WORLD TRADE ORGANIZATION

RESTRICTED

IP/C/W/125/Add.17
19 May 1999

(99-2036)

Council for Trade-Related Aspects of Intellectual Property Rights

Original: English

REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b)

Information from Members

Addendum

NORWAY

The present document represents the information requested by the Council for Trade-Related Aspects of Intellectual Property Rights which the Secretariat has received from Norway, by means of a communication from its Permanent Mission, dated 30 April 1999.

I. RESPONSES TO THE ILLUSTRATIVE LIST OF QUESTIONS PREPARED BY THE SECRETARIAT (DOCUMENT IP/C/W/122)

A. PATENT PROTECTION OF PLANT AND ANIMAL INVENTIONS

1. To what extent are inventions concerning plants or animals, whether products or processes, patentable under your country's law, if they meet the conditions for patentability stipulated in Article 27.1 of the TRIPS Agreement?

Plants and animals, included cell-lines which can differentiate from animals or plants, and processes for the production of plants and animals are excluded from patent protection. Micro-organisms and parts of plants and animals which can not differentiate from plants or animals are eligible to be patented.

2. Where any such inventions are not patentable, even if they meet these conditions:

(i) To what extent is this due to per se exclusions from patentability?

The exclusion from patentability of plants, animals, and processes for their production is a *per se* exclusion.

(ii) To what extent is this based on other grounds (for example because conditions for patentability other than those stipulated in Article 27.1 are not met or in order to protect ordre public or morality (see Article 27.2 of the Agreement))?

The exclusion is not based on *ordre public* or morality as mentioned in Article 27.2 of the TRIPS Agreement.

3. Please describe any specific provisions, guidelines, final judicial decisions and administrative rulings of general application concerning the application of the conditions for patentability stipulated in Article 27.1 to subject-matter addressed by Article 27.3(b).

The Norwegian Patents Act Section 1 fourth indent number 2 states:

> Patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants and animals. Patents may, however, be granted for micro-biological processes and the products thereof.

This provision is interpreted as a general prohibition of granting patents for plants, animals, and processed for their production.

4. Where plant varieties are not as such patentable subject-matter under your country's law, please indicate the extent to which the scope of protection under patents for inventions concerning plants can nevertheless embrace plant varieties or a botanical taxon whose plants express a trait covered by the claims of a patent.

Plant varieties are protected by plant breeder's rights in accordance with UPOV 1978, and can subsequently not be protected by a patent.

5. Please provide any definitions used under your country's law with regard to subject-matter specifically excluded from patentability or specifically patentable (e.g. micro-organisms, microbiological processes, non-biological processes, plant varieties).

There are no such definitions apart from the definitions in the Patents Act. See answer to question 3 above.

6. To what extent is subject-matter that is identical to what occurs in nature patentable under your country's law?

Subject-matter concerning micro-organisms, chemical substances as for example genes, including human material, which is identical to what occurs in nature, is patentable if it is isolated and meets the other requirements of the Patents Act, as for example level of inventiveness.

7. Explain the requirements under your country's law for ensuring adequate disclosure of the patentable inventions referred to above.

Adequate disclosure of the patentable invention is secured through Section 8 second indent and Section 8a of the Patents Act. The provisions comply with the Budapest Treaty 1977 (as modified in 1980).

8. What rights are conferred upon owners of the patents referred to above? Are product and process patents subject to the same rules as other patents? Do they benefit from the same protection as stipulated in Article 28 of the TRIPS Agreement?

Such patents, whether patents for products or processes, benefit from the protection stipulated in Article 28 of the TRIPS Agreement and are subject to the same rules as other patents. However, it is assumed that the rights conferred by a patent for a gene do not extend to plants or animals that contain that gene.

9. Are there any specific exceptions to these rights (affecting the scope or duration of the patents referred to above)? To what extent are exceptions, available in respect of plant variety rights (e.g. those referred to under question B.4(i) below), available in respect of rights conferred upon patent owners?

There are no specific exceptions affecting the scope or duration of micro-biological patents. (The general exceptions are listed in IP/Q3/NOR/1 -Answers to questions 3 and 4 from Japan.) As plants are excluded from patentability, the exceptions to a plant breeder's rights and the exceptions to patent rights are not comparable.

