and animal varieties. A patent may, however, be granted for an invention which concerns plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety. The concept of a plant variety is defined in Chapter 1, Article 3, of the Act on the Protection of Plant Breeders' Rights (1997:306).

Patents are not granted for essentially biological processes for the production of plants or animals. As an essentially biological process for the production of plants or animals shall be considered any process which in its entirety consists of natural phenomena such as crossing or selection. A patent may, however, be granted for an invention that concerns a microbiological process or another technical process or a product made by means of such a process. As a microbiological process shall be considered any process which is performed on microbiological material or through which such material is used or is produced.

An invention may be patentable even if it concerns a product which consists of, or contains, biological material or a process through which biological material is produced, processed or used. A biological material which is isolated from its natural environment, or which is produced by means of a technical process, may be the subject of an invention even if it previously occurred in nature. Biological material comprises material that contains genetic information and which is itself capable of reproduction or which may be reproduced in a biological system.

1*b*. The human body at the various stages of its formation and development as well as the simple discovery of one of its elements, including the sequence of a gene or a partial sequence of a gene, can not constitute a patentable invention.

An isolated element of the human body or an element otherwise produced by means of a technical process, including the sequence of a gene or a partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical with that of a natural element.

1*c*. A patent is not granted for an invention the commercial exploitation of which would be contrary to public order or morality.

An exploitation shall not be considered to be contrary to public order or morality merely because it is prohibited by law or other statutes.

For the application of the first Paragraph, the following shall, *inter alia*, be considered to be contrary to public order or morality,

1. processes for cloning human beings,

2. processes for modifying the germ line genetic identity of human beings,

3. uses of human embryos for industrial or commercial purposes.

4. such processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal.

The provisions of the third Paragraph, item 4, concerning processes for modifying the genetic identity of animals apply, *mutatis mutandis,* to animals which are produced by means of such a process.

3. The exclusive right conferred by a patent implies, with the exceptions stated below, that no one may, without the consent of the holder of the patent, exploit the invention by

1. making, offering for sale, putting on the market or using a product protected by the patent or importing or possessing such a product for any of these purposes,

2. making use of a process protected by the patent, or, where he or she knows, or it is obvious from the circumstances, that the process may not be used without the consent of the holder of the patent, offering the process for use in Sweden,

3. offering, putting on the market or making use of a product that has been produced by a process protected by the patent or importing or possessing the product for these purposes.

The exclusive right also implies that no one may, without the consent of the holder of the patent, exploit the invention by offering or supplying a person who has no right to exploit the invention, such means for carrying out the invention which relate to an essential element of the invention, if the person who offers or supplies the means knows, or it is obvious from the circumstances, that the said means are suited and intended for use in the carrying out of the invention. If the means are a staple commercial product, this applies only if the person offering or supplying the means attempts to induce the receiver to commit acts referred to in the first Paragraph. For the application of the provisions of this Paragraph, the person making use of the invention in the way referred to in the third Paragraph, items 1, 3 or 4, shall not be regarded as having the right to exploit the invention.

From the exclusive right are exempted

1. acts of exploitation which are not commercial,

2. acts of exploitation of a product protected by a patent which has been put on the market within the European Economic Area by the holder of the patent or with his or her consent; as regards biological material this applies also to acts of exploitation in the form of propagation or multiplication when the propagation or multiplication is a necessary step in the use for which the biological material has been put on the market, on condition that the product obtained is not subsequently used for further propagation or multiplication.

3. acts of exploitation of an invention for experiments concerning the invention itself,

4. preparations in a pharmacy of a medicine in accordance with prescriptions by physicians in individual cases, or acts relating to medicines prepared in such cases.

3*a*. 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 the propagation or multiplication in an identical or divergent form and possessing those same characteristics.

The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics a result of the invention, shall extend to, in addition to the biological material possessing those characteristics which is directly obtained by this process, any other biological material in identical or divergent form possessing those same characteristics and obtained through propagation or multiplication from the biological material first produced.

The exclusive right conferred by a patent on a product containing or consisting of genetic information shall, with the exception of such that can not, according to Article 1*b*, constitute a patentable invention, extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function.

3*b*. Where the holder of the patent or someone with his or her consent assigns plant propagating material to a farmer for agricultural use, the farmer may, by way of derogation from Articles 3 and 3*a*, use the product of his or her harvest for propagation or multiplication in his or her own farm. The extent of, and the conditions for, this exception from the exclusive right of the holder of the patent are contained in Article 14 of the Regulation (EC) nr 2100/94, of July 27, 1994 on the Community Plant Breeders' Right and the Implementing Provisions issued on the basis of that Article.

Where the holder of the patent or someone with his or her consent assigns breeding stock or other animal reproductive material to a farmer, the farmer may, by way of derogation from Articles 3 and 3*a*, use the livestock or other animal reproductive material for agricultural purposes within his or her agricultural activity. The farmer may, however, not sell protected breeding stock or other material within the framework or for the purpose of a commercial reproduction activity.