10. Are there any specific provisions under your country's law for compulsory licensing in respect of the patents referred to above?

There are no specific provisions for compulsory licences in respect of the kinds of patents in question.

B. PROTECTION OF PLANT VARIETIES

1. Does your country's law provide for the protection of plant varieties by plant breeder's rights, plant patents or any other sui generis system for the protection of plant varieties?

Norway provides for protection of plant varieties by plant breeders' rights.

2. (a) If your country is a party to the International Convention for the Protection of New Varieties of Plants (UPOV), please indicate which Act or Acts of the UPOV Convention your country has signed; which it has ratified; to which it has acceded; and to the standards of which its law conforms but to which it has not (yet) adhered.

(b) If your country is not a party to the UPOV Convention, does the protection offered to plant varieties under your country's law conform to the standards of any of the Acts of the UPOV Convention and, if so, which?

Norway has acceded to the International Convention of 2 December 1961 for the Protection of New Varieties of Plants (UPOV Convention) as revised on 23 October 1978. The Norwegian Plant Variety Act and supplementary regulations are in conformity with this convention and partly also with UPOV 1991.

3. Please indicate whether concurrent protection under your country's plant variety protection law and its patent law is available (see also question A.4 above).

Concurrent protection is not available.

4. Please provide the following details of your country's sui generis system for the protection of plant varieties:

(a) the relevant laws and regulations and, if they have been notified to the Council for TRIPS, a reference to the relevant WTO documents;

(b) the definition of "plant variety";

(c) the conditions required for protection;

(d) the extent to which subject-matter that is already known to the public or identical to what occurs in nature is protectable under your country's sui generis system for the protection of plant varieties;

(e) the extent to which protection can be based on characteristics of germplasm, as opposed to characteristics of plant varieties derived from such germplasm;

(f) who is entitled to the rights;

(g) the procedure for the acquisition of rights, including the authority in charge of administering the rights;

(h) the rights conferred;

(i) exceptions to the rights conferred, such as:
- *acts performed for research or experimental purposes;*
- *acts performed to develop new varieties of plants;*
- *acts performed to commercialize such newly developed varieties;*
- *any "farmer's privilege" (e.g. acts performed by a farmer on his own land in respect of seed saved from the previous harvest);*
- *acts done privately and for non-commercial purposes;*
- *compulsory licensing.*

(j) the duration of protection;

(k) transfer of rights;

(l) enforcement of the rights.

Plant breeders' rights are governed by the Plant Variety Act No. 32, of 12 March 1993 and Regulations of 6 August 1993. They have been notified to the TRIPS Council, cf. IP/N/1/NOR/1. As we understand the questionnaire, subquestions (b) to (l) refer to other *sui generis* systems.

II. RESPONSES TO ADDITIONAL QUESTIONS INFORMALLY SUGGESTED BY CANADA, THE EUROPEAN COMMUNITIES, JAPAN AND THE UNITED STATES (DOCUMENT IP/C/W/126)

A. Patent System Questions

1. In your territory, is there <u>any</u> basis for denying a patent on an invention consisting of an entire plant or animal that is novel and involves an inventive step?

According to the Norwegian Patents Act, Section 1, fourth indent, number 2, as it is interpreted, patents cannot be granted for plants, animals, and processes for their production.

2. If the answer to question 1 is yes, please respond to the following questions:

(a) Does your patent system exclude entire plants or animals as inventions? If it does, please cite the legal basis for this.

An entire, new plant or animal might well be an invention, but it will nevertheless not be patentable. Cf. answer to question 1 above.

(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes all, please cite the legal basis for their exclusion (e.g. lack of industrial applicability). If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded and cite the legal basis for their exclusion.

Plants and animals are excluded *per se* from patentability.

(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step and are capable of industrial application? If so, please cite the legal basis for that exclusion from patent eligibility.

There is no other general legal basis that excludes plants and animals from patentability, than the provisions of the Patents Act mentioned in answer 1.

3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?

(a) A patent claim that is not limited to a specific plant or animal variety.

(b) A patent claim that is expressly limited to a plant or animal variety.

(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.

Neither groups nor varieties of plants or animals can be patented.

(d) If the answers you provide to question (3)(a) to (c) vary, please provide the definitions of a "plant variety" and an "animal variety" that are used by your examining authority.

Not applicable.

4. Is it possible to obtain a patent in your territory on a microorganism that is novel, involves an inventive step and is capable of industrial application? If not, please identify the legal basis under which these inventions are deemed ineligible to be patented.

Micro-organisms that meet the general requirements of patentability are eligible to be patented.

5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)? If not, please identify the legal basis under which a patent on such a process would be denied.

It is not possible to obtain a patent for an essentially biological process for the production of plants or animals.

6. Is it possible to obtain a patent in your territory covering subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?

It is not possible to obtain a patent in Norway covering plants and animals in their natural state. However, micro-organisms identical to those found in nature are eligible to be patented if they are isolated and meet the conditions for patentability.

B. Plant Variety Protection Systems

7. Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?

Yes.

8. If the answer to question 7 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?

Yes.

9. If the answer to question 8 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).

Norway has acceded to the International Convention for the Protection of New Varieties of Plants (UPOV Convention) of 2 December 1961, as revised on 23 October 1978. The Norwegian Plant Variety Act and supplementary regulations are in conformity with this convention and partly also conform to UPOV 1991.

10. If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:

(a) acts performed for research or experimental purposes, or to develop new varieties of plants;

No. However, consent is necessary if producing the new variety for commercial purposes involves continuous use of the protected variety.

(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics?

No, provided that the new variety is distinct from the protected variety in the characteristics that define the latter. This will be determined on a case-by-case basis.

(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land.

No.

If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?

No, the party is not required to provide the right holder with remuneration if the activity does not necessitate a consent.

11. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?

Protection cannot be obtained for a variety that has been offered for sale in Norway with the right holder's consent prior to the filing of an application for a plant breeder's right. Offering for sale abroad that has taken place less than four years prior to the filing date, does not preclude protection. For varieties of trees and vine stock the period is six years. In other cases, public knowledge of the variety prior to the filing date does not preclude protection.

12. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?

No, a plant variety cannot be defined by reference to unexpressed genetic characteristics.

III. ANSWERS FROM NORWAY TO OECD DOCUMENT TD/TC/WP(97)17 WITH AMENDMENTS TO DOCUMENT TD/TC/WP(98)15/REV 1

A. PATENT EXAMINATION PRACTICES RELATED TO BIOTECHNOLOGY INVENTIONS

Inventions Eligible to be Patented

(a) Indicate whether all product inventions in the categories specified below are eligible to be patented in your country, and if not, please specify which inventions are ineligible and the grounds therefor:

(i) chemical structures composed of a sequence of nucleic acids that corresponds, in part, in whole or through the redundancy of the genetic code, to genes or other forms of genetic information in a living organism. Please indicate whether distinctions are made within your law or practice as to the source of the genetic information (i.e., viruses, bacteria, plants, animals, humans) or the form of the nucleic acid sequence;

(ii) chemical structures composed principally of a sequence of amino acids that corresponds, in part or in whole, to an amino acid sequence found in a living organism. Please indicate whether distinctions are made within your law or practice as to the source of the amino acid sequence (i.e., bacteria, plants, animals, humans);

(iii) materials (e.g., compounds or compositions) other than the chemical structures noted in points (i) and (ii) that are isolated from uni- or multicellular organisms;

(iv) living unicellular organisms (e.g., bacteria, yeasts);

All product inventions in these cathegories are eligible to be patented.

(v) plants, per se, parts of plants or plant varieties;

According to the Norwegian Patents Act, patents may not be granted for plant varieties, which is interpreted to extend to plants in general, included parts of plants or cell-lines which can differenciate to whole plants. «Parts of plants» which can not differenciate from whole plants, are eligible to be patented.

(vi) animals, per se, animal organs or animal varieties;

According to domestic law, patents may not be granted for animal species, which is interpreted to extend to animals in general, included cell-lines which can differenciate from animals. Animal organs are eligible to be patented.

(vii) humans, human organs or human derived products, including cell lines, genes and nucleic or amino acid sequences.

Domestic law states that patent may not be granted for inventions of which the exploitation would be contrary to morality or public order, which is interpreted to exclude from patentability humans and human germ-lines. Other elements isolated from the human body may constitute a patentable invention.