The right of the farmer under the second Paragraph must not be exercised to an extent wider than what is reasonable taking into account the needs of the farmer and the interests of the holder of the patent.

8. An application for a patent shall be made in writing and be filed with the Patent Authority or, in cases referred to in Chapter 3, with a Patent Authority in a foreign State or with an International Organization.

The application shall contain a description of the invention, comprising also drawings if such are needed, and distinct statements about what is sought to be protected by the patent (patent claim). The fact that the invention relates to a chemical compound does not imply that a specified use must be disclosed in the patent claim. The application shall contain a statement as to how the invention can be industrially exploited, if that does not follow from

the character of the invention. However, if the invention concerns a gene sequence or a partial sequence of a gene, the application shall always indicate how the invention can be applied industrially. The description shall be sufficiently clear so as to enable a person skilled in the art to carry out the invention with the guidance thereof. An invention that relates to a biological material, or implies the use of such a material, shall, in the cases referred to in Article 8*a*, be deemed to be sufficiently clearly indicated only where also the conditions in that Article are fulfilled.

The application shall also contain an abstract of the description and the patent claims. The abstract is intended only to give technical information about the contents of the patent application and may not be taken into account for any other purpose.

The name of the inventor shall be stated in the application. Where a patent is applied for by someone other than the inventor, the applicant shall prove his or her title to the invention.

The applicant shall pay an application fee. For the application, an annual fee shall also be paid for each fee year which commences before the application has been finally decided on.

A fee year according to this Act comprises one year and is calculated from the date when the application was filed or shall be deemed to have been filed, and thereafter from the corresponding date according to the calendar.

8*a*. If an invention concerns a biological material which is neither available to the public nor can be described in the application documents in such a way as to enable a person skilled in the art to carry out the invention with the guidance of those, or if the invention implies the use of such a material, the biological material shall be deposited no later than the date of the filing of the application. The biological material shall thereafter be continuously kept on deposit so that anyone who under this Act is entitled to receive samples of the material can obtain the sample delivered in Sweden. The Government shall prescribe where deposits may be made.

If a deposited biological material ceased to be viable or if samples from of the material can not for other reasons be supplied, the material may be replaced by a new deposit of the same biological material within the time and in the manner specified by the Government. Where this has been done, the new deposit shall be deemed as having been made already on the date when the earlier deposit was made.

22. From the day when the patent is granted, the documents in the case shall be made available to anyone.

After eighteen months from the date when the patent application was filed or, where priority is claimed, the date from which priority is claimed, the documents shall, if they have not already been made available according to the first Paragraph, be made available to anyone. If, however, the application has been dismissed or rejected, the application shall be made available to the public only if the applicant requests the application to be resumed, or lodges an appeal or makes a petition pursuant to Article 72 or 73.

At the request of the applicant, the documents shall be made available earlier than what follows from the first and second Paragraphs.

When the documents become available pursuant to the second or third Paragraph, this fact shall be announced.

If a document contains a business secret and if that does not concern an invention for which a patent is sought or has been granted, the Patent Authority may, upon request and if

there are special reasons for this, order that the document shall not be delivered. If such a request has been made, the document may not be delivered until the request has been refused through a decision that has gained legal force.

If a biological material has been deposited pursuant to Article 8*a*, anyone has, subject to the limitations prescribed in this and the following Paragraphs, the right to obtain a sample of the material after the documents have been made available to the public according to the first, second or third Paragraph. This applies regardless of whether the patent has expired or is invalidated. A sample may not be delivered to anyone who, pursuant to provisions in law or other statute, is not entitled to handle the deposited material. Furthermore, a sample may not be delivered to anyone whose handling of the sample may be assumed to involve a evident risk in view of the harmful properties of the material.

Until the patent has been granted or the patent application has been finally decided on without having resulted in a patent, samples from a deposit may be delivered only to a special expert, if the applicant so requests. If the patent application is rejected or is withdrawn, the corresponding applies for a period of 20 years from the day when the application was filed. The Government prescribes the time within which a request may be made and who may be called upon as an expert by a person wishing to obtain a sample.

Anyone who wants to obtain a sample shall make a written request in this respect to the Patent Authority and file a commitment with the contents as prescribed by the Government to prevent misuse of the sample. If a sample may be delivered only to a special expert, the commitment shall instead be filed by him or her.

25. The Patent Authority shall, after an opposition has been filed, revoke the patent, if it

1. has been granted despite the fact that the conditions under Articles 1–2 have not been fulfilled,

2. concerns an invention which has not been clearly disclosed so that a person skilled in the art is able to carry out the invention with the guidance of the description, or

3. covers something that did not emerge from the application when it was made.