(b) Indicate whether all process inventions in the categories specified below are eligible to patented in your country, and if not, please specify which inventions are ineligible and the grounds therefor:

(i) methods of treatment of humans or animals by surgery;

(ii) methods of treatment of humans or animals by therapy, including, in particular,

- *by germ line gene therapy*
- *by somatic cell gene therapy*
- *through use of biopharmaceutical or other agents that indirectly affect genetic modifications;*

(iii) methods of diagnosis practiced on humans or animals;

According to the Patents Act methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals, shall not be considered as patentable inventions.

(iv) methods involving genetic engineering of humans or animals for purposes other than surgery, therapy, or diagnosis (e.g., animal experimentation or tests for research purposes); and

Inventions, as mentioned in A.b)iv), are not eligible to be patented in Norway.

(v) essentially biological processes, such as natural cross-breeding processes.

Essentially biological processes are ineligible to be patented.

(c) Are gene therapies considered to be methods of medical treatment? Are biopharmaceutical products (i.e. genetically-modified cells) produced by gene therapy techniques eligible to be patented?

Gene therapies are considered to be methods of medical treatment. A biopharmaceutical product, however, i.e.genetically-modified cells, are eligible to be patented.

(d) Indicate whether a party can obtain protection for a novel and non-obvious use of a known compound for therapeutic or diagnostic purposes in connection with a human or animal, notwithstanding the absence of process patent protection for that use. If so, please indicate how such protection is made available.

Patents for products, including substances and compositions of substances, for use in therapeutic treatment or diagnostic methods, are eligible to be patented.

(e) Would the answers provided in reference to questions A.b) i) to iii) change if the process involved surgery, treatment or diagnosis of parts of the human or animal body in vivo or ex vivo (e.g., testing or treatment of blood, stimulation of an immune response)?

Testing or treatment of blood or stimulation of an immune response ex vivo are methods which are eligible to be patented.

(f) Indicate whether, on the basis of ethical or moral concerns, your examining authority excludes biotechnological inventions from patentability. If so, please indicate how the standard is applied and to what subject matter. Please refer to any relevant administrative or judicial precedent.

Patents are not granted for inventions of which the exploitation would be contrary to morality or public order.

(g) Indicate whether there are any other exclusions from patentability for the inventions set out in questions A(a) and (b) above provided under your system.

The criterion «essentially biological processes for the production of plants and animals» is interpreted to extend to *all* processes for the production of plants and animals, i.e. also microbiological processes and other technical processes.

General Patentability Standards and Procedures

(h) Explain the standard used by your examining authority to determine whether an invention directed to a therapeutic application has industrial applicability or is useful.

Inventions directed to a therapeutic application, are ineligible to be patented.

(i) Explain whether your examining authority has found recurring types of deficiencies related to industrial applicability/utility or sufficiency of disclosure in applications directed to the nucleic acid sequences where the characteristics or functions of protein(s) coded for by the sequence are not known and are not described by the applicant.

The Norwegian Patent Office has not found deficiencies related to industrial applicability/utility in applications directed to nucleic acid sequences.

(j) Explain the test, if any, that your examining authority uses to determine whether a disclosure provides a sufficient basis to defeat the novelty of a claimed invention.

A sufficient basis to defeat the novelty of a claimed invention exists when there is «a reasonable technical difference».

(k) Inventive step/non-obviousness:

(i) Explain how the standard of inventive step/non-obviousness has been applied by your examining authority in determining whether biotechnological inventions are patentable;

(ii) Indicate whether application of this standard in the field of biotechnology has been discussed in any administrative or judicial decision. If so, please provide a summary of the issues and findings of such decisions;

(iii) Indicate whether specific difficulties have been encountered by your examining authority in applying the standard of inventive step/non-obviousness and the nature of the steps taken to address or resolve those difficulties.

Patents shall only be granted for inventions which differ essentially from what has been known before the filing date of the patent application, i.e. patents have not been granted for applications directed to a nucleic acid gene sequence, when the protein coded for by the gene sequence is not new.

(l) Indicate whether, through the application of one or more conditions of patentability, products or compositions that are not considered to differ from their natural state, are generally found non-patentable in your country. Please explain the nature of tests, if any, that govern this issue in your system.

Biological material which is isolated from its natural environment, may be the subject of an invention even if it previously occured in nature.