The Patent Authority shall reject the opposition if there is not, according to the first Paragraph, any obstacle to maintaining the patent.

If the holder of the patent has, in the course of the opposition procedure, made such amendments that there is no obstacle, according to the first Paragraph, to maintaining the patent as amended, the Patent Authority shall declare that the patent is maintained as amended.

When the decision by the Patent Authority relating to an opposition has gained legal force, it shall be announced. If the decision implies that the patent is amended, a new patent document shall be kept available at the Patent Authority and new letters patent be issued.

45. A compulsory license for the use of an invention in Sweden may be granted if

1. three years have expired from the granting of the patent and four years from the filing of the patent application,

2. the invention is not used to a reasonable extent in Sweden, and

3. there is no acceptable reason for the non-use of the invention.

For the purposes of the application of the first Paragraph, item 2, use of an invention equals importation of the invention to Sweden from a State within the European Economic

Area or a State which is party to, or a territory which is member of, the World Trade Organization (WTO).

46. A holder of a patent for an invention of which the exploitation is depending on a patent which belongs to someone else may be granted a compulsory license to exploit the invention protected by the other patent. Such a license may be granted only if the applicant proves that the first-mentioned invention constitutes a significant technical progress of considerable economic interest compared with the other invention.

If a compulsory license is issued in accordance with the first Paragraph, the holder of the patent for which a compulsory license has been granted is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the other invention.

46*a*. A plant breeder who can not obtain or exploit a plant breeders' right without infringing a prior patent, may obtain a compulsory license to exploit the invention which is protected by the patent, inasmuch as such a license is necessary for the plant variety to be exploited. Such a license may be granted only if the applicant proves that the plant variety constitutes a significant technical progress of considerable economic interest compared with the invention.

If a holder of a patent obtains a compulsory license in a plant breeders' right, the holder of the plant breeders' right is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the invention of the holder of the patent.

Provisions on the possibility for the holder of a patent on a biotechnical invention to obtain, under certain conditions, a compulsory license to exploit a protected plant variety are contained in Chapter 7, Article 3*a*, of the Act on the Protection of Plant Breeders' Rights (1997:306).

49. A compulsory license may be granted only to a person who can be assumed to exploit the invention in an acceptable manner and in accordance with the license. The applicant must also prove that he or she has unsuccessfully turned to the patent holder to obtain a contractual license on reasonable conditions.

A compulsory license does not prevent the patent holder from exploiting himself or herself the invention or to grant licenses. A compulsory license may be assigned to someone else only together with a business where it is exploited or intended to be exploited. In respect of such compulsory licenses as mentioned in Article 46, first Paragraph, and Article 46*a*, first Paragraph, also applies that the license may be assigned only together with the patent or the plant breeders' right to which the license applies.

52. If a claim to this effect is made, the Court shall invalidate a patent if

1. it has been granted despite the fact that the requirements under Articles 1–2 are not fulfilled,

2. it concerns an invention which is not disclosed in a manner sufficiently clear for a person skilled in the art to carry out the invention with the guidance of the description,

3. it contains something that did not appear from the application as filed, or

4. the scope of the patent protection has been extended after the granting of the patent.

A patent must not be invalidated on the ground that the person who has been granted the patent is entitled only to a certain part of it.

Except in cases as provided for in the fourth Paragraph, a court action may be brought by anyone to whom the patent exposes a detriment and, where this is called for in the public interest, by a public authority designated by the Government.

An action based on the ground that the patent has been granted to someone else than the one who is entitled to the patent under Article 1, may only be brought by the one who claims to be entitled to the patent. The action shall be brought within one year after the person who claims to be entitled obtained knowledge of the grant of the patent and of other facts on which the action is founded. If the holder of the patent was in good faith when the patent was granted or when it was assigned to him or her, the action may, however, be brought no later than three years from the grant of the patent.

56. If a patent applicant invokes his or her application against another party before the documents in the case have been made available to the public pursuant to Article 22, the applicant is obliged to consent, upon request, to give the other party access to the documents. If the patent application includes such a deposit of biological material as referred to in Article 8*a*, the consent shall also encompass the right to obtain a sample of the material. The provisions of Article 22, sixth Paragraph, third and fourth sentences, and seventh and eighth Paragraphs apply when a person wants to obtain a sample on the basis of such a consent.

Anyone who indicates, either by addressing himself or herself directly to another party, or in an advertisement, or by inscription on a product or its packaging, or in any other way, that a patent has been applied for, or granted, without at the same time indicating the number of the application or the patent, shall be obliged to provide, upon request, the said information without delay. If it has not been stated expressly that a patent has been applied for, or granted, but the circumstances are liable to create the impression that such is the case, then, upon request, information shall be given without delay as to whether a patent has been applied for or granted.

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1. This Act enters into force on May 1, 2004.
2. The new provisions apply also to patents which have been granted or applied for before the entry into force.