(m) Deposit of biological material:

(i) Indicate the general criteria that your examining authority uses to determine if a deposit of a sample is necessary to support enablement of an invention in the field of biotechnology.

In addition , please indicate:

- *whether the deposit of biological material can be required, and if so, under what conditions;*

- *whether an applicant can satisfy enablement requirements other than through a deposit of a sample with a recognised institution (e.g. through reference to morphological or other written descriptions or a clause assuring access from the applicant); and*

- *the nature of materials (e.g. genes, plasmids, cells, zygotes, tissue samples, living organisms) that have been recognised as appropriate forms of deposits.*

(ii) As regards the deposits made in the context of a patent procedure, please indicate:

- *whether deposit after filing is allowed;*

- *under what conditions the amendment of "accession numbers" is permitted;*

- *whether it is possible to file an application drawn to an invention whose practice can be effected using biological material that has already been deposited by a third party and under which conditions;*

- *whether access to the deposited biological material is provided or limited after the first publication of the patent application especially when an application is refused or withdrawn;*

- *with respect to deposits made in connection with plant inventions, the number of seeds typically required to be provided in a deposit; and*

- *whether deposits in other institutions than those listed by the Budapest Treaty are considered, and what requirements are set for such institutions.*

Where an invention involves the use of or concern a microorganism which is not available to the public, and which can not 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 microorganism shall be deposited within a recognised depositary institution.

(n) Indicate whether any special provisions, rules or procedures concerning electronic filing requirement for inventions dependent on nucleic or amino acid sequence information have been developed by the examining authority to address questions of enablement[1] or full description of any of the categories of inventions specified in question A.a). In their answers examining authorities should explain how such procedures operate and whether difficulties have been encountered in the practical application of those rules or procedures.

Deposit after filing, but within the priority year, can cause loss of priority rights.

A new deposit of the microorganism is permitted on the same terms as those laid down in the Budapest Treaty. Access to deposited material can be limited to an independent expert until the granting of the patent or to the refusing or withdrawing of the application.

(o) Explain how your examining authority handles applications claiming protection for large numbers of chemical structures composed of nucleic or amino acid sequences. Examples might include requiring the applicant to file separate applications drawn to one or more set of such structures or imposing additional examination fees through application of a unity of invention requirement.

In Norway we do accept large numbers of sequences if they relate to a single inventive concept. If this is not the case, lack of unity is likely to be objected and the applicant will be required to file divisional applications and pay supplemental fees.

(p) Explain any special procedures or considerations that are employed by your examining authority to search and evaluate information in the course of applying the standards of novelty and inventive step/non-obviousness to chemical structures composed of nucleic or amino acid sequences. Such procedures or considerations might include the use of computerised search systems of nucleic or amino acid sequence information, software to compare similarities between claimed sequences and prior art sequences, or presumptions relied on by examiners.

Dgene-database.

[1] Enablement: A disclosure sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

(q) Identify the sources which your examining authority relies upon in novelty searches e.g. applicant's disclosure, other examining authorities searches, electronic databases, academic journals, others).

Other searching authorities that the Norwegian Patent Office rely on in novelty searches are:

- international searching authorities (ISA/PCT),
- European Patent Office,
- other nordic countries.

(r) Indicate in what instances a biotechnology patent may currently be granted when the patent application contains (i) functional and structural claims, (ii) only functional claims; and (iii) only structural claims?

A patent may be granted when the application contains both functional and structural claims or only functional or only structural claims.

(s) Explain how your examining authority would proceed to determine whether an applicant has disclosed the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

Every examination include a separate evaluation, and there are no standard proceedings.

(t) Explain how your examining authority has proceeded where no specific details concerning the practice of the invention are provided in the disclosure, but where a person skilled in the art could practice the invention using known techniques and without an undue amount of experimentation.

When a person skilled in the art could practice the invention using known techniques and without an undue amount of experimentation, the invention is disclosed in a manner which is sufficiently clear.

(u) Explain what test has been used by your examining authority to determine whether a claim has sufficient support in the specification, and how has this test been applied in the following circumstances

A claim has only sufficient support in the specifications when it is directed to products which are descibed in «working examples» in the application.

(i) a disclosure provides one or several "working examples" or specific embodiments, but a claim is directed generically to a class of products or their use;

In Norway, a claim wider than the specification may have sufficient support in the specification, but this will be determined on a case-by-case basis.

(ii) a claim defines a product only with respect to physiological, biological or other functions possessed by the product, rather than the physical characteristics of the product; and

May constitute a patentable invention.

(iii) a disclosure provides one therapeutic application of a product, but a claim encompasses any therapeutic or diagnostic use of a product.

In the situation described in this question, in Norway, the claims would be limited to the application disclosed.

B. PATENT ENFORCEMENT ISSUES RELATED TO PATENTED BIOTECHNOLOGY INVENTIONS

Claim Interpretation Questions

(a) List the judicial decisions that have issued in your country concerning the enforcement of patent claims covering any of the inventions specified in questions A.a) or b).

(b) Indicate whether any judicial decisions in your country have addressed the following issues, and if so, please explain the findings and conclusions of the decision(s) :

(i) whether claims have been interpreted to cover subject matter not specifically claimed (i.e., equivalents of the specifically claimed invention, other uses of the invention), and if so, what criteria are used to determine whether a finding of infringement in such situations is justified;

(ii) whether claims can be interpreted to cover a scope that is less than that literally defined by the terms of the claim;

(iii) whether claim language specifying physiological, biological or other functional characteristics of a product specified in question A.a) has been interpreted in the

(iv) whether a claim to a biotechnological process has been found to cover a product obtained directly from the practice of the process, even of the product per se cannot be patented;

(v) whether a claim to a process or a product that covers a self-replicating organism extends to successive identical generations of organisms derived from the original organism.

There are no judicial decisions on these issues in Norway.

Use for Non-commercial Research

(c) Indicate whether the standard governing liability for unauthorised use of a patented invention for research or experimentation purposes differs for inventions in the field of biotechnology, as compared to inventions in other fields of technology. List any judicial decisions that have issued in your country where a third party has been found liable for the unauthorised use of a patented invention where such use was for research or experimental purposes.

For inventions in the field of biotechnlogy, as for inventions in other fields of technology, the exclusive rights do not preclude others from performing experiments relating to the subject matter of the invention.

Patent Enforcement Issues in Respect of Plant Varieties

(d) Indicate whether any judicial decisions in your country have addressed the following issues, and if so, please explain the findings and conclusions of the decision(s) :

(i) an action by a patent holder in response to the use of a patented gene manipulation procedure to produce a new plant or plant variety without the prior authorisation of the patent holder;

(ii) an action by a patent holder in response to the use of a plant subject to a patent to produce a new plant variety without the prior authorisation of the patent holder ;

(iii) an action by a patent holder in response to the use or sale of products harvested from a specific plant variety that has been produced using a patented plant or plant that has incorporated a patented gene.

There are no judicial decisions.

Use without Authorization of the Patent Holder

(e) Indicate whether and explain the circumstances under which a party can obtain the right to use a patented biotechnological invention specified in questions A.a) and b) without the authorisation of the patent holder. If so, please indicate how frequently such rights to use are granted and whether any such right to use has been granted with respect to patented biotechnological inventions specified in questions A.a) or b).

Compulsory license to exploit an invention can be obtained if a «new» invention is dependent on a prior patent owned by someone else, and the «new» invention is found to constitute a significant technical progress of considerable economic interests.

C. PLANT VARIETY PROTECTION ISSUES RELEVANT TO PLANT INVENTIONS

Availability of Plant Variety Protection

(a) Indicate:

(i) whether plant varieties are protected under a sui generis system in your country;

(ii) the Act of the UPOV Convention which your country has acceded to or ratified (i.e., 1991, 1978, 1972 or 1961), if any; and

(iii) whether your country has implemented changes to conform to the 1991 Act of UPOV.

Norway provides for protection of plant varieties by plant breeder’s rights and has acceded to the International Convention of 2 Dece mber 1961 for the Protection of New Varieties of Plants (UPOV Convention) as revised on 23 October 1978. The Norwegian Plant Variety Act and supplementary regulations are in conformity with this convention and partly conform to UPOV 1991.

Concurrent Protection

(b) Indicate whether patent protection can be enjoyed in your country with respect to botanical genera and species of plants, if any, that are excluded from protection under your plant variety protection system.

Botanical genera and species of plants are ineligible to be patented.

(c) Indicate whether a party can enjoy concurrent patent rights and plant variety protection for the identical plant variety under your law with respect to plant varieties that are eligible to be protected through your plant variety protection system.

Plant varieties are ineligible to be patented.

(d) Indicate whether any judicial decision in your country has addressed the issue of whether an entity that holds a plant variety protection certificate has been unable to commercially exploit the plant variety subject to that protection due to action by a second entity that holds and has enforced patent protection covering that plant variety.

There are no judicial decisions.

Commercial Sales of Propagating Material by Third Parties / Farmer's Privilege

(e) Indicate whether any of the following uses by persons other than the owner of a plant variety protection right and not having his/her consent is permitted under your law :

(i) commercial sales of propagating material,

No.

(ii) storage by the person that harvests seed from his own holdings in order to use the seed in subsequent plantings on those holdings, or

Yes.

(iii) other uses of the propagating material (e.g. banter or seed exchange).

Plant Protection for Variety Containing Patented Gene

(f) Assuming that a new plant variety containing a patented gene has been bred

(i) by the patent holder;

(ii) by a third person not having the consent of the patent holder

indicate whether that person is eligible for plant variety protection in respect of this new variety in your country.

A plant variety may be eligible for a plant variety protection by breeder's rights even if the plant variety contains a patented gene.

Annex A.

Statistical Reporting related to Patents and Plant Variety Protection

Member countries should respond to questions contained in this Annex to the extent they have readily available relevant information. For the purpose of the Annex, biotechnology will cover items corresponding to the following International Patent Classification marks:

(a) From the date that your examining authority began issuing patents for products specified in the above list of IPC codes, please indicate, on a year-by-year basis :

(i) the number of patents filed and granted, per IPC category;

Number of patents filed:

A01H:	approximately 1-3 applications each year
A01K 67/027, 67/033, 67/04:	approximately 0-1 application each year
C07H 21/02-21/04:	approximately 15 applications each year
C07K 2/00-16/46, 19/00:	approximately 130 applications each year
C12N:	approximately 70 applications each year
C12Q:	approximately 25 applications each year
G01N 33/50-33/98:	approximately 50 applications each year
A61K 35/12-35/84:	approximately 15 applications each year
A61K 38/00-38/58:	approximately 35 applications each yaer
A61K 39/00-39/44:	approximately 20 applications each yaer
A61K 48/00:	approximately 5 applications each year
A61K 51/10:	0

In general about 60% of patents filed are granted.

(ii) number of patents filed and granted to nationals of foreign countries;

More than 95% of the applications reported under a) i) are applications submitted by nationals of foreign countries.

The total number of applications filed are approximately 6000 (i.e. in any technology) each year.

(b) Indicate the year in which the first patent with claims to the following organisms was granted:

(i) a unicellular organism;

In 1992.

(ii) a plant;

No patent directed to a plant has been granted.

(iii) any multicellular organism;

No patent directed to a multicellular organism has been granted.

(iv) a mammal.

No patent directed to a mammal has been granted.

(c) Indicate the number of examiners that are presently employed by your examining authority to handle biotechnology applications, and the approximate total number of applications assigned to such examiners that are currently pending. Indicate the total number of examiners (in all technologies) and the approximate total number of applications pending.

Nine (9) examiners are employed to handle biotechnological applications, and at present we have approximately 2000 applications that are currently pending. The total numbers of examiners (in all technologies) are approximately seventy (70), and at present we have about 23 000 applications that are currently pending.

(d) Indicate the date of the oldest biotechnology patent application which has not been examined but is still pending.

From 1979.

(e) Indicate the number of judicial decisions issued on biotechnology patents or patent applications during the past five years.

(f) Indicate the median time that is required for examination of a biotechnology patent application and grant of the patent by your examining authority. Indicate the median time required for applications in general (in all technologies) to be examined from the time of filing.

The average time required for examination and granting of a patent in the biotechnological field, is about four to five (4-5) years. For applications in general the average time for examination and granting are approximately three (3) years.

(g) Indicate the number of plant variety protection certificates/rights filed and granted in your country over the past 10 years.

Approximately 200 plant varieties have been granted since 1993.

(h) Indicate the number of plant species that are eligible to be protected by plant variety protection in your country and whether this number has changed over the past 10 years.

All plant varieties are eligible to be protected.

